Recall Index

2025 edition 3

Product safety and recall

United States edition

DATA, TRENDS & PREDICTIONS FOR U.S. INDUSTRIES

sedgwick

Introduction

Sedgwick's Product Safety and Recall Index is the definitive resource for manufacturers, suppliers, and retailers seeking an impartial perspective on the data and dynamics shaping product safety, recall activity, and regulatory enforcement. Each quarter, the report reviews five key industries – Automotive, Consumer Products, Food and Drink, Pharmaceutical, and Medical Device.

The Index compiles and analyzes recall data from the U.S. National Highway Traffic Safety Administration (NHTSA), U.S. Consumer Product Safety Commission (CPSC), U.S. Food and Drug Administration (FDA), and U.S. Department of Agriculture (USDA). This combined dataset offers the most comprehensive view of the recall environment available, empowering businesses to identify trends, benchmark performance, and strengthen their brand protection strategies.

This edition covers recall activity from Q3 2025 (July through September) and includes an early preview of October data. During the quarter, total recall events fell to 782, compared to 861 in Q2 2025. Most industries saw fewer recalls, with two exceptions: Pharmaceutical, which maintained the same number of recalls quarter over quarter, and FDA Food, which recorded a slight increase.

Year-to-date, there have been 2,418 recalls across all sectors, affecting 470.22 million units, compared to 2,452 recalls and 580.43 million units in the first three quarters of 2024.

While the number of events declined, the scale of impact grew significantly. The total number of affected units rose 201.6%, from 85.87 million in Q2 to 258.98 million in Q3—the highest quarterly total in nearly three years. Every sector experienced an increase in recalled units. USDA Food reached a 13-year high with 58.52 million pounds affected, while the Pharmaceutical sector recorded its largest quarterly figure since Q1 2023, with 44.56 million units recalled.

Sedgwick's Product Safety and Recall Index provides far more than data. It delivers strategic interpretation, examining what's driving regulatory change, how enforcement is evolving, and what it all means for business leaders responsible for product integrity and consumer safety. We include perspectives from some of our strategic partners at global law firms, insurance companies, and regulatory and safety organizations to help businesses protect their brands and mitigate risk.

Regulatory momentum remained strong in Q3. NHTSA, CPSC, FDA, and USDA all proposed new measures spanning automated driving systems, lithium-ion batteries, children's toys, and meat products. The FDA also called for infant formula manufacturers, suppliers, and distributors to strengthen recall communication protocols—an initiative underscoring the agency's continued focus on transparency and consumer protection.

Meanwhile, the federal government introduced several initiatives aimed at enhancing domestic production. These included stricter enforcement of "Made in the USA" labeling claims, new incentives for pharmaceutical manufacturing facilities, and potential tariffs or quotas on imported medical devices and personal protective equipment (PPE).

However, oversight relaxed in some areas. The FDA signaled plans to rescind a rule that would have imposed stricter requirements on laboratory-developed tests. Discussions also continued around easing automotive tailpipe emission standards, and the agency clarified that it does not intend to broadly restrict the use of PFAS in medical devices.

As the regulatory environment grows more complex, businesses face a renewed imperative: to remain agile, vigilant, and resilient. Product safety and recall readiness are no longer reactive functions, they are strategic disciplines that protect reputation, preserve trust, and reinforce operational strength. Whether read in full or explored by sector, the insights in this report are designed to help organizations anticipate disruption and act decisively in the face of change

One final note: This edition of the Product Safety and Recall Index focuses on U.S. recall data and regulatory developments. If your business also operates outside the U.S. or your supply chain is affected by global issues, we recommend that you also read our other publications.

Our European edition shares recall data from regulatory agencies and offers exclusive analysis regarding product safety and policy changes, but from the perspective of companies and regulators operating in the UK and the European Union.

Our biannual Australian Product Safety and Recall Index report provides insights on regulations and recall data for that market.

Q3 2025 European edition, click here

H1 2025 Australian edition, click here

If you would like more information about what we have observed in recent quarters, you can find previous editions of the Recall Index below:

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Q4 2024 U.S. Recall Index: click here

Q3 2024 U.S. Recall Index: click here

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Automotive

The U.S. automotive industry continues to navigate global tariffs on vehicles, materials, and components. Automotive News predicts that the impact will be even greater in the second half of the year. A trade deal with the European Union set automotive tariffs at 15% between the two jurisdictions beginning on August 01, which may provide a little certainty for those trading partners.

However, the U.S. Commerce Department imposed preliminary anti-dumping duties of 93.5% on Chinese imports of graphite in July. The mineral is a key component in batteries. In addition, fees for semiconductors—another critical automotive component—were still being negotiated in September.

In what some manufacturers may see as a bright spot, the Trump Administration ended penalties for automakers who did not meet their vehicle fuel economy requirements from 2022-2025. These fines have cost major manufacturers hundreds of millions of dollars in previous years. The Environmental Protection Agency (EPA) is considering extensive changes to these rules.

The Federal Highway Administration (FHWA) issued new guidance for the National Electric Vehicle Infrastructure (NEVI) Program. The changes ease some eligibility requirements and streamline how states apply for federal funds to build a national interconnected charging infrastructure for EVs.

Both the National Highway Traffic Safety Administration (NHTSA) and Congress took action in the third quarter to update safety regulations to reflect technologies in automated vehicles and automated driving systems. New rulemaking is expected to advance in the coming months.

The automotive industry is currently navigating a complex landscape of challenges and opportunities. Manufacturers who have prioritised the development and launch of lower emissions vehicles must carefully consider whether to revise their strategies in response to potential shifts in governmental regulations.

> **“With emissions rollbacks, AV rulemaking, and shifting EV infrastructure commitments, automakers must balance short-term adaptation with long-term safety and investment commitments.”**

Easing of emissions rules expected

In July, President Trump signed a law that ended penalties for automakers who did not meet the Corporate Average Fuel Economy (CAFE) standards for vehicles from the model years 2022-2025. CAFE standards regulate how far vehicles must travel on a gallon of fuel.

The presidential decision could mean significant savings for many large manufacturers. According to Reuters, one leading automaker paid $190.7 million in civil penalties for failing to meet U.S. fuel economy requirements for 2019 and 2020 and nearly $400 million for penalties from 2016 through 2019. Another global manufacturer paid $128.2 million in penalties for 2016 and 2017.

The Alliance for Automotive Innovation, a trade group representing nearly all major automakers, also asked the Environmental Protection Agency (EPA) to roll back aggressive vehicle emissions limits. In its filing, the association claims the standards force the industry to increase its production of electric vehicles (EVs) and that the emissions reduction goals set in 2024 are “simply not achievable.”

In July, EPA Administrator Lee Zeldin announced a proposal to eliminate the standards that limit greenhouse gas pollution from vehicle tailpipes. The EPA has also suggested rescinding the long-standing finding that greenhouse gas emissions are dangerous to human health.

An NPR story shared the agency’s arguments for making these changes, including the idea that if carbon dioxide is not “air pollution” as traditionally understood, then EPA cannot regulate it. The agency also pointed to a report from five scientists who reject the scientific consensus on climate change.

The NPR article notes that the EPA’s proposal must go through a public comment period. There are also likely to be lawsuits from organizations against these revisions, so while automakers may be optimistic, uncertainty remains. Still, several major manufacturers have chosen to scrap plans for U.S. EV production in favor of hybrid and gas-powered vehicles.

Where the U.S. standards end up will have a wider impact beyond domestic policy. A joint statement on trade between the U.S. and EU that was signed in August states that the two regions are committed to working together “to reduce or eliminate non-tariff barriers” for automobiles. This includes the intention to “accept and provide mutual recognition to each other’s standards.” What this will mean if the U.S. continues to roll back commitments for transitioning to EVs is unclear.

Automotive manufacturers and distributors will need to adapt to the changing regulations and update their business planning to take advantage of evolving opportunities. However, consumer perceptions will also factor into automakers’ decisions. Some buyers may continue to place higher value on products from companies who maintain strong environmental commitments.

New guidance issued on National Electric Vehicle Infrastructure Program

Earlier this year, the Federal Highway Administration (FHWA) rescinded all versions of the National Electric Vehicle Infrastructure (NEVI) Program Guidance and suspended approval of State Electric Vehicle Infrastructure Deployment Plans for all fiscal years.

The NEVI Program was established under the Infrastructure Investment and Jobs Act to create an interconnected EV charging infrastructure along federal highways that have been designated as Alternative Fuel Corridors (AFCs).

In August, the FHWA issued new guidance designed to simplify the approval process for state deployment plans under the initiative. While Transportation Secretary Sean Duffy has opposed the initiative, a federal court blocked attempts to freeze NEVI funds, according to Bloomberg News.

Duffy said the new guidance will “make sure this program uses federal resources efficiently.” The initiative was granted $5 billion in funding for charging infrastructure in 2021. That money is set to wind down in 2026.

An analysis of the FHWA's revisions by attorneys with Nossaman LLP highlights several of the key changes, including scaling back the components that must be in a state's deployment plan and allowing states the flexibility to determine the "reasonable" distance between stations along AFCs instead of using the previous standard of "no more than 50 miles."

The updated version also gives states more leeway to determine when their system is fully built out. Once the system is complete, NEVI funds could be used for other projects on public roads across the state.

Additional changes include aligning community engagement requirements with regulatory requirements and reducing the consultation requirements to advance projects. Furthermore, states are no longer required to conduct community outreach with rural, tribal, and disadvantaged communities—as well as other groups—to facilitate equitable and accessible deployment of EV charging infrastructure.

States were required to submit new Electric Vehicle Infrastructure Deployment Plans by September 10, 2025. With the Administration's focus away from EVs and the public's slowing adoption of the vehicles, it is uncertain how many states will try to leverage the NEVI funds for new projects.

Vehicle safety remains a top priority

In September, Transportation Secretary Sean Duffy announced that NHTSA would launch three rulemakings to modernize the Federal Motor Vehicle Safety Standards (FMVSS) for vehicles with automated driving systems (ADS). The agency wants to ensure that current safety standards consider automated vehicles (AVs) and ADS technology.

The proposed amendments to the FMVSS are part of the federal Spring Unified Agenda of Regulatory and Deregulatory Actions. The new rules would impact standards for transmissions, windshield systems, and lamps and other reflective devices to account for vehicles with ADS and no manual controls.

The recommendations follow updates from NHTSA's July report on Research and Rulemaking Activities on Vehicles Equipped with Automated Driving Systems in which the agency said it had conducted research using augmented reality objects to assess the sensing modalities of ADS technology. NHTSA hopes to develop testing methodology that can integrate virtual and real-world elements.

Another area of ADS-equipped vehicle research has been potential air bag deployment injuries to children who are seated in what is traditionally the driver's seat. NHTSA is also assessing how self-driving vehicles may be designed to cater to non-traditional seating positions or users, including passengers who use wheelchairs or seats that don't face forward as in a traditional vehicle.

Jonathan Morrison, who was confirmed as NHTSA's Administrator in September, emphasized the need for regulations to keep pace with evolving technologies—including AVs and ADS—in his confirmation testimony. He stated that NHTSA leadership must have "deep and sustained engagement with industry, state and local governments, and technical safety experts."

Congress is also focused on ensuring new vehicle technologies are safe. The House introduced the AV Safety Data Act in July to improve incident reporting for certain AVs. The measure calls for information reported to NHTSA after an AV-related crash to include data such as weather conditions and injuries to passengers. Representatives also want the information to be available to the public.

NHTSA is one of many agencies facing challenges to ensure that new technologies that can offer advantages to consumers are balanced with regulations to maintain high safety standards. Automakers will have to monitor how new rules could impact their vehicles' designs, as well as any reporting and testing obligations.

By the numbers

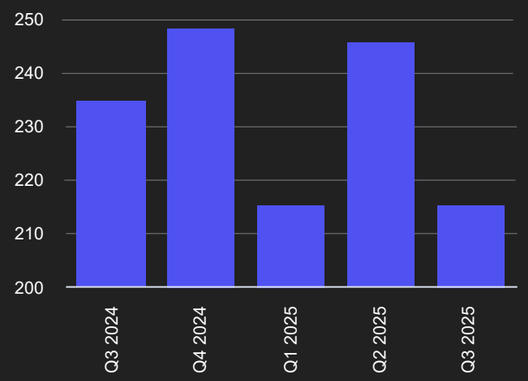
In Q3 2025, NHTSA issued 215 automotive recalls, down 12.6% compared to 246 in Q2 2025. In contrast, the number of affected units increased by 25.3% from 7.36 million in Q2 to 9.23 million in Q3. There was only one recall that involved more than 1 million units.

In the first three quarters of 2025, there have been 676 automotive recalls involving 20.32 million units. This is lower by event and volume than the same period in 2024, which had 740 recalls impacting 24.57 million units. Year-to-date, 2025 marks a 5-year low for automotive recall events, and a 13-year low for the number of impacted vehicles.

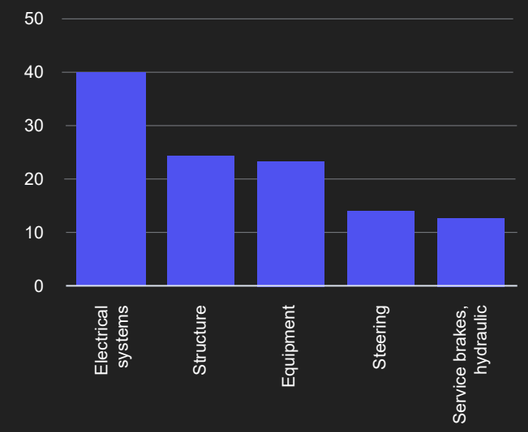
Electrical systems were the leading cause of U.S. automotive recalls in Q3 2025, linked to 40 events, down from 49 last quarter. This has been the leading cause of NHTSA recall events for the past four quarters, making it the most recalled category year-to-date. Structure issues were the second-most cited cause, involved in 24 recalls. Equipment concerns were third, with 23 events reported.

By volume, back-over prevention systems were the leading recall category with 2.09 million units affected, including one recall involving 1.46 million units. Back-over prevention was also the leading cause in the previous quarter with 2.59 million units impacted, making it the leading category year-to-date. These are the only two quarters in the past 10 years to exceed 2 million units for this component. Electrical systems ranked second with 1.62 million units impacted, which is up from the 397,151 units recorded in Q2. Gasoline fuel systems were the third-highest category by volume with 1.60 million units affected across nine recalls.

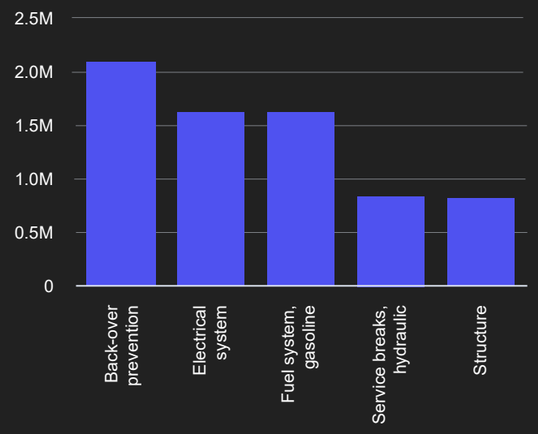
Number of recall events by quarter



Number of recall events by category (top 5)



Number of recalled units by category (top 5)



“Escalating penalties, AI-enabled enforcement, and shifting CPSC priorities signal a tougher regulatory environment. Manufacturers and retailers must remain vigilant, monitor emerging risks, and anticipate new enforcement trends.”

Consumer products

In July, the U.S. and the EU jointly announced a trade deal for a range of products. Under the new framework, almost all EU goods entering the U.S.—including semiconductors—will be subject to a maximum baseline tariff of 15%. The U.S. and EU agreed to zero-for-zero tariffs on specific products such as all aircraft and their components, certain chemicals, natural resources, and critical raw materials. While policy makers in other countries continue to negotiate rates for certain goods, the EU agreement provides a little more certainty for some companies.

The Department of Justice (DOJ) reached an agreement in August regarding civil and criminal claims against a portable air conditioner manufacturer over violations of the Consumer Product Safety Act (CPSA). The company agreed to pay a $16.03 million civil penalty—the maximum authorized under the CPSA. It also committed to nearly $400,000 in restitution and pleaded guilty to one count of knowingly and willfully failing to report a product safety hazard to the Consumer Product Safety Commission (CPSC).

The DOJ alleged that the company had imported and sold more than 33,000 defective air conditioners between 2008 and 2014 and that those products were linked to more than 40 fires and one death. This is only the second time in history that a company has entered into a criminal resolution in a CPSA case. The last time was in 2021 and company executives in that matter were sentenced to prison.

In Q3, the CPSC continued to issue safety warnings and conduct regulatory business, despite being reduced to one Commissioner—Acting Chair Peter Feldman. One way the agency may try to do more with less staff is through the use of AI to anticipate product safety issues.

The CPSC announced a final rule in August that establishes mandatory safety requirements for water bead toys and toys that contain water beads and said it was finalizing new safety requirements for infant neck floats. These actions show the agency’s continued commitment to the safety of children’s products.

In addition, the Commission advanced a rule that would set mandatory safety standards for micromobility devices powered by lithium-ion batteries. These standards have been on the agency's agenda for some time.

The Federal Trade Commission (FTC) stepped up enforcement of products that violate "Made in the USA" regulations. The agency declared July to be "Made in the USA" Month and sent warning letters to both manufacturers and major online marketplaces, which may suggest a broader scope for issuing fines.

Manufacturers and distributors, especially those selling products for children and those containing lithium-ion batteries, must remain vigilant in upholding high safety standards.

CPSC continues to evolve

In Q2, the five-member Consumer Product Safety Commission (CPSC) was reduced to only two members after President Trump removed the three Democrat Commissioners. In July, the U.S. Supreme Court stayed a lower court ruling that would have reinstated the three CPSC commissioners.

In late August, Republican Commissioner Douglas Dziak announced that he was resigning, leaving Acting Chair Peter Feldman as the sole Commissioner. Before Dziak's departure, he and Feldman voted to delegate the Commission's adjudicatory enforcement authorities, civil and criminal enforcement authorities, and regulatory authorities to the Acting Chair, at least temporarily.

To reinforce this, Feldman issued a statement clarifying that under the CPSA, "Congress expressly empowered the Commission to delegate its authorities to officers and employees of the agency to maintain continuity of operations." He went on to say that the statutory authority is broad and includes all powers with the sole exception of certain subpoenas.

Feldman said that the CPSC expected no impediment to its work going forward, including with respect to investigations. The Acting Chair also announced in August that the CPSC was "returning to a safety mission rooted in sound science, robust data, and common sense." He said the agency was withdrawing several pending rulemakings and would not issue final rules that it believed "promote unscientific ideological agendas, impose unnecessary costs, restrict consumer choice, or reduce competition, entrepreneurship, and innovation."

Attorneys with Crowell & Moring LLP highlighted an August 27, 2025 public meeting with Feldman and CPSC Executive Director Brian Lorenze, who stated that the agency intends to use AI and predictive analytics to conduct its product hazard detection and prevention activities.

The agency wants to shift from reactive enforcement and traditional methods such as consumer portal reports and mandated company disclosures, to using integrated AI to mine injury trends from broader sources, including social media and online reviews.

The legal experts raised concerns regarding the reliability of social media, particularly in light of its susceptibility to widespread misinformation. This is even more worrisome since many social media platforms ended fact-checking efforts earlier this year and some reports suggest that roughly 20% of content on certain platforms comes from bot accounts.

Lorenze stressed that AI would automate routine tasks to help the agency identify and trace hazardous products across a complex global supply chain, but staff would still have oversight.

The attorneys noted that it is unclear if the CPSC will use AI to conduct predictive, early-stage investigations or use the technology to alert companies of emerging risks identified through AI and expect the organizations to respond.

While the CPSC remains committed to protecting consumers, stakeholders can expect continued changes around enforcement tools and priorities. Manufacturers and retailers should follow existing product safety regulations and expect robust enforcement. They would also be wise to monitor for new rules or the elimination of old ones.

Lithium-ion battery rules prioritized

In August, Acting CPSC Chair Peter Feldman announced that a notice of proposed rulemaking for lithium-ion batteries in micromobility devices had advanced to the Office of Information and Regulatory Affairs (OIRA) for interagency review. The measure specifically addresses the use of these batteries in products such as eBikes, eScooters, hoverboards, and eUnicycles, as well as replaceable battery packs, aftermarket chargers, and conversion kit components sold separately.

Feldman said that working through OIRA ensures a “whole-of-government approach” to complex safety challenges. Efforts to move these regulations forward earlier this year stalled when the three Democrat Commissioners were removed from the CPSC.

The proposed rule would introduce mandatory consumer safety standards to address the potential risk of death and injury from electric shock, fires, explosions, expulsion of gas or flames, burns, overheating, and smoke inhalation and other hazards related to micromobility products. Currently, there are only voluntary standards in place. The regulation would also impose performance requirements for the relevant devices.

The CPSC, Congress, and state and local regulators have been pushing for mandatory standards for years. The Senate introduced the “Setting Consumer Standards for Lithium-Ion Batteries Act” earlier this year. If passed, the CPSC would have 180 days to put new micromobility regulations in place.

Manufacturers of micromobility devices and their related power supplies should review their current product specifications. Hopefully, most companies have already been adhering to the voluntary standards so compliance with the new rule may not be overly burdensome. However, there may be additional reporting requirements.

“Made in the USA” claims under scrutiny

The Federal Trade Commission (FTC) stepped up its focus on fraudulent “Made in USA” claims for consumer products by declaring July 2025 to be “Made in the USA Month.” This issue has long been a priority for the agency. It issued more than $5 million in fines to two companies in the first half of 2024. The agency’s aggressive stance aligns with President Trump’s repeated emphasis on U.S. manufacturing.

On July 8, the FTC sent warning letters to four consumer product manufacturers, reminding them of their need to comply with the FTC Act and the Made in USA (MUSA) Labeling Rule for products advertised as “Made in USA.” Specifically, those products must be “all or virtually all” made in the United States. Violations of these rules may result in legal action, including the issuance of an administrative subpoena, the filing of a federal lawsuit, injunctive relief, and civil penalties or other monetary relief.

In addition to the manufacturers, the FTC also sent letters to two major online sellers to stress that the MUSA requirements also apply to online marketplaces. The agency identified third-party sellers who may be making deceptive U.S.-origin claims on those online platforms that would violate the FTC Act and be contrary to the retailers’ specific terms of service.

Attorneys with Wiley Rein note that not only do manufacturers and retailers face risk from FTC enforcement, but there has also been a rise in private litigation when companies bring suits against their competitors over “Made in USA” advertising claims. According to a June 2025 Wall Street Journal article, 13 proposed class-action suits were filed over “Made in USA” claims in the first six months of 2025 across a range of industries. That is nearly double the number of cases filed in all of 2024.

The legal experts recommend that manufacturers and marketers carefully review their advertising and product labels to ensure they don’t make unqualified MUSA claims. Further, they should be sure that any claims can be substantiated. Companies should also routinely evaluate advertising and labeling for consistency, especially if they change sourcing partners.

By the numbers

In Q3 2025, there were 80 CPSC recalls, a 26.6% decrease from 109 events in Q2. In contrast, the number of units recalled rose 7.3% from 12.21 million units last quarter to 13.10 million this quarter. The average recall size also grew from 112,035 in Q2 to 163,780 in Q3. There were three recalls that each impacted more than 1.3 million units.

In the first three quarters of 2025, there have been 290 consumer product recall events impacting 29.95 million units. That compares to 246 recalls involving 72.61 million units during the same time period in 2024. In terms of events, 2025's figure is currently at an 18-year high.

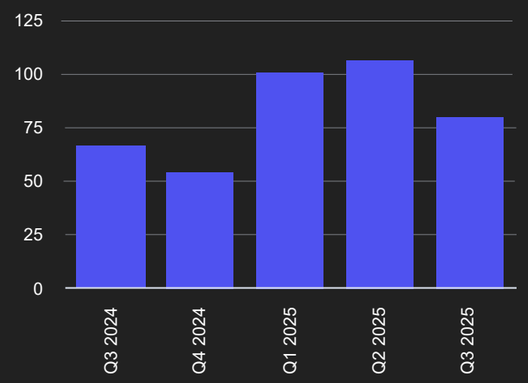
Electronics accounted for the most recalls by product category in Q3 2025, linked to 19 events, one more than last quarter. Children's Products were second with 11 events, followed by Yard & Garden with 10 recalls.

In terms of recalled units, Yard & Garden was the top category with 4.72 million units impacted in Q3. This was predominantly driven by a recall of 3.60 million garden hoses that posed a risk of injury from bursting. Electronics had 3.61 million units recalled, making it the second-highest category by volume. This included a recall of 2.90 million attic fans due to a fire hazard from a motor defect. Kitchen products was the third-highest product category in Q3 with 2.42 million units recalled. 57.7% of these units were linked to a recall of 1.40 million countertop ovens that could potentially burn consumers.

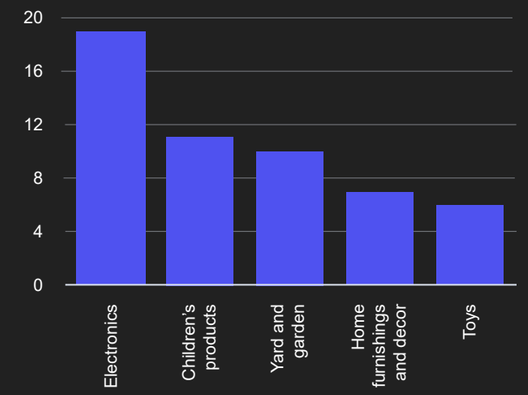
The combination of burns and fire was the top consumer product hazard by event in Q3 2025, tied to 10 recalls. Fire, burn, poisoning, and entrapment were second with eight events each, followed by injury and internal chemical burns, which had seven recalls apiece.

Injury was the leading risk by volume, impacting 4.45 million units. Fire was second by volume, connected to the recall of 2.99 million units. Burns were third and impacted 1.48 million units. However, the combination of burns and fire was linked to an additional 1.38 million units, illustrating a broader and more complex hazard landscape for these two risks this quarter.

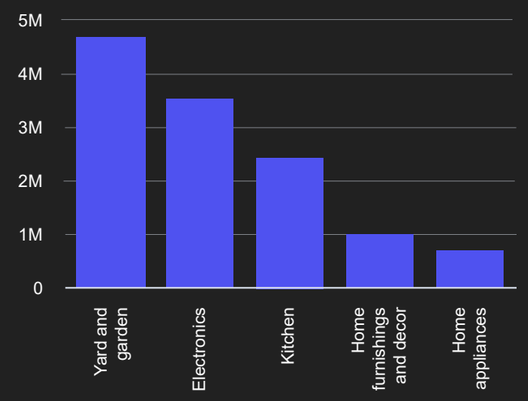
Number of recall events by quarter



Number of recall events by category (top 5)



Number of recalled units by category (top 5)



The recall long game: effective remedies may prevent future litigation

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Every year, millions of consumer products, vehicles, food items, medical devices, and drugs are recalled. Some recalls are voluntarily implemented by the manufacturer, while others are mandated by regulatory authorities. Recalls are costly, interrupt normal business operations, and often result in legal action.

The recall remedy ultimately chosen for a corrective action plan often has a large cost component. Inspections, repair kits, replacement components and products, and refunds all impact a company's bottom line.

In this article, we look at the effect—and perhaps the benefit—that the choice of remedy can have on litigation arising out of the recalled product. The remedy offered, its timing, and how the recall is communicated can each provide certain legal defenses to a recalling firm, including for class actions cases.

Customers who decide to bring legal actions may encounter obstacles—and even outright dismissal of a lawsuit—if the recalling firm can demonstrate that the plaintiffs are merely seeking the same remedy already offered to them in a recall.

In a putative class action lawsuit filed against a major U.S. automaker, a trial court dismissed the plaintiffs' claims, stating that the alleged injury had already been cured by a recall. The manufacturer issued a recall notice in January 2013 to owners of certain model years of a popular vehicle. The company told owners that a component installed on those vehicles could experience an "electrical overstress condition." This condition, in turn, could cause the airbag warning light to illuminate and the airbag to immediately deploy inadvertently.

To address the issue, the company offered to repair the flaw "as quickly as possible." Months after the lead plaintiff received the recall notice, the airbag warning light in his car illuminated, but the airbag did not deploy. He contacted his local dealership regarding the issue but could not immediately schedule the repair because the dealer was waiting to receive the necessary replacement parts from the manufacturer. Instead of waiting for the replacement parts and repair offered in the recall, the owner took his vehicle to a different dealership and paid for a "diagnosis."

The man then initiated a putative class action against the automaker and the component part manufacturer, seeking monetary damages and an order declaring that a safety defect existed in the airbag systems of the class member vehicles. Shortly after the suit was filed, the automaker sent notices to owners who had similar experiences to the plaintiff, informing them that it had obtained the necessary parts to make repairs. The manufacturer instructed owners to contact their dealers immediately to schedule the free repair. Many did.

The defendants moved to dismiss the plaintiffs' suit and the court granted the motion finding that it lacked subject matter jurisdiction. The plaintiffs appealed. The Court of Appeals for the Sixth Circuit affirmed the dismissal, rejecting the monetary damages claim and finding the claims for declaratory judgment and injunctive relief moot because the automaker already acknowledged the defect and offered to repair it. The court reasoned that there was never a dispute as to whether a safety defect existed or whether the company would repair it, leaving nothing left for the court to adjudicate.

A similar result occurred in another case against a different U.S. automaker. However, due to the timing of that recall, the court allowed plaintiffs to recover attorneys' fees incurred during litigation leading up to the manufacturer's recall. The plaintiffs had filed a putative class action on behalf of individuals who purchased or leased certain hybrid vehicles, alleging that the vehicles contained defective coolant pumps that caused an abrupt loss of power and presented a safety risk.

A year into the litigation, the automaker informed the National Highway Traffic Safety Administration (NHTSA) of its plan to conduct a voluntary safety recall related to pump failures in its hybrid vehicles. The company notified the owners of the vehicles about the potential for pump failure and offered free repair and replacement components. It also said it would reimburse them for any out-of-pocket repairs that they sustained prior to the date of the recall notice. Once the recall was issued, the lead plaintiff's case was dismissed because the court found that the recall rendered the claims moot.

A properly timed and effective recall remedy can also provide a strong defense to class certification related to the recalled product. In another lawsuit involving an automotive recall, a district court in Philadelphia considered the terms of a recall in its class certification analysis. The putative class representative experienced a rear axle fracture on his vehicle, which he claimed resulted from premature metal fatigue caused by a poorly designed axle.

The same month that the named plaintiff experienced his rear axle fracture, NHTSA launched an investigation based on consumer complaints concerning the rear axles on the same make and model vehicle. NHTSA ultimately determined that the axle's design allowed road salt to collect and corrode the metal in very short time periods. This conclusion prompted the automaker to conduct a voluntary recall in the 21 states considered to be high-corrosion states.

As a remedy, the manufacturer offered free inspections of the potentially affected models and a free replacement if the inspection revealed signs of cracking in the axle. If there were no signs of cracking, the company offered to install reinforcement brackets, also without charge. The lead plaintiff chose not to participate in the recall and instead pursued his lawsuit.

He moved the court to certify four different classes of vehicle owners involving various model years and four different legal theories, including breach of express and implied warranties, unjust enrichment, and violations of state consumer protection laws. Using the well-established rubric for class certification set forth in Federal Rule of Civil Procedure 23, the court declined to certify any of the four proposed classes, finding that none of them met the predominance and superiority requirements under Rule 23(b)(3).

The superiority requirement requires that plaintiffs show that a class action is superior to other available adjudication methods. In this matter, the court concluded that a class action under the circumstances was inefficient and not a superior method by which to adjudicate the claims.

The court emphasized that a recall was already underway across the country, publicized on NHTSA's website, and that the recall remedy was available to the putative class members. In addition, the automaker reported that a third of the plaintiffs had already received a repair or replacement axle. Furthermore, because the lead plaintiff was offered, but declined, the remedies he sought through a class action, the Court found that his interests were not completely in line with the class members he purported to represent.

These types of cases are not exclusive to the automotive sector. The toy industry saw a putative class action denied certification, albeit for a slightly different reason. In this matter, the Seventh Circuit Court of Appeals affirmed a district court's denial of class certification finding that the named plaintiffs were asking the court for remedies that most of the class members had already received or which still remained available to them.

While the court declined to find that a recall program was an "adjudication," it nevertheless denied class certification, finding that the named class representatives did not adequately represent the claims of the class members as required by the mandate in Rule 23(a)(4).

According to the court, the named plaintiff's claims that obtaining a refund would cause the class members to incur high transaction costs and expenses—such as notice and attorneys' fees—did not adequately protect the interests of the class. This was due to the fact that the manufacturer was already offering a refund as part of the recall.

Other Benefits of an Effective Recall Remedy

In addition to minimizing legal risk, a properly timed and effective recall remedy can protect a recalling firm from civil and criminal penalties and disruptive government audits by the Consumer Product Safety Commission, the Food and Drug Administration, NHTSA, and other regulators. A proactive recall strategy with a strong remedy conducted in good faith may also help a company recover recall-related expenses under relevant insurance policies.

Beyond financial considerations, strong recall remedies offer valuable reputational benefits. A company that acts swiftly and offers full remedies that can be easily obtained by customers during a recall demonstrates a commitment to safety and consumer goodwill. A well-managed recall can showcase excellent customer service. It may also offer companies a rare chance to enter a feedback loop with consumers. By communicating transparently and offering support, a company can bolster brand reputation and encourage customer loyalty and repeat business, even during a recall.

Preparation is key to an efficient and effective recall. There are several actions companies can take prior to a crisis to help things run more smoothly when a recall occurs. These include securing product recall insurance, establishing clear internal protocols for incident review and escalation, and implementing comprehensive systems to track product components, suppliers, and product batches.

In addition, companies should identify key personnel across departments who will be involved in the recall process. These include the full range of operational teams such as communications, inventory management, finance, compliance, and legal. Furthermore, businesses are advised to consider full and strong remedies in their corrective action plans.

For most companies, recalls are an inevitable part of business. However, there are steps that companies can take to lessen the impact on their customers, partners, and reputation when an in-market event occurs.

The views expressed in this article are those of the author and do not necessarily reflect the opinions of Sedgwick.

Food and drink

Food and drink businesses are currently navigating a rapidly evolving landscape of policy and regulatory shifts. Notably, the sector was expected to comply with the U.S. Food and Drug Administration's (FDA) Food Traceability Rule from 20 January 2026.

However, in August, the FDA proposed an extension, moving the compliance deadline by an additional 30 months to 20 July 2028. This extension is intended to give organisations sufficient time to develop and integrate the robust systems necessary for meeting the rule's far-reaching requirements. Under this regulation, companies involved in the manufacturing, processing, packing, or holding of designated foods must capture and maintain key data as products progress through the supply chain, ensuring this information is readily shared with partners.

Lead contamination in ground cinnamon remains an issue for the sector. The FDA expanded its public health alert to include five additional brands in September and early October following the detection of elevated lead levels.

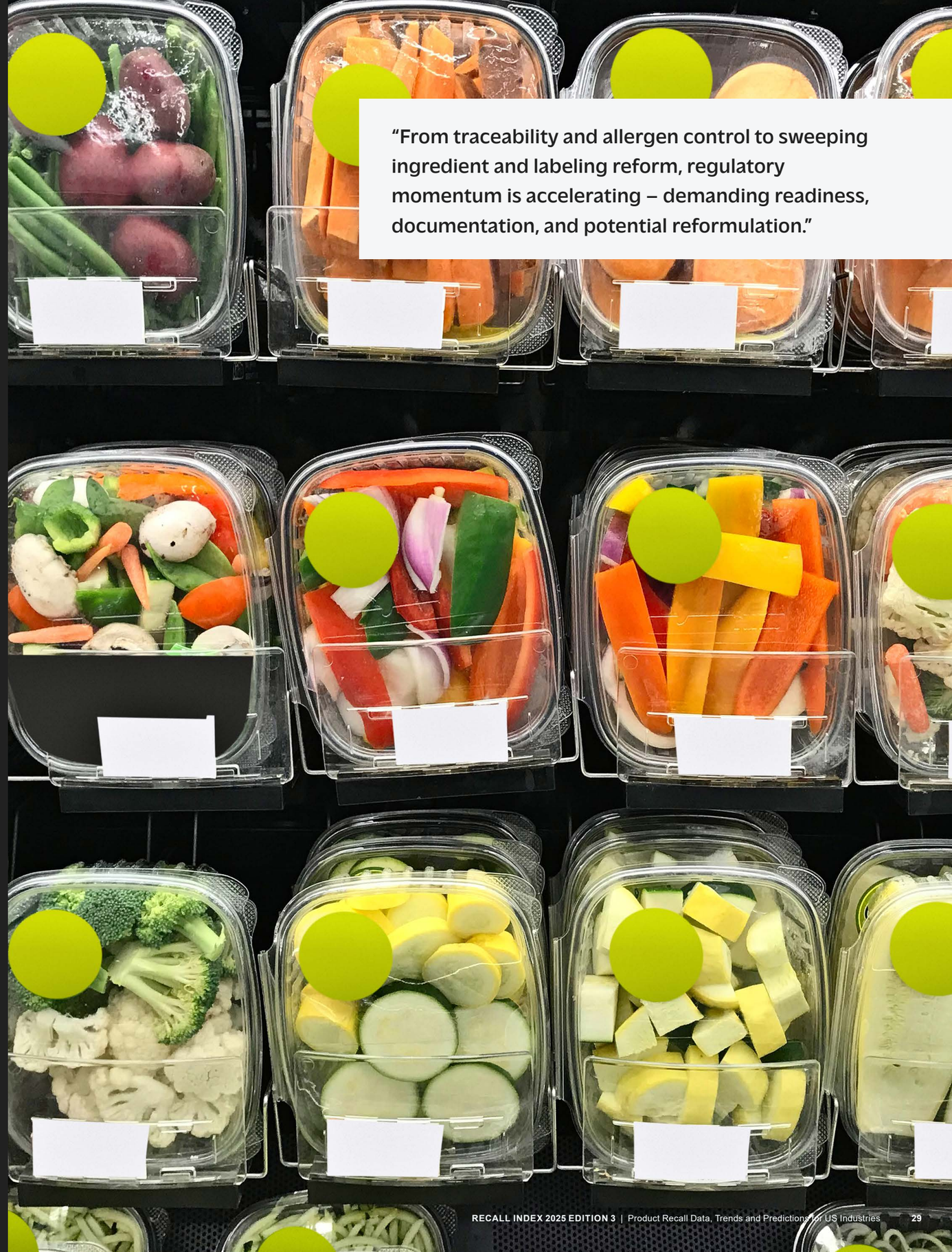
In September, the U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) directed its inspection program personnel (IPP) to include gluten in their verification activities for major allergens. Even though gluten is not one of the Big Nine major food allergens, establishments will need to accurately control and label it in the same way they address the recognized allergens. This could result in big changes for food companies and restaurants.

In July, the FDA asked for more collaboration from infant formula, baby food, and children's food manufacturers, distributors, and suppliers around recall communications for these products. FDA Commissioner Dr. Martin Makary laid out short- and long-term goals to overhaul how the agency and the public are informed about in-market events.

The Make America Healthy Again Commission issued its "Make Our Children Healthy Again Strategy Report." The plan includes more than 120 recommendations that would dramatically impact the food sector, including plans to eliminate the ability to self-affirm an ingredient as generally recognized as safe (GRAS), as well as other ingredient and labeling changes.

The USDA announced a new initiative to fight foodborne illness. The program includes more training for inspectors and more collaboration with state agencies. In addition, the FDA released the Reagan-Udall Foundation's (RUF's) Roadmap to Produce Safety: Summary Report of the Produce Safety Dialogue. The foundation gathered input from more than 170 stakeholders to explore ways to transform produce safety.

Communication and collaboration are clear themes throughout all the new policy proposals. However, robust enforcement will also continue to be a priority for agencies.



"From traceability and allergen control to sweeping ingredient and labeling reform, regulatory momentum is accelerating – demanding readiness, documentation, and potential reformulation."

FDA calls for improved infant formula recall communications

In July, FDA Commissioner Dr. Martin Makary sent a letter to stakeholders across the infant formula, baby food, and children's food sectors asking for companies to work with the agency to collaboratively transform "how we manage and communicate food recalls," particularly for food products intended for young children and babies.

The Commissioner called on both manufacturers and distributors to enhance public communication during food recalls. He also reminded them to immediately inform the FDA when they decide to initiate a recall and urged companies to consider expanded use of public notifications to ensure that consumers quickly have access to the most up-to-date information about product safety.

The letter sets forth both short- and long-term goals in the agency's efforts to strategically overhaul recall communications. Currently, the FDA is hoping for voluntary compliance instead of issuing new regulations.

The short-term goals include creating a centralized, consumer-focused webpage for streamlined public access to critical recall information—with an emphasis on infant formula, baby foods, and foods intended for children. Another objective is to evaluate internal and external recall communications protocols to ensure they align with current best practices and public health priorities. In addition, the agency wants to upgrade the FDA Enforcement Report and improve recall data granularity and accessibility, which would allow the public to refine and target searches for recall information.

In the short-term, the agency also wants to leverage focus group research and other stakeholder feedback on risk communications strategies to improve the reach and clarity of FDA recall communications. In addition, the FDA plans to implement process improvements that would further increase the speed of recall classification.

One long-term goal under this initiative is to redesign and digitize key recall documentation to support automated data extraction and AI-assisted analysis that would improve overall recall process efficiency.

The FDA also wants to implement an advanced digital platform for industry partners to submit standardized data to enhance efficiency in recall information processing, dissemination, and classification, as well as to modernize the data submission infrastructure.

The latest communication from Makary follows the announcement of "Operation Stork Speed" in March. That program includes provisions for regular communication between the FDA, consumers, and industry stakeholders as significant developments occur.

The new request from the agency to work more closely with manufacturers, packers, distributors, exporters, importers, and retailers shows just how interconnected business and regulators are and how reliant consumer safety is on cooperation.

While there is no clear implementation timeline for the FDA's goals, industry stakeholders should review the agency's priorities and determine whether they need to change their recall communications plans to be ready.

They should also confirm that they have processes in place to reach out to the agency early and with sufficient information and regular updates in the event of an in-market event.

MAHA Report urges changes to food industry

On September 9, 2025, the Make America Healthy Again (MAHA) Commission released its "Make Our Children Healthy Again Strategy Report." The Commission laid out more than 120 recommendations to reshape current U.S. policies and regulations that it claims "fueled America's childhood chronic disease epidemic."

The report emphasizes five key areas: restoring science and research, executive actions, process reform and deregulation, public awareness and education, and private sector collaboration. The proposed initiatives include significant changes across the food and drink sector, such as eliminating the self-declared pathway to determine that food ingredients are generally regarded as safe (GRAS), revising front-of-package labeling to highlight added sugars and sodium, and continuing efforts to limit or ban certain food additives such as synthetic colors.

The strategy also suggests expanding National Institutes of Health (NIH) research into chronic disease prevention with a focus on nutrition and metabolic health, food quality, and precision agriculture, among other factors.

Policy reforms that are expected from the initiative include new 2025-2030 Dietary Guidelines for Americans, a definition of ultra-processed foods, and advancing the post-market assessment of chemicals in food that the FDA announced in May.

Furthermore, the plan suggests that federal nutrition programs, such as Supplemental Nutrition Assistance Program, Head Start, school meals, and Women, Infants, and Children, prioritize “whole, healthy foods” and reduce their reliance on highly processed foods. It also recommends that the FDA update the nutrient requirements and testing for infant formula with a focus on reducing heavy metals.

The plan calls for the USDA to streamline organic certification processes to encourage small farms to transition to organic practices and to reduce the regulatory compliance burdens for small farms, particularly for specific Environmental Protection Agency (EPA) regulations. These are just some of the many proposed agriculture and food deregulatory actions.

From a structural standpoint, the strategy outlines several organizational changes, including the Department of Health and Human Services establishing an Administration for a Healthy America, which would centralize leadership on childhood chronic disease prevention. There are also proposed changes for the EPA and NIH.

Attorneys with Beveridge & Diamond PC note that by packaging its recommendations into a comprehensive, interagency strategy, the MAHA Commission could “compress timelines for policy development and increase the likelihood of parallel actions across multiple agencies.”

The legal experts caution food and food chemical manufacturers to expect more intense scrutiny of their products’ additives, colorants, and labeling. They advise businesses to assess their products to determine which ones contain FDA-approved synthetic color additives and evaluate their options to reformulate the ingredients or use natural color alternatives. In addition, they recommend that manufacturers have clear support for any claims, especially for statements such as “no artificial colors.”

Food companies also need to monitor Congressional actions. In July, several Senate Democrats introduced the Ensuring Safe and Toxic-Free Foods Act of 2025, which would eliminate the GRAS loophole that is addressed in the MAHA Strategy. In August, House Democrats introduced a bill that would make significant changes to how food additives are regulated by the FDA and another measure to revoke the legal status of several synthetic color additives commonly used in food products.

Before any new policies take effect, the relevant agencies or Congress will need to draft rulemakings, guidance, and enforcement priorities. The attorney’s counsel urges stakeholders to watch for proposed rules, draft frameworks, and requests for information in the Federal Registry as any new regulations move forward.

USDA announces new plan to boost food safety

In July, Secretary of Agriculture Brooke Rollins announced a comprehensive plan to boost the USDA's efforts to combat foodborne illness. The strategy focuses on the USDA's Food Safety and Inspection Service (FSIS), which is responsible for ensuring meat, poultry, and egg products are safe, wholesome, and properly labeled.

The new plan is built around five primary elements. The first is enhancing microbiological testing and inspection oversight. The USDA has upgraded its laboratory facilities and increased foodborne illness testing. One example is a 200% increase in the number of samples tested for Listeria monocytogenes between 2024 and 2025. FSIS is also committed to conducting more robust, in-person Food Safety Assessments (FSAs) and prioritizing ready-to-eat (RTE) meat and poultry establishments given several large recalls in the past 12 months for prepared meats.

Another element is to update FSIS inspectors' training and tools. These include a weekly questionnaire for frontline inspectors to collect data on specific Listeria monocytogenes-related risk factors. There is also revised guidance on identifying systemic problems and Listeria-specific training for frontline inspection personnel.

A third factor in the new approach is how the agency addresses Salmonella in poultry. Rollins has instructed FSIS to find a "more effective and achievable approach to address Salmonella in poultry products." This comes after a proposed Salmonella framework was withdrawn earlier this year over stakeholder concerns. FSIS and its public health partners investigated 14 Salmonella outbreaks and approximately 200 illnesses between 1998 and 2024. The bacteria continues to be an important target in food safety.

The USDA's plan also focuses on strengthening partnerships with states. The agency is increasing financial and technical support for state-level meat and poultry inspection programs. More than 1,500 American businesses rely on state inspections, including small and very small meat and poultry processors. The agency will also enhance its oversight over Talmadge-Aiken (TA) state cooperative programs.

Already this year, FSIS signed updated, comprehensive cooperative agreements with all 29 states that operate state meat and poultry programs. The revisions clarified expectations for oversight and enforcement of food safety laws, provided comprehensive training for inspectors, and ensured regular coordination with FSIS.

The final component of the USDA's strategy is to empower FSIS inspectors to take measures to drive compliance. This includes increasing enforcement actions and deploying field supervisors for follow-up visits if inspectors identify systemic issues at a facility. FSIS took 103 enforcement actions in the first six months of 2025, a 36% increase over the same period in 2024.

The USDA is not the only agency updating its food safety policies. On July 28, the FDA released the Roadmap to Produce Safety: Summary Report of the Produce Safety Dialogue from the Reagan-Udall Foundation. The report was commissioned by the agency to analyze input from more than 170 produce sector stakeholders about transformative change in produce safety management through collaboration.

The 73-page assessment identified four overarching priorities: making the case for and developing a strategy to increase public investment in produce safety; focusing on developing and implementing science-based, risk-reducing best practices; expanding technical assistance and other resources to support industry implementation of best practices; and increasing incentives for growers to implement best practices.

How these concerns will be translated into action and policy has yet to be seen. What is certain is that regulators will continue to focus on food safety and producers and distributors should be prepared for more oversight. They may also be asked for more collaboration to find and implement solutions.

By the numbers

The number of FDA food recalls rose 1.4% in Q3 2025 compared to Q2, increasing to 145 events. This is the second-highest quarterly total since Q1 2020. Notably, the volume of affected units surged 75.8%, rising from 14.32 million last quarter to 25.17 million this quarter. There were five recalls that affected more than 1.1 million units.

Year-to-date, there have been 415 recalls involving 109.74 million units. This marks a notable increase compared to the same period in 2024, when 363 recalls impacted just 45.02 million units.

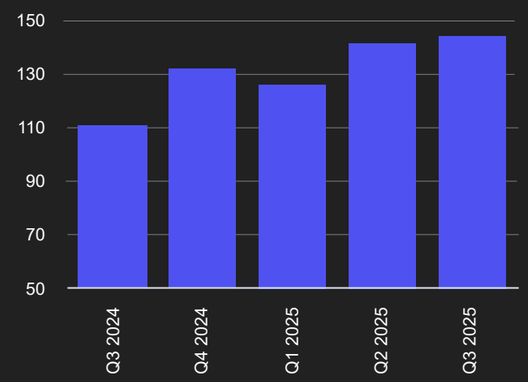
In Q3 2025, undeclared allergens remained the leading cause of FDA food recalls with 48 events. The most common allergens cited were soy, milk, and nuts, which were each linked to 10 recalls. Bacterial contamination was the second-highest cause of FDA food recalls in Q3 with 37 events, up from 32 in Q2. Listeria was the most common hazard, cited in 23 recalls. Non-bacterial contamination had the third-highest number of recalls with 13. Six of these were linked to shrimp contaminated by Cesium-137, a radioactive isotope.

Bacterial contamination impacted 13.33 million units, the most of any hazard in Q3. Undeclared allergens were second by volume with 8.00 million units recalled, including a recall of 1.11 million frozen fruit bars for undeclared milk and 3.70 million wasabi packets for undeclared color. Foreign materials were third and impacted 2.65 million units, mostly tied to a recall of yogurt that contained plastic.

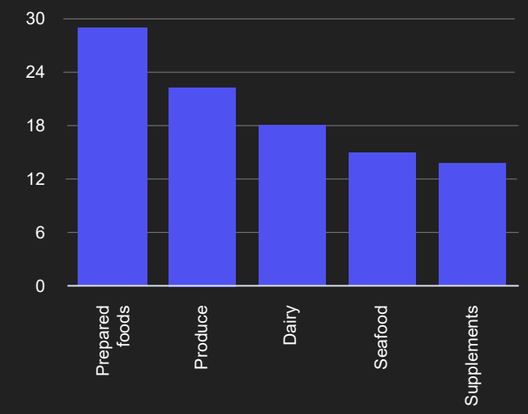
Prepared Foods experienced the most recalls of any FDA food product category in Q3 2025. There were 29 events, down from 50 last quarter. Produce was second with 22 events. Dairy was third with 18 recalls.

In terms of units impacted in Q3, Prepared Foods led with 17.05 million, including a recall of 10.59 million ice cream bars for concerns about Listeria. Dairy was second with 2.60 million units, tied largely to the yogurt recall. Eggs were third due to a single recall of 1.70 million units for Salmonella.

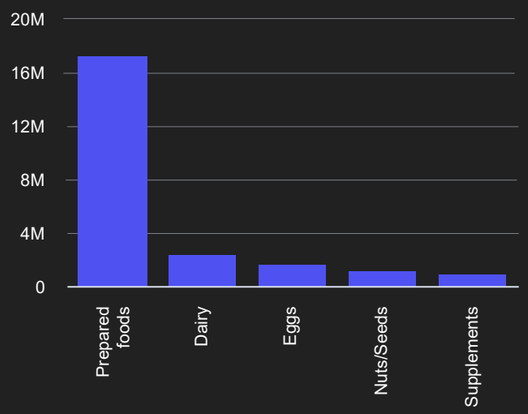
Number of recall events by quarter



Number of recall events by category (top 5)



Number of recalled units by category (top 5)



By the numbers

In Q3 2025, the number of U.S. Department of Agriculture (USDA) food recalls fell by 60.0% to six events, compared to 15 recalls in Q2. However, the number of units impacted surged 5,511.8% from 1.04 million pounds last quarter to 58.52 million pounds this quarter. That is the highest quarterly total in more than 13 years.

The 2025 total for the first three quarters is higher than the same period in 2024 for both events and units. Year-to-date, there have been 30 recalls involving 59.99 million pounds in 2025. This is compared to 28 recalls impacting 7.91 million pounds from January through September 2024.

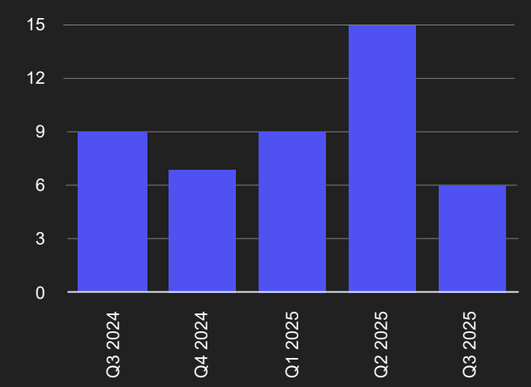
In Q3 2025, the most prevalent cause of USDA recall by event was foreign material with three. No inspection recorded two, and bacterial contamination had one.

By unit count, foreign materials was the leading cause of USDA food recalls, impacting 58.03 million pounds in Q3, primarily due to a recall of corn dogs that contained wood. No inspection was second by volume this quarter, tied to 367,812 pounds of recalled product. Bacterial contamination was third with 130,916 pounds.

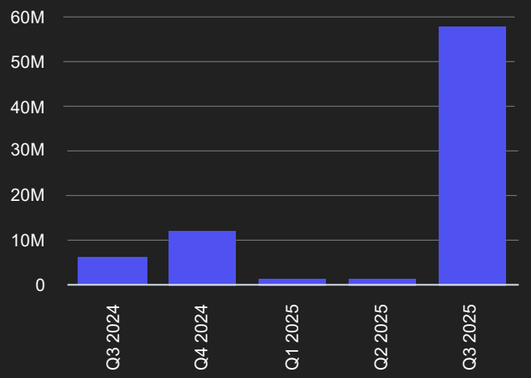
Pork and poultry each had two recalls in Q3 2025. Fish and beef were cited in one recall event apiece.

Pork was responsible for the most units recalled by product category with 58.03 million pounds affected in Q3 2025. Poultry was second with 391,985 pounds impacted, followed by fish with 98,916 pounds.

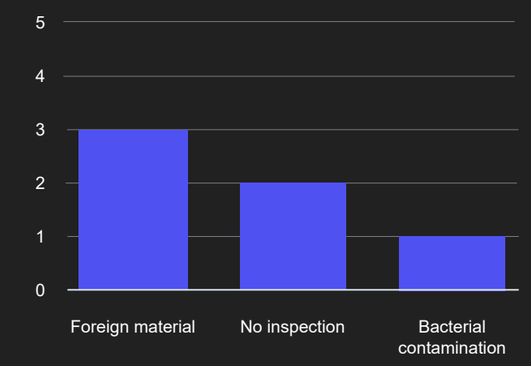
Number of recall events by quarter



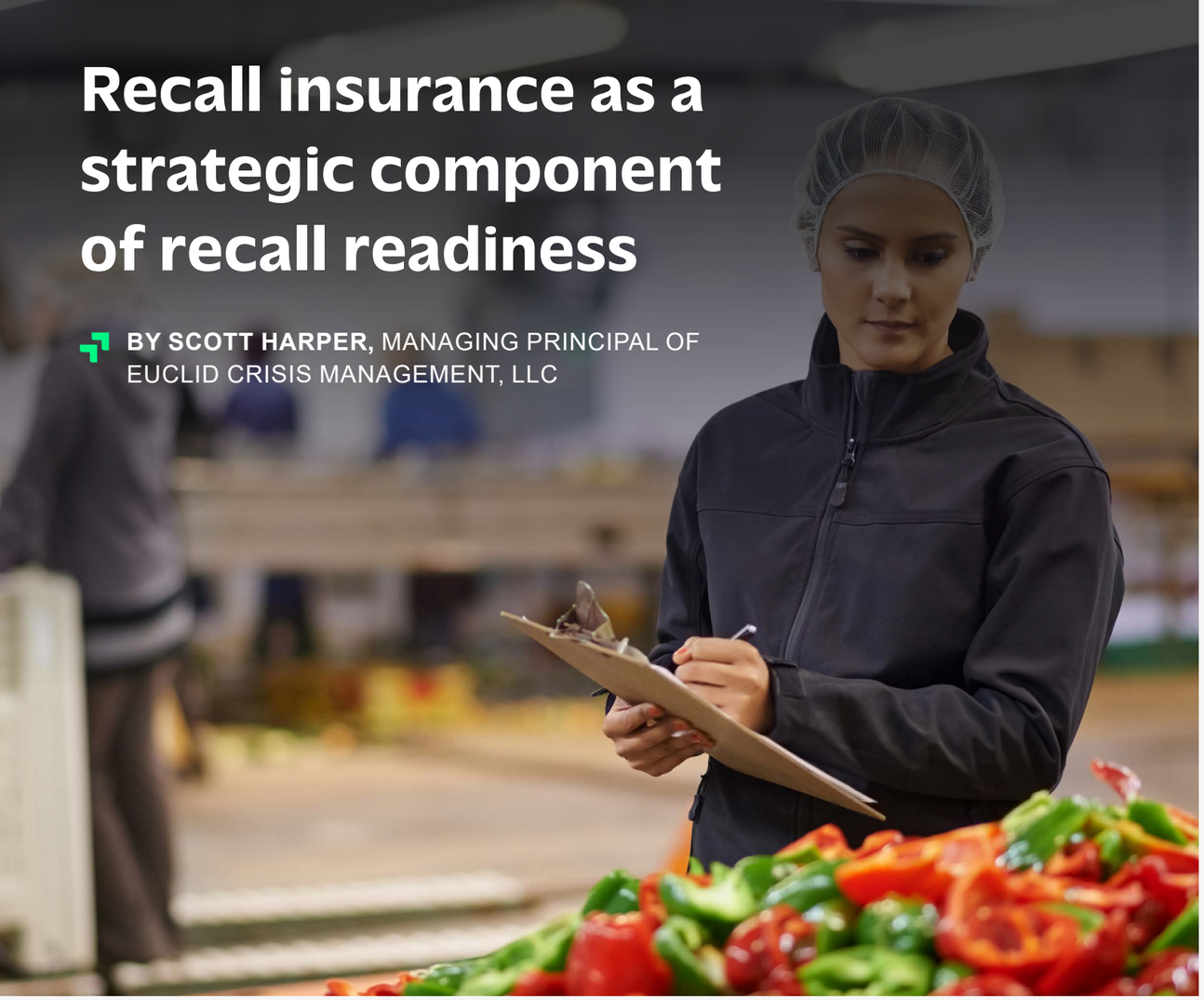
Number of pounds recalled by quarter



Number of recall events by risk (top 3)



Recall insurance as a strategic component of recall readiness



BY SCOTT HARPER, MANAGING PRINCIPAL OF EUCLID CRISIS MANAGEMENT, LLC

Product recalls no longer happen occasionally. They're the new normal for industries, including the food and drink sector. As business operations evolve and government oversight intensifies, accountability is expanding for everyone involved in the supply chain.

Triggered by contamination, defects, mislabeling, adverse publicity, or government involvement, recalls need instant, concerted action. Yet, many companies either choose not to buy recall insurance or see it only as a backup measure to be utilized after losses are sustained. That thinking is changing as more companies recognize recall insurance as a proactive tool for preparedness, protection, and resilience.

Recall insurance fills the gap left by traditional coverage

Recall insurance is designed to specifically address exposures that fall outside the scope of traditional liability and property insurance. Liability insurance—either general liability or products liability—typically responds to third-party claims for bodily injury or property damage caused by a company's products or operations. This differs from property insurance, which covers physical damage to the insured's own property from perils like fire or theft. Neither liability nor property insurance policies are built to handle the financial and operational fallout from a product recall, including the costs related to the actual products and brands involved.

Some liability carriers may offer limited recall or withdrawal expense endorsements, but these are generally narrow in scope, with modest limits and restrictive triggers. They are not a substitute for a dedicated recall policy. Their primary purpose is to provide minimal coverage for recall-related expenses that could help mitigate potential bodily injury claims under the liability policy, should contaminated products remain in the marketplace.

Recall insurance complements liability insurance by offering more comprehensive first-party coverage, including reimbursing the insured for their own losses stemming from a recall or contamination event. Unlike liability insurance, which addresses third-party claims for bodily injury or property damage, recall insurance protects the insured's balance sheet, helping the business maintain operations.

Another key distinction is that recall insurance can be triggered by the potential for harm, not just actual damage. Coverage may apply even if no one has been injured and no property has been damaged. In fact, certain events can trigger coverage even when the product itself is not contaminated. A liability or property policy is not intended to respond to any of these scenarios.

Furthermore, recall insurance can include a breadth of coverage enhancements that traditional liability or property policies exclude, including recall expenses, business interruption, product replacement or destruction, brand rehabilitation, crisis management, public relations, and third-party economic losses.

Coverage for pre-incident loss mitigation

The primary function of product recall insurance is to assist a company through navigating its recall scenario and reimbursing it for covered losses once the dust settles. However, this type of policy also has the unique ability to spring into action even before a recall takes place.

Most product recall insurance providers recognize the value of early intervention and allocate a portion of the policy premium toward proactive, pre-incident loss mitigation. Insurers know that companies with established recall plans and tested protocols are better equipped to contain losses when an event occurs. This may be particularly relevant to the food sector as new regulations around controlling Listeria and other rules are put into place.

A well-prepared company is not only more resilient but it also represents a lower risk for providers, which can lead to more favorable underwriting terms. Conversely, when a company is unprepared for a recall, losses can escalate quickly and there may not be clear direction on how to bounce back. With a solid plan in place, companies are far more likely to minimize their losses and recover quickly.

Access to expert consultants without the overhead

Perhaps the most underappreciated benefit of recall insurance is access to a network of expert consultants—specialists that few companies have in-house. Recall insurers provide access to counselors in crisis management, product recall, regulatory coordination, public relations, and consumer communications. These professionals stand ready to leap in the moment a recall is suspected, guiding the insured through each step of the event.

It may be costly, time-consuming, and overwhelming to engage these experts individually—especially in the middle of a crisis. A recall policy removes that strain by providing immediate access to vetted professionals who understand the regulatory landscape and how to handle high-stakes events. In addition, the policy covers the cost of their expertise. Having this knowledge available can decrease response times dramatically, improve communication with regulators and customers, and help contain reputational damage.

Recall insurance is not just about financial reimbursement. It's about having the right team in place when it matters most.

Why you need recall insurance

It is a common question: “If another company caused the recall, shouldn’t they be responsible for reimbursing me?” In theory, yes. But in practice, relying on another party to cover your losses is risky.

Even if a third party—such as a supplier, co-packer, or distributor—is clearly at fault, there is no guarantee that they will be able or willing to make you whole. They may not carry adequate insurance and could be underinsured or even insolvent. If they are based overseas, pursuing recovery could be slow, expensive, or legally complicated. And if multiple companies are affected, you may find yourself waiting in line with others, hoping for partial reimbursement.

That is why having your own recall insurance is essential. It’s designed to respond to your losses, regardless of who caused the event and without waiting for someone else to take responsibility.

Customers are now requiring recall insurance

As product recall insurance becomes more widely understood and adopted, major retailers will routinely require their suppliers to carry recall insurance as part of their contractual agreements. This may become even more standard as large food recalls become increasingly common. The U.S. Department of Agriculture continues to break records for the size of its recalls.

For now, this practice of mandatory coverage remains largely confined to large retail chains, leaving a gap in risk management for many other small and medium-sized enterprises. Any company that relies on supplied goods—whether ingredients, packaging, or components—should strongly consider mandating recall insurance for its suppliers.

The rationale is straightforward. If a supplier provides a contaminated or defective product, having recall insurance in place ensures they have the financial resources to cover the resulting losses. This not only protects the buyer from direct financial exposure but also helps preserve brand reputation and operational continuity.

Incorporating recall insurance requirements into supplier contracts is a proactive step toward building a more resilient supply chain. It helps shift a portion of the financial risk back to the source of the issue and reinforces accountability across the production ecosystem.

On the other hand, for smaller companies or emerging brands looking to get products into larger supply chains, proactively carrying recall insurance can serve as a strategic differentiator. It signals strong risk management practices and may make the business a more attractive partner to industry leaders.

Turning risk into readiness

In today’s environment, food and drink companies that view recall insurance as a strategic risk management tool are best positioned to respond expeditiously, protect their brand, and quickly rebound. Far more than a financial backstop, recall insurance delivers operational support, technical guidance, and early planning tools that can make the difference between a controlled response and a costly crisis.

Adding recall insurance is a prudent business strategy for any type of company—from supplier or manufacturer to brand owner or retailer. It is essential to long-term viability and success in an increasingly accountable marketplace.

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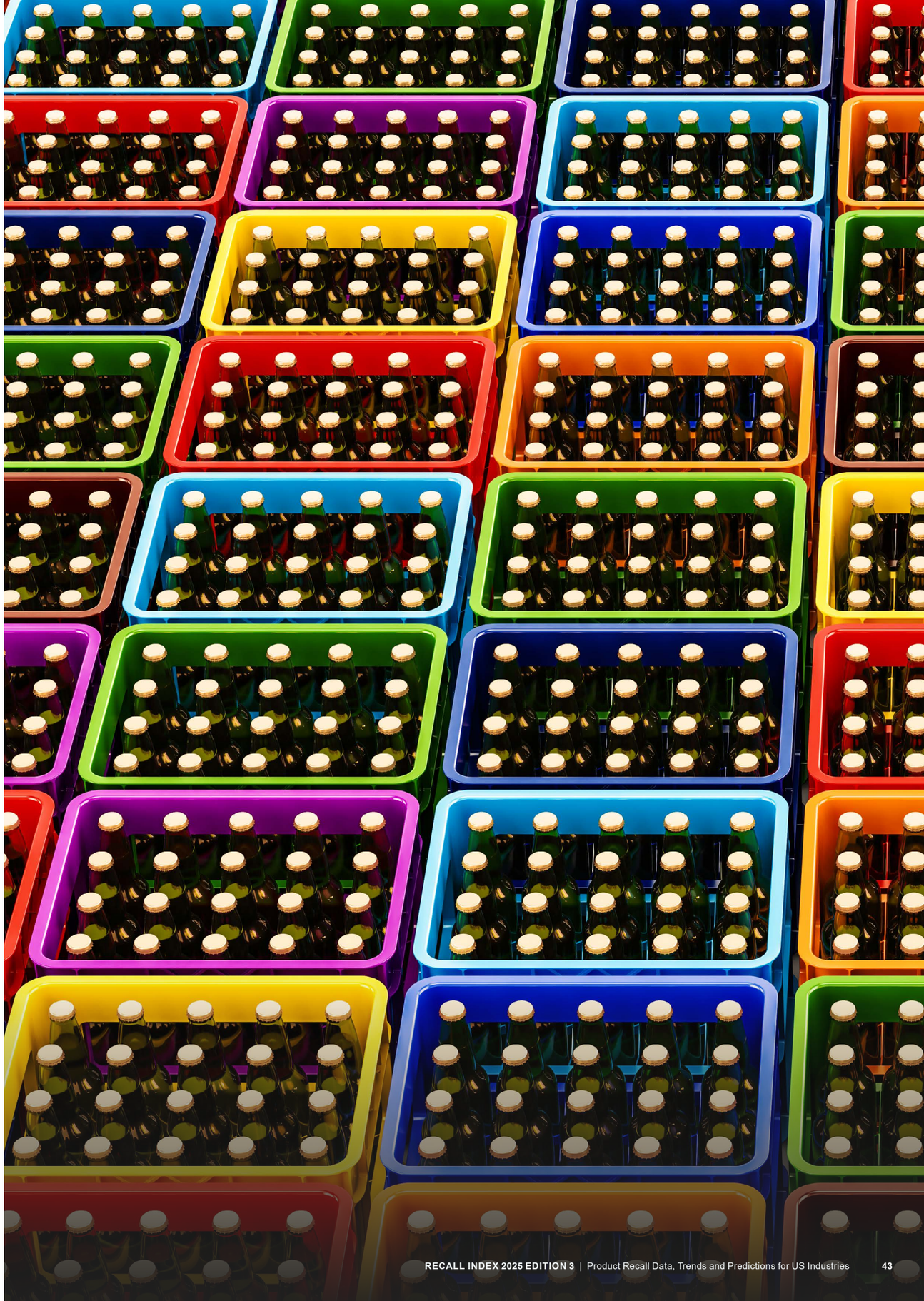


> “Cybersecurity enforcement, shifting diagnostics regulation, PFAS divergence, and trade investigations point to increasing regulatory complexity – requiring resilient supply chains and proactive engagement with regulators.”

Medical device

In July, the Department of Justice (DOJ) announced a settlement in a first-of-its-kind lawsuit for violations of the False Claims Act tied to alleged cybersecurity vulnerabilities in genomic sequencing systems. The defendant, a global genomics company, agreed to pay $9.8 million. The case raises concerns about emerging risks facing medical device companies.

In August, the U.S. Food and Drug Administration (FDA) issued a notice to the Office of Information and Regulatory Affairs indicating it would rescind its final rule on laboratory developed tests (LDTs). The agency’s move came after a U.S. District Court ruling vacated the regulation.

The law would have moved oversight of LDTs from the Center for Medicare and Medicaid Services (CMS) to the FDA. Many stakeholders opposed the rule, which would have classified LDTs as in vitro diagnostics (IVDs) and imposed stricter regulatory standards on them.

While multiple lawmakers are pushing for more restrictions on the use of perfluoroalkyl and polyfluoroalkyl substances (PFAS), the FDA stated that certain types of these chemicals are well-tested and safe for use in medical devices. In fact, the agency said they are essential for certain applications, including pacemakers and other lifesaving devices.

Medical device manufacturers and suppliers may face new costs and more complex supply chains. The Department of Commerce has launched a Section 232 tariff investigation into personal protective equipment (PPE), medical consumables, and medical equipment—including medical devices. The findings could result in tariffs or quotas on imported medical products.

The FDA announced the Medical Device User Fee Amendments for 2026, which lists the costs companies will need to pay for certain filings such as de novo classifications and 510(k)s. The agency is also seeking input for the next round of amendments.

While some device manufacturers may applaud the rescinding of the LDT rule, there are still many changes ahead that could increase operating fees and impact supply chains across the industry.

PFAS use permitted in medical devices

In August, the FDA issued an updated position on the use of perfluoroalkyl and polyfluoroalkyl substances (PFAS) in medical devices. The agency said that "currently there is no reason to restrict their continued use in [medical] devices."

This statement comes as the number of PFAS regulations continues to rise from other federal agencies, as well as state and local governments and international authorities.

The FDA stresses that there are more than 15,000 chemicals classified as PFAS with different molecular compositions and a range of uses. Fluoropolymers—the large molecule PFAS used in medical devices—are different than the kind that have been detected in drinking water and linked to health concerns. The FDA emphasized that fluoropolymers have been safely used in medical devices for decades, citing one specific type—polytetrafluoroethylene (PTFE)—that has been utilized since the 1950s.

The FDA also emphasized that PFAS, like PTFE, have unique properties that are vital for lifesaving devices, including cardiovascular stents, pacemakers, vascular grafts, and guidewires. For example, these chemicals provide electrical insulation in pacemaker wires and give biostability to medical devices that stay in the body so that they don't break down inside a patient.

To illustrate the safety of these chemicals, the FDA referenced a 2021 review that looked at data from more than 1,800 health care provider organizations around the country, more than 1,750 published and peer-reviewed scientific articles, and real-world surveillance of clinics and health care providers. The report "found no conclusive evidence of patient health issues associated with PTFE as a material."

Attorneys at Greenberg Traurig caution that while the FDA doesn't plan to impose a blanket PFAS restriction for medical device applications, global manufacturers and distributors need to monitor other jurisdictions. The European Chemicals Agency (ECHA) is evaluating a proposal to restrict PFAS in the EU, though some versions of the measure include an exemption for medical devices.

Trade policy changes impact industry

In September, the Department of Commerce's Bureau of Industry and Security (BIS) initiated a Section 232 tariff investigation into personal protective equipment (PPE), medical consumables, and medical equipment—including medical devices. These types of inquiries are designed to determine if imports of certain products pose a national security threat or harm domestic industries. Tariffs or import limits can be imposed based on the findings of the investigation.

During a comment period that ended on October 17, the BIS solicited input on 12 issues related to medical devices, including information about the current and projected demand for PPE, medical consumables, and medical equipment in the U.S. and the extent to which domestic production of these goods can meet U.S. demand. The agency also wanted to know what role foreign supply chains play in meeting U.S. demand and the concentration of U.S. imports that come from a small number of suppliers or foreign nations, as well as the risks associated with a limited number of suppliers.

Other questions sought to identify the impact of foreign government subsidies and predatory trade practices on competitiveness and whether unfair foreign trade practices and state-sponsored overproduction create artificially suppressed prices for imported medical devices and other goods. In addition, the BIS asked if increasing domestic capacity for these products could reduce import reliance and whether tariffs or quotas are necessary to protect national security, among other issues.

Attorneys with Hogan Lovells recommend that manufacturers assess their supply chain risks in light of the issues raised in the investigation to understand how much they rely on imports and where tariffs or quotas could disrupt their operations.

The legal experts also encourage companies to understand the regulatory and trade implications and to be ready to adapt quickly if new policies are implemented. Businesses may need to adjust their supply chains, update existing contracts, or alter product designs to ensure more components are produced domestically. Or they will need to prepare for higher supply costs and possible scarcity of materials.

Another change impacting medical devices is President Trump's suspension of the duty-free status for imported goods that are valued at $800 or less. Previously, these products were eligible for the de minimis exemption. They are now subject to applicable duties.

A message from U.S. Customs and Border Protection issued in July specifically states that "all shipments of FDA-regulated products, regardless of quantity and value are subject to the same regulatory requirements" and that "all FDA-regulated products must be submitted to the FDA for review. All prior communications exempting certain low-value FDA-regulated products are rescinded."

Medical device manufacturers, suppliers, and distributors should plan to provide more documentation for imported products previously granted de minimis exemptions. They should also explore the different scenarios they could face depending on the results of the Section 232 investigation.

User fees set for 2026

In August, the FDA held a public meeting to discuss the reauthorization of the Medical Device User Fee Amendments for fiscal years 2028 through 2032 (MDUFA VI). The fee schedule must be renewed by Congress and the legislative authority for the current MDUFA V ends on September 30, 2027.

Medical device companies are required to pay the FDA fees as determined by the MDUFA. The costs vary by the type of filing and company size. For example, the standard fee for a de novo classification request is $173,782; for any type of 510(k) it is $26,067. There is also an annual establishment registration for periodic reporting on Class III devices set at $20,275.

In the August meeting, the agency was seeking stakeholder input regarding the overall performance of the current MDUFA and any features that should be reduced or discontinued to ensure the continued efficiency and effectiveness of the medical device review process. Other topics included any new features the FDA should consider adding to improve the review process and changes that could be made to facilitate product development and timely access to new devices for consumers.

Prior to the meeting, the agency had issued its final guidance on small business qualifications for the MDUFA. Companies that meet the small business requirements are eligible for substantial discounts on the fees.

An assessment of the amendments by lawyers with Hogan Lovells found that overall there are more restrictions to the application process, the window to apply for a small business designation has been shortened, and some international sponsors may face stricter documentation requirements.

Certain basic elements of the small business program were unchanged, including maintaining the threshold to qualify set at companies with gross receipts of $100 million or less annually. For the first premarket application/report waiver, the eligibility requirement to have $30 million or less in gross receipts also remains the same.

The legal experts note that the guidance does not address how businesses that were recently created—and thus lack a tax return or national taxing authority (NTA) certificate—can apply. Typically, the FDA demands one of these two pieces of documentation as part of a small business waiver application.

It seems that the FDA has made it harder for manufacturers to qualify as a small business and be eligible for the lower fees. Companies should review the latest information from the agency to ensure they have the proper support for their application and are aware of the current fee schedule.

MEDICAL DEVICE

By the numbers

In Q3 2025, the number of FDA medical device recalls decreased by 4.8% compared to Q2, falling from 251 events to 239. However, the number of units recalled increased by 237.0% from 32.17 million to 108.39 million. That includes 11 recalls that impacted more than 1.00 million units each.

Year-to-date, there have been 726 recalls involving 159.15 million units in 2025. That is considerably lower than the 800 recalls and 408.29 million units recalled in the first three quarters of 2024.

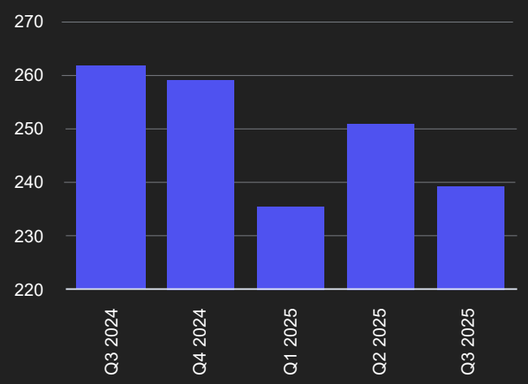
Device failure was the leading cause of medical device recalls in Q3 2025, accounting for 35 events. Software concerns were the second-most common concern with 28 events, down from 44 last quarter. Mislabeling was third with 24.

Products outside of specifications were responsible for the most units recalled this quarter with 33.20 million, primarily linked to a large recall of 33.16 million infusion pumps. The second-most common reason for medical device recalls by volume was no pre-market clearance with 24.70 million units impacted, largely due to two recalls of 24.69 million test cartridges used to analyze blood. False results had the third-highest number of units recalled, with 20.52 million, including one recall of 20.12 million cholinesterase enzyme (CHE) slides.

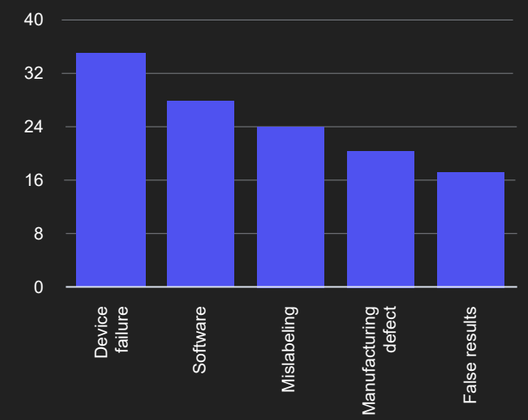
The number of Class I recalls remained steady at 36; however, the quantity of affected units surged from 4.29 million last quarter to 50.02 million. Class I incidents have now reached their highest level in more than twenty years. Although Class II events fell to 196 from 212 in Q2, the number of units impacted more than doubled, rising from 27.88 million to 58.19 million. Regarding Class III, both the event count and affected units increased this quarter, totalling seven and 177,913 respectively.

While the majority of companies encountered a single recall event, a minority faced repeated challenges: 28 companies were affected by two to nine recalls, and two companies contended with ten or more recalls—one of which experienced as many as 19.

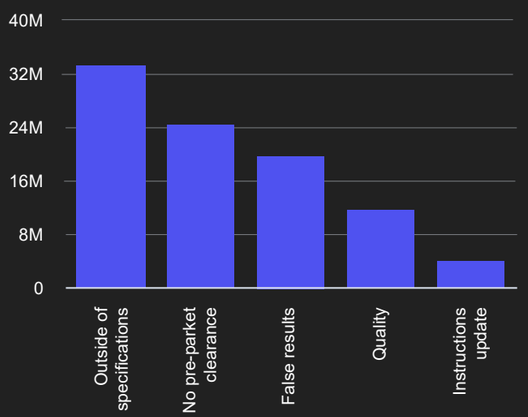
Number of recall events by quarter

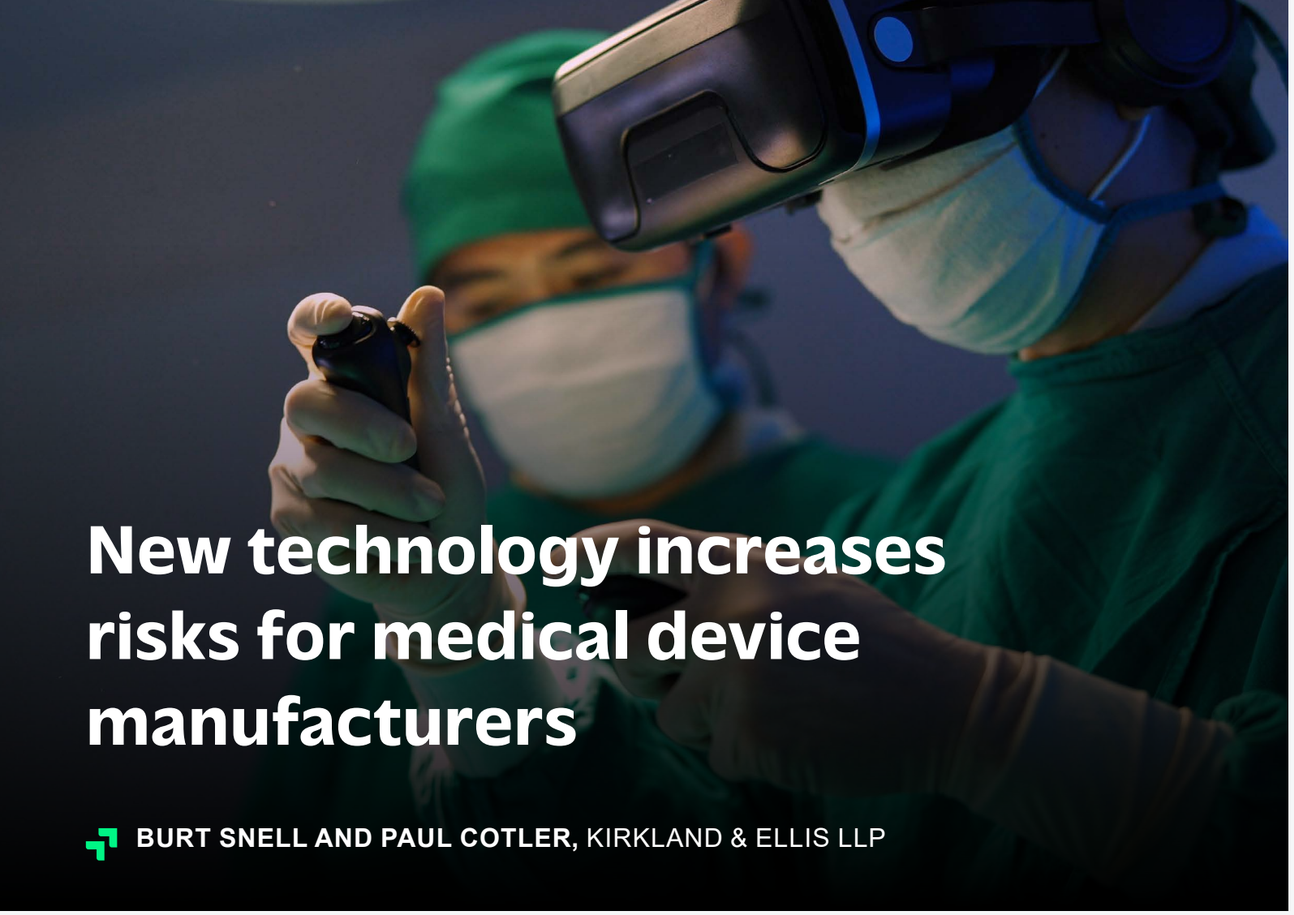


Number of recall events by risk (top 5)



Number of recalled units by risk (top 5)





New technology increases risks for medical device manufacturers

BURT SNELL AND PAUL COTLER, KIRKLAND & ELLIS LLP

Technology has been a dominant regulatory priority for the medical device sector recently. Manufacturers, marketers, and their counsel have been waiting for new and updated FDA direction on cutting-edge topics like cybersecurity, artificial intelligence, and associated recall trends with bated anticipation.

The past quarter saw a confluence of factors that accelerated the adoption of technology in medical devices. From FDA guidance and actions on these issues to publications in the scientific literature identifying risks, the stakes are increasing. Also on the rise are the market requirements, downstream enforcement, and legal risk.

Cybersecurity

Today, an ever-increasing number of medical devices rely on network and wireless connectivity for patient treatment. They collect and track patient data, transmit diagnostic images, and alert patients and care providers when a regimen changes or immediate medical attention is needed. And they largely do so accurately and efficiently in a growing variety of both common and more complicated, difficult-to-manage treatment settings.

Unfortunately, added connectivity also presents opportunities for bad actors to infiltrate the devices and potentially harm patients and medical systems. This risk gives medical device manufacturers more exposure from regulators and plaintiffs' lawyers.

In December 2022, the Food, Drug, & Cosmetic Act (FD&C Act) was amended to add a new section—524B Ensuring Cybersecurity of Devices. In September 2023, the FDA issued final guidance providing recommendations on premarket submissions for medical device cybersecurity considerations.

The guidelines were broad, influenced by prior security breaches. They warned marketers and manufacturers that their cybersecurity measures are "not limited to devices that include a device software function" or to "devices that are network-enabled or contain other connected capabilities."

On June 27, 2025, the FDA issued superseding guidance, which added an amendment on "cyber devices" to section 524B of the FD&C Act. This action followed an increase in cyberthreats and breaches and more than 100,000 public comments submitted to the regulatory docket.

The new section clarified which products were covered and the extent of enforcement. In the June guidance, connectivity is a key requirement, broadly defined by the FDA "to include devices that are able to connect to the internet, whether intentionally or unintentionally, through any means." Under the latest guidelines in section 542B, manufacturers of these types of devices must submit compliant documentation on cybersecurity to the FDA.

Examples of relevant connectivity features include network, server, or Cloud Service Provider connections and radio-frequency communications such as Wi-Fi, cellular, Bluetooth, and Bluetooth Low Energy. It also comprises magnetic inductive communications and hardware connectors capable of connecting to the internet, including USB, ethernet, and serial ports.

This last category can encompass a large group of devices not previously thought to be connected devices. The FDA's rationale is that "a device may need to be serviced via a USB connection. While the connection may be brief, the ability to connect is present and the device is therefore considered to have the ability to connect to the internet."

Other cybersecurity plans mandated in the latest guidance are various disclosures, procedures, documentation, updates, and patches.

Hackers are the primary cyberthreat for connected medical devices. While hospitals and medical centers have been targets of hacking for more than a decade, recently the sophistication, attacks, and risks have increased.

Medical device companies must be ready to respond quickly. Corrective measures may include the need to deactivate certain device functionality. For example, in July 2025 the FDA updated a Recall Safety Communication where it reported that a device manufacturer had implemented a new software patch that "fully removes networking functionality … making them only usable for local monitoring." In another cybersecurity recall in April 2025, a manufacturer permanently removed the medical device from the market.

In a stark enforcement environment, medical device companies are in the crosshairs. Following earlier action by the FDA, the Department of Justice (DOJ) utilized the False Claims Act to obtain a $9.8 million settlement from a large U.S. biotech company in July 2025. The DOJ alleged cybersecurity vulnerabilities, a lack of sufficient quality systems, and the company's failure to incorporate product cybersecurity in its software design, development, installation, and on-market monitoring for its medical device genomic sequencing products.

No large private litigation has begun to crop up in this area yet. However, it appears that some enterprising plaintiffs' lawyers are beginning to recruit potential cases focused on medical devices that have been hacked, espousing causes of actions rooted in product liability, healthcare facility liability, and even healthcare provider liability.

Artificial Intelligence and Software as Medical Device

The FDA has recently been active in a related field of technology—artificial intelligence (AI). As of October 2025, there are 1,247 medical devices on the FDA's AI-Enabled Medical Device List. While some of these were approved as far back as 1995, about half were approved just within the last two years. This signifies the incredible recent growth of the AI-enabled medical device market.

In August 2025, the FDA published final guidance for premarket submissions of AI-enabled devices, specifically addressing "Predetermined Change Control Plans" (PCCPs) in an effort to "promote the development of safe and effective AI-enabled devices." AI-enabled devices derive some of their effectiveness from "learning" through data collection and AI processes. This means that the final product's new characteristics are the result of an iterative process, which the FDA calls a "modification." That product may not resemble the approved premarket version of the same product.

PCCP's are intended to address these otherwise unapproved "modifications" by providing utmost transparency in AI-engineering and product development, modification protocols, and a comprehensive control plan for in-the-market products that may eventually undergo modifications.

Additionally, in September 2025, the FDA opened a Request For Public Comment (RPC) on "Measuring and Evaluating Artificial Intelligence-enabled Medical Device Performance in the Real-World." The agency is seeking help in evaluating and mitigating performance changes over time in these devices.

Among the topics addressed in the RPC are how to reduce performance degradation, bias, or reliability issues as a result of "data drift" that can occur while the AI-enabled device continues to "learn" over time. Data drift is the gradual changes that can occur in data or clinical practices that degrade the accuracy of an AI model over time. This degradation is a central concern for postmarket monitoring.

A retrospective study released in October evaluated the accuracy of an AI-enabled imaging device over hundreds of thousands of image sets. The research concluded that despite demonstrating high diagnostic accuracy, false positives could be attributed in part to drift. This issue poses "a significant challenge for accurate and timely performance monitoring," which potentially compromises "the safe and effective use of AI in clinical workflows."

AI and machine learning operate in an ongoing development phase. The FDA's recommendations for addressing these important concerns will likely be followed closely by manufacturers. The agency's RPC closes on December 1, 2025.

All medical device manufacturers and marketers should be aware of the FDA's regular enforcement of AI best practices. The agency has issued warning letters to multiple companies over concerns that certain AI-enabled medical devices were adulterated and misbranded. In some cases, these determinations were based on marketing language contained on the companies' websites.

Companies that are marketing the AI functionalities of their medical devices should be prepared to provide the FDA with a fulsome accounting of the devices' developmental processes and the manufacturer's plans to deal with foreseeable "modifications."

Recall Trends

Recalls of medical devices for software-related issues are a common occurrence. There were 28 recalls related to software in Q3, which impacted 2.59 million units. A study published in August suggests that attention is turning to AI-enabled medical devices. The report shows that a lack of clinical validation for these types of products was associated with a higher rate of product recalls.

Such a finding underlines the importance of thorough evaluation and developmental processes for any AI component used as a feature in a medical device. Another recent study addressed potential safety aspects, including benefit-risk reporting with AI-enabled medical devices.

Looking Ahead

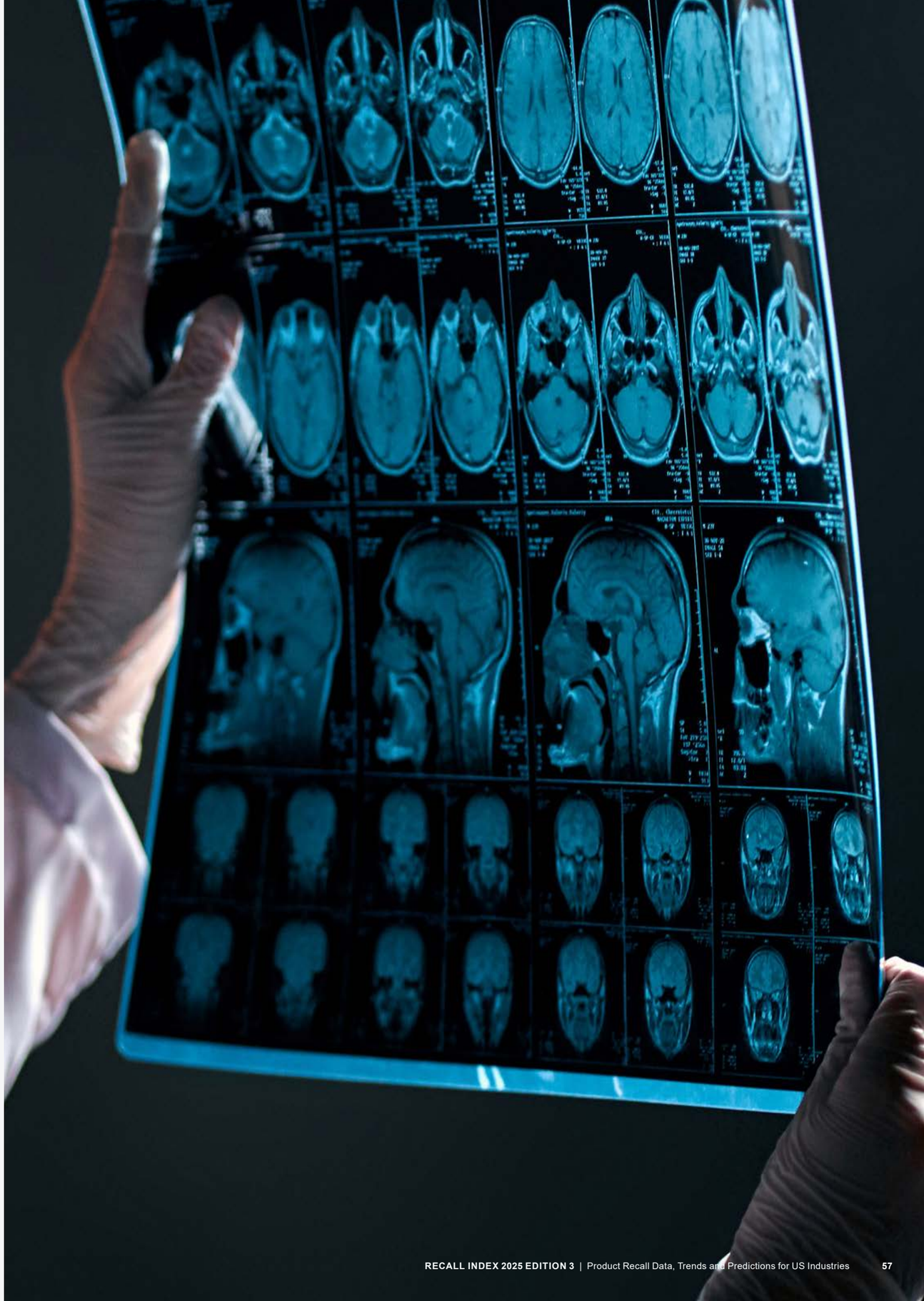
Publicity may nudge the FDA to take an even more proactive stance in regulating this developing area, while also serving as a potential inflection point for government investigations, private lawsuits, and other actions.

On September 29, 2025, the FDA's Center for Devices and Radiological Health (CDRH) announced that it was expanding the Communications Pilot to Enhance the Medical Device Recall Program, which encompassed devices classified into a limited group of medical specialty panels.

CDRH will now issue Early Alerts for potentially high-risk removals or corrections for all medical devices. Thus, more AI-enabled medical devices may be the subject of these early recall alerts given that the vast majority of these devices are indicated for radiological use.

Risks for medical device manufacturers continue to rise around software, cybersecurity, and AI. Companies will need to ensure that they maintain robust quality assurance and recall programs to avoid regulatory and legal challenges.

The views expressed in this article are those of the author and do not necessarily reflect the opinions of Sedgwick.



Pharmaceutical

Pricing and tariffs were key issues across the pharmaceutical sector in the third quarter of 2025. On August 21, the U.S. and EU issued a joint statement on a trade agreement committing the U.S. to apply the higher of either the U.S. Most Favored Nation (MFN) tariff rate or a tariff rate of 15% on a range of goods originating in the EU. Included on the list are generic pharmaceuticals and their ingredients and chemical precursors.

That agreement was followed by an announcement from President Trump on September 25 ordering a 100% tariff on "any branded or patented pharmaceutical product, unless a company is building their pharmaceutical manufacturing plant in America."

A few days later, the White House publicized the U.S.'s first MFN pricing agreement with a leading drug company. The manufacturer will be given a three-year grace period during which its products won't face tariffs that other companies may have to pay as a result of an ongoing Section 232 investigation. For now, tariffs on other branded drug manufacturers are temporarily paused while MFN negotiations continue.

In a move that could be troublesome for pharmaceutical companies, the U.S. Food and Drug Administration (FDA) has also begun releasing complete response letters (CRLs). Initially, the agency was publishing old CRLs from the archives, but in September it issued letters soon after sending them to sponsors. Historically, the agency would wait for approval from the companies involved. The FDA also released CRLs for currently pending or withdrawn drug and biologic applications.

Attorneys with Ropes & Gray LLP caution that sponsors whose CRLs are released may view this action by the FDA as an infringement of their trade secrets and confidential commercial information that could be used unfairly by their competitors.

"With shifting tariff policies, renewed FDA transparency, and tighter oversight of advertising and inspections, pharmaceutical companies must prepare for greater scrutiny while navigating incentives to reshore production."

Another action that could create more liability for drug companies is the FDA's move to more aggressively enforce policies around direct-to-consumer (DTC) drug advertisements. The agency and the White House claim that manufacturers are not doing enough to ensure consumers are aware of all the potential risks posed by medications. They also state that many DTC advertisements violate standards in the Federal Food, Drug, & Cosmetics Act.

In addition, the FDA is looking to expand the use of remote regulatory assessments and other alternatives to in-person inspections. The agency issued a guidance in September that established a risk-based framework for the use of these tools to supplement or replace on-site inspections for pending drugs and biologics applications.

There are also new measures to promote more U.S.-based production of critical medicines. In August, the FDA announced its FDA PreCheck program, which is designed to strengthen the domestic pharmaceutical supply chain.

The pharmaceutical industry can expect continued changes as the new leaders across the FDA and the Department of Health and Human Services (HHS) work to implement their agenda.

Regulators to restrict pharmaceutical advertising

Currently, the U.S. is one of the only countries to allow direct-to-consumer (DTC) advertising of prescription drugs. On September 9, the White House issued a memorandum about what it characterized as "misleading direct-to-consumer prescription drug advertisements." It alleged that amidst a skyrocketing amount of advertising by drug manufacturers in recent decades, the amount of information provided to the public about possible risks has been incomplete and misleading.

The administration called on the HHS Secretary and the FDA Commissioner to take appropriate actions to ensure transparency and accuracy in DTC prescription drug advertising. The regulators are also charged with enforcing the Federal Food, Drug, and Cosmetic Act's (FD&C Act's) prescription drug advertising provisions to prevent misleading information.

This idea was echoed in the Make Our Children Healthy Again Strategy Report released by the Make America Healthy Again (MAHA) Commission on the same day that the White House memo was published. These two actions coincided with a press release from the FDA announcing planned rulemaking and more immediate enforcement actions and strategies for DTC drug advertising.

The agency also sent form letters to virtually all pharmaceutical product application holders, as well as cease-and-desist notices to approximately 100 companies, directing them to remove "any noncompliant advertising" and to "bring all promotional communications into compliance." More than half of the 100 warning letters targeted advertisements for compounded drugs—including GLP-1 weight loss drugs. The remainder focused on FDA-approved drugs and biological products.

Changing DTC advertising rules is a bipartisan issue. In June, Senator Bernie Sanders and Senator Angus King, both Independents, introduced the End Prescription Drug Ads Now Act. The measure was designed to ban all DTC prescription drug advertising and was co-sponsored by five Democrats. It is unclear whether the FDA's support for the change will help move the legislation forward.

The FDA's press release and letters to companies made it clear that in addition to advertisements on traditional broadcast media, social media ads will also be carefully monitored. Lawyers with Morgan, Lewis & Bockius LLP caution that the FD&C Act is a criminal statute. Violating the rule could result in criminal misbranding charges as well as potential deceptive advertising charges from state attorneys general that involve both federal and state law. There is even the risk of claims being brought under the federal civil False Claims Act (FCA).

The legal experts note other potential legal hurdles. The proposed restrictions may raise questions about balancing consumer protection for patients and First Amendment protections for commercial speech. Companies may challenge the FDA under the Administrative Procedure Act.

To protect their brands, the lawyers recommend that companies immediately review all existing and planned advertising and promotional campaigns across all platforms. Manufacturers and marketers should assess compliance with both current FD&C Act obligations and changes that the FDA is likely to impose, especially around the “adequate provision” standard.

The lawyers also suggest that drug manufacturers and distributors prepare for enforcement actions by developing response strategies in advance. This includes documenting good-faith compliance efforts and establishing protocols for responding to warning letters, cease-and-desist notices, criminal grand jury and HIPAA subpoenas, and FCA civil investigative demands.

Remote regulatory assessment guidance finalized

Remote regulatory assessments (RRAs) became an incredibly important tool for the FDA during the COVID-19 pandemic when in-person inspections were not an option. Even after the pandemic, the agency has continued to use this alternative method for inspections.

In September, the FDA issued a guidance that lays out a risk-based framework for how to use remote and collaborative tools to support or replace traditional on-site inspections for pending applications for drugs and biologics.

As part of the Prescription Drug User Fee Act (PDUFA VII) and Biosimilar User Fee Act (BsUFA III), the agency promised more clarity around how alternative tools could be used to evaluate facilities listed in new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologics license applications (BLAs). The FDA wants to approve applications in a timely manner without sacrificing product quality and patient safety.

The latest guidance outlines several tools that the agency explicitly states can be used to support facility evaluations for pending applications in addition to traditional on-site inspections. These alternatives include RRAs, trusted foreign partner inspections, and remote subject matter experts (SMEs).

According to the FDA, RRAs can be mandatory, which is often the case with remote records requests, or voluntary remote interactive evaluations (RIEs).

However, the agency cautions that “declining to participate in an RIE may prolong a decision on an application.”

While trusted foreign partner inspections cannot be used for preapproval or prelicense inspections, inspection reports from trusted partners may be considered in facility assessments. According to the latest guidance, the FDA is participating in a pilot program evaluating collaborative hybrid inspections by multiple regulatory authorities run by the International Coalition of Medicines Regulatory Authorities. Depending on the results of this trial, the tasks that trusted foreign partners are authorized to do may expand.

The new guidelines also allow on-site FDA teams to utilize remote FDA SMEs who would connect virtually to provide technical expertise during inspections. As with the RRAs, the FDA notes that a facility’s agreement to the involvement of remote agency personnel is voluntary, but declining may result in a delay in the application.

Attorneys with Sidley Austin LLP highlight some of the legal and regulatory considerations of the latest guidance, including the fact that failing to fully comply with a Section §704(a)(4) records request or not complying in a timely manner may result in delays, complete response letters, or potential regulatory action.

In addition, relying on foreign regulatory partners can reduce duplicative inspections, but it may also result in a divergence in inspectional scope or findings. The lawyers advise companies with a presence in multiple jurisdictions to ensure their systems are consistently robust across every site.

The legal experts also suggest that manufacturers remain inspection ready. That includes evaluating their technical capabilities to support remote interactive evaluations and remote SME participation with tools such as secure livestreaming, teleconferences, and digital record-sharing.

The attorneys note that the FDA is looking to streamline the application review process. By aligning with the recommendations in the latest guidance, manufacturers can leverage the advantages of these alternative tools to improve their regulatory timelines and approval pathways.

FDA announces PreCheck program

A main focus of the Trump Administration across all industries has been a push to move more manufacturing to the United States. In May, the president issued an executive order to promote the domestic production of critical medicines. In response, the FDA announced its new FDA PreCheck program in August to strengthen the domestic pharmaceutical supply chain. The voluntary initiative will increase regulatory predictability and facilitate the construction of manufacturing sites in the United States.

According to the FDA, more than half of the pharmaceuticals distributed in the U.S. are manufactured overseas. In addition, U.S. manufacturers heavily rely on overseas sources for active pharmaceutical ingredients (APIs).

The PreCheck program will use a two-phase approach to facilitate new U.S. drug manufacturing facilities. The first step is the Facility Readiness Phase, which provides manufacturers with more frequent FDA communication at critical development stages, including facility design, construction, and pre-production. Pharmaceutical manufacturers will be encouraged to provide the agency with comprehensive facility-specific information through a Type V Drug Master File (DMF).

The DMF should include site operations layouts and descriptions, Pharmaceutical Quality System elements, and Quality Management Maturity practices. This information will help the FDA offer input regarding the consistency and effectiveness of quality procedures. The goal is to reduce the risk of cGMP deficiencies that could impact product quality, patient safety, and application approval.

The second step is the Application Submission Phase, which centers on streamlining development of the Chemistry, Manufacturing, and Controls (CMC) section of the application through pre-application meetings and early feedback. Applicants and their manufacturers will be able to share facility and manufacturing strategies for specific drugs with the FDA to allow assessment and inspection activities earlier in the review cycle.

This phase will also offer the agency the opportunity to anticipate data or logistical needs required to support review and inspection processes and to inform the manufacturer in advance to help accelerate quality element assessments.

The FDA solicited public comments through October 30, 2025 around four key areas. These included what stakeholders consider to be the most significant regulatory hurdle in establishing a new domestic pharmaceutical manufacturing facility and which specific element(s) of the FDA PreCheck proposal are most likely to help establish new U.S. manufacturing facilities. The FDA also wanted to know if there are additional elements or implementation considerations that should be considered in the FDA PreCheck proposal and any concerns companies have about providing relevant information about manufacturing facilities—such as facility design, quality systems, cGMP compliance, or validation data—in advance of, or separate from, an application submission.

The agency also held a public meeting on September 30, 2025. According to attorneys with Hogan Lovells, industry stakeholders strongly supported the new program, though had questions about how it would be implemented and asked for more clarity around the project's scope, eligibility requirements, and accommodations for different product types. There were also questions about how the initiative would integrate with existing regulatory pathways, programs, and tools.

Stakeholders urged the agency to offer "meaningful incentives"—such as inspection waivers, simplified CMC submissions, and accelerated timelines—to promote participation. The legal experts stated that meeting participants raised concerns that certain information shared with the FDA under the PreCheck program could trigger FDA enforcement activities later at the facility, such as targeted inspections.

The lawyers with Hogan Lovells note that FDA regulatory requirements are only one of many factors that companies consider when deciding where to locate manufacturing operations. Concerns such as cost, supply chain logistics, workforce availability, tariff policy, and incentives and policies offered by other nations also play a role.

The PreCheck program may be a helpful tool for companies who were already considering new manufacturing facilities in the United States. However, it may not be strong enough to be the only factor that encourages companies to shift or expand production.

By the numbers

There were 97 FDA pharmaceutical recalls in Q3 2025, the same number as in Q2. In contrast, the total number of units rose by 137.4% from 18.77 million in Q2 to 44.56 million this quarter. The average recall size more than doubled quarter-over-quarter, growing from 193,472 to 459,361. There were four recalls that impacted 3.00 million or more units.

Year-to-date, there have been 281 recalls involving 91.07 million units in 2025. That compares to 275 recalls impacting 22.04 million units in the first three quarters of 2024. In terms of events, 2025 is currently the second-highest figure recorded in the past 14 years.

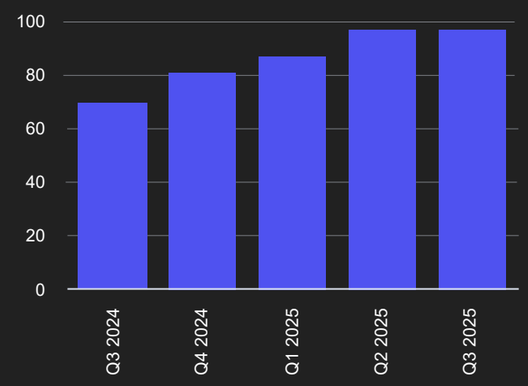
The leading cause of pharmaceutical recalls in Q3 2025 was failed specifications with 17 events. That was followed by cGMP deviations with 15 events. Foreign materials were third and was linked to 13 recalls.

Mislabeling impacted the most units by volume with 20.27 million, including one recall of 20.00 million vials of penicillin G potassium. Subpotency was second by volume, affecting approximately 13.42 million units, with most of them (13.12 million) tied to a recall of alcohol swabs. Sterility concerns impacted 4.82 million units, the third-highest total of any pharmaceutical risk this quarter. This included a recall of 3.85 million antiseptic towelettes.

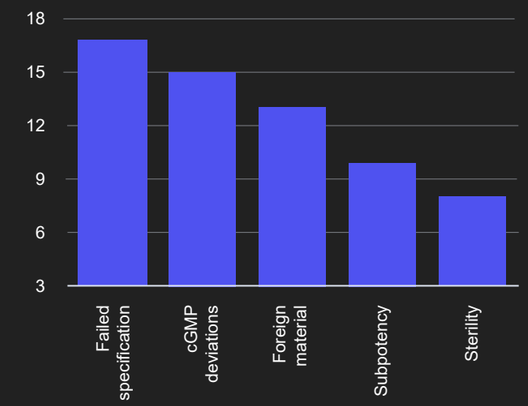
The number of Class I and Class III pharmaceutical recalls and units impacted rose quarter-over-quarter from Q2 2025 to Q3. Year-to-date, 2025's figure for Class I impacted units is at its second-highest level in the past 20 years. This quarter had seven Class I recalls and 11 Class III recalls. While the number of Class II recalls decreased from 87 to 79, the number of units involved increased from 18.67 million in Q2 to 19.92 million in Q3.

There were 58 unique companies involved in recalls this quarter. Twenty-three companies had between two and four events. The remaining companies had only one incident each.

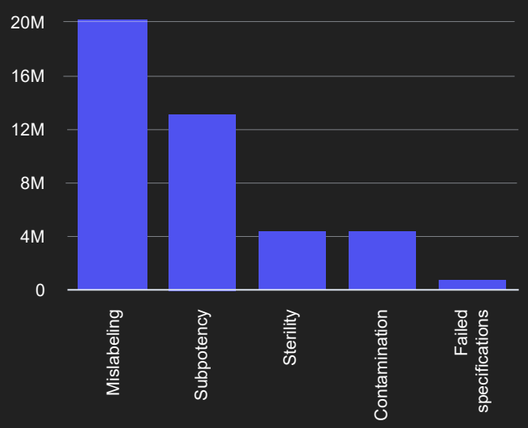
Number of recall events by quarter



Number of recall events by risk (top 5)



Number of recalled units by risk (top 5)



Pharmaceutical companies face multiple challenges ahead

STEVEN M. HARKINS, GREENBERG TRAURIG, LLP

The pharmaceutical industry faces complex challenges as 2025 comes to a close and we look ahead to 2026. Chief among these is a problem created in no small part by the industry's own advancement and success.

Improved testing methods and quality controls have undoubtedly led to safer, greener, and more efficient drug manufacturing processes. However, these same advancements increasingly reveal the presence of trace chemical impurities or raise questions about potential cross-contamination and sterility in Food and Drug Administration (FDA)-approved — and in many cases long-established — processes. Even more challenging, while these issues traditionally fall under the umbrella of "safety," it is increasingly clear that not everything revealed by advancing technology poses a real risk to patients.

Another concern across the pharmaceutical sector is the complicated legal landscape for pharmaceutical products, which are increasingly manufactured in whole or in part with active pharmaceutical ingredients (APIs) from outside of the United States. Enhanced regulatory scrutiny, together with rapidly evolving financial challenges, make the environment more fraught than ever. Navigating these issues daily and responding quickly when faced with potential recall events will be crucial for manufacturers and suppliers in the coming year.

The Biggest Product Safety Challenges

Advances in pharmaceutical manufacturing testing, validation, and quality control methods have the potential to reveal trace chemical impurities and potential cross-contamination during drug manufacturing. According to an article from Agno Pharma, more than ever, manufacturers are taking it upon themselves to implement and refine these processes rather than waiting for regulators.

However, these improvements can be a double-edged sword. Companies may struggle with how to respond when internal controls reveal previously unknown and unanticipated "quality" issues. This is especially true where existing regulatory guidance and guidelines — as well as FDA-approved testing and product specifications — do not contemplate or anticipate the issues being uncovered.

For example, the identification of trace chemical impurities at levels far below those previously identified as actionable in FDA guidance and standards has triggered dramatic responses from the industry. The FDA reports that impurities, cross-contamination, and sterilization continue to drive pharmaceutical recalls. The speed with which technology is evolving to identify a potential impurity greatly outpaces how quickly science can quantify whether the presence of the substance at a given level poses a risk to patients. Companies need to consider if potential risks — even without clear supporting evidence — outweigh the benefits of ensuring that patients have access to the drug and preventing drug shortages.

The legal landscape surrounding pharmaceuticals is also becoming more complex, particularly for products using imported APIs, which now face heightened regulatory scrutiny and increased financial burdens from tariffs. These continuously evolving regulations can potentially delay the time it takes for medications sourced abroad to reach patients.

The FDA's intensified scrutiny of foreign manufacturers presents another challenge. Before the U.S. House of Representatives Committee on Energy and Commerce's Subcommittee on Health, Chairman Buddy Carter underscored that reliance on imported APIs, especially those from China and India, increases the chance of the production of critical drugs being disrupted due to geopolitical tensions, natural disasters, or regulatory shutdowns.

How Manufacturers Can Prepare

Pharmaceutical manufacturers must act strategically and proactively to overcome these complex challenges. With respect to the identification of trace impurities or other quality-adjacent concerns, establishing an open dialogue with the FDA is crucial. Particularly where safety risks posed by the underlying issues are speculative or potentially nonexistent, drug shortage concerns may merit keeping the product on the market while industry and the FDA analyze the patient impact and consider whether to amend existing standards. Impurity profiling and HPLC methods for drug quality compliance | AMSbiopharma.

Companies increasingly face both internal and external pressure to act quickly. This tension may make a measured response difficult if clear lines of communication with regulators are not established. Manufacturers at all levels of the supply chain cannot ignore the threat of litigation — whether they take immediate action or a more measured approach to potential quality concerns. Pharmaceutical Risk Report: Supply Chain Central to Risk Landscape - Dow Jones. Declining to initiate a recall in the face of quality concerns carries obvious risk, but it is well documented that the mere fact of a recall announcement has the potential to spur litigation. Navigating Recall Litigation: Identifying Key Trends for Biotech in 2025.

Companies operating abroad or sourcing APIs from outside the United States must ensure their quality systems conform with current FDA expectations. For example, some companies with disparate operations around the world have begun implementing cloud-based quality management systems (QMS) to try and standardize their internal processes. (Regulatory Trends in Pharma Manufacturing to Watch in 2025). While these advancements may aid companies juggling the varying regulatory requirements of different countries, the bedrock principles of pharmaceutical manufacturing remain the same: Thorough quality assessments and testing procedures are essential, as is traceable and proactive auditing, and manufacturers must constantly monitor their compliance with Current Good Manufacturing Practices (cGMPs).

With the increased skepticism of non-U.S. suppliers, expanding the supply chain is another step manufacturers may consider if forces outside the company's control limit or complicate access to a particular source. Though more costly, it may be advisable for manufacturers to seek new suppliers, establish new manufacturing sites, or reformulate bulk drugs to reduce the risk of supply shortages.

Identifying a mix of domestic and global sources with greater geographic diversification in sourcing ingredients represents a particular challenge that may nevertheless benefit the right product. Addressing supply chain issues through strategic supplier relationships and technological investments can also reduce recall risks and improve product quality. Top Challenges Facing the Pharmaceutical Industry in 2025

The Evolving Pharmaceutical Recall Landscape

There has been an increase in Class I recalls in 2025. Given the range of issues, including regulatory changes, supply disruptions, and vulnerabilities in global sourcing and manufacturing, the threat of recalls will stay at the forefront of the industries and regulators' minds heading into 2026. Product Recall Trends and Risk Mitigation Strategies.

Companies must maintain heightened vigilance in sourcing, production, and testing protocols, but the focus cannot only be on regulators. Consumer awareness and social media increasingly influence recall responses, which may be driven by news stories, citizens' petitions, and nontraditional reporting. All these factors force companies to communicate more openly with the public and stay apprised of news and reactions from nontraditional outlets.

Predictions for the Pharmaceutical Industry in 2026

Looking forward to 2026, the pharmaceutical industry likely will grapple with multiple product safety challenges, including trace impurities, cross-contamination, and regulatory scrutiny of foreign manufacturers.

The risk of drug shortages and recalls will likely remain high due to supply chain issues and stricter regulation. This risk is even more present in the case of non-U.S. API suppliers and manufacturing operations.

Companies and regulators will prioritize transparency and communication with the public on recalls and product safety issues. Open and frequent dialogue with the FDA is essential.

Finally, according to the House of Representatives Subcommittee on Health, it has been suggested that the FDA may push for mandatory domestic API sourcing for essential drugs. This would represent a significant sea change for pharmaceutical manufacturers with potentially huge implications for both existing and in-development drug products. Pharmaceutical manufacturers will need to monitor regulatory changes and assess their production, procurement, and quality assurance processes to be ready to respond.

The views expressed in this article are those of the author and do not necessarily reflect the opinions of Sedgwick.

October insights

Explore the insights below for a clearer view of how the landscape is evolving, and what to keep an eye on as we head toward 2026. While Q3 set the pace, October reveals notable shifts in recall drivers, regulatory priorities, and product categories that will influence next year's safety strategies.

Automotive:

There were 91 U.S. automotive recalls in October 2025, up 26.9% compared to the Q3 2025 monthly average of 72 events. The 4.43 million units recalled by NHTSA in October represent a 44.1% increase compared to the monthly average of 3.08 million impacted in Q3 2025.

Equipment defects led to 20 recalls, making it the leading cause of recalls for the automotive sector in October 2025. That was followed by electrical systems with 13 events and power trains with 10 recalls.

By volume, back-over prevention systems had the most units recalled in October with 2.24 million. This included a recall of 1.45 million vehicles—the only event in October involving more than 1.00 million units. Electrical systems were second in terms of quantity with 597,151 units recalled. Power trains were third with 373,795 units affected.

Consumer product:

There were 51 U.S. consumer product recalls in October 2025, 91.0% more than the Q3 2025 monthly average of 27 events. In contrast, the number of units recalled decreased by 65.9% from the Q3 2025 monthly average of 4.37 million units to 1.49 million units in October. The largest recall in October involved 350,000 units.

Home Furnishings & Décor was the top category for October 2025 consumer product recalls with 14 events. Electronics and Sports & Recreation tied for second with seven recalls each. In third place was Children's Products with six events.

Personal Care had the most units impacted in October with 361,470. By volume, Home Furnishings & Décor was second with 328,870 units recalled. Electronics were third with 289,175 units affected.

Food and drink – FDA:

The FDA issued 69 food and drink recalls in October 2025, up 42.9% from the Q3 2025 monthly average of 48 events. The number of units recalled increased 13.6% from the Q3 monthly average of 8.39 million to 9.53 million in October. There were two recalls in October that involved 1.40 million or more units.

Undeclared allergens were the leading cause of FDA food recalls in October 2025 with 26 events. Bacterial contamination was the second-most common concern with 22 events, followed by foreign materials with 10 events. There were four reports of lead contamination in food in October.

Foreign materials impacted the largest volume of FDA food recalled, accounting for 7.40 million units in October 2025. This included a recall of 5.45 million units of cheese and 1.48 million units of freeze-dried strawberries for metal and steel pieces.

Undeclared allergens was the second-highest concern by volume, linked to 1.03 million units. Bacterial contamination was third with 894,523 units impacted.

Food and drink – USDA:

In October 2025, the USDA issued five recalls, up from the Q3 2025 monthly average of two events. The number of pounds recalled fell by 61.6% from a monthly average of 19.51 million pounds in Q3 to 7.49 million pounds in October.

It is worth noting that last quarter set an 11-year record for the volume of pounds recalled. While the October total is below the Q3 quarterly average, there are only three full quarters since Q1 2019 that have had more pounds recalled than the one-month total for October.

Of the five USDA recalls, four were for foreign materials. One was linked to bacterial contamination, specifically Listeria, which impacted 91,585 pounds of egg products. The leading category in October by both volume and events was poultry with two events involving a total of 4.99 million pounds. Pork was cited in two recalls involving 2.41 million pounds.

Pharmaceutical:

There were 43 pharmaceutical recalls in October 2025. This is 33.1% more than the monthly average of 32 events in Q3 2025. The number of units recalled dropped by 83.7% from the Q3 2025 monthly average of 14.85 million units to 2.43 million units in October.

Failed specifications was the most common reason cited in October 2025 by event with 14 recalls. Sterility and cGMP deviations tied for second with seven events each. Mislabeling had six recalls in October, making it the third-most common cause cited.

Foreign materials was the leading risk by volume, linked to 687,440 units. Sterility was second and impacted 581,977 units. cGMP deviations were third with 444,881 units affected in October 2025.

The FDA classified one pharmaceutical recall in October 2025 as Class I. There were 853 units impacted. Five events were designated as Class III and the remaining 37 recalls were classified as Class II. These categories involved 36,081 and 2.39 million units, respectively.

Medical device:

In October 2025, there were 99 medical device recalls, a 24.3% increase from the Q3 2025 monthly average of 80 events. The number of units recalled rose more dramatically from a Q3 monthly average of 36.13 million units to 194.19 million units in October. This is an increase of 437.5% and the second-highest total in the past three and a half years. October had six recalls involving 1.29 million or more units.

In terms of events, software concerns were the most common cause for medical device recalls in October 2025 with 14 events. Device failure was second with 12 recalls, followed by false results and manufacturing defects, which were both linked to nine events.

Instructions update was the leading cause of recalls by volume and impacted 172.50 million units. Most of these were linked to a recall of dialyzer devices used to remove waste from blood. Quality issues led to the second-highest number of medical device units recalled with 8.37 million, largely due to a recall of 8.27 million IV saline syringes. In third place was false results, which affected 4.32 million units, primarily tied to a recall of 4.27 million blood collection tubes.

The FDA classified 18 medical device recalls in October 2025 as Class I. These recalls impacted a total of 2.65 million units. One recall was designated as Class III. The remaining 80 recalls were categorized as Class II and were linked to 191.54 million recalled units.

Conclusion

The regulatory landscape across industries remains dynamic. The FDA introduced guidance around remote regulatory assessments that may enable the agency to conduct more inspections with fewer internal resources. The agency could also start using AI for some oversight functions, including monitoring direct-to-consumer prescription drug advertising to ensure companies are complying with the rules around disclosing product risks. The CPSC has also indicated that it would use AI to automate routine tasks.

The Trump Administration reached trade agreements with several countries—including the EU—on a range of goods in Q3. However, there is still uncertainty as tariff negotiations with other nations continue and regulators investigate possible import quotas and drug pricing.

Companies will need to be flexible and adapt their business plans and risk profiles in response to policy changes. That could mean finding new suppliers, charging higher fees to consumers or partners, building new manufacturing facilities, or using different components or ingredients in their products.

Given the uncertainty, companies must plan for risks across a variety of areas, including:

- Business interruptions
- Supply chain challenges
- Regulatory and legislative changes
- Financial impacts
- Product updates, upgrades, and warranty work
- Product recalls and market withdrawals
- Data privacy and cybersecurity issues
- Innovation and advancements in technology
- Dynamic consumer demand
- Customer and partner apprehension

Unfortunately, recalls and other incidents are inevitable in today's business environment. Many regulatory agencies recommend, even mandate, that companies have recall, incident response, and/or risk management plans in place as part of their standard business processes. Advance planning means better protection for your customers, brand, and bottom line when product issues do occur.

Whether planning for or actively managing a product safety crisis or other in-market event, leveraging the experience and insight of an external partner can save millions of dollars in regulatory and litigation costs, as well as time and stress on other internal resources. In addition, their expertise will help you honor your commitments to customers, supply chain partners, industry groups, and regulators, while protecting your reputation among the stakeholders that matter most.

Sedgwick Recall

When their reputations are on the line, leading global brands trust Sedgwick Recall. With more than 30 years of experience managing complex product recalls and crisis events across industries and borders, we provide the strategic expertise and operational precision needed to protect consumers and safeguard businesses.

Sedgwick has helped companies in 150+ countries prepare and adapt during some of the most challenging events in their history. Our three decades of global experience executing 8,000+ recalls affecting 500+ million units gives us unparalleled insights that we put to work to help you.

We are the leader in global product recall services. We've managed some of the largest product recalls and are a recognized authority in recall and incident response solutions. We offer a full suite of end-to-end solutions to help businesses navigate complex and evolving regulatory landscapes with confidence. Whether you need help managing the entire process from pre-incident planning to final disposal of a defective product or modular support for any step in between, we work as an extension of your team to resolve issues quickly and in compliance with all regulatory requirements while helping you use your resources wisely.

We also leverage our extensive skills in acting quickly in a crisis to provide expert incident response solutions. Our experienced team helps businesses operate well under pressure to find the best solution for dynamic, evolving situations. We will partner with you throughout the event to assess rapidly changing situations and continually adjust our plans to achieve the best outcome for your business, including rapid notifications, scaling up a multilingual call center, or removing a product from the market.

Sedgwick offers the experience and the global reach to help you with proactive planning to mitigate risk and quick, effective actions in times of crisis.

To find out more about our product recall capabilities, contact us today.

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