



More than 1 billion units recalled in 2021; heightened regulation and enforcement activity ahead in 2022

Sedgwick brand protection releases full year of U.S. product recall data and analysis

MEMPHIS, Tenn., February 28, 2022 – More than 1 billion units of food, drugs, medical devices, automobiles and consumer products were recalled in the U.S. in 2021. According to the latest [‘State of the Nation Recall Index report’](#) published by Sedgwick, 2021 marks the second year in the last decade to surpass the 1 billion milestone. As regulation and enforcement increases amongst industries, understanding and managing risks will be pertinent in 2022.

As a global leader in recall and remediation services, Sedgwick’s brand protection experts are uniquely positioned to deliver industry-leading product safety research and analysis. Working in partnership with clients across all industries, Sedgwick manages the risks and minimizes the impacts of in-market business and product crises. Unlike Sedgwick’s traditional quarterly Index reviews, this extended edition takes a year-in-review review of 2021. It is the only report of its kind that aggregates and tracks essential sector data to help U.S. business leaders mitigate litigation and reputational damage caused by recalls and other in-market product incidents.

Some of the recall highlights:

- The automotive industry saw 28.4 million units recalled in all of 2021, approximately 44% fewer than in 2020.
- With 218 recalls in 2021, the consumer product industry saw its lowest overall number of recalls in the past five years.
- FDA food recalls continued its decline with just 414 recalls in all of 2021, marking the fewest recalls in the past 11 years.
- The pharmaceutical industry saw a five-year low for the number of recall events with a total of 274 for all of 2021.
- In 2021, the medical device industry saw the highest number of units recalled in the past ten years with 602.5 million units impacted.

Looking ahead in 2022:

- For the automotive industry, advancements in vehicle technology continue to create more safety and regulatory challenges that automakers must monitor and adapt to. Data privacy concerns around connected vehicles, the safety of new technology and the newest crash-safety features rolling out on autonomous and electric vehicles must all be considered.
- As 2021 closed, consumer product manufacturers were looking ahead at the myriad of regulations set to take effect in January 2022. While the Consumer Product Safety Commission (CPSC) looks for ways to make reporting easier for businesses, there is no

sign that they are pulling back on the firm stance they have taken on compliance and enforcement. The agency is also clearly committed to ensuring that businesses take a holistic approach to notifying consumers about recalls.

- The Food and Drug Administration (FDA) announced its Foodborne Outbreak Response Improvement Plan in December of 2021. It is clear the actions presented in the plan will not be only for the agency, but also for manufacturers. How reporting and tracing regulations will change for companies is still unclear, but businesses should review the guidelines and start planning for how their operations and reporting structures may need to adapt.
- The growing number of cyberattacks on hospitals and healthcare systems is a concern that regulators are following in the medical device space. Not only are devices at risk of being the source of a data or security breach, but there is also an added risk to patient care and health. The FDA is responding to cybersecurity concerns in a variety of ways, including creating a new leadership position focused on medical device security within the FDA's Center for Devices and Radiological Health (CDRH).
- The dramatic rise in the use of Emergency Use Authorizations (EUAs) has changed the pharmaceutical industry. It is expected that the FDA will continue to grant EUAs in an effort to end and contain the pandemic. As pharmaceutical companies seek these special authorizations, they should ensure not rush anything on compliance and recall preparedness. The pharmaceutical industry should also be planning for post-pandemic life and how to navigate the transition from EUAs to normal regulatory approvals.

“While the ongoing global health crisis continues, it seems that regulators across most market categories are looking ahead and starting to increase surveillance and enforcement,” said Chris Harvey, Sedgwick senior vice president. “Businesses, especially those that made changes to their operations or suppliers during the pandemic, must be ready for more inspections and oversight. My advice is to review all recall management, crisis and communications plans now before the regulators come knocking.”

The recall index is produced by Sedgwick's brand protection experts every quarter. It is an essential reference for manufacturers and retailers seeking impartial and reliable perspective on past, present and future recall data and product safety trends. For more information, please visit www.sedgwick.com/brandprotection.

To download the U.S. 2022 state of the national recall index report, visit [U.S. product recall index report](#).

About Sedgwick

Sedgwick is a leading global provider of technology-enabled risk, benefits and integrated business solutions. The company provides a broad range of resources tailored to our clients' specific needs in casualty, property, marine, benefits, brand protection and other lines. At Sedgwick, caring counts; through the dedication and expertise of nearly 30,000 colleagues across 65 countries, the company takes care of people and organizations by mitigating and reducing risks and losses, promoting health and productivity, protecting brand reputations, and

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