SLIDE 1: Our project focuses on analyzing drug recalls using openFDA data. We examined recalls of drugs between January 2020 and August 2024, looking closely at which firms, drugs, and manufacturing issues were most prevalent. This analysis helps us understand patterns in FDA recalls and their broader implications on public safety

SLIDE 2: WHAT DOES FDA STAND FOR AND WHAT DO THEY DO?

The FDA, or Food and Drug Administration, is a U.S. government agency responsible for safeguarding public health. It regulates a wide array of products, including food, drugs, medical devices, and even products that emit radiation. Our focus today is on how the FDA manages drug recalls to ensure that unsafe products are quickly removed from the market

SLIDE 3: READ

SLIDE 4: Of the 132 firms associated with recalls in our dataset, 10 significantly stand out with the most recalled drugs. Leading the list are Cardinal Health and Vita Pharmacy, both with high recall numbers. These firms are key players in the industry, so understanding their recalls helps us identify significant patterns and trends within the pharmaceutical sector.

SLIDE 5: the most common reason for recalls falls under CGMP Deviations, or Current Good Manufacturing Practices and Sterility assurance. CGMP refers to manufacturing regulations enforced by the FDA as it assures proper design, monitoring, and control of manufacturing processes. This helps to prevent contamination, mix- ups, failures, and errors. CGMP is important because it assures that drug products meet their quality standards

The other majority of reason for recall in distribution is Sterility assurance issues which is a vital aspect of the manufacturing process where sterile conditions are crucial for safety and effectiveness, such as in the production of injectable drugs, surgical instruments, and other medical products.

Non-compliance with Current Good Manufacturing Practices (CGMP) and Sterility Assurance standards may lead to life-threatening consequences.

SLIDE 6: Class II medications are the most frequently recalled by the FDA due to moderate health risks. Examples include commonly prescribed drugs like oxycodone, methadone, Adderall, klonopin, and hydromorphone. These medications are used to treat conditions such as severe pain, anxiety, insomnia, and ADHD.

SLIDE 7: Class II drugs are recalled more often because even though they pose moderate health risks, they’re not immediately life-threatening. Their large-scale production raises the probability of issues like contamination or mislabeling. Even minor quality concerns in such widely prescribed drugs trigger recalls, reflecting the FDA’s strict standards to keep patients safe

SLIDE 8: This stacked bar graph shows the number of recalls by drug classification for the top ten recalling firms. You’ll notice that Class II drugs make up the majority of these recalls, emphasizing their prevalence in the recall data due to the reasons previously discussed

\*may remove this slide SLIDE 9: here you can see that class 2 drugs were recalled significantly more than class 1 and 3 drugs.

SLIDE 10: Here we see a trend over time: II drugs remain the most recalled across multiple years. Suggesting a persistent challenge in the production and quality control of these drugs.

SLIDE 11: Which states had the most recalls by drug classification?

SLIDE 12: states impacted by class 3 drugs

SLIDE 13 states impacted by class 2 drugs

SLIDE 14: states impacted by class 1 drugs

SLIDE 15: Certain states, like New Jersey, California, and Texas, have been more affected by drug recalls. This could reflect the high concentration of pharmaceutical firms in these regions, as well as their major role in the nationwide drug distribution network.

SLIDE 16: What is the average duration from the initiation to the termination of a drug recall?

SLIDE 17: The FDA's recall process is a multi-step procedure designed to ensure the safety of the public by addressing potentially harmful products.

* The first step is the Initiation of the recall beginning when a potential issue is identified, either by the company itself, the FDA, or external sources. Once the risk is recognized, the company initiates the recall process, notifying the FDA of the affected product.
* Next the recall is classified by Risk Level, The FDA assesses the potential health risks posed by the recalled product and assigns it a classification. Recalls are categorized into one of the three classes:

Class I: products that pose a serious health risk or could lead to death.

Class II: products that may cause temporary or medically reversible health issues, with a lower likelihood of serious consequences.

Class III: products that are unlikely to cause adverse health effects but violate FDA regulations.

* Then a Public Notification of the recall information is made publicly available. This ensures that healthcare providers and consumers are aware of the recall and can take necessary precautions.
* After that the Correction or Removal of Affected Products starts depending on the product and the nature of the risk, the company may need to correct the defect or remove the affected product from the market
* Then the FDA closely monitors the company’s actions to ensure that the recall is effectively carried out. This includes verifying that all steps are being followed and that the health risks associated with the recalled product are being mitigated.
* Lastly, Termination of the Recall. Once the FDA confirms that all affected products have been accounted for and appropriate corrective actions have been implemented, it formally terminates the recall. This marks the end of the recall process, signaling that the product no longer poses a threat to public health.

This systematic approach allows the FDA to manage recalls efficiently while protecting consumers from potentially harmful products.

SLIDE 18: Class III recalls, which are less common, still highlight significant delays in the recall process. For instance, Teligent Pharma had only two recalls, but they took three times longer to close compared to other firms. This delay can be crucial in preventing potential harm from prolonged exposure to recalled products

SLIDE 19: For Class II recalls, firms like Fusion 4 Pharmaceuticals and Herbal Doctor Remedies had extended recall durations, taking over 1,400 days in some cases. This long delay impacts patient safety, as it slows down the process of removing problematic drugs from the market

SLIDE 20: Class I recalls, which are the most serious, are generally handled faster. Accord Healthcare and Teligent Pharma each had a single Class I recall, with Teligent taking almost double the time to close. These delays highlight the importance of effective response times, especially for high-risk products

SLIDE 21: This slide shows the average recall duration across all drug classes for the top firms. Long recall times can have significant public health implications, so understanding which firms take longer helps us identify areas where the recall process could be improved

SLIDE 22: -25: These pie charts show the distribution of each class of drug recall by the top firms. The drugs we analyzed aren’t just limited to the U.S.—many are distributed internationally. This global distribution underscores the FDA’s role in protecting not only American consumers but also impacting worldwide health standards

SLIDE 26 CONCLUSION:

* FDA’s Critical Role: Protecting public health through stringent drug recall standards.
* Class II Drug Recalls: Frequent recalls indicate ongoing quality control challenges, especially in widely prescribed drugs.
* Importance of Regulatory Oversight: Highlights the need for continuous, vigilant oversight to ensure patient safety.
* Growing Industry, Growing Responsibility: As the pharmaceutical sector expands, both regulatory vigilance and industry commitment are essential.
* Patient Protection: Collaborative efforts between the FDA and firms are vital for minimizing risks and safeguarding public health.