

## 1.Problem Statement

An estimated 33 million Americans live with food allergies, celiac disease, or emerging conditions like alpha-gal syndrome—a number that is growing each year. While food labeling regulations have improved safety for many, medications often contain hidden allergens such as lactose, gluten, wheat, and soy as inactive ingredients. Unfortunately, these allergens are not clearly labeled or easily identifiable, putting millions at risk for unexpected and sometimes life-threatening reactions.

## The Scope of the Issue

Many commonly prescribed medications contain major food allergens, as illustrated in my initial data collection:

Ingredient		% Occurrence in Medications	Sample Size
Lactose/Milk/Casein		44.86%	42,052
Corn starch/Wheat starch		36.58%	42,052
Gluten		52.60%	108
Soy		20.60%	108

These numbers demonstrate that exposure to allergens in medications is not rare—and is likely under-recognized by both patients and healthcare providers.

## Unmet Need

Despite the magnitude of this issue, there is no standardized, real-time system to alert clinicians or patients to the presence of common food allergens in medications during prescribing or dispensing. There is a lack of integrated tools that systematically cross-reference a patient's allergies with inactive drug ingredients. This gap puts 33 million Americans at continued risk for preventable harm, resulting in prolonged symptoms, loss of quality of life, and, in severe cases, life-threatening reactions.

## Current Solutions

Currently, the burden of safety falls largely on the patient:

Patients must be super aware and vigilant, researching every new prescription themselves—often struggling to find complete or accurate ingredient lists.

They rely on fragmented online databases or advocacy organization resources, which are limited in scope and not always maintained.

Electronic Health Records (EHRs) and pharmacy systems do not routinely flag or cross-match inactive ingredients against documented allergies at the point of prescribing or dispensing.

Most clinicians and pharmacists lack easy-to-use, comprehensive tools to help them identify and avoid allergen risks for sensitive patients.

Potential Solution on the Horizon:

The ADINA Act (Allergen Disclosure In Non-food Articles Act), recently introduced in Congress, proposes mandatory labeling of major food allergens in prescription medications. If enacted, this would mark an important policy advancement. However, it is not yet law. Even with its eventual adoption, there will remain a pressing need for integrated, real-time digital decision support tools to help translate allergen information into clinical practice and safeguard patient safety.

## In summary:

Despite the enormous scale of this issue, there is no integrated clinical decision support tool that systematically flags potential food allergens in medications. Developing such a solution addresses a critical, unmet need for the safety of 33 million (and growing) Americans and empowers both providers and patients.

## CDSS:

### Vision for Impact:

This system aims to transform healthcare by ending the cycle of preventable adverse drug reactions due to undisclosed or under-recognized allergens, a risk affecting over 33 million Americans. Our vision is that every patient—regardless of health literacy, clinical setting, or provider—can safely access the medications they need, without hidden dangers, delays in diagnosis, or the burden of self-advocacy. In doing so, we promote equity, restore trust, and drive a new standard for personalized, precision medicine.

What do you want to accomplish in this venture over the next year? What help do you need?

1. For the Clinical Decision Support System – EHR Plugin/Webpage/Mobile App:
  - a. Access to a comprehensive, version-controlled pharmacy ingredient database.
  - b. Input and validation from allergists, pharmacists, and GI specialists.
  - c. Patients and clinicians willing to test, provide feedback, and iterate on the prototype.

Status: Did not get selected but working as a free agent for **Pinkert Healthcare Accelerator** - <https://zli.umich.edu/program/pinkert-healthcare-accelerator/>