

Immunify Health Manifesto

I spent a summer working in an allergy clinic in Granbury, Texas. Every morning, before the first patient arrived, a nurse named Linda would stand at a counter in the back and begin mixing. Vial after vial. Syringe after syringe. Eleven years of the same routine—pull 0.5 mL from this extract, 0.3 mL from that one, combine them in precise ratios for each patient. Her hands were steady. She rarely made mistakes. But watching her, I couldn't shake a simple question: why is this still done by hand?

The clinic wasn't stuck in the past. Electronic health records. Modern scheduling software. State-of-the-art diagnostics. Yet the actual preparation of treatments—the thing that helps patients overcome allergies permanently—looked like something from decades ago.

Linda earned around \$90,000 a year. She was smart, capable, wonderful with patients when she had time. But most of her hours went to measuring liquids and filling vials. It struck me as a profound waste. Not just of money. A waste of human potential.

More than fifty million Americans suffer from allergies. The market for treatment exceeds two billion dollars globally, growing at double digits annually. And here's what should bother everyone: we know how to fix this.

Immunotherapy works. Expose the immune system to gradually increasing doses of allergens and it learns tolerance. Unlike antihistamines that suppress symptoms, immunotherapy addresses the root cause. For many patients, it's the closest thing to a cure. Yet most sufferers never receive it.

The reasons are complicated—insurance gaps, patient reluctance, limited specialists—but one factor rarely gets discussed: every immunotherapy practice needs someone like Linda. A trained professional dedicated full-time to compounding serums. That requirement alone prices out smaller practices, limits how many patients large clinics can treat, and creates access barriers that have nothing to do with medical necessity.

Two companies—ALK-Abelló and Stallergenes Greer—dominate the allergen extract supply chain. They make excellent products. But that last mile, from bulk extracts to patient-ready vials, remains stubbornly manual in an era when nearly every other pharmaceutical preparation has been automated.

The shift toward sublingual immunotherapy changes everything. Traditional shots require strict sterility, trained administration, post-injection observation. Sublingual drops are simpler. Patients can self-administer at home. That's why sublingual is growing at 12.5% annually while the broader market grows at 8-10%.

What's less obvious: sublingual's simplicity makes automation finally tractable. The engineering challenges shrink. The regulatory pathway clarifies. The economics work out much better. So I recognized this gap last winter and started building.

The machine isn't revolutionary in its components. Peristaltic pumps, stepper motors, microcontrollers—all commodity hardware. What's novel is the integration: bringing these elements together specifically for immunotherapy preparation in a form factor that fits existing clinical workflows.

Serum bottles sit inverted in a refrigerated compartment, each connected to sterile tubing. Precision pumps draw exact quantities, combine them correctly, dispense into treatment vials. A revolving mechanism switches nozzles to prevent cross-contamination. An integrated label maker prints patient information on completed vials.

Select a patient, confirm the protocol, press start. What took Linda twenty minutes takes the machine two, with perfect consistency every time. The FDA classifies pharmacy compounding devices as Class II, cleared through the 510(k) process. Similar systems exist for IV compounding. The regulatory path is established. The provisional patent was filed in January.

Three ENT specialists running allergy practices all expressed immediate interest. One said he'd been hoping someone would build this for years. Another asked when he could buy one. Over four days in January, I surveyed 186 patients at the Granbury clinic. Among sublingual patients: 95.2% would accept machine-prepared treatments. 97.6% preferred standardization. And 81% said they'd pick up treatments at a CVS or Walgreens if available.

That last number opened my eyes to the real opportunity. Retail clinics already handle vaccinations, diagnostics, chronic disease monitoring. The only barrier to sublingual immunotherapy has been preparation. Remove it, and the addressable market expands dramatically.

It also got me thinking about direct-to-consumer. Companies like Wyndly have built businesses shipping personalized drops to patients' doors—no specialist visit required. Compelling model. But what keeps DTC founders up at night is scale. A clinic serves hundreds. A national platform serves tens of thousands. Manual preparation doesn't just limit growth at that scale; it breaks.

I reached out to Wyndly suspecting they felt this pressure. I was right and secured an LOI. This was just even more validation that the problem extends far beyond one Texas clinic.

The prototype is in active development—components sourced, housing being fabricated. I expect a functional unit within the month. But functional isn't finished. Software needs development. FDA submission requires extensive documentation and testing.

Update: I've paused the project for now. Not because the opportunity disappeared—it hasn't. The market is still growing. The problem is still unsolved. The physicians I spoke with are still waiting for someone to build this. I paused because building medical devices right takes resources, focus, and timing. Rushing it would mean cutting corners I'm not willing to cut. The regulatory path alone demands

a level of rigor that doesn't bend to impatience. The bottleneck in allergy immunotherapy isn't going anywhere.