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Week 3

Drug Cost Reform

"You pay the same price as every other country. No more."

1. The Problem

Americans pay 2.56 times more for prescription drugs than citizens of other developed countries for identical products — confirmed by RAND Corporation analysis of 2018 OECD data. For brand-name drugs the gap is even larger: 3.44 times higher than OECD comparison countries. A vial of Humalog insulin costs approximately \$32 in Canada and \$320 in the United States at list price — the same manufacturer, the same drug, the same formula. Medicare Part D drug spending is approximately \$130-145 billion per year — paid by American taxpayers for drugs that cost a fraction of that price in every other developed country.

2. The Governing Principle

Every other developed country in the world negotiates the price of prescription drugs. The United States pays full retail price while everyone else pays the negotiated price. The result: Americans subsidize pharmaceutical R&D for the entire world while paying 2.56 times what any other country pays. Medicare was legally prohibited from negotiating drug prices for 19 years. The Inflation Reduction Act granted partial authority in 2022. Week 3 completes the job: Medicare negotiates every drug. Americans pay the same price as everyone else.

3. The Specific Policy

The Price Gap — Verified from Primary Sources

- RAND Corporation, January 2021 — using 2018 OECD data: U.S. drug prices overall are 256% of prices in other countries — 2.56 times higher. For brand-name drugs: 344% — 3.44 times higher. For generic drugs: 84% of other countries — generics are slightly cheaper in the U.S. Source: rand.org/pubs/research_reports/RR2956.html
- Insulin — the documented example: Humalog insulin (Eli Lilly, same manufacturer, same product) costs approximately \$32 per vial in Canada and approximately \$320 per vial in the United States at list price — a 10x gap at gross price. After estimated rebates and discounts, U.S. net insulin prices are approximately 2.33 times Canadian prices per updated RAND analysis using 2022 data. Source: RAND Health Quarterly, 2024; 11(3):3.
- Important nuance on insulin prices: U.S. list prices are substantially higher than net prices after rebates. Insured patients with good coverage may pay less than list price. Uninsured patients and

those with high deductibles pay full list price. The IRA capped Medicare insulin cost-sharing at \$35 per month beginning 2024. The \$35 cap applies to Medicare beneficiaries only — not all Americans.

- Medicare Part D drug spending: approximately \$130-145 billion per year — the total gross drug cost for prescription claims under the Medicare Part D program. This is not total Medicare spending — total Medicare spending is approximately \$1 trillion annually. The platform previously stated \$400 billion in Medicare drug expenditures — that figure is incorrect and is corrected here.
- The IRA partial solution: the Inflation Reduction Act of 2022 granted Medicare negotiating authority for 10 drugs in 2026, growing to 20 by 2029 — a fraction of the drugs Medicare purchases. Week 3 extends full negotiating authority to every drug Medicare purchases.

International Reference Pricing

- Medicare pays no more than the median price paid by Canada, Germany, France, UK, Japan, and Australia for any drug: six-country benchmark covers the largest peer economies with functional drug pricing systems. Median of the six prevents any single outlier from distorting the benchmark.
- Market access leverage: pharmaceutical companies can sell in America at the international reference price or lose Medicare market access. Access to 65 million Medicare beneficiaries is leverage no company will abandon. The argument that companies will exit the U.S. market is not supported by evidence — no major pharmaceutical company has abandoned the UK, Germany, or France after accepting negotiated prices there.
- The VA precedent: the VA already negotiates drug prices and pays approximately 40% less than Medicare for identical drugs — confirmed by VA and Medicare payment data. This proves government negotiation works within the existing U.S. system.

Direct-to-Consumer Advertising Ban

- The U.S. and New Zealand are the only developed countries that allow direct-to-consumer prescription drug advertising: pharmaceutical companies spend approximately \$6-10 billion per year on DTC advertising — the exact figure varies by year and source. DTC ads create consumer demand that drives prescribing toward advertised, often more expensive, drugs over therapeutic equivalents.
- DTC ban does not restrict B2B advertising to physicians and prescribers: pharmaceutical companies may still inform physicians of their products through professional channels. The ban applies only to consumer-facing advertising.

Generic and Biosimilar Acceleration

- Pay-for-delay agreements prohibited: brand-name companies sometimes pay generic manufacturers to delay market entry. These agreements reduce competition and increase prices. Week 3 prohibits pay-for-delay agreements explicitly.
- Biosimilar substitution at the pharmacy level: without requiring physician re-authorization. Reduces the friction that has slowed biosimilar adoption in the U.S. compared to Europe.

Domestic Generic Manufacturing Reform — Eliminating the ANDA Filing Fee

The United States pays more for generic drugs not only because of pricing gaps with other countries, but because the regulatory structure actively discourages domestic manufacturers from entering the

market for low-volume generics. The Abbreviated New Drug Application (ANDA) is the FDA approval process that allows a manufacturer to produce a generic equivalent of an approved brand-name drug — abbreviated because the manufacturer does not repeat full clinical trials, only proves bioequivalence.

The problem: the FDA charges \$365,000 per ANDA filing. This fee applies regardless of whether the drug is a high-volume blockbuster or a rarely prescribed medication needed by 5,000 patients nationwide. The result:

- Low-volume generic drugs never attract ANDA filers — no manufacturer can recover \$365,000 on a small patient population, so the brand-name drug remains the only available option at whatever price the manufacturer sets.
- Domestic small-batch manufacturers are priced out of the market entirely. Large Indian and Chinese manufacturers absorb the ANDA fee across dozens of global markets — it is one revenue stream among many. For a domestic manufacturer serving only the U.S. market, the fee is often the entire margin.
- Drug shortages and supply chain vulnerability: when a single foreign manufacturer supplies 80% of a generic, a plant shutdown or geopolitical disruption creates an immediate shortage. The ANDA fee structure has concentrated generic manufacturing offshore.

The Week 3 Proposal:

- **Eliminate the ANDA filing fee entirely for all domestic manufacturers.** A manufacturer building a generic drug plant in Dallas, Texas pays nothing to file — the same as what a foreign manufacturer competing against them should not receive. The \$365,000 fee that has priced American manufacturers out of their own market is gone, for every drug, for every domestic filer.
- **The full \$365,000 ANDA fee remains in place for foreign manufacturers:** the fee does not disappear — it shifts. Foreign filers continue paying the current rate. American manufacturers pay nothing. This creates a structural cost advantage for domestic production without subsidizing it with taxpayer dollars.
- **FDA ANDA fast-track for domestic shortage drugs:** applications from domestic manufacturers for drugs on the FDA shortage list receive a 90-day review target instead of the standard 10-month timeline. Speed to market is as important as cost when a shortage exists.
- **FDA Small Manufacturer Technical Assistance Program:** the FDA's Chemistry, Manufacturing, and Controls (CMC) documentation requirements were written for large pharmaceutical companies with dedicated regulatory departments. A small domestic manufacturer without that infrastructure is forced to hire specialized consultants at \$300-500 per hour simply to translate FDA guidance into compliant submissions — adding \$500K-\$2M in regulatory consulting costs on top of the filing fee. Week 3 establishes a free FDA technical assistance program for domestic generic manufacturers with under \$50 million in annual revenue: FDA regulatory staff provide direct CMC guidance, submission formatting support, and pre-submission review at no charge. The scientific standards do not change. The unnecessary consulting overhead is eliminated. This is the same model the SBA uses to help small businesses navigate federal contracting — applied to drug manufacturing.
- **Estimated cost to federal revenue:** ANDA fees collected by the FDA total approximately \$1.5-2 billion per year across all filers. Domestic manufacturers represent a small fraction of current filings. As domestic filing increases under the fee elimination, foreign filer fees continue funding FDA generic drug operations. Net revenue impact is estimated to be modest and offset many times over by reduced drug prices and reduced shortage-related emergency spending.

The Result: American manufacturers can compete. Low-volume generics become economically viable to produce domestically. Drug shortages decrease as domestic supply chains develop. The \$365,000 fee that has been pricing American manufacturers out of their own market is gone for the drugs that need it most.

4. Estimated Cost Savings

RAND Corporation estimate: international reference pricing could reduce U.S. drug spending 40-60% for the drugs covered. Applied to Medicare Part D spending of approximately \$130-145 billion per year: potential savings of \$52-87 billion per year in Part D alone. Platform uses a conservative estimate. Total U.S. prescription drug spending is approximately \$400 billion annually across all payers — the savings opportunity extends beyond Medicare. All savings estimates subject to CBO independent scoring within 90 days of inauguration.

5. Year 1 Implementation and Measurable Result

Year 1 measurable result: Medicare negotiating authority extended to all drugs purchased by Medicare — legislation introduced within 30 days; DTC advertising ban enacted; 50 highest-cost drugs negotiating price using international reference benchmark within 180 days; VA-Medicare price parity published publicly; first annual drug price transparency report published comparing U.S. negotiated prices to six-country benchmark; ANDA fee elimination for domestic shortage-drug manufacturers enacted; FDA domestic shortage-drug fast-track program launched.