



Interbiome Foundation Testimony on Public Production of Insulin

Challenge: There is a proven need for guaranteed, affordable access to insulin for Type-1 diabetics worldwide. A similar challenge also exists, to gracefully solve demand for a wide array of other neglected, abandoned or otherwise low-margin yet needed “utility” products and services.

Context: Although insulin has been off-patent for ~90 years, commercial producers and distributors alike struggle to provide insulin at costs that serve stockholders as well as stakeholders. That gulf cannot be optimally bridged by private profit models alone, since the role of private profit in capitalism is to drive technical innovation, not subsidize highly conserved, low direct-margin commodities such as national security, hospitals, schools, transport, water, sewage, power and now increasingly, ... base supplies for Population Health management. *This is a Public Policy challenge, not a private investor challenge.*

For example, during the last 2 years, we would have been better off re-allocating the few, large, centralized, commercial insulin-production facilities to make adequate volumes of the novel SARS-COV-2 vaccines that were transiently needed. We do not need our most innovative technical minds dedicated to making commodity drugs. The conundrum is that producing both staid commodities and innovative products with the same model requires stockholder driven firms to charge the same facility-use rates for both purposes, in order to justify asset allocation to stockholders.

We have an underlying need for a “buffer-capacity” of commodity production facilities, operating at a cost that allows electorates to accurately allocate adequate proportions of aggregate national assets to innovation without undermining required access to basic utility products and services. The challenge of insulin as a candidate “Utility Drug” opens the door to additional improvements in aggregate asset allocation.



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Hurdles and Milestone Goals for stable, aggregate production of necessary commodity supplies:

- 1) Production should be distributed, in-country and in-region, as a buffer against supply chain disruptions
- 2) Production costs should be insulated against the fluctuating demands of private investors.
- 3) Production of the basic commodity should be separated from ongoing innovations in delivery & usage.
- 4) Product metrics should be standardized and highly regulated, so output can be shared when needed.
- 5) The underlying Intellectual Property should become a fully Open Sourced, public commodity.

Solution:

Open-Insulin Foundation: To hold all base IP for a standard insulin product (short & long acting forms).

Public Utility production: To guarantee buffer-supply of commodity insulin, at costs low enough to establish Population Health tolerance limits, protected from stockholder volatility.

Insulin Production Institute:

- a) Build 2 standardized Insulin-Production Pilot Facilities (short & long-acting forms),
- b) Achieve FDA-biosimilar approval (including proven manufacturing process) for production at said facilities
- c) Share (at cost) physical facility design, QA processes and Intellectual Property with other regions
- d) Assist with duplication of Pilot Insulin Production in any and all regions seeking resilient insulin supply

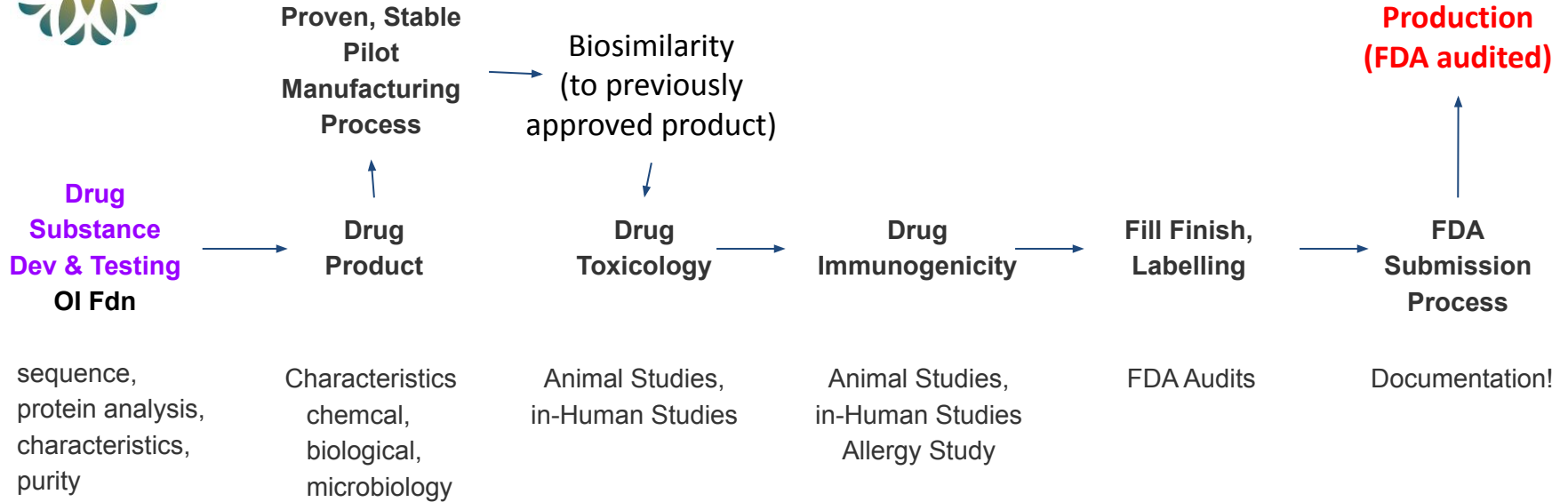
Timeline: 2 years to build/validate facilities, pass FDA registration & facility audits, & start continuous production

Launch Costs: ~\$48 Million (FDA registration, build, equip, staff and train)

Operating Costs: ~\$8 Million/year (~\$4 Million per facility, including separate fill-finish costs)



Summary: FDA BioSimilar Process: Estimated Budget for first 2 pilot factories, producing long/short acting OpenSource Insulin, as Public Utility model



Projected Costs (2 facilities; each producing 100k units/yr [long/short acting Insulin]):

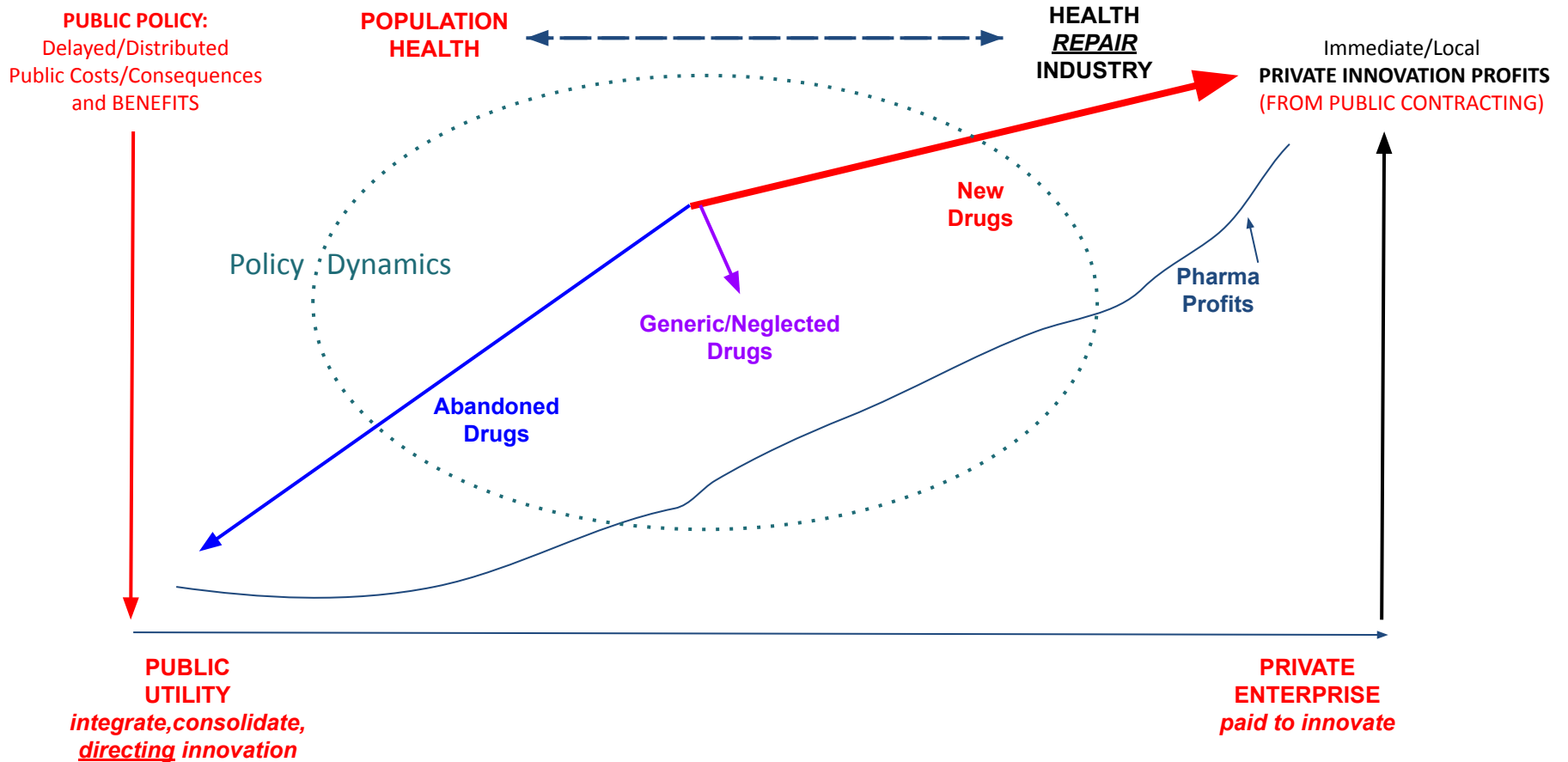
	DSD&T	BioSimilarity Studies	Immunogenicity Studies	Mfg Scale-Up	FDA regulatory submission	Totals
Long-Acting Insulin	x	-✓-	-✓-	---	-✓-	: \$~10 Mil
Short-Acting Insulin	x	-✓-	-✓-	---	-✓-	: \$~10 Mil
2x pilot mfg facilities (facilities, equipment, Quality Assurance, FDA audits)				-✓-		: \$~20 Mil
2x (\$3 Mil) yearly operating costs (or ~zero, if product sold at cost)						: \$ ~6 Mil
Initially outsourced Fill-Finish operations (to existing, private firms; yearly cost)						: \$ ~2 Mil
Total project launch cost: (2 pilot facilities; cost shared worldwide; to be duplicated worldwide)						\$~48 Mil



Situational Awareness: Model Context Change Before Analysing Data

Data Have No Meaning Apart from Context

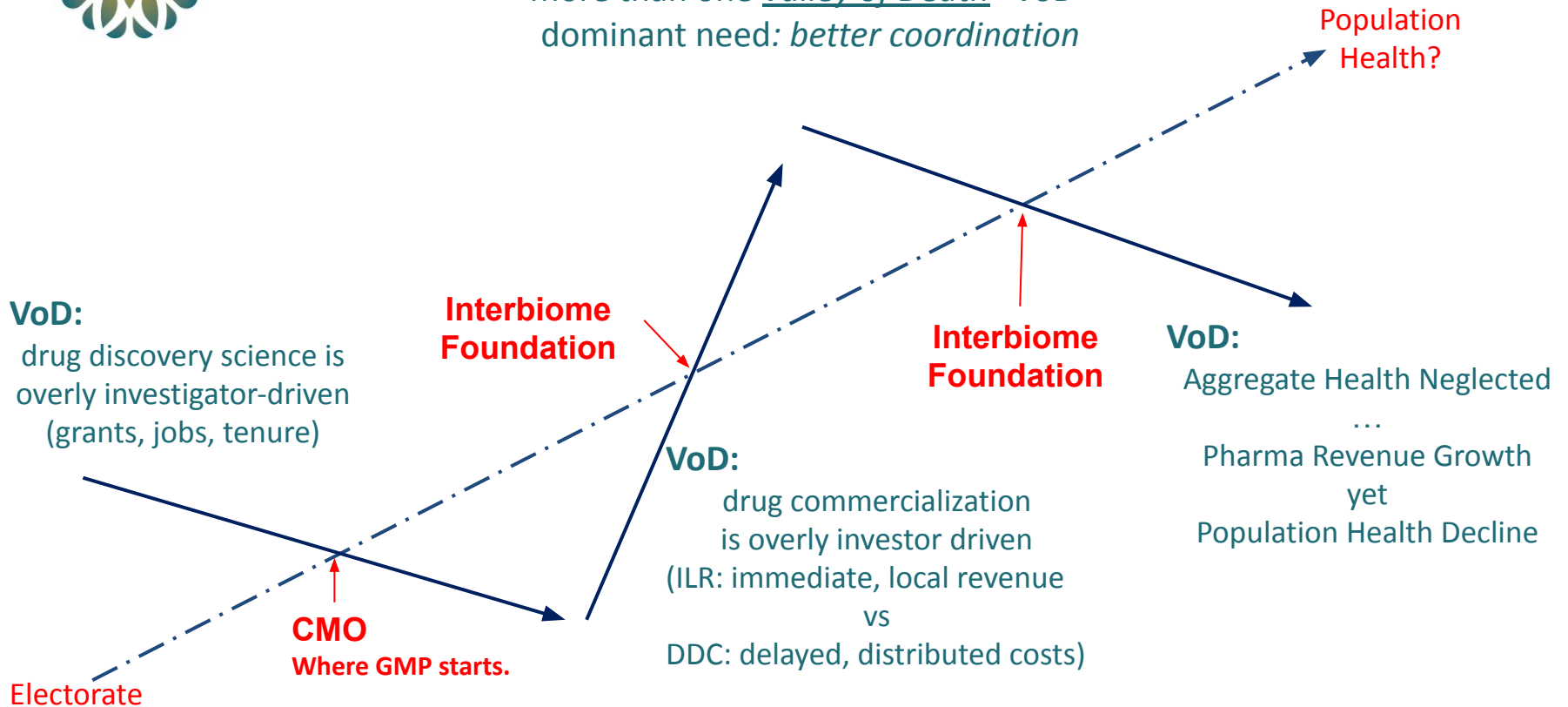
There is both constant divergence and emerging convergence between private enterprise and Public Policy.





POPULATION HEALTH DISCONNECTS

more than one Valley of Death "VoD"
dominant need: *better coordination*

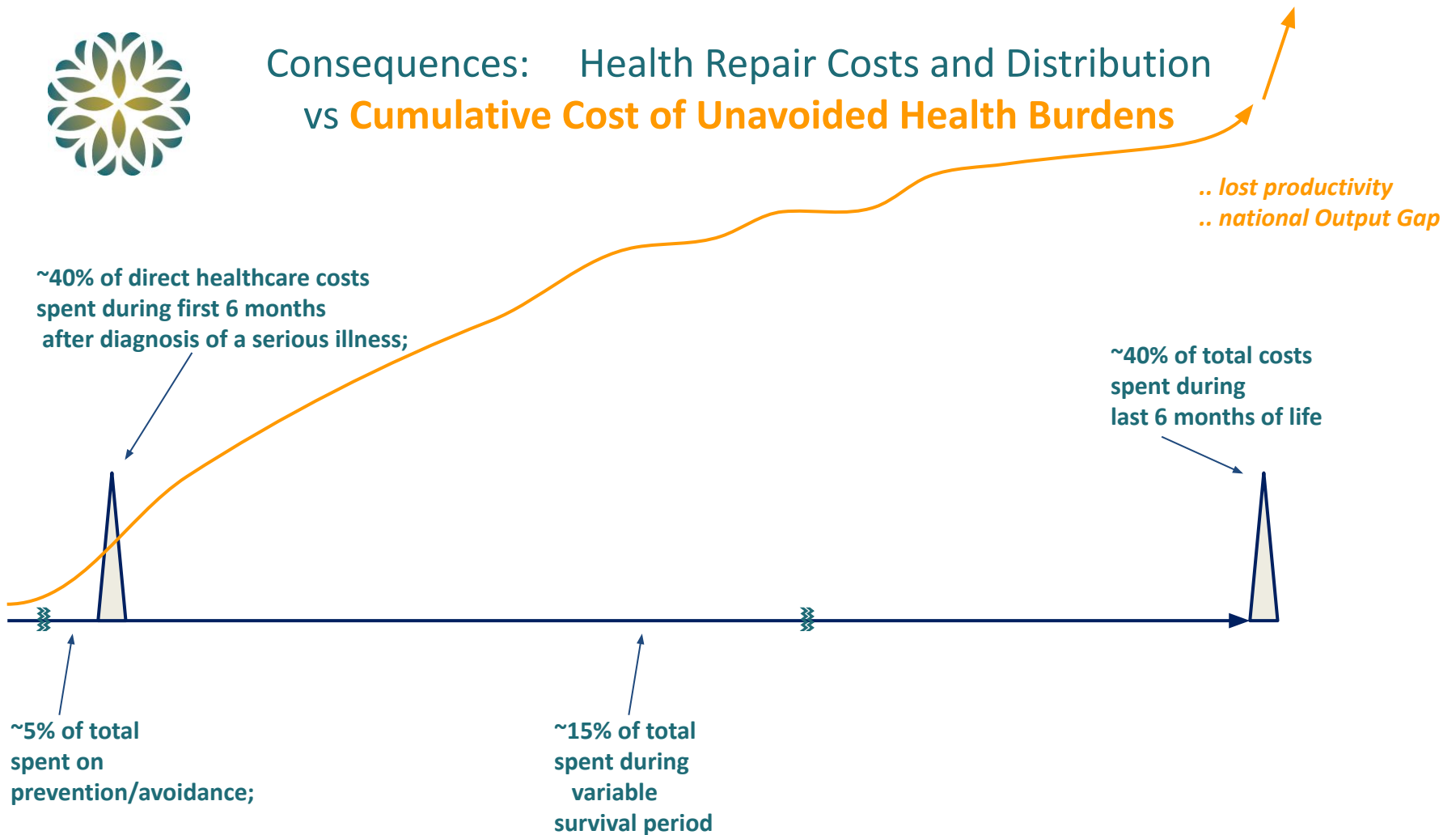


Outcome: current Public Policy and pharma industry imbalance

- serving personal health-repair customers
- neglecting Population Health customers (*employers, insurers, nations*)



Consequences: Health Repair Costs and Distribution vs **Cumulative Cost of Unavoided Health Burdens**



We track direct repair costs. We do not manage the sum of delayed, distributed costs to citizens, employers & nation.

Cost of lost productivity & added National Output Gap? >>>total direct healthcare expenditures?



Example challenge: Lagging, over-expensive, fragile **Insulin Supply Chain**

Solution:

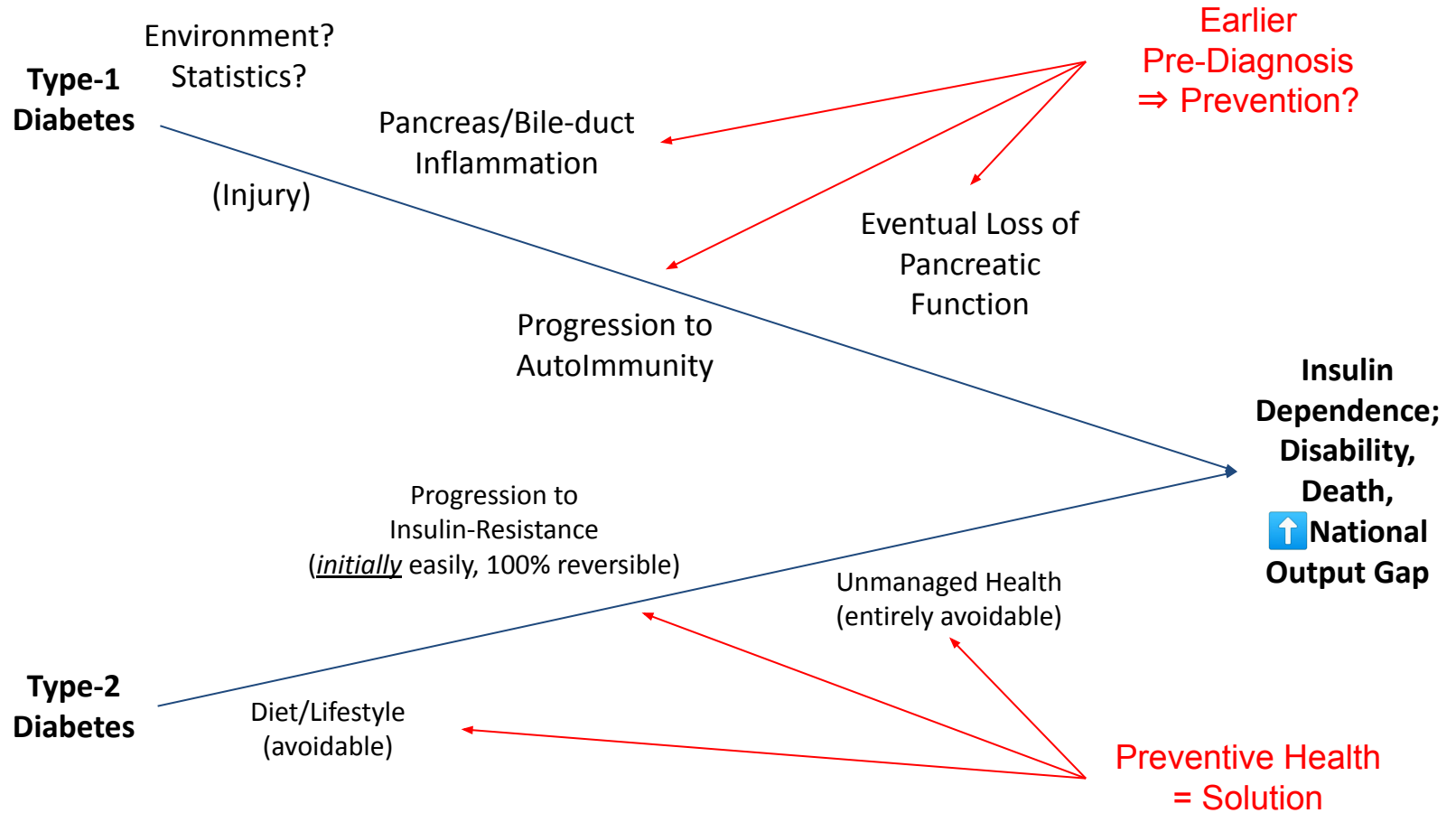
- Public Utility, not private-enterprise model for *SELECTED, COMMODITY* drugs
 - (at-cost or near-cost production)
- Distributed, not centralized production (RESILIENCY over transient efficiency)
- Standardized product, worldwide
- Pilot Facility & Reference Design (meet USA FDA standards, duplicate anywhere)
 - FREE TO REPLICATE PRODUCTION STANDARDS ANYWHERE; “OpenSource”
 - Population Health Tolerance Limits, i.e., standards
 - Interoperable, Interchangeable (e.g., like Power Grids)
 - In-Country or Regional production ⇒ RESILIENCY

- Costs:
 - up to \$20 Million to finalize 2x FDA Biosimilar Validations (short & long acting biosimilars)
 - ~\$20 Million to build, equip, validate & staff 2 facilities (50-100 employees)
 - Total Startup Cost: ~\$40 Million
 - *cost shared worldwide (e.g., 40 countries X \$1 Million each?)*
 - ~\$6 Million/yr to operate (~\$3 Million/facility - ~100,000 Insulin units/yr/facility)
 - ~\$2 Million/yr to fund initially separate Fill/Finish operations
 - Cost to replicate Pilot Factories locally? (depends on locale; << original cost)
 - *local facility replication/operation costs funded locally*
 - *final Fill/Finish costs funded locally (allows product flexibility)*



Future Considerations

Diabetes Natural History





Some of many additional factors

Commercial insulin producers must charge what their factories would make if they were manufacturing other, more cutting-edge products.

(We have better places where they should be innovating.)

(We have additional topics needing Public Health Policy Attention, after solving insulin)

Once started, Public Utility Insulin MUST be prepared to scale further, to meet aggregate demand (one or more of three largest commercial producers would eventually leave the market)

Commercial innovation would not stop:

Insulin itself is a bulk commodity.

Insulin delivery (needles, syringes, “Epi-Pens” & Insulin Pumps are delivery mechanisms)

An ounce of prevention will always be worth more than a pound of repair.

Rather than over-optimizing expensive, late-stage repair methods,

Public Policy absolutely must manage Population Health by avoiding Health Damage

Population Health = Base - Damage + Repair

(Public Policy: managing insulin demand is even more important than managing supply)