

My name is Anthony Di Franco. I have had type 1 diabetes since 2005, and my parents and grandparents all had or have type 2 diabetes. My mother uses insulin now and my father relied on insulin until he died from complications of diabetes in 2004. I myself have rationed insulin at times, my father struggled with the financial burdens of diabetes and insulin, and my mother does now.

I'm also the founder and president of the Open Insulin Foundation, an effort to make open source means for producing insulin and to organize production under the direct control of the users of insulin.

We found in preliminary studies that insulin can be produced safely and economically at a small scale using techniques similar to those that contract manufacturers use to produce biologic drugs for clinical trials, academic research, small commercial production runs, and personalized medicine. The approximate cost of doing so is projected to be about \$7 per vial, which is far below the list prices of several hundred dollar per vial that diabetics without sufficient health coverage face, and is even far below the typical copay for insured diabetics.

In collaboration with Roger Erickson of Interbiome, which is a nonprofit biologic manufacturer, we determined that small scale manufacturing facilities that could each serve the needs several hundred thousand insulin dependent diabetics could be established at a cost of about \$10-\$20 million each, including costs of regulatory compliance in the US and the physical plant. This projection relies in part on recent draft guidance from the FDA on a streamlined procedure for the approval of insulin, which is discussed here: <https://www.fda.gov/news-events/press-announcements/insulin-gains-new-pathway-increased-competition>

This means that local or regional networks of production centers could easily meet the needs of the many people going without sufficient insulin, and could form the basis for expanding to address needs for other medicines. A recent FDA study found that the introduction of competing sources of medicines reduces prices by significant increments of around a third or more for each one, meaning that the introduction of alternative sources of medicines should be a first-line strategy for increasing accessibility of those medicines. That study is available here: <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices>

Worldwide, we estimate that around a million people a month die for lack of insulin, making the insulin access problem one of the deadliest phenomena in history, comparable to the second world war. Maine shares in this burden, and has the opportunity to lead in solving the problem by carrying out a comprehensive and actionable study on local insulin production and distribution.