Holden Rohrer

Markley

English Composition II

8 Nov 2020

Annotated Bibliography

Hilgenfeld, Rolf et al. "The evolution of insulin glargine and its continuing contribution to diabetes care." *Drugs* vol. 74,8 (2014): 911-27. doi:10.1007/s40265-014-0226-4

This article lists the various innovations that allowed insulin glargine to eventually be developed. It emphasizes the number of trials that were made in the area of recombinant DNA production of insulin, and structural biology around lengthening absorption time, which I want to include directly in my narrative. It is pretty uniquely comprehensive, and its heavy reliance on medical rather than historical evidence is useful. I want to talk accurately about what the drugs do and how they work, like how NPH is very different from insulin glargine in manufacturing. The specific timeline for these innovations is useful in framing more general policy changes, (of monopolies or Medicare, for example) but patents and funding are de-emphasized in this article. One interesting data point is that insulin glargine is exactly three amino acid changes, out of 51, a discovery worthy of patent. This source is very well-sourced and behind the paywall, (PubMed) so I consider it high-quality.

Herkert, Darby, et al. "Cost-Related Insulin Underuse Among Patients With Diabetes." *JAMA Internal Medicine*, vol. 179, no. 1, Jan. 2019, pp. 112–14, doi:10.1001/jamainternmed.2018.5008.

The authors examined a group of adults with diabetes' responses to a survey about cost-based underuse and the measurable health outcome of It found a strong correlation between lower incomes and patients saying they tried to stretch or waited to use insulin. This underuse, in turn, correlated with worse health outcomes: their blood sugar levels were worse controlled. Because it focuses on financial struggles and insulin, it's very relevant to my video, demonstrating both a material need (for lower-cost insulin) and a real medical

harm that's being done by not providing enough. This study uses a survey of patients and a blood glucose test as its source data, on a probably representative population of people with diabetes. The authors found 25% of survey recipients sometimes stretched or avoided using insulin because of cost concerns.

Shuchman, Miriam, M.D. "Delaying Generic Competition - Corporate Payoffs and the Future of Plavix." *The New England Journal of Medicine,* vol. 355, no. 13, 2006, pp. 1297-300. ProQuest, https://go.openathens.net/redirector/gatech.edu?url=https://search.proquest.com/docview/223927797?accountid=11107.

This article is about the genericization of a non-insulin drug made and marketed by Sanofi and Bristol-Myers in 2006. These two paid off a generics manufacturer in the millions, a so-called "pay-for-delay" scheme. The article directly challenges the legitimacy of these companies' actions, and even though it's in a medical journal, uses court cases, senators' statements, and quotes as evidence. I want to talk about this kind of market manipulation in general, like payoffs, evergreening (repeatedly patenting different parts of a drug), and strong lobbying interests. Generics are going to be central to my video, and this is one of the reasons they're unavailable. Combined with newer evidence, like from the FTC, this article proves anti-consumer damages of these schemes and a failure to regulate.

Gotham, Dzintars et al. "Production costs and potential prices for biosimilars of human insulin and insulin analogues." *BMJ global health* vol. 3,5 e000850. 25 Sep. 2018, doi:10.1136/bmjgh-2018-000850

This article determines the price for a company to mass-produce insulins, including insulin glargine: using very conservative assumptions, only $7.38 per vial or $108 per year. At the time of its publication, companies charged over $87 per vial in the US and $36–40 in its industrial peer nations. The article includes largely original calculations from a methodology used in an HIV medicines study and sources its basic prices for bulk active pharmaceutical ingredient directly. This analysis is useful for my argument because significantly reduced prices would be feasible according to this model. I also want to talk about

the different insulin prices in different countries in my video. There is a very large difference in the market, which entirely comes down to "ability to pay." Given that which nation insulin is being sold in has such strong bearing on market pricing, the pricing clearly isn't inflexible for companies, and policy changes will probably be impactful.

Fuglestein Biniek, John, and William Johnson. "Spending on Individuals with Type 1 Diabetes and the Role of Rapidly Increasing Insulin Prices." *Health Cost Institute,* https://healthcostinstitute.org/diabetes-and-insulin/spending-on-individuals-with-type-1-diabetes-and-the-role-of-rapidly-increasing-insulin-prices.

This is a brief on the rapidly rising cost of insulin products in 2012 to 2016. Lantus, Sanofi's brand of insulin glargine, rose by 98%, and the average diabetic spent $5,700 on insulin alone and more than $12,800 on other care in 2016. These prices are only for people with employer-sponsored health insurance, and this study doesn't account for rebates on drugs. The year this study came out is also somewhat limiting, but the trends plus contemporary cost data on Lantus will give a useful trend and an alarming problem—$20,000 is excessive just to stay alive. The study, however, checks some contingencies to determine that the increase in payments from diabetics is in fact because of corporations raising prices. The number of units patients take has stayed roughly the same, and even if significant rebates were available, insulin prices have still hiked.