## Testimony of Allan Coukell, BSc (Pharmacy) Senior Vice President, Public Policy, Civica Inc. (Civica Rx) & President, Civica Foundation

# Before the Michigan State Legislature House Health Policy Committee 28 February 2024

Chair Rogers and members of the Health Policy Committee,

Thank you for the opportunity to provide remarks at this hearing, and for your continued efforts to ensure access to insulin at fair prices.

My name is Allan Coukell. I am a pharmacist by training, and I am the Senior Vice President for Public Policy with Civica — also known as Civica Rx. I am also the President of the Civica Foundation.

#### **About Civica**

Civica Inc. (Civica, Civica Rx) is a non-stock, non-profit pharmaceutical company that is developing quality, affordable insulin for the benefit of the 8 million Americans with diabetes who depend on this life-saving drug.

Civica was founded by health systems and philanthropies to address the problem of drug shortages in hospitals. Subsequently, we expanded the mission to lowering drug costs for consumers at the pharmacy counter. To do so, we formed an operating unit called CivicaScript, founded in partnership with health plans and other entities who share this mission. With this goal in mind, we have several drugs on the market or in development, including insulin.

#### **Civica Insulin**

Civica will manufacture the three insulins that account for most daily use in the United States – insulin glargine, lispro and aspart. These correspond to Lantus, Humalog and Novolog, respectively, and we expect Civica insulins to be interchangeable with those products. We will manufacture both in vials and prefilled pens and will be manufactured in our new, state-of-the-art U.S. manufacturing facility.

We are funding the cost of developing these insulins and bringing them to market through philanthropic contributions, including from leading diabetes organizations, and through a partnership with the State of California.

Civica's goal is to ensure that quality insulin is affordable to anyone who needs it, and we plan to set a recommended maximum price to the consumer of *no more*<sup>2</sup> than \$30 per vial of insulin and no more than \$55 for a box of five pen cartridges, a significant discount compared to prices charged to uninsured individuals today.

Our intent with this pricing strategy is both to offer low-priced insulin directly to consumers and to create marketplace competition that will lead other insulin manufacturers to lower their prices. (Indeed, our announced pricing is one of multiple factors that has already contributed to recent price reductions by the brand name insulin manufacturers.)<sup>3</sup> Crucially, we also aim to eliminate the pattern

<sup>&</sup>lt;sup>1</sup> In FDA parlance, "biosimilar" is the term for the "generic" version of a biologic drug, such as insulin. Interchangeable means a biosimilar that can be substituted for the brand product without requiring a specific new prescription.

<sup>&</sup>lt;sup>2</sup> Some pharmacies may charge less.

<sup>&</sup>lt;sup>3</sup> Dafney, L. "Falling Insulin Prices—What Just Happened?" N Engl J Med 2023; 388:1636-1639 DOI: 10.1056/NEJMp2303279. https://www.nejm.org/doi/pdf/10.1056/NEJMp2303279

of high list prices and non-transparent rebates that are common in the drug supply chain, and which serve to harm consumers — especially the uninsured and anyone who must pay out of pocket based on list price at any point during the calendar year.

We know too well the stories of people forced to ration insulin because of cost, leading to devastating health consequences and painful tradeoffs between insulin and other household expenses, such as rent or food. These hardships affect the uninsured and the insured alike.

### Michigan legislation

I would like to speak in support of **HB 4890**, and **specifically Chapter 8F**, which you are considering today.

As I have said, vials and pre-filled pens of Civica insulin will be manufactured in our recently completed state-of-the-art U.S. manufacturing facility. The drug substance — that is, the "raw" insulin that goes into the vials and pens — will be manufactured under contract for Civica by a partner company located outside the United States. We would like to bring that part of the manufacturing process back to the U.S., and if Civica were the private sector contractor selected under Chapter 8F, we would be able to do so.

We have assessed currently available and potential insulin manufacturing (i.e. biopharmaceutical microbial fermentation) capacity in the US and have determined that there is a need for more.

Such a manufacturing facility in Michigan would create 150 to 200 good paying jobs. It would produce both fast-acting and long-acting insulin drug substance, and could supply, not only for the people of Michigan, but for the entire nation. It would help to ensure the availability, quality, and affordability of insulin for the long term.

The legislation requires the insulin manufacturer to sell insulin to pharmacies without providing PBM rebates and, as I have described, that is consistent with our approach to insulin pricing and affordability.

In addition, the legislation also allows the state to purchase "Michigan-branded" insulin, and we welcome the potential opportunity to supply the state whatever number of batches it would like to purchase.

Thank you for your important work on insulin affordability. I welcome any questions.