Testimony of Allan Coukell, BSc (Pharmacy)

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Civica Inc. (Civica Rx)

Before the Maine State Legislature

Committee on Health Coverage, Insurance and Financial Services

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Senator Bailey, Representative Perry and members of the 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 the three insulins that account for most daily use in the United States – insulin glargine, lispro and aspart (insulin biosimilars¹ corresponding to, and expected to be interchangeable with, Lantus, Humalog and Novolog, respectively). Each will be available 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.

As with any drug that Civica supplies, our insulin will be available at a single transparent price, without rebates (except as required by law) or off-invoice discounts. Our approach is to make insulin available as affordably as we can, taking into account the costs to manufacture and distribute the product and to operate our non-profit organization on a break-even basis.

Civica plans to set a recommended price to the consumer of no more 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. We will make it available to any pharmacy that is willing to abide by our pricing policy, which allows for a fair dispensing fee to the pharmacy but prevents any entity from adding excessive markups that harm consumers.

To maximize transparency and limit predatory supply chain markups, Civica will include a QR code on the drug packaging to make it clear that this is a maximum amount that consumers should pay, although some pharmacies may charge less.

Our intent with this pricing strategy is both to encourage other insulin manufacturers to lower their prices (one of multiple factors that likely contributed to recent price reductions by the brand name insulin manufacturers). Crucially, we also aim to eliminate the pattern 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.

¹ In FDA parlance, "biosimilar" is the term for the "generic" version of a biologic drug, such as insulin.

All too often, these high prices for insulin have led to people not filling prescriptions or rationing their insulin. Several studies have suggested that about one-quarter of insulin users ration during the year, which can lead to devastating consequences.

Other people who are harmed by prevailing pricing strategies include anyone who has insurance coverage but may need an extra vial. We have heard from many people with diabetes who live in fear of dropping a vial or leaving it in the car in summer, lest they have to replace it at full cost.

Maine legislation

I would like to speak in support of the legislation you are considering today, which would protect insulin users in Maine, especially those who lack insurance or have to pay based on list price, and would facilitate competition in the marketplace. Because of prevailing financial incentives, high-cost drugs are often preferred, even when lower cost competitors are available. This legislation will ensure that PBMs provide coverage of low-net-cost insulin products and do not continue to favor the rebated pricing long offered by brand insulin companies.

If an insulin has the lowest list price, it would be covered without any administrative or financial barrier to access. If some other insulin product is less costly after rebates and discounts, then that could be covered preferentially, but again ensuring access and affordability. This will ensure that competition in the insulin marketplace works the way it should – to benefit consumers.

I also thank you for the provision in this legislation that would exempt makers of low-cost insulins from the annual license fee in the state of Maine. This will allow a company, like Civica, to keep prices as low as possible. Just as we are funding the start-up of our affordable insulin program through philanthropic contributions and state partnerships so that we don't have to build the cost of development into the cost of the product, this exemption will help us avoid another cost that otherwise would have to be added into the price. It is a change that will allow us to keep our prices as low as possible for good.

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