SLIDE 1: Hi, my name is Kelly Close and I’ve been a patient with diabetes for nearly 30 years.

SLIDE 2:

* I am the president of Close Concerns, a healthcare information organization focused on diabetes and obesity.
* Our main newsletter, Closer Look, is subscription-based, and the sponsor today, with several dozen other for-profit, nonprofit, and government organizations, pay for it, which supports our work writing about the field. That is my only disclosure.
* All in, Close Concerns writes about three million words per year about diabetes, based on a range of scientific, regulatory, reimbursement, and advocacy meetings, journal articles, and other goings on.
* We have a sister company dQ&A to follow what others in the diabetes community believe. dQ&A surveys 12,000 patients quarterly, as well as 500 diabetes educators and nearly 150 primary care doctors periodically. My comments today draw on work in both organizations.

SLIDE 3: There are 4,000 endos in the US and declining. Over 5,000 people per day are diagnosed with diabetes in the US; 1,150 more people today were diagnosed since our meeting started this morning and 312 were diagnosed since we broke for lunch.

The **exposure** that the US faces is what is scariest to me about the diabetes environment today. I especially care about all the patients doing worst. The percentage of patients not doing well is increasing, the percentage of people with diabetes doing the worst might not be changing but the *number* of patients in that group is exploding.

They’re staying older longer, and the paradigm must change for how *all* patients can succeed on therapy. SO many patients *are* successful on todays’ therapies but many aren’t, and more alternatives would be so welcome for the burgeoning number of patients.

The US spent $200 billion last year on diabetes, compared to $16 billion the year I was diagnosed and compared to estimates we see of up to half a trillion by 2030.

SLIDE 4: Insulin is a really dangerous drug and can be quite hard to take successfully. In the absence of traditional mealtime insulin that works well for **all** patients, being open to alternative forms of insulin is something that I hope you will consider. We appreciate you’re trying to avoid risk for us all but we also want to make sure you understand well the risks we face routinely every day.

SLIDE 5: Hypoglycemia is not only daunting physically; it’s also really costly. I’ve been in the emergency room 24 times for hypoglycemia over the last 27 years. If the hypoglycemia data holds up with this product, that would be quite valuable. Many patients on insulin worry about deaths caused by dosing the wrong amount of a drug we take every few hours to stay alive.

SLIDE 6: We rely on PCPs to be at the front line on insulin use. It’s not just success for patients we need – we also need success for doctors and nurses. Simpler to prescribe and teach and simpler to take therapies are needed, partly due to expanding system constraints.

SLIDE 7: For example, patients get very little time with doctors – about one hour a year if they are lucky. If their treatments are working, that is great. If not, do they need simpler or more complex regimens? What direction to you want to push therapy?

SLIDE 8: When you talk to PCPs about challenges with starting patients on insulin, needles/injections are at the top of the list. When we have a product that addresses the top objection, I think it’s one we should take seriously if we think it can address adherence problems – perhaps our biggest issue. Even if such insulins were *less* efficacious for some patients, the fact that they would be taking insulin at all is a positive for many of the patients faring worst. Changes to population A1c isn’t the only thing to consider – what’s the change to A1c for patients who won’t take traditional mealtime insulin at all?

When we talk about diabetes, stigma is a major problem. Stigma is rampant pretty much among all patient groups. Look at how much stigma people with diabetes feel – it gets worse for people on insulin and for people with higher A1cs.

We have a huge opportunity to improve patients’ lives by helping lower the stigma associated with traditional insulin and thereby increase adherence. On this I have no data –adherence data is notoriously hard to get – but with what the US is facing, standing in the way of this therapy with patients and HCPS who have so many problems with traditional mealtime insulin seems a really troubling message for you to send patients.

ADA has CLEARLY STATED the need to individualize therapy to help patients see more success and to get away from the treat to failure paradigm that is serving so many patients so badly. Please think creatively how to help them and what you want to look back and say you did in ten years, when you think about how the pandemic is faring. It’s not just a message you give regulators – it’s a message you give researchers, scientists, patients, families, partners, and society. There are a lot of problem with data but it means, all the more so, that you can think creatively about conditional approvals, approvals with specific parameters, etc.

SLIDE 9: You guys on the panel – and at FDA – have a really hard day job. Thank you so much for being here and letting me share with you why alternative forms of insulin have the potential to make a significant difference for patients and the American healthcare system that you are all leading so very ably.