



MEMORANDUM

EMPA-REG OUTCOME: The investment and the payoff - FDA OPH by Emily Regier - June 28, 2016

Executive Highlights

- Our very own Ms. Emily Regier spoke in favor of a cardiovascular mortality benefit indication for Lilly/BI's Jardiance (empagliflozin) and Synjardy (empagliflozin/metformin) at the [June 28, 2016 FDA Endocrinologic and Metabolic Drugs Advisory Committee](#) meeting.

Good afternoon, and thank you for the opportunity to speak today. My name is Emily Regier, and I am representing Close Concerns, a healthcare information company that aims to improve patient outcomes by making people smarter about diabetes and obesity. As far as disclosures go, today's sponsor is one of almost 300 organizations that subscribe to our fee-based newsletter, Closer Look.

Today, I would like to take a step back and offer a few big-picture thoughts on what Jardiance, and especially the benefits demonstrated in EMPA-REG OUTCOME, mean for patients with diabetes and their healthcare providers. Thanks to the FDA's recommendation that these major outcomes trials be done, we now have valuable information on Jardiance that can help healthcare providers as they choose among the many different options for patients with type 2 diabetes. We know this trial required a substantial investment of time and money, and we want to ensure the diabetes community can gain as much value as possible from that investment.

People with diabetes want to live long and they want to live well. Few people expected that findings of lower cardiovascular risk would emerge so clearly in this trial, even if for only a small group of patients. Given the staggering prevalence and cost of diabetes and its complications, a product that reduces the risk of a bad outcome for even a small percentage of patients could have a significant impact on the healthcare system. We understand that any label update would need to include statements about the limitations of the data and how much it can be generalized, and we will leave it to the experts to debate the more technical questions related to trial design. However, we think it is important for today's busy healthcare providers to have the opportunity to at least speak broadly with patients at high risk of cardiovascular disease about the potential benefits of this medication. We would love to see increased awareness among people with diabetes about the risks of cardiovascular disease, and we think that including this data on the label can be an important component of that effort. Thank you again for the opportunity to speak and for your consideration on these matters.

-- by Emily Regier and Kelly Close