From: Eli Lilly and Company

To: Healthcare Providers

Subject: Potential Risk of Medullary Thyroid Carcinoma and Risk of Pancreatitis with Trulicity (Dulaglutide)

trulicity™
dulaglutide injection
0.75 mg/0.5 mL, 1.5 mg/0.5 mL

TRULICITY REMS

FDA Required REMS Safety Information

- **Potential Risk of Medullary Thyroid Carcinoma (MTC)**
- **Risk of Pancreatitis**

Important Safety Notice

The FDA has required this safety notice as part of the TRULICITY REMS (Risk Evaluation and Mitigation Strategy) to inform healthcare providers about the following **serious risks of TRULICITY (dulaglutide):**

Potential Risk of Medullary Thyroid Carcinoma (MTC).

- In male and female rats, dulaglutide causes a dose-related and treatment-duration-dependent increase in the incidence of thyroid C-cell tumors (adenomas and carcinomas) after lifetime exposure. It is unknown whether TRULICITY causes thyroid C-cell tumors, including MTC, in humans as the human relevance of dulaglutide-induced rodent thyroid C-cell tumors has not been determined.
- Cases of MTC in patients treated with liraglutide, another GLP-1 receptor agonist, have been reported in the postmarketing period. The data in these reports are insufficient to establish or exclude a causal relationship between MTC and GLP-1 receptor agonist use in humans.

Risk of Pancreatitis.

- Pancreatitis has been reported with the use of GLP-1 receptor agonists. Cases of pancreatitis have been described in association with TRULICITY during clinical trials.

TRULICITY is not recommended as first-line therapy for patients with type 2 diabetes mellitus inadequately controlled on diet and exercise.

A non-promotional factsheet, reviewed by the FDA, with more detailed safety information about these risks is available at www.TRULICITYREMS.com.

Please visit www.TRULICITYREMS.com for more information.

Indication: TRULICITY is a GLP-1 receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

This letter does not contain the complete safety information for TRULICITY. To review the Prescribing Information and Medication Guide, see links below:

Prescribing Information	Medication Guide
Active link to be included in communication	Active link to be included in communication

Reporting Adverse Events

You are encouraged to report negative side effects of prescription drugs to Eli Lilly and Company (the Sponsor) at 1-800-LillyRx (1-800-545-5979) and/or the FDA at www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please contact The Lilly Answers Center at 1-800-545-5979 with any questions about the information in this letter or the safe and effective use of TRULICITY.

Sincerely,

Robert W. Baker, M.D.
Vice President, Global Patient Safety
Eli Lilly and Company