Excel Diagnostic Imaging Clinics

**March 27, 2018**
**To whom it may concern:**

During floor debate on the federal Right to Try bill on March 21, 2018, Congressman Frank Pallone read from a letter written by a Canadian activist named Andrew McFayden that included categorically false information about myself and my work treating cancer patients.

My reputation and the reputation of my work is extremely important to me. I am currently Chairman and Medical Director of Excel Diagnostics and Nuclear Oncology Center, and I hold an academic position as Clinical Professor in Radiation Oncology at the University of Texas, Medical Branch and Adjunct Associate Professor in Nuclear Medicine at Baylor College of Medicine, in Houston. I am board certified in nuclear medicine and a Fellow of the American College of Nuclear Medicine. I have previously served as deputy chairman, associate professor, and chief of clinical nuclear medicine at M.D. Anderson Cancer Center in Houston. I was also Director of Therapeutic Nuclear Medicine at MD Anderson. I have run several clinical trials under the approval of the FDA for years, and my results have been published in peer reviewed medical journals, including *New England Journal of Medicine, Pancreas Journal: The Journal of Neuroendocrine Tumors and Pancreatic Diseases and Science,* and *Clinical Nuclear Medicine.*

Starting in 2010, our clinic, Excel Diagnostics and Nuclear Oncology Center, was the first center in the United States starting a phase II Expanded Access treatment protocol for Lu-177 DOTATATE in patients with metastatic neuroendocrine cancers. This was a physician-sponsored, FDA-approved Investigational New Drug application and I was the principle investigator of this trial. Before the approval of this IND, our patients had to travel to Europe to get this life-saving and expanding treatment. Our European colleagues had started this treatment several years before and their promising results were published in several peer reviewed publications. Under the Phase II Expanded Access IND, I treated 144 patients, and later, I treated 178 patients under Texas's Right to Try law.

Our Center, was also among 14 in the United States participating in a multi-center clinical trial (NETTER-1) that led to FDA approval of Lu-177 DOTATATE (LutaThera®) in January of 2018. The results of this study have been published in a manuscript I co-authored in the *New England Journal of Medicine*, one the most prestigious medical journals in the world.

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It's unjust and irresponsible for a member of Congress to cite unverified rumors on the floor of the House in an official debate on a serious piece of legislation. I do not know Mr. McFayden; I have never met him, nor has he spoken with me about my work. Congressman Pallone never called me to ask if the accusations made by Mr. McFayden were true. Instead, he repeated these unsubstantiated falsehoods on the floor of the House in an attempt to bolster his untrue arguments against Right to Try and to damage my career and practice and tarnish my reputation.

Because this misinformation is damaging not only to me and my practice, but to the patients being helped by the Right to Try laws – and those who can be helped by a federal Right to Try law – I want to set the record straight.

First, Mr. McFayden claims the FDA placed a clinical hold on my study due to a failed inspection. That is untrue. Here is an accurate timeline of events.

After receiving FDA approval in June 2010, I treated my first patient in August 2010. Our initial approval was to treat 60 patients. The treatment showed such promise that I sought permission to treat additional patients. The FDA granted several subsequent requests to treat up to 150 patients. In February 2015, when I had enrolled about 130 patients, I filed an amendment to our program to increase the number to 250 patients. My reason for requesting additional enrollment in our program was due to the fact that the NETTER-1 clinical trial was completed in January 2015 (please see attached), and we did not anticipate the approval and commercialization of the drug for at least 2-3 years. Therefore, our program was the only path for our patients to continue to receive treatment in the United States, until the FDA gave final approval to the drug.

On March 17, 2015, I received a call from FDA to discuss my request to treat an additional 100 patients. During the call, the FDA representative informed me that my request was denied. Their justification was that our program was interfering with recruitment of patients in the NETTER-1 trial and the drug does not appear to be efficacious in treating patients. I informed the agency during the call that enrollment for the NETTER-1 trial was completed in January 2015; so there was no way that our program could have had an effect on the trial – it was already over. I also discussed the effectiveness of the drug, according to our annual reports submitted to the Agency and multiple peer reviewed publications. The FDA representative then told me that "we need to agree to disagree." At the conclusion of the phone call, my impression, and the impression of my director of clinical research who was present during the phone call, was that because the FDA did not agree to increase our program's enrollment, we would have to stop enrollment after we reached 150 patients, as previously was



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authorized by the agency. It was only when written confirmation was received via email on April 14, 2015, that we realized it had been FDA's intention for us to stop enrolling patients as of March 17, the day of the teleconference. In the month between the call and receiving the email, we had enrolled an additional six patients. But, we did stop enrolling new patients as soon as we received the email. We notified the division director Dr. Patricia Keagan regarding this misunderstanding (please see attached email to Dr. Keagan April 24, 2015), and with the agency's express permission, we completed treatment of the last six enrollees.[1]

On April 16, we were notified that the FDA would be at our office for inspection. The FDA inspector, Ms. Zerita White, was in our office from April 16 to May 4 and reviewed all our files related to the program. The 483 form that Mr. McFayden referenced in his letter was the outcome from this lengthy inspection. **The main focus of the 483 was the enrollment of six patients after the phone call of March 15, 2015, about which we informed FDA promptly and received permission to continue to treat.** ***The 483 was not a result of safety concerns*****.**

Mr. McFayden also claims that I failed to promptly report adverse events to the FDA. The 483 form reports three occasions where we failed to report adverse events within 7 days of the date that we were notified. These three incidences were reported five, four, and seven days, respectively, outside the time window, **but they were all reported**. **None of the adverse events were related to the treatment drug.** Without meaning to minimize the importance of adherence to protocol, we would note that these deviations from protocol occurred in the course of treating 144 patients and giving more than 420 infusions of drug.

Ms. White conducted a thorough investigation and later told me that had it not been for my enrolling six additional patients the FDA would not have issued the 483 form, at all. In other words, the citation was triggered by a miscommunication over the number of patients who were authorized to be treated, *not* any concern about safety. In fact, Ms. White told me that if she or anyone in her family were to be diagnosed with neuroendocrine cancer, she would trust their treatment to me and my team.

As further proof that the FDA was thoroughly satisfied with my treatment protocols and the safety of my work, the agency allowed me to continue to treat the six patients I had already enrolled after the miscommunication, in

[1] Attached is an April 29, 2015 email from Ms. Libeg stating that we were permitted to "continue the planned treatment course" for these patients.



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addition to all those who were enrolled prior. Simply put: I was never told to stop treating any patients that I ever treated and there were no safety issues with my treatments.

Mr. McFayden claims that patients didn't need Right to Try or my services, because FDA-approved treatment was available elsewhere. Again, this is false. In 2015, the multi-center clinical trial was complete, and the FDA refused to allow me to enroll additional patients in my treatment program. Indeed, *no* additional expanded access programs had been activated in the entire United States – and would not be for a *whole year*. In that one year alone, Texas's Right to Try law enabled me to treat 70 patients who had *no other treatment options in the United States*. Had it not been for Right to Try, those patients would have had to travel to Europe to receive treatment. Those who could not have managed such a trip would have been simply out of luck.

Even after the FDA eventually activated additional expanded access programs, those programs were *exceedingly* small – capped at just a handful of patients. And many patients did not meet the strict eligibility criteria (limited to very precise types of neuroendocrine cancer) for those expanded access programs. Many of these patients were told they had mere months to live. But thanks to Right to Try, many of them are alive today.

The simple fact is that had it not been for Right to Try, my patients would have been out of options and out of hope.

Mr. McFayden claims that his "understanding of the situation is that the company running the clinical trial distanced themselves from Dr. Delpassand after these failed inspections" and that Right to Try is just a loophole for people who can't follow safety requirements. His understanding and speculation is categorically false and insulting. My institution and I are currently involved in several physician or pharmaceutical company-sponsored FDA-approved clinical trials, and I am constantly being approached to participate in new trials.

As previously stated, my team did not fail *any* safety inspections, nor did we end up at odds with the FDA. As Mr. McFayden admits, the treatment was approved by the FDA in January 2018. This is a testament to the fact that the treatment was safe and effective – and also that it was wrong of the FDA to deny many patients access to the treatment. Right to Try allowed me to help those terminal patients who fell through the cracks of the system.



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There is one point upon which Mr. McFayden and I do agree: sometimes, it is drug companies that stand in the way of patients receiving treatments they need, and Right to Try doesn't completely solve that problem. But no one claims Right to Try is a cure-all. It's simply an important step in the right direction.

In fact, that is why we need the federal Right to Try law, which includes important components to incentivize companies to participate.

I want to make clear that I am not against the FDA. I consider it an important part of the drug approval process and I always appreciate the hard work of our colleagues at the agency. But the patient has the right to make decisions about his or her life when he or she is dealing with a catastrophic illness. His or her doctor is the best person to help make this decision, because the physician is the person most familiar with, and invested in, the patient's condition. This becomes even more critical when dealing with a rare disease. Taking the choice away from the patients and the doctor, and giving it to FDA officials and scientists who have never seen the patient, or have no experience in treating a rare condition, is unfair both to the patient *and* to the FDA. Right to Try takes the burden of micromanaging doctors off the FDA so it can focus on its proper task. And it allows doctors like myself to help patients whose lives are on the line – individuals who would otherwise be out of hope.

Yours most sincerely,

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