Mallinckrodt Pharmaceuticals

October 10, 2014

Dear Valued Nuclear Medicine Customer,

I am writing to you today to provide visibility into some of the significant cost drivers that the nuclear medicine industry and Mallinckrodt are experiencing, which necessitates our increasing prices over the next several years.

Mallinckrodt Pharmaceuticals was founded 147 years ago on three important core values: quality, integrity and service. For more than 40 of these years, Mallinckrodt has been a leader in the production of Technetium-99m (Tc-99m) generators – the lifeblood of nuclear medicine – and other radiopharmaceutical products important to the patients we all serve. Today, Mallinckrodt is the world's largest and most vertically integrated supplier of Tc-99m generators and we're a leader in producing its parent isotope, Molybdenum-99 (Mo-99).

Since 2009, our industry has faced many difficult challenges impacting patients, technologists, physicians, pharmacists, healthcare facilities and manufacturers. This began with the unexpected shutdown and necessary repairs to some of the global research reactors used in irradiating uranium targets to produce Mo-99 and other isotopes. The resulting supply disruptions created the first worldwide Tc-99m shortage, which lasted nearly 18 months. The impact of this can still be felt today as the number of nuclear medicine studies in the U.S. has not yet returned to pre-shortage levels, despite the significant value our modality has in the diagnosis and treatment of patients.

During and after that difficult time, Mallinckrodt made it a priority to communicate with and listen to industry stakeholders. The recurring message we heard: use our expertise, size and vertical integration (supplying both Mo-99 and Tc-99m generators) to help prevent future such shortages.

I am proud to say that Mallinckrodt has repeatedly risen to that challenge, starting by bringing the Polish Maria reactor into the global Mo-99 supply chain to further diversify and strengthen the nuclear medicine community's ability to meet patient needs around the world. We have also successfully increased our Mo-99 production capacity through contracting for extra target irradiation positions with our reactor partners, known as Outage Reserve Capacity (ORC), allowing irradiation of extra targets for unexpected additional Mo-99 needs. Yet while ORC helps to increase reliable access to Tc-99m for patients, these irradiation positions must be paid for whether or not they are used, increasing overall Mo-99 production costs. Mallinckrodt has also helped overcome intermittent supply disruptions by negotiating access to every Mo-99 supplier available to the global market and skillfully utilizing this access when required.

So we have successfully strengthened global supply stability through many actions – that some of you may be unaware of – yet it has come at considerable cost. And while Mallinckrodt has been investing in supply improvements requested by nuclear medicine stakeholders, other forces have been acting upon our industry. For example, for decades our profession has relied on the supply of highly enriched uranium (HEU) to produce Mo-99 and other isotopes. To support global non-proliferation efforts, the U.S. government has mandated conversion from HEU to low-enriched uranium (LEU) or non-uranium based production methods for medical isotopes. As a major Mo-99 producer, Mallinckrodt supports this conversion which requires significant time and investment throughout the industry to complete the scientific and technical modifications necessary to operate without HEU. Beyond the conversion outlay, Mo-99 production using LEU will be inherently more costly than using HEU.

In addition to these factors, Tc-99m supply is impacted by the cost to produce and distribute Mo-99. These costs have continued to rise, driven by increased irradiation charges and Full Cost Recovery (FCR) models currently being implemented by reactor operators. The impact of FCR will continue to be felt as it is fully implemented around the world. The ability for manufacturers to pass these costs on to customers is challenged by reimbursement for Tc-99m-based procedures.

The price increases we have been forced to implement in recent years have in no way matched our increased Mo-99 costs. To help offset this differential, we have focused heavily on reducing our internal costs, restructuring both manufacturing and commercial operations to be as efficient as possible while preserving our heritage of safe and stable production.

As nuclear medicine costs have risen, the average price of Tc-99m-based patient doses has declined, in some cases, to less than the price of a pizza. Although nuclear medicine is a very cost-effective and useful tool for clinicians, the low price and reimbursement for these procedures do not adequately reflect the true costs throughout the chain, which include:

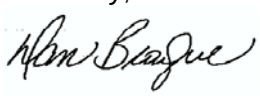
- Irradiating and processing uranium targets
- Disposing of radioactive waste produced in the purification processes
- Manufacturing under cGMP and NRC standards
- Shipping rapidly decaying products around the world in a timely manner
- Preparation of patient-specific doses by nuclear pharmacies
- Delivery of the final product to healthcare facilities globally

This model is unprofitable and unsustainable. Without an adequate return on investment, innovation and development is leaving our industry. Today, consolidation has resulted in fewer products and fewer manufacturers to meet patient needs. With greater frequency products are only available from one source. Ultimately this results in less choice for physicians when considering nuclear medicine as an option for their patients.

Mallinckrodt has been, and continues to be, committed to the stability of nuclear medicine, but these many cost-impacting factors – ORC, FCR, transportation, LEU conversion – simply cannot continue to be absorbed. Thus, we will be implementing a series of price increases over the next few years that will be easier for our customers to pass through rather than a single, larger increase. We will be sharing more details of this plan with you in the coming weeks.

I hope you continue to share our passion for and dedication to nuclear medicine, knowing the utility for Tc-99m-based procedures and other radiopharmaceuticals remain strong due to their unique characteristics. With appropriate planning and collaboration across the industry, we can all help to ensure nuclear medicines' vital role in healthcare is maintained.

Sincerely,



Dan Bragué
Vice President & General Manager
Imaging - North America
Mallinckrodt Pharmaceuticals