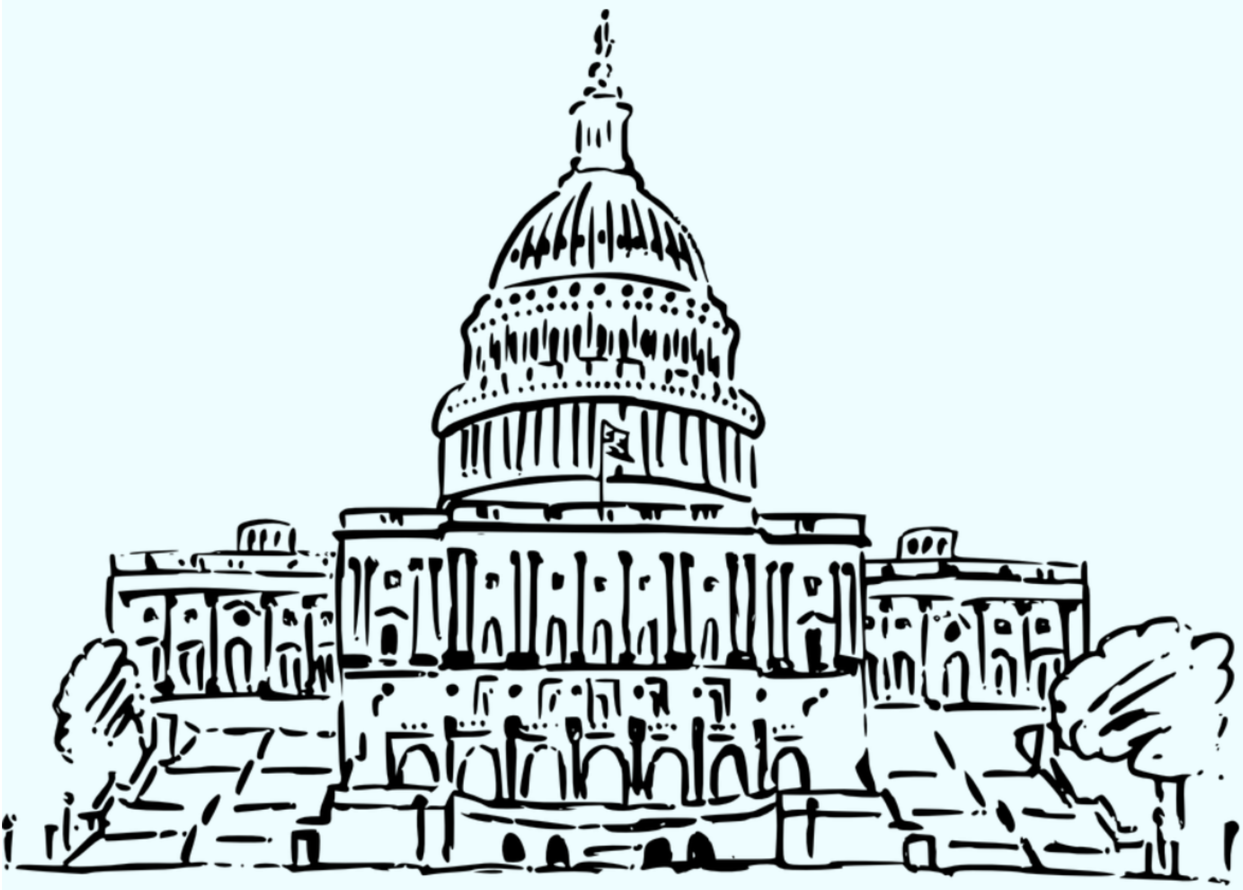
SUMMER
2022

Improving the Domestic Supply Chain of Medical Grade Isotopes

Tiara M. Carrasquillo Pérez



WISE
WASHINGTON INTERNSHIPS for STUDENTS of ENGINEERING

American Nuclear Society

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Executive Summary

With about thirty-eight million procedures performed worldwide each year, nuclear medicine has become one of the most frequently utilized diagnostic scanning procedures. This powerful technique enables physicians to gather images within the body and scan for various medical ailments in a non-invasive manner. With a relatively low radiation exposure to the patient, the application of radionuclides within medicine is growing in the medical practice worldwide.

About Author

Tiara M. Carrasquillo Perez is a señor in the University of Puerto Rico- Rio Piedras Campus. She is scheduled to gradutiate with a Bachelors on Medicine on Nuclear Medicine Technitian and a minor on Radiology technictian as an Undergradutate Scholar in May 2024. During her time in the University of Puerto Rico she has balanced her course work, community service, campus leader oriantator, and college parttime worker to work on her future career goals. Working as a freshmen oriantenter and guide have taught her leasons in leadership and cooperation to help those in need and support her peers. As well as, her work as in a computure lab as partime work have taught her the skills to work and understand technology and its inner workings. Tiara's career goals are still wide and varied but is looking to graduate with a Medical degree with specialization in Nuclear Medicine and a Doctorate in Nuclear Health. The American Nuclear Society selected John Starkey for sponcering in the WISE 2022 Program.

About WISE

Founded in 1980 through the collaborative efforts of several professional engineering societies, the Washington Internships for Students of Engineering (WISE) has become one of the premier Washington internship programs. The WISE goal is to prepare future leaders of the engineering profession in the United States who are aware of, and who can contribute to, the increasingly important issues at the intersection of science, technology, and public policy.

Each year, the WISE societies select outstanding 3rd or 4th year engineering/ computer science students, or students in STEM, from a nation-wide pool of applicants. The students spend nine weeks in the summer in Washington, D.C. during which they learn how government officials make decisions on complex technological issues, and how engineers can contribute to legislative and regulatory public policy decisions.

Acknowledgments

I would like to thank all of the members of the Americn Nuclear Society for sponsoring my involment in the 2022 WISE program. This program has been an eye opening experience that has truly impacted my career path and my academicapproach in ways that are indescribable. I would to talk the 2022 Faculty Member in Residence, Dr. Gilbret Brown, and my mentor, Dr. Alan Levin. With out their guidence and leadership, none of my research would have even begun to take form and body. I would also like to thank Tomoko Steen, Leila Safavi-Tehrani, Carmen Bigles, Raymond Furstenau, John Starkey, Craig Piercy, Cindy Tomlison, Thomas Eiden, Amber Johnson, and Shikha Kumar. This paper is nothing but my interpretation and analysis of the knowledge of others, and it would not have been possible without their guidance. Finally, I would like to thank all of my fellow inters during the course of the program. They made this experience truly special

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Introduction

Within the Nuclear industry, the emphasis on energy has been one of the most relevant. Without it, our way of life would fall and be subject to disaster and chaos, as such the nuclear industry has maintained a steady focus on its maintenance and innovation. On the other hand, although no less important, nuclear medicine has been left on a state of stand-by where growth could potentially flourish. Nothing seems to be done of it until tragedy strikes, not to say that its progress has been non-existent, but it is placed on the back burner to deal with what seems to be more president matters. As for the cases of isotope production, the industry focuses on the use of uranium-235 as its main source of production and development. In recent years as recent as February 2022, the biggest supplier of this material turned against a peaceful nation bringing forth a dilemma that was thought of but not addressed. Talk of uranium independence and larger domestic supply has been a long-spoken topic of the industry but never quite addressed. This sudden war that arose left the US in a difficult position as the Biden administration imposed sanctions against Russia to begin economic warfare. This has left the nuclear industry in a difficult position as Russia contains around 5.43% of the world's uranium† which the US is heavily reliant on. As such, actions have been taken to ensure the importation of uranium remains steady, but this has once raised the question of how the US will initiate its energy fuel independence. Work on domestic production has long been initiated even before the beginnings of this altercation and several companies, as well as well-known industries, have received incentives to begin a transition to a more domestic supply. Although, it is not quite certain how stable this supply chain might present itself to be as various sources have indicated different outcomes to this issue. Some state that the US is prepared for a shortage† if a stagnant supply were to occur. Other sources state that the US doesn’t have a stable enough supply chain to maintain it. This issue could become a very difficult one as the Isotope supply chain becomes more demanding.

As new radiopharmaceuticals are developed as time progresses many of these isotopes could start to become scarce as demand for them grows. This has been a concerning factor as there is talk of a possible impending shortage of not just Mo-99 but a variety of alpha emitters such as Lu-177. As the government continues to impose embargoes on Russia it is suspected a possibility of this becoming a total embargo on Russian goods, this would include U-235. Although circumstances would prove to be quite different the lack of material could cause a shortage and as such, the US must be prepared. Some policies have begun to be implemented† and efforts to push domestic production have grown as the DOE pushes the NSA to employ more incentivized programs with different major companies. This is a very efficient way to instigate production, but we must ask if this is enough. Many startup companies are looking to partake in the production of these isotopes, but many have been on the initial steps of licensing and building. As such, there needs to be a bigger push to move these companies further or at least an active measure to ensure the supply chain. Whether this is approached from a different foreign production source or to push the supply in the US a change must be done to secure the medical industry and the patients treated with it.

Background

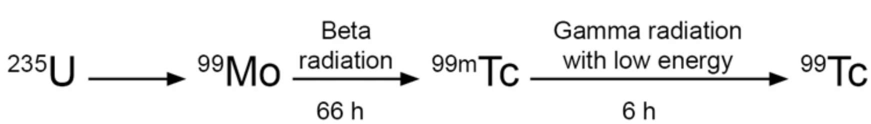
Use and Applications of Medical Isotopes

Nuclear medicine is a specialized area in radiology that uses small amounts of radioactive material to diagnose and treat patients with various conditions as well as diseases. The production of radiopharmaceuticals used in these procedures is done via the use of radioisotopes. These radioisotopes also known as medical isotopes are used in up to 40 million procedures and account for nearly 80% of nuclear medicine treatments and 85% of diagnostics throughout the entire world. In the United States alone it is estimated to do up to 20 million procedures and its use is increasing by approximately 10% annually. As their relatively short half-live periods lower the chances of harming the patient and can be naturally eliminated from the body. The most common type of isotope used in this sector is molybdenum-99 (Mo-99) a fission product of Uranium-235 (U-235); from Mo-99 it decays to create technetium-99m(Tc-99m).

Radioisotopes are used in diagnostic procedures by administering a small dose of specific radiopharmaceuticals to the patient. The pharmaceutical can be administered via injection, inhalation, or orally to the patient being examined. There are a variety of medical isotopes that are used for diagnostic like rubidium-82 and fluorine-18, which are commonly used for CT/PET scans. The therapeutic uses of medical isotopes are less than their uses in diagnosis but just as important when used especially for cancer treatment. The susceptibility of cancer cells to radiation allows the treatment to diminish if not completely remove the cancerous growth. This kind of treatment is known as radiosurgery, and it has different types of ways that it can be administered. External irradiation(teletherapy), which is the application of radiation from outside of the body, can be performed using gamma beams with cobalt-60 as a source, although throughout time more high-energy X-ray sources are being used. Internal radionuclide therapy is performed, by implanting a small source of radiation (either gamma or beta radiation). Many of the treatments that are used in nuclear medicine are aimed to reduce pain, such as the use of strontium-89 or samarium-153, which are used to relieve bone pain caused by cancer. Many diseases and conditions, including cancer and thyroid conditions, require the use of nuclear medicine to eliminate or lessen tumors or damaged cells in the body. No need to repeat this here. You could just say "procedures" or something similar. Repetitive. This sentence can be deleted. I was under the impression that Tc-99m was used only for diagnostic purposes, not therapeutic ones "half lives" This is not a sentence. Mo-99 is not "fissioned." It decays to Tc-99m. medical isotopes which are performed by As originally written, this was not a sentence.

Production of isotopes

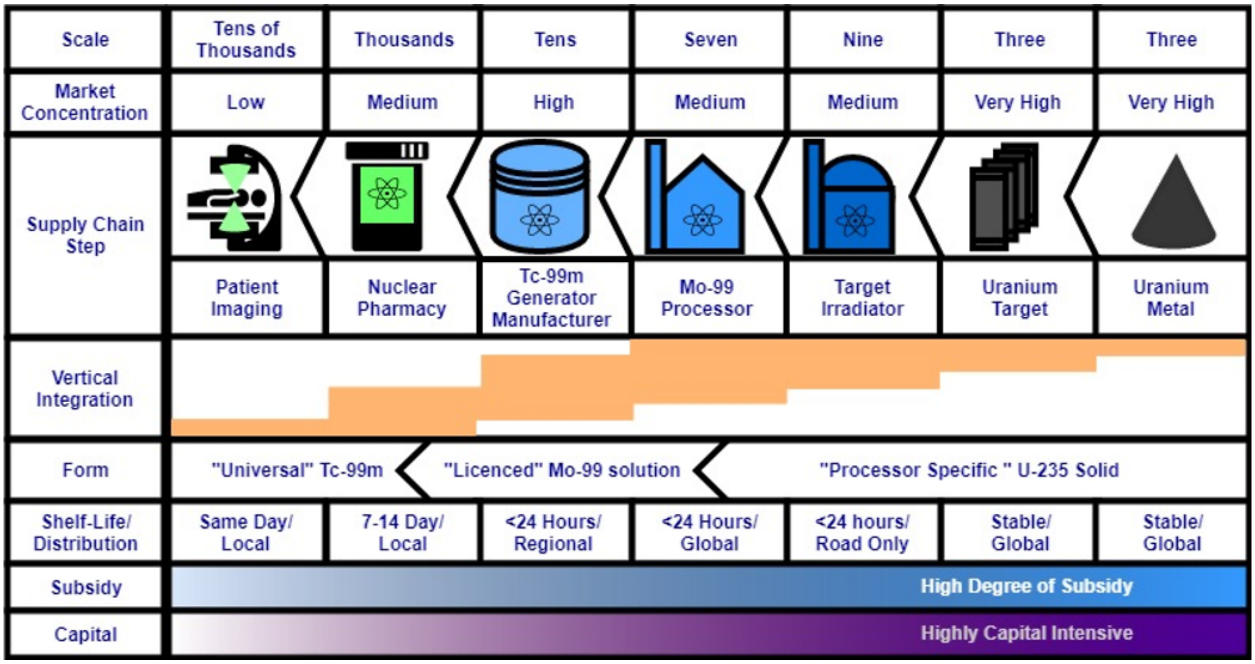
The development of medical isotopes is done through the process of fission of U-235 to Mo-99 to later produce Tc-99m. This is achieved through beta decay of Mo-99 into its



daughter isotope Tc-99.

The production of the most used isotope begins with irradiating U-235 into Al-coated plates or tube targets. Later dissolved in a processing facility with chemical dissolvents where the fission product Mo-99 is bound and separated by the chemical. The Mo-99 extracted is later transported to the manufacturer that creates Mo-99/TC-99m generators, which are then finally delivered to hospitals. In these generators is where the Mo-99 decays into Tc-99 for it to be extracted and placed in use for diagnosing the patient. Tc-99m has a short half-life of 6 hours which makes it difficult to store for later uses, as such when extracted it must be put to mediate use. For this reason, Mo-99 is typically produced in larger quantities as it has a much longer half-life.

The production of Mo-99 can be done in two ways: it can be done through a nuclear reactor or accelerators (detail reactor production vs. accelerator production)



<u>Isotope Shortages and resolves</u>

In May 2009, a Canadian reactor had to abruptly shut down due to maintenance issues due to corrosion and leaks inside the National Research Universal (NUR) reactor in Ontario, Canada. This disruption of isotope had left many doctors unable to administer the appropriate procedures to their patients. Previously, this reactor had proven to be unreliable in 2007 when it was forced to shut down due to repairs. Following the Canadian reactor shutdown, the High Flux Reactor in the Netherlands had to also be shut down. The combination of both reactors becoming offline accounted for about 70% of the world's isotopes and almost the entire U.S. supply was cut off suddenly. The shutdown had left only three other reactors operating: Safari in South Africa, BR2 in

Belgium, and Osiris in France. It took about six months for these plants to return to function, but only the Canadian reactor shut down indefinably. This placed a strain on many countries, such as the U.S., and the search for a solution for this crisis sparked conversations that brought bills to address this issue.

Current Supply Chain Threats

Russian Dominance of US Uranium Market

Since the (SOMETHING ABOUT AMERICANS Backing down from uranium supply chain) the Russian have dominated the uranium market. Due to its cheap market price American industries couldn't keep up and became reliant on Russia's cheaper prices to obtain uranium for fuel and production. Russia's supply chain of natural uranium in the market accounts for about 40% of the world's supply. Although its market sales are not as big as they once were they hold dominance in export markets for new reactors for uranium development and processing. They produce more than 60 radioactive isotopes as well as closed source alpha, beta, gamma, and neutron radiation products for medical use; many of which are of critical use in hospitals across the U.S. This is of importance as many of the isotopes that the U.S. uses are solely produced and developed in Russia. This places Russia at an advantage as it makes the U.S. need to rely on them to obtain their isotopes, thus ensuring a market.

Some of the isotopes Russia has market control over would be

Sanctions on Russia due to war

On February 24, 2022, Russia invaded Ukraine, claiming that this was retribution for a provoked attack from Ukraine on Russia. As such Russia had begun an invasion of Ukraine to control the country once more as the Russian president Putin exclaimed that Ukraine was part of their territory. With this, the Biden administration along with several allied nations began emplacing sanctions on Russia to stop moving forward with the war and obtaining the materials needed to continue pursuing the war successfully. The

Biden administration issued an executive order to stop all investments, imports, and exports from the US to Russia. There has been talking of a total ban of Russian Uranium and their products to completely shut them off. Nothing has yet to be done regarding the Uranium supply and byproducts of the sanctions.

Regulatory Standers and Legislation

“American Medical Isotope Production of 2011”

The United States House of Representatives had proposed on September 9, 2009, the “American Medical Isotope Production Act of 2009” at a hearing to discuss what the U.S. should do as a response to the two reactors shutdowns. This bill is backed by the Society of Nuclear Medicine, the American College of Radiology, the University of Missouri, and others. During this hearing, congress discussed the domestic supply of Mo-99 as the failure of foreign producers had left the U.S. supply in a crisis. This bill also stated the complete halt of the use of HEU as reactor fuel. It was stated in this hearing “This legislation will accelerate greatly and enhance the development of the reliable supply of this isotope for the use in the USA medical community and further support U.S. objectives to reduce the use of proliferation-sensitive HEU in civilian applications.” This bill established that it was feasible to use LEU to replace HEU for safety and economic reasons and use it to aid isotope production efforts. The bill was not passed that year and was re-proposed on January 1rt, 2011 but was handed to the National Defense Authorization Act (NDAA) for the 2013 fiscal year (FY). After this, it was passed by the House and Senate in December 2012 and signed by the president in January 2013. This bill was incorporated as Title XXXI, subtitle F of the NDAA where it is titled “American Medical Isotope Production Act 2012.” With this, the production of domestic medical grade isotopes was approved and was ready to be implemented in the commercialization of the same. The passing of the bill also allowed for private companies to begin searching for ways to do production as well as provide ways for outside companies to invest in the development of domestic production.

Current Policy Applications and Production Management

Although many actions have been taken to further develop the domestic supply within the nation there is still improvement to be made and perused. Currently, domestic production is minimum due to there not having many facilities that produce Mo-99 to be distributed to Hospitals nationwide in a constant stream. This can also be said for other types of developed isotopes that are still under testing like Actinium- 225. Advances to ensure safe and stable manufacturing of radioactive isotopes have been funded and incentivized by the Department of Energy (DOE) as most projects are for better ensuring the supply chain as well as better commercializing. Even though the lack of domestic producers hinders the progression of a more stable supply chain and potential treats of the cut-off Russian supply could impact the production even further. Due to the import of target-based Mo-99 extractions the potential embargo of these materials could prove staggering to domestic production.

"Department of Energy Science of the Future Act 2022"

Introduced on May 28th, 2021, the Department of Energy Science of the Future Act was discussed for evaluation and processed. Later it was presented at a committee hearing on March 1st, 2022, aimed to further push the development of science and technology in the United States. This speaks on the current state in which the industry's supply has been seen thus far. It proposes a program that will carry out the production of critical radioactive and stable isotopes which are deemed needed for research, treatment, or other related purposes. This includes critical isotopes that are in short supply along with their excess product and other material that is processed along with it. It always strives to conserve and amplify the infrastructure needed for its production and distribution for medical and research applications and to enhance the same. Lastly to diminish or hopefully remove the dependence of foreign suppliers for these materials to ensure national security and preparedness. The bill also calls for the exclusion of Mo-99 as it states that it has been worked with and dealt with in the Medical Isotope Production Act 2011 bill.

Mo-99 Supplier and developers

The Facilities and established research companies have pushed to ensure that the uranium used for its production and development were properly and securely applied were that of the Department of Energy (DOE), Nuclear Regulatory Commission (NRC), and Environmental Protection Agency (EPA). Although these three groups control most of the uranium's regulations, legislations, and policies. With a variety of goals but ultimately one same vision; to ensure the health and safety of those who use and work with nuclear material of any sort.

North Star

NorthStar works with an accelerator-based production of Mo-99, which is achieved using electron-beam accelerators that utilize Mo-100 to then modify into an aMo-99. This method of production doesn't require uranium and uses a process known as the "neutron knock-out" method. NorthStar states that through this method of manufacturing the company can produce about 30% more product per gram of target material than it uses neutron irradiation of Mo-98. Which works by having Mo-98 be irradiated by neutrons converting into mo-99 with this method. NorthStar has also been initiating the producers to begin the production of Actinium- 225 to produce more medical isotopes to be implemented into the supply chain.

SHINE Fusion

SHINE Fusion, much to their company name, works with the world's strongest neutron generator that facilitates the use of nuclear fusion-based energy, specifically beam-target fusion. With the use of an electrically driven particle accelerator, they can utilize neutron radiation to extract their product as this type of isotope extraction has proven to be very useful in a variety of applications in the industry itself. SHINE's use of fusion-based energy presents a more affordable and sustainable way of isotope production, thus addressing any production problems for possible near-term shortages the industry could face. They specialize in the production of Mo-99 but also produce Lutetium-177 (Lu-177). They aim to expand their fusion-based reactor usage; they are looking to expand their utility to nuclear waste management, energy production as well as a possible use for explosive detection and neutron activation analysis. This production is achieved via the use of LEU with their deuterium-tritium gas-target neutron source. A recent conference in the Wisconsin Entrepreneurs' conference stated they aim to increase isotope production for 2023, as the company moves further into phase two in medical grade isotope production.

University of Missouri (MURR)

The reactor located in the University of Missouri also known as MURR began operating on October 13, 1966, with a 5-megawatt capacity, only to be later upgraded in 1974 to its current 10-MW capacity. MURR currently hosts and supports research and production for a variety of isotopes. MURR has researched using neutrons for both industrial applications and to verify the safety and reliability of the products for production use. MURR has provided a steady production of various isotopes and has been able to aid the nuclear medical industry in the rising crisis in the US and European Nations. This reactor is a large producer of Mo-99, I-131, and Lu-177 for U.S. hospitals. Although with small surging incidents and shortages, MURR has had to increase its production to provide for both the US and international demand if need be. The production capability of this reactor has demonstrated its critical stance in the supply chain. As their production capability is critical for the maintenance of the supply chain due to many critical isotopes have short half-lives. This means that their solid production capability allows U.S. hospitals to receive the necessary equipment and materials to treat and diagnose their patients. MURR's capability to aid when the international and domestic supply chain depletes is what makes this reactor so important to developing and maintaining a supply chain.

Government funding of production and research projects

Several projects from the DOE and NNSA have been initiated since (…) to further invest in the domestic supply chain through research companies like NorthStar and SHINE Fusion. By offering incentives to further invest in isotope development, as to further push the commercialization of stable radioisotopes domestically within USA borders. Through the funding of research & development (R&D), much of the industry has flourished with stable investment reports. But many of the incentives are not driven to push for more private company involvement. NorthStar and SHINE are commercial companies incentivized by the DOE and NNSA…

Production facility deficiency

Since the isotopes crisis in 2009, there has been little activity to focus on the stabilization of isotopes domestically. The US is currently not equipped to properly sustain a domestic supply chain. This is due to the lack of facilities that would actively work on Mo-99 development, which are quite limited. There are rising companies looking to better stabilize the Mo-99 production within the United States but are met with a disconnection between the public and private sections for development. Although with the current public and private sectors the US is still left lacking in these areas of production. Companies like NorthStar and the MURR reactor are good steps to further push the Mo-99 production but are short-handed without the support of other companies. Not to mention, their role is placed with a significant amount of pressure as they must suppler a supply chain that has very little to work off from.

Policy Recommendations

Currently, nuclear medicine has a great deficiency which is known and stated by expects and even stated in up-and-coming bills. As the industry lacks not only productions but facilities that can uphold the current demands of the US. requires. The current bills and programs need better support and a few improvements to ensure a more stable supply chain. With the rise of Russia's war against Ukraine once more highlighting the flaws within our supply chain we must begin to look at how to further secure the supply chain. As such immediate action must be taken to reinforce already established Law as well as improve upon current bills that are in the process to be approved as well as current legislation. Taking into account possible laws and incentives that can promote the push to secure isotope production and hopefully find replacements for currently Russian-dependent products and materials. Some recommendation to do as follows:

Further improvement of the presented Bill

The bill Science of the future 2022 calls as previously mentioned calls for the exclusion of Mo-99 as it states in the bill it was previously addressed in the 2012 bill. There needs to be further implementation of the development of Mo-99 and its research for productions through means of accelerators or other methods. The 2012 bill addressed the issues being faced during the isotope crisis that had occurred in 2009 but as we are being to see what could be seen as a possible impending crisis the security and production of Mo-99 should be revitalized to better adjust to the times. New technology and equipment have served as a great improvement for the industry, but the industry is still faltering on several issues.

Investments in nuclear reactor equipment and accelerators

Further investment in nuclear reactors and particle accelerators could push for not better production but also for bette workj within the industry. Investing in nuclear reactor could help revive previously shut down reactors to be used for production and subsecuently updated with new technologies and man power to work with production. This would prove beneficiary not only for a concern of lack of isotopes but also revive previews infustructure to be used once more. Whiles in vesting in particle accelerators could help to continue the improvement of this relatively new technology. Investing it in would allow for better research and development for them as well as aid in the production of isotopes for it to reach commercial production.

Government incentive to university reactors for further production and research

For gorverment agencies to further incentivise research would allow for not only educational opportunities but also help with in the supply chain. Having grants and scholarships that grant both undergraduate and those of higher education to be able to implement research in national laboratories and possible local reseach facilities. For more stem student to be implemented in national laboraties it could help them prep for the their career desion and pasions seeing the work in action and having a first hand view of them. For local resreach, invesments in grants and scholarships could help a collage that uses reactors or accelerators for research could help not only to educate but help local hopitals that requiere the use of isotopes for treatment. This allows for a faster means of production and security for univisities to have the access to this equiment and promovent the industry and support it at the same time.

Project management through financial advisory

Appointing a financial advisor to administer and oversee the the financial expenses of both resreach and development would allow for better porudtion and industrial success. Their knowledge in economis would allow for better understanding of where the giving stipends and fund that are giving to various research and production instetus is coming and going. This would allow the advisor to see where the industry is failing and promptly suggest and direct where would the industry better their work and manage the income. Thus ensuring better results for the industry and allow for there to be a better strucktured supply chain. This would also allow for a more unified comunication of both the DOE and NNSA having project for both isotopes in genral and Mo-99. Having to report fidning could allow for there to be a more orgaized and stable front of knowledge and led to better overall results with in the U.S. industry.

More engagement in public-private partnerships

There have been projects and programs as detailed before and a lot of funding for research companies to push to a more domestic market, specifically, Mo-99 since. Companies like Shine and NorthStar have led much of the DOE and NNSA funds to not only research new medical isotopes to better the medical field. This has left out partially the private sector of production after their initial involvement around 2015 when the Global Medical Isotope Systems (GMIS) said that they would partake in isotope development. Many public-private partnerships(PPP) joined signing the, at the time, first cooperative research and development agreement (CRADA) to further push isotope production. This was a good step to further secure and establish the much-needed domestic supply but this seemed hindered. Due to many DOE supported facilities profiting from the national laboratories PPP was left to wait on several programs. As development would be discovered but they had to wait for research facilities to work on them first.

Conclusion

The utilization of radionuclides for diagnostic medicine is critical to insure the health and well being of patients around the world. But it must be said that this issue is not a new one, as ther ehave been previous talk to address these issues and have been met with a lack of urgency until now. Seeing the progression of the Russian war agaisnt Ukraine has once more demonstrated how unprepared the industry and how dependant they are of foreign supply. Although this issue is a a fast apporoching one we do not possess the capability to follow be an indendant source of such critical materials that are vastly requiered for medical work and treatment. We Currently do not have a short-term solution to this issue and no other alternatives to our current predicament. But this is a pivital moment to further insure and address when the domestic industry is faltering and help it further secure the domestic supply.

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