

Future of Nuclear Medicine, Part 1: Marketing Research Forecasts

Frost & Sullivan was commissioned by Battelle Pacific Northwest National Laboratory to provide an assessment of nuclear medicine diagnostics and therapeutics markets in the United States in the years 2001–2020. This study focuses on reactor-produced isotopes specifically and does not evaluate cyclotron or linear accelerator produced isotopes.

OBJECTIVES OF THE STUDY

The objectives of this research are to:

- Identify disease indications currently being treated with medical isotopes in the United States
- Provide an overview of the nuclear diagnostics market in the United States and forecast revenues in the years 2001–2020
- Identify specific medical isotopes that offer the greatest market opportunities in nuclear therapeutics
- Determine and forecast revenues and the revenue growth rate for the total nuclear medicine therapeutic market in the United States from 2001 to 2020
- Identify the radiopharmaceutical companies currently involved in nuclear therapy development
- Assess the market with respect to the FFTF reactor and its capabilities

RESEARCH METHODOLOGY

Frost & Sullivan adopted a three-fold approach for this study:

- Primary research focusing on interviews with leading nuclear medicine physicians, industry executives, and regulatory officials
- Secondary research focusing on utilizing the vast information provided on the Internet and in published articles and reports on nuclear medicine
- Quantitative and qualitative analysis of the primary and secondary data utilizing Frost & Sullivan's extensive market research and consulting experience in nuclear medicine and a comprehensive understanding of the marketplace

The analyst team conducted over 70 interviews with opinion leaders and experts with vast knowledge and experience in nuclear medicine. Respondents to the study were selected from four areas of the nuclear medicine community:

- Manufacturers of radiopharmaceuticals
- Distributors of radiopharmaceuticals, specifically radiopharmacies
- Nuclear medicine physicians and scientists
- Regulatory authorities

Note: This material was reprinted from *FFTF Medical Isotopes Market Study (2001–2020)* with permission of Frost & Sullivan, Mountain View, CA, and Battelle Pacific Northwest National Laboratory, Richland, WA.

The quantitative and qualitative analysis was conducted in accordance with a research methodology developed by Frost & Sullivan. Under this methodology, revenue forecasts were determined based on the following factors:

- Patient populations in targeted disease indications.
- Acceptance and adoption of nuclear medicine as an alternative or used in combination with other modalities by the physician community.
- Treatment costs in 1997.
- Penetration rate achieved by nuclear medicine products in the marketplace. The estimated penetration rates are based on the impact of successful deployment of key marketing and product position strategies by the manufacturers and the nuclear medicine community.
- Quantification of awareness and increased referral base established by various programs undertaken by manufacturers and physician groups.
- Strengths and weaknesses of competing modalities.

CURRENT MARKET OVERVIEW

Nuclear medicine is divided into two major areas: diagnostics and therapeutics. The diagnostic side is mature, while the therapeutic side of nuclear medicine is in its infancy.

Over 100 diagnostic radiopharmaceutical products are available. The largest number of these radiopharmaceuticals have applications in cardiology, followed by oncology and neurology. A few radiopharmaceuticals have applications in other areas, such as infection imaging and nephrology.

Nuclear medicine is at present primarily used as a therapeutic modality to treat three conditions:

- Thyroid cancer
- Hyperthyroidism
- Bone pain palliation

Polycythaemia vera is also treated with nuclear medicine on a small scale.

Ongoing research trials throughout the United States are investigating new radiopharmaceuticals for more than 35 other potential diseases. Many of these new drugs are expected to enter the marketplace by 2005. Table 1-1 lists some medical isotopes in trial research programs in the United States.

Most participants in this study believe the future of nuclear medicine resides in the growth potential of the emerging therapeutics market. Respondents also believe that healthy growth in nuclear diagnostics will contribute to market expansion.

Frost & Sullivan estimates that 90 percent of the medical isotopes currently utilized by U.S. nuclear medicine come from other countries. While the United States accounts for 47 percent of revenues in the total world nuclear medicine market,

TABLE 1-1

Diagnostic and Therapeutic Radiopharmaceuticals Market:
List of Selected Therapeutic Isotopes and Disease
Indications Under Research (U.S.), 1997

Disease indication	Isotope
Leukemia, Lymphoma, Breast cancer	Y-90
Hemophilia, Heart disease, Polycythaemia	P-32
Prostate cancer, Uterine cancer	Ir-192
Brain tumor, Ovarian cancer	Au-198
Rheumatoid arthritis, Prostate cancer	Re-186

Source: Frost & Sullivan

TABLE 1-2

Diagnostic and Therapeutic Radiopharmaceuticals Market:
Selected Isotopes Commonly Used in Nuclear Diagnostics
(U.S.), 1997

Isotope	Application	Source
Tc-99m	Cardiology	Reactor
Tl-201	Cardiology	Accelerator
I-131	Oncology	Reactor
Xe-133	Respiratory	Reactor
In-111	Neurology	Accelerator
Ga-67	Oncology	Accelerator
P-32	Oncology	Reactor

Source: Frost & Sullivan

TABLE 1-3

Diagnostic and Therapeutic Radiopharmaceuticals Market:
Percentage of Market Revenues by Diagnostic Applications
(U.S.), 1996

Application	% of Market Revenues
Cardiology	46
Oncology	34
Neurology	10
Other	10
TOTAL	100

Note: All figures are rounded.

Source: Frost & Sullivan

the country accounts for only 10 percent of the world's production of medical isotopes.

Despite these statistics, the Department of Energy (DOE) has ordered the shutdown of several of its nuclear reactors. Fewer facilities in the United States are able to supply nuclear medicine with the isotopes that the industry needs. Future expansion in nuclear diagnostics and therapeutics will create higher demand for medical isotopes. The DOE should design a strategy to supply this increasing demand for medical isotopes so that U.S. nuclear medicine can continue to grow.

Indications and Isotopes

The most utilized isotope in nuclear diagnostics is Technetium-99m (Tc-99m), a daughter isotope of Molybdenum-99 (Mo-99). The largest supplier of Tc-99m to the United States nuclear medicine diagnostics market is MDS Nordion, located near Ottawa, Canada. Recently, Mallinckrodt received FDA approval to sell the Mo-99 produced at the company's reactor

TABLE 1-4

Diagnostic and Therapeutic Radiopharmaceuticals Market:
Percentage of Market Revenues by Therapeutic
Applications (U.S.), 1996

Application	Isotope	% of Market Revenues
Thyroid cancer	I-131	50
Bone pain palliation	Sr-89/Sm-153	34
Hyperthyroidism	I-131	15
Polycythaemia Vera	P-32	4
TOTAL		100

Note: All figures are rounded.

Source: Frost & Sullivan

in Petten, The Netherlands, in the United States. Table 1-2 exhibits a selected list of medical isotopes commonly used in nuclear medicine diagnostics.

Table 1-3 presents Frost & Sullivan's estimates of the percentage breakdown of diagnostic radiopharmaceutical revenues by application.

There are only four therapeutic applications for radioisotopes. Table 1-4 exhibits the medical isotopes used in nuclear therapeutics and also the percentage breakdown of therapeutic radiopharmaceutical revenues by application.

Revenues and Market Data

Frost & Sullivan estimates that revenues for the United States nuclear medicine diagnostics market were \$531 million in 1996. Revenues for the nuclear medicine therapeutics market are estimated to have been \$48 million in 1996. Table 1-5 exhibits total nuclear medicine market revenues and revenue breakdown by market segments in 1996.

Many of the companies involved in nuclear medicine offer radiopharmaceutical products for diagnostic and therapeutic procedures. Table 1-6 lists radiopharmaceutical companies that offer products in the United States marketplace.

MARKET OUTLOOK

In its early years, nuclear medicine diagnostics largely concentrated on bone scanning and cardiology applications. This changed as competition from other imaging modalities cut into nuclear medicine diagnostics' market. To regain market share, nuclear medicine diagnostics expanded into applications where other imaging modalities were not as effective. Oncology is a very promising area—experts believe this to be an application where nuclear medicine diagnostics can outperform its competitors. Nuclear medicine is also expanding into neurology and infection imaging.

Nuclear therapy provides effective pain relief from metastatic bone pain and treating bone marrow disease. It is also successfully used for treatment of thyroid-related diseases.

Frost & Sullivan expects that nuclear medicine will expand into other therapeutic areas. Currently, over 35 clinical trials throughout the United States are researching the potential of nuclear therapeutics. These trials are investigating the use of a large number of isotopes in treating several diseases. Some radiopharmaceutical companies are trying to design "smart bullets" to deliver therapeutic radiopharmaceutical drugs to

TABLE 1-5
Diagnostic and Therapeutic Radiopharmaceuticals Market:
Market Revenues by Segment (U.S.), 1996-2020

Year	Diagnostics (\$ Million)	Therapeutics (\$ Million)
1996	531	48
2001	869	440
2006	1,873	699
2010	3,303	1,587
2016	8,773	4,036
2020	16,400	6,014

*Note: All figures are rounded.
Source: Frost & Sullivan*

TABLE 1-6
Diagnostic and Therapeutic Radiopharmaceuticals Market:
Radiopharmaceutical Companies (U.S.), 1997

Company	Product Applications
Amersham Medi-Physics	Diagnostics, Therapeutics
Mallinckrodt Medical	Diagnostics, Therapeutics
DuPont Merck	Diagnostics
Bracco Diagnostics	Diagnostics
CIS US	Diagnostics, Therapeutics
Cytogen	Diagnostics, Therapeutics
Biomira, Inc.	Diagnostics, Therapeutics
Medco Research	Diagnostics
Coulter Pharmaceuticals	Diagnostics, Therapeutics
Centocor	Diagnostics
NeoRx	Diagnostics
Neoprobe	Diagnostics
Diatide	Diagnostics
Immunomedics	Diagnostics
Guilford Pharmaceutical	Diagnostics

Source: Frost & Sullivan

disease sites without affecting healthy tissue.

FUTURE REVENUES AND MARKET DATA

Frost & Sullivan forecasts that nuclear medicine diagnostics could grow into a \$17 billion market by 2020 from about \$531 million in 1996. Table 1-5 exhibits potential market revenue growth for nuclear diagnostics and nuclear therapeutics from 1996 to 2020. For the diagnostic radiopharmaceuticals market forecast to be realized, several challenges need to be overcome. These challenges will be discussed in Part 2 of this series.

Currently, over 100 diagnostic radiopharmaceuticals are available in the marketplace. Several diagnostic radiopharmaceutical products are awaiting FDA approval; many more are in research trials around the country. Market growth is likely to be enhanced by nuclear diagnostics' expansion into oncology, as well as into

other areas in which it currently has little market presence.

Frost & Sullivan forecasts that the nuclear therapeutics market could reach \$6 billion in 2020, compared to an estimated \$48 million in 1996. Industry experts expect that smaller radiopharmaceutical companies will play a very important role in designing therapeutic radiopharmaceuticals, while larger companies will most likely handle marketing and distribution.

Nuclear therapeutics is an infant market. It faces very serious challenges which hinder growth. These challenges, as well as other issues, will be discussed in Part 3 of this *Newsline* series.

To realize its growth potential, nuclear therapeutics needs to continue to develop improved methods to bring therapeutic radiopharmaceuticals to disease sites. Once a "smart bullet" is discovered, this treatment modality can be expected to expand rapidly. But growth might be hindered by the unreliable supply of some of the medical isotopes with the most promising future in nuclear therapies.

CHALLENGES OF THE MARKET

The key challenges for the market are the following:

- Effects of managed health care
- High cost of nuclear medicine procedures
- Competition from other imaging modalities
- Lack of education and awareness programs
- Shrinking number of nuclear medicine physicians
- Unreliable supply of medical isotopes
- Excessive FDA and NRC regulations
- Reduction of research budgets in the United States

DRIVERS OF THE MARKET

Although challenges affecting nuclear medicine constrain the market's current expansion, several market drivers can contribute decisively to future expansion. Among these drivers are:

- New radiopharmaceuticals for oncology
- Cost-effectiveness of nuclear medicine
- Development of new therapeutic applications
- Nuclear medicine education
- New pediatric applications
- Aging population that demands cost-effective treatment
- Development of targeting techniques

Note: This is the first of a three-part series. Parts 2 and 3 will appear in future issues of *Newsline*.