MEDICAL ISOTOPES

DOE expects increase in demand, but how much?

A DOE-appointed panel examined existing studies to gauge the future of the medical isotope market.

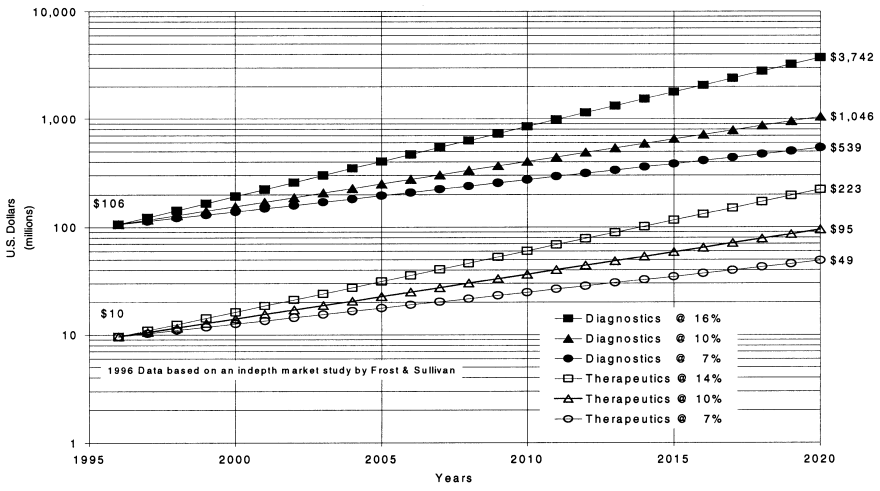
WHEN PEERED INTO, most crystal balls yield more crystal than visions of tomorrow. This fact was not lost on the 13-member panel of physicians and industry experts that was assigned the daunting task of assessing the demand for medical radioisotopes during the next 20 years and naming the isotopes that would be most in demand. This much is certain: the industry is expected to grow, it will need the proven isotopes, and would like access to some yet-to-be-proven isotopes.

Those are some of the conclusions described in a report, "Expert Panel: Forecast Future Demand for Medical Isotopes," dated March 1999, written by the Department of Energy–appointed panel.

The chasm between estimates of *how much* the industry will grow is enough to put a few gray hairs on an investor's head. "We looked at all the reports that had been out there," said panel member Roy Brown, director of regulatory compliance for Mallinckrodt, Inc., a radiopharmaceutical manufacturer, "and we saw such a strange variation, such a large variation—from very modest growth to very, very aggressive growth."

The panel's prediction of 7–16 percent annual growth in diagnostic radioisotope demand and 7–14 percent annual growth in therapeutic radioisotope demand through 2020 can mean that revenues from production of isotopes for both applications will range anywhere from almost $600 million by 2020 at the low end to nearly $4 billion by 2020 at the high end. Revenues from isotope production in 1996 totaled $116 million, which means revenues are expected to increase anywhere between just over fivefold to just over thirty-fourfold within a 24-year span, according to the report. "The last time you tried to look into the future you probably didn't have much luck either," commented Owen Lowe, associate director in the DOE's Office of Isotope Programs. "That's what these folks took on doing."

The report noted that the DOE is attempting to secure its position as an international leader in the biomedical sciences in the 21st century. And the report comes as the DOE struggles to meet even a fraction of the radioisotopes demanded by the American nuclear medicine community. The DOE is responsible for assuring a supply of commercial isotopes that can be produced only in unique DOE facilities, and the department currently satisfies just 10 percent of the reactor-produced radioisotopes demanded by U.S. nuclear medicine, according to the report. To the dismay of the American biomedical community, 90 percent of biomedical radioisotopes are produced outside the United States, according to the report.



Estimated isotope production revenues (1996–2020)

Indeed, the various existing reports the panel was asked to study—although varying in their market growth predictions—all agreed in identifying the same woeful trends: expected shortages of some major isotopes, lack of a reliable supply of research isotopes produced at a reasonable cost, crumbling DOE infrastructure, and overdependence on foreign radionuclide production.

"The whole industry is frustrated," Brown said, "because it's very difficult for some researchers to get the radioisotopes they need to conduct their research. And quite often they'll be right in the middle of a research project and they won't be able to get the radionuclides they need, and the research will come to a grinding halt waiting for the nuclides."

To help prevent shortages of isotopes, reduce dependence on foreign sources, and stimulate biomedical research, the panel prioritized lists of radionuclides that the DOE should consider producing. The isotopes the panel recommended on the primary list were chosen because of their proven clinical efficacy and because they face supply and cost concerns that could dramatically affect the practice of nuclear medicine. They include yttrium-90, molybdenum-99, iodine-123, and rhenium-186. The secondary list consists of fluorine-18, phosphorous-32, krypton-81m, strontium-89, palladium-103, tin-117m, xenon-127, I-125, I-131, and samarium-153—and these isotopes were chosen because

of lack of availability and high prices are inhibiting their development. The isotopes on the final list were chosen because they show promise but are not being explored because of lack of availability or high prices. The isotopes include scandium-47, zinc-62, copper-64, germanium-68, and gadolinium-153.

As Lowe cautioned, however, all talk of growth and any plans for the future are contingent upon a few conditions that must initially be met. "The first is that DOE needs to do a good job right now of making isotopes available to support current research," he said. "And that research itself must adequately support research in nuclear medicine. If either of those circumstances does not occur, then those growth rates will be on the low side rather than the high side."

A Nuclear Energy Research Advisory Committee subcommittee is expected to take the next step and issue a report in December providing recommendations on where the DOE should produce isotopes, Lowe said.

Copies of the report can be downloaded from the DOE's Office of Energy, Science, and Technology Web site at <www.ne.doe.gov>.—*Patrick Sinco* NN