Congressional Subcommittee Scrutinizes Looming U.S. Radioisotope Supply Crisis

With lawmakers seeking renewed cooperation between government and industry, the outlook improves for the proposed National Biomedical Tracer Facility.

ALERTED TO THE LOOMING radioisotope crisis in the U.S., a congressional oversight subcommittee, which met on August 12, began an exhaustive inquiry into the government's isotope production program and has already criticized officials of the Department of Energy for failing to include funds for a National Biomedical Tracer Facility in the department's upcoming budget year.

The House Environment, Energy, and Natural Resources Subcommittee of the Committee on Government Operations has issued recommendations to Energy Secretary James D. Watkins (see p. 22N). The lawmakers cited the need for new mechanisms for funding isotope production and cooperation between industry and government to develop an NBTF

Among the scientists testifying at the hearing were representatives of The Society of Nuclear Medicine and the American College of Nuclear Physicians. Also present were industry representatives, DOE officials, and investigators from the General Accounting Office who were called in to examine DOE's isotope program last year by Representative Mike Synar, chairman of the subcommittee.

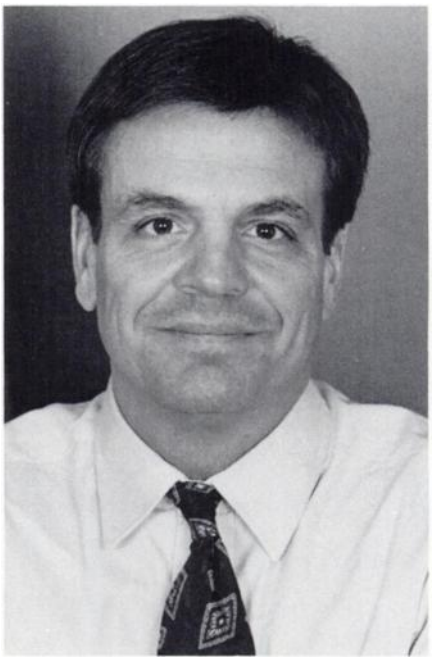
The hearing came three weeks after the settlement of a threatened strike at a Canadian nuclear reactor facility that would have halted the supply of molybdenum-99 and after Rep. Synar released the findings of the GAO (see *Newsline* September 1992, p. 19N). Although plans for the National Biomedical Tracer Facility do not include the production of ^{99}Mo, much of the testimony and questioning at the hearing focused on the NBTF project.

As outlined in a 1991 planning and feasibility study carried out by SNM and ACNP—with congressionally directed support from DOE—the NBTF would include laboratories for research and teaching and an 100 million electron volt particle accelerator for producing radioisotopes. Cost estimates for the facility range from $40 million to $100 million. Since 1988, official reports from the DOE's Health and Environmental Research Advisory Committee and two other DOE-sponsored panels have spelled out the need for such a facility, yet the DOE hierarchy has continued to ignore the NBTF project.

"Please don't tell us to do another study," Richard C. Reba, MD, president-elect of SNM told the subcommittee. "It is expected that DOE labs will cease to produce accelerator isotopes within the next two years. If the U.S. is to maintain a continuous supply of isotopes, the NBTF must be operational by 1997."

Rep. Synar and fellow subcommittee members repeatedly attacked the Energy Department's William H. Young, assistant secretary for nuclear energy, for his handling of the proposal for establishing the NBTF. Criticizing what he called a lack of priority for biomedical isotope production, Rep. Synar said that the importance of the NBTF made the DOE's superconducting supercollider and other highly visible projects "pale in comparison."

When Rep. Synar learned that Assistant Secretary Young had no recollection of a 1988 report by the DOE Inspector General on isotope production, the Oklahoma Democrat took every chance he could to berate Mr. Young, at one point questioning his qualifications to oversee the isotope program. DOE officials have tried to deflect the complaints, saying that House Democrats are motivated by partisan politics in an election year. But many of criticisms raised at the hearing are difficult to brush aside.



Democratic Rep. Mike Synar has been a longstanding critic of the Energy Department

In a pivotal exchange with Mr. Young, Representative John W. Cox, Jr. of Illinois, concluded, "So the record is clear — you have not done anything in terms of the department to come up with approaches, ideas, options, whatever it might take to accomplish what you believe is necessary for this [biomedical tracer] facility to be implemented."

Through a series of pointed questions, Rep. Cox, a Democrat, expressed skepticism of the rationale behind the DOE's decision to exclude a request for a modest $2 million for the NBTF in the DOE's $20 billion budget. Energy Secretary James Watkins had told Congress in a June 1991 letter that the department recommended the funding for a project definition study, but in answers to questions, Mr. Young acknowledged that he had not even submitted a request for the NBTF funds.

Citing the department's fiscal crunch as a reason for his decision, the assistant secretary also explicitly said he thought that the project definition study "was not needed [because] there was a venture that was already looking at the potential for investing in this facility." (He was referring to a plan that never materialized by the North Texas Research Institute, an affiliate of the University of North Texas, to build a production accelerator purportedly without the need for government funding.) Pressed for details, Mr. Young said he couldn't recall the specific sequence of events that led to his decision to dump the funding request.

But Rep. Cox secured from Mr. Young a pledge to work with the radiopharmaceutical makers and the biomedical research community to forge realistic plans for the NBTF. Mr. Young assured the subcommittee that he would report on progress within months. While the establishment of the NBTF remains far from certain, the oversight hearing revealed a growing momentum behind the project in Congress.

Doubts about U.S. Molybdenum Production

The NBTF, however, would only solve a small portion of the country's isotope problems. Many other vexing issues, including nuclear medicine's dependence on a single foreign supplier of molybdenum-99, continue to stir uneasiness among physicians and even more so among scientists.

Although the DOE claims that it will be ready to regularly deliver ^{99}Mo by April 1993, the oversight committee expressed doubts that the DOE could succeed in that production effort, given DuPont-Merck Pharmaceutical Co.'s ten-year exclusive contract for ^{99}Mo with Nordion International of Canada, and plans by Mallinckrodt Medical Inc. to develop a source for the isotope in the Netherlands. Rep. Synar pointed out that Amersham International, the parent of Medi-Physics, Inc., holds a 14% stake in Nordion, and that Amersham recently invested in a joint venture with the Russian Ministry of Atomic Energy and Industry to produce radioisotopes at Chelyabinsk, until recently a top-secret Soviet weapons production site.

"We're having contracts with the Russians, we're having contracts with Canadians, but we don't have contracts with our own people," said Rep. Synar. "How are we going to get industry to cooperate with DOE?" he asked.

Rep. Synar pressed representatives of DuPont, Mallinckrodt, and Medi-Physics, Inc., a subsidiary Amersham International, to explain why they didn't go along with the DOE plan to produce ^{99}Mo. "It takes two to get married, and I'm trying to figure out who left who at the aisle," said the congressman.

While each company initially contributed $40,000 for a feasibility study, none of the companies committed to buying a set percentage of ^{99}Mo from DOE, a stipulation made by Donald E. Erb, director of the department's isotope production program.

Carl Seidel, a production manager at DuPont, told the subcommittee that the DOE failed to convince his company that it could supply the isotope "reliably" and at a competitive cost. "Their price was not even close to what [Nordion offered]," he said. Mallinckrodt's Roy W. Brown, manager of regulatory compliance, cited the same concerns about reliability and price and added that DOE would not agree to performance guarantees with penalties for missed deliveries.

Rep. Synar insisted that Nordion could undercut DOE prices to preserve its monopoly on the isotope. "There won't be a market for you then," he said to the DOE's Mr. Erb. Interviewed following the hearing, Mr. Erb said he is counting on some foreign orders for ^{99}Mo and he predicted that his program will be able to secure a market share once it demonstrates reliable delivery of quality ^{99}Mo.

William H. Young, DOE assistant secretary for nuclear energy, took the heat from congressional overseers for the department's escalating isotope production problems.

Uneasiness of Basic Research Scientists

Because there is a strong demand for ^{99}Mo, DOE stands a good chance of succeeding in its production, but this is probably not true of most other isotopes, particularly those used in minute quantities by basic science researchers. The DOE has been constrained since 1990 by the requirement that isotope production be self-supporting, which many scientists contend hamstrings the DOE's efforts to supply stable and radioisotopes for which there is no viable commercial market.

Some scientists are already worried that isotopes with biomedical applications will take priority. "The biomedical and nuclear medicine communities, the

Congressional Overseers Report Disturbing Findings to Secretary of Energy

In examining the U.S. government's troubled isotope supply program, the House Subcommittee on Environment, Energy, and Natural Resources says it has uncovered "disturbing" revelations and is calling for new mechanisms for funding and organization of the Energy Department's isotope program. The following is taken from an August 14, 1992 letter to Energy Secretary James D. Watkins from Rep. Mike Synar, chairman of the subcommittee. The letter was also signed by Rep. William F. Clinger, Jr. and Rep. John W. Cox, Jr.

The Subcommittee has learned a number of extremely disturbing facts concerning the heavy dependence of the U.S. on a single foreign isotope supplier. For example, testimony before the Subcommittee indicated that virtually all of certain essential medical isotopes used in the U.S. are provided by one Canadian supplier. As you know, last month that supplier was the subject of a labor dispute which could have had the effect of terminating thousands of critical medical procedures in the U.S. within a matter of days. No alternative source of supply exists to meet U.S. needs.

Testimony by representatives of a National Academy of Sciences panel examining the availability of isotopes in research indicated that research in the U.S. is being hampered by a lack of stable and radioactive isotopes at affordable prices.

Witnesses representing U.S. medical and industrial users also stated that our isotope supply was inadequate both in terms of availability and price.

We are further concerned over the Energy Department's inability to reach agreements with the research community to develop new isotope production capacity, such as the proposed National Biomedical Tracer Facility (NBTF), or with the radiopharmaceutical industry. Testimony before the Subcommittee indicated that the Department has been taking no action whatsoever on the NBTF proposal despite your recommendation to the Appropriations Committee in June 1991 that a $2 million project definition study be conducted.

Also of deep concern to us is the fact that the revolving fund established in 1989 to finance the program is entirely depleted and that the Department is borrowing millions of dollars from the Treasury to fund its isotope operations and the development of new isotope production capacity at Los Alamos. Although the Department has already embarked on the effort to create this new capacity, testimony before the Subcommittee indicated the Department may not have a market for isotopes from this new facility and has not formally established a policy on the extent to which it will attempt to compete with other domestic and foreign suppliers. Indeed, the Department's witness was not even aware that establishment of such a policy was recommended by the DOE's Inspector General in a February 1988 report.

Finally, we are seriously troubled by the low overall priority this program is receiving within DOE. Indeed, DOE's witness at our August 12 hearing confirmed that the isotope program was not a high priority for the Department despite its critical importance to an untold number of Americans, the research community and our industrial sector.

We believe that a full and immediate reexamination of the Department's isotope program and the role of the Federal government in providing isotopes is essential. We are aware of the fact that the Department has retained a consulting firm to conduct a study of the isotope program; such a study was endorsed by the General Accounting Office. Because of the seriousness of the isotope supply problem, we urge you to ensure that this program is fully reexamined in consultation with isotope users and appropriate Federal agencies. This review should examine new mechanisms for funding and organization of the Department's isotope program, including involvement of the private sector in joint public-private partnerships, and the future role of the Federal government in the supply of isotopes. ■

radiopharmaceuticals [companies] have a lot more clout for the products that they're interested in because of the dollar value associated with them," said chemist Richard L. Hahn, PhD, group leader of the chemistry department at Brookhaven National Laboratory in Upton, New York. He told the subcommittee that at least 225 stable isotopes are used in geochemistry, environmental science, nuclear physics, materials research, nutrition, and other fields. But with annual demand limited to fractions of a gram quantities, such uses could not sustain operation of existing DOE separation facilities. Earlier this year, in fact, lack of funding forced the DOE to halt stable isotope enrichment and put the electromagnetic separators at Oak Ridge National Laboratory in Tennessee on standby.

Although Dr. Hahn acknowledged that projects like the NBTF are a beginning, he stressed the need for a comprehensive, long-term solution to the problems of all researchers. "We're depending on technology that was developed during the Manhattan project," he said. "Are those facilities adequate today? Should they be modernized? Should they be replaced?" Dr. Hahn, who is chairman of the Committee on Nuclear and Radiochemistry of the National Research Council, said the NRC is prepared to conduct an in-depth study to suggest priorities and long-term direction for isotope production in the U.S.

The DOE's piecemeal attempts to assign priorities and designate which facilities to keep open and what isotopes to produce have disappointed just about

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The congressional investigators released a report in July that criticized DOE planning and warned of possible loss of reactor services. "Without timely planning for the retirement or replacement of the reactors, safety may be compromised, operating expenses may be increased, reactor performance may be decreased and gaps may occur in needed reactor services." The GAO report went so far as to encourage the DOE "to consider the cost and benefits of using the Fast Flux Test Facility, now on standby, as a possible replacement rather than constructing a newer, more expensive reactor." The FFTF has been used to produce gadolinium-153, rhenium-186, and a few other radioisotopes with medical applications.

Although Dr. Happer doesn't specify in his letter to BESAC what concerns necessitated the eleventh hour review, he mentions recent technical developments in accelerator production of neutrons. Since the DOE began designing the Advanced Neutron Source, Great Britain brought on-line a high-energy accelerator used as a neutron source. That facility, known as ISIS, has functioned well, according to Walter Kohn, PhD, chairman of the BESAC panel and professor emeritus in the physics department at the University of California, Santa Barbara.

The BESAC panel invited nearly 100 scientists, including Richard C. Reba, MD, president-elect of The Society of Nuclear Medicine, to meet on September 8 to put together recommendations in time for the DOE's fiscal 1994 budget. The panel expressed special interest in the views of the scientific community on current and future needs and applications for both reactor-produced and accelerator-produced radioisotopes.

The panel will meet again this month to draft a final report. Scientists and professional groups can still send comments to the panel via William Kamitakahara, Scientific Secretary, BESAC Panel, NIST, Bldg. 235, Gaithersburg, MD 20899, fax: 301-921-9847. ■

Radioisotopes

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everyone who needs isotopes. While the nuclear medicine community is backing the establishment of an NBTF, other groups are rallying to save the Oak Ridge calutrons for stable isotope enrichment. The radiography industry wants the DOE to step-up production of iridium-192, which is in critically short supply. Legislators from Washington state, including Rep. Sid Morrison who appeared at the oversight hearing, are lobbying for the Fast Flux Test Facility (FFTF). (The DOE slated the FFTF for decommissioning in 1990, but congressional patrons have so far managed to save the research reactor.

With the number of competing interests making demands on the DOE for various isotope initiatives, the department faces enormous pressure to base decisions of priority on well-reasoned criteria.

The DOE's Mr. Young was able to report at least some progress toward assuaging the isotope problems. On July 29, the department signed a lucrative three-year contract with an unspecified radiopharmaceutical manufacturer for stable isotopes of strontium and nickel separated at the Oak Ridge calutrons. The contract would yield about half the revenue needed to resume operation of the facility. The department recently retained the management consulting firm Arthur Andersen & Co. to evaluate the structure of the isotope production program compared to foreign suppliers, and to recommend changes to make the DOE program more competitive and financially sound. The study won't be completed until early next year.

Disfavor with Revolving Fund

All of the DOE's isotope problems ultimately hinge on the decision to make isotope production support itself through a revolving fund. Research scientists like Dr. Hahn say they objected to the revolving fund from the beginning. Although DOE officials often blame the restrictions of the revolving fund on Congress, according to the GAO, the DOE requested that the revolving fund be established in 1990 at the urging of the Administration's Office of Management and Budget. Congress then approved the plan to make isotope production a self-sufficient enterprise. But many lawmakers are now questioning the wisdom of the idea. As Rep. Cox put it, "We don't expect the Hubble telescope to finance itself."

While the only Republican lawmaker present at the oversight hearing, Rep. William F. Clinger, Jr. of Pennsylvania, questioned the need for government to be involved at all in isotope production, ample testimony at the hearing made it clear that private companies are unwilling to take over from the Federal government the responsibility of developing research isotopes. Another House Democrat, Rep. Marilyn Lloyd of Tennessee said in written testimony that it's time to "rethink the whole cost recovery idea." Like Rep. Morrison with the FFTF, the Tennessee representative has a vested interest in that the Oak Ridge facility in her state stands to benefit from stepped-up funding for isotope production. Nevertheless, there appears to be a growing consensus about the necessity of government's role in subsidizing isotope production. That is perhaps the most promising sign for scientists to emerge from the oversight hearing.

J. Rojas-Burke