

Volume 42  
Number 10  
October 2001

October 17, 2001

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# The Journal of Nuclear Medicine

# JNM

Official Publication of the Society of Nuclear Medicine

*THE JOURNAL OF NUCLEAR MEDICINE* (ISSN 0161-5505) is published monthly by the Society of Nuclear Medicine, Inc., 1850 Samuel Morse Drive, Reston, VA 20190-5316. Periodicals postage paid at Herndon, VA, and additional mailing offices.

**POSTMASTER**, send address changes to The Journal of Nuclear Medicine, 1850 Samuel Morse Drive, Reston, VA 20190-5316.

**EDITORIAL COMMUNICATIONS** dealing with articles currently in review or revision should be sent to:

Editor-in-Chief, Martin P. Sandler, MD  
JNM Office, Society of Nuclear Medicine  
1850 Samuel Morse Drive  
Reston, VA 20190-5316  
Phone: (703) 326-1185  
Fax: (703) 708-9018

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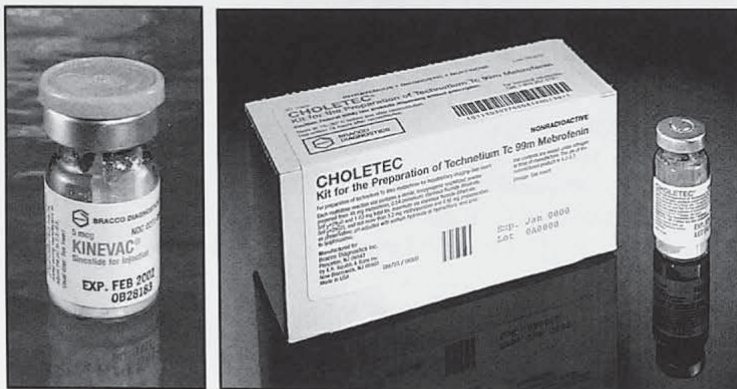
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# Unexpected Shortfalls of Two Nuclear Medicine Pharmaceuticals

Through an unfortunate confluence of manufacturing, scheduling, and regulatory occurrences, two pharmaceuticals widely used in nuclear medicine practice became temporarily unavailable for distribution in August. During the first week of that month, Bracco Diagnostics Inc. (Princeton, NJ) mailed separate letters to customers, notifying them that shortages of Kinevac (sincalide for injection) and Choletec (kit for preparation of  $^{99m}\text{Tc}$ -mebrofenin) were imminent.



In one letter, Marion Meeks, PhD, Director, Medical Affairs and Professional Services at Bracco, told customers that Kinevac would be out of stock and unavailable for approximately 1 year. "This back-order situation is the result of issues encountered during a change in manufacturers," wrote Meeks. "Bracco is committed to resolving this situation as soon as possible."

The letter also noted that a rationing program would be used to distribute the remaining inventory of Kinevac during the month of August. Customers who purchased Kinevac directly from Bracco were allowed to place one order for a maximum of two boxes of Kinevac. Radiopharmacies with average monthly orders larger than two boxes per month of Kinevac over the past 12 months were allowed to order their average monthly purchase volume. Fulfillment of these orders was to be based on product availability, with all orders to be placed before September 1.

In the second letter, dated August 7, Adrian Trevisan, Product Manager, Nuclear Medicine at Bracco, informed customers of "further delays in the transfer of manufacturing" for the Choletec kits. Trevisan wrote, "We will continue

our rationing program until product on hand is exhausted. At that point, the product will go on backorder." According to the letter, the backorder occurred because of "an unexpected business interruption" at one of the raw material providers.

## The Nuclear Medicine Community Reacts

Reaction among nuclear medicine practitioners was one of dismay, as e-mails and phone calls about rationing, shortfalls, and possible alternative pharmaceuticals circulated among practitioners and Society of Nuclear Medicine (SNM) officers and staff. On August 10, Edward B. Silberstein, MD, Chair of the SNM Committee on Radiopharmaceuticals, talked with Bracco representatives and issued a statement on behalf of the committee. "The good news is that this radiopharmaceutical shortfall was not a direct business decision to cut production of materials with a low profit margin," said Silberstein.

The bad news, of course, was that shortages would cause inconveniences to practitioners and could affect the quality of patient care in some facilities. The experience of Terence Beven, MD, Director of Nuclear Medicine at Our Lady of the Lake Regional Medical Center, Baton Rouge, LA, is typical of many nuclear medicine specialists who received the letters from Bracco. "At the time we received this news we had about a 1-month supply of Kinevac," he noted in mid September. "Since that time we have obtained about a 1-year supply from a number of different sources. Not being able to meet the demand for these procedures would have an adverse impact on our credibility as nuclear medicine physicians and cause a loss of interest in the specialty in the eyes of referring physicians, particularly those specialists who have learned to depend on these procedures as a significant part of their patient management."

## Different Reasons for Shortfalls

With the two announcements coming within a span of 8 days, the immediate assumption in the nuclear medicine community was that the shortfalls were related. In fact, although both pharmaceuticals were in the middle of a trans-

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