CHARLES S. ROBB
VIRGINIA

STATE OFFICE:
The Irontronts, Suite 310
1011 East Main Street
Richmond, VA 23219
(804) 771-2221
Email: senator@robb.senate.gov

United States Senate

WASHINGTON, DC 20510-4603

COMMITTEES
ARMED SERVICES
FOREIGN RELATIONS
INTELLIGENCE
JOINT ECONOMIC COMMITTEE
Vice Chairman
Democratic Policy Committee

August 19, 1996

Mr. Dennis K. Rathbun
Director
Nuclear Regulatory Commission
Office of Congressional Affairs
Washington, DC 20555

Dear Mr. Rathbun:

Enclosed is correspondence I received in reference to a matter involving your agency. Your assistance with the requests and concerns expressed in this case would be greatly appreciated.

It would be very helpful if you would reply in duplicate and return the enclosure. In your reply, please reference Tri-Med Specialties, Inc.

Your correspondence should be mailed to my office at the address indicated above.

Again, thank you for your assistance.

Sincerely,

Charles S. Robb

CSR/sds

Enclosure

Washington Office:
Russell Senate Office Building
First and Constitution Avenue, NE
Room 154
Washington, DC 20510
202: 224-4024

Regional Offices:
Dominion Towers, Suite 107
999 Waterside Drive
Norfolk, VA 23510
(804) 441-3124

First Union Bank Building
Main Street
Clintwood, VA 24228
(540) 926-4104

Signet Bank Building
530 Main Street
Danville, VA 24541
(804) 791-0330

Crestar Bank Building
310 First Street SW, Suite 102
Roanoke, VA 24011
(540) 985-0103

TRI-MED
Specialties Inc.

1500 AVON STREET EXT'D
CHARLOTTESVILLE, VA 22902
PHONE (804) 977-8711 FAX (804) 977-8760

July 24, 1996

Honorable Charles S. Robb
154 Russell Senate Office Bldg.
Washington, DC 20510

Dear Senator Robb,

I work with Tri-Med Specialties, Inc. a medical research and development company in Charlottesville. Several of my colleagues and I would like to meet with you to discuss a problem we have encountered with the Nuclear Regulatory Commission.

Tri-Med has developed a new medical diagnostic test, the Carbon 14 Urea Breath Test (PYtest), to diagnose a bacterial infection (Helicobacter pylori) which has been proven to cause stomach ulcers and possibly gastric cancer. To perform this very simple test, the patient swallows a capsule and 10 minutes later blows up a balloon. The breath sample is then analyzed to determine if the patient has the bacterial infection. An antibiotic combination can then be administered to destroy the bacteria. The medical savings from this new method of treating ulcers is tremendous. A New Drug Application for this test is currently pending with the FDA. It was filed on May 12, 1995. It is anticipated that approval will be granted by the end of 1996.

Due to the small amount of radioactivity in the capsule (less than that found in a smoke detector) this test is regulated by the NRC. In order for a physician to administer the test they must have a license with the NRC. This license costs approximately $4000 a year with untold hidden administrative costs. We feel our test will be sold for approximately $50.00. The cost of the license will restrict many physicians from performing the test.

For this reason, Tri-Med Specialties, Inc., on August 23, 1994, filed a petition with the NRC for either a rule change or an exemption from licensing for the ^{14}C-urea Breath Test (PYtest). An announcement of the petition filed with the NRC was published in the Federal Register on December 2, 1994 along with a request for comments. The comment period extended until February 10, 1995. It is our understanding that 304 comments were received; 302 in favor and 2 opposed. On October 18, 1995 the petition was discussed at the ACMUI(Advisory Committee for the Medical Use of Isotopes). It seemed, at that meeting that the committee came to a consensus that a special exemption for the test should be granted under the conditions that final approval from the FDA is granted and that the drug is prescribed by a

physician. The committee recommended the exemption route versus a rule change because it would be the most expeditious and the easiest means of resolving this issue.

When this process was begun, we were advised by the NRC that the entire process would take approximately one year. In December of 1995 in a conversation with John Glenn, (Branch Chief for the NRC) I was told the final ruling would take place as early as July, 1996 or no later than December.1996. Last week, I again spoke with John Glenn to get an update on the progress of our application. Mr. Glenn informed me that the application was not yet close to a ruling. I asked him to explain to me the steps remaining in the process. Following is a list of those steps.

1. Finish the "rule plan" He stated this should take about another month.
2. The plan is then sent to the NRC- specifically to the 5 commissioners (these 5 people are appointed by the President)
3. If the commissioners approve the rule plan, the rule is then sent to the 29 agreement states for their approval. They have 45 days to respond. If any of the states suggest a change, the rule plan has to be revised and re-approved by the commissioners.
4. Once the rule plan is approved they actually write the rule (we know from past experience that this can take 6 months) The rule is then published in the Federal Register. There is a set 75 day comment period.
5. If there are no negative comments they can then make the decision to accept the rule. (note that even ONE negative comment can stop the whole process)

I was also told by Mr. Glenn that this application is not considered a priority because the NRC is not preventing physicians who have a license with the NRC from obtaining the test. Therefore the NRC is not prohibiting patients from receiving the test by delaying or not granting the waiver.

Looking at the steps listed above it is obvious that a ruling will not be made by the end of 1996

It has already been 2 years since the submission of our application and a final ruling is nowhere in sight. The NRC advisory committee recommended approval of this application almost a year ago. Both the NRC Advisory Committee and the FDA Advisory Panel Committee (February 96) have concluded that this is a safe test.

We currently have a meeting scheduled with the FDA at 9:30 am on August 1st. Another meeting is also scheduled on Capitol Hill at 2:30 PM on August 1st. Each of these meetings should take approximately 1 ½ hours. If you have any time available on July 31st or August 1 we would greatly appreciate the opportunity to meet with you to discuss the situation. If you have any questions please feel free to contact me at 804-977-8711.

Sincerely,

Susie Hoffman

Susie R. Hoffman RN BSN
Product Development Coordinator

U.S. SENATOR CHARLES ROBB

COMMONWEALTH OF VIRGINIA

FAX TRANSMISSION

1011 E. MAIN STREET, SUITE 310
THE IRONFRONTS
RICHMOND, VIRGINIA 23219
804-771-2221
FAX: 804-771-8313

TO: Lorie DATE: 9/20/96

FAX #: PAGES: 3, INCLUDING THIS COVER SHEET.

FROM: SHELLEY DUGUID SPEARS, SDS
REGIONAL REPRESENTATIVE

SUBJ:

X URGENT X AS DISCUSSED ___PLEASE HANDLE ___PLEASE CALL ME

MESSAGE: I have tried to ~~fax~~ this
for days! Problems on my end,
though. Sorry for the delay.
Please let what can be done
& thanks for your patience —
Shelley

CONGRESSIONAL CORRESPONDENCE SYSTEM
DOCUMENT PREPARATION CHECKLIST

This check list is to be submitted with each document (or group of Qs/As) sent for processing into the CCS.

1. *BRIEF DESCRIPTION OF DOCUMENT(S)* Ltr to Sen Lobb

2. *TYPE OF DOCUMENT* X *CORRESPONDENCE* ____ *HEARINGS (Qs/As)*

3. *DOCUMENT CONTROL* ___ *SENSITIVE (NRC ONLY)* X *NON-SENSITIVE*

4. *CONGRESSIONAL COMMITTEE AND SUBCOMMITTEE (if applicable)*
   _____ *Congressional Committee*
   _____ *Subcommittee*

5. *SUBJECT CODES*
   (A) _____
   (B) _____
   (C) _____

6. *SOURCE OF DOCUMENTS*
   (A) _____ *5520 (DOCUMENT NAME* _____*)*
   (B) _____ *SCAN (C)* _____ *ATTACHMENTS*
   (D) _____ *OTHER* _____

7. *SYSTEM LOG DATES*
   (A) 1/2/06 *DATA OCA SENT DOCUMENT TO CCS*
   (B) _____ *DATE CCS RECEIVED DOCUMENT*
   (C) _____ *DATE RETURNED TO OCA FOR ADDITIONAL INFORMATION*
   (D) _____ *DATE RESUBMITTED BY OCA TO CCS*
   (E) _____ *DATE ENTERED INTO CCS BY* _____
   (F) _____ *DATE OCA NOTIFIED THAT DOCUMENT IS IN CCS*

COMMENTS:

RELEASE TO PDR

210078