



May 27, 1997

UCLA SCHOOL OF MEDICINE  
HARBOR - UCLA MEDICAL CENTER  
DEPARTMENT OF RADIOLOGY  
1000 CARSON STREET  
TORRANCE, CALIFORNIA 90509

Hugh L. Thompson, Jr., Deputy Executive  
for Regulator Programs  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555

Dear Hugh:

Pursuant to my letter to you on 29 Apr. 97 and my telephone call 14 May 97, I had a telephone meeting with Larry Camper, Kathy Haney, and Donna-Beth Howe on 5/21/97 from 0800-0910 hrs. We discussed some of the points made in my letter concerning DG-0007.

Larry agreed that the radiochemical availability issue from manufacturers other than those registered with FDA or state equivalents is a problem and that it will be fixed. He assured me that NRC has no intention of limiting nuclear physician/pharmacist access to radiochemicals unapproved as drugs or drug components. He read me a section of DuPont-Merck's current license and promised that this sort of mechanism would continue. We discussed possible problems obtaining radiochemicals from DOE or foreign reactors, and he vowed to assure that we would not have difficulties due to NRC's licensing policies. All this sounds very comforting, and I trust it will be fixed.

We also discussed NRC's requirement for naming each chemical form of each radionuclide on a manufacturer's license (or a pharmacy or medical license), and I pointed out that such requirements would impose severe restrictions on licensees and destroy our flexibility under the Radiopharmacy Rule. NRC has no need to know any of the chemical compounds; these may change depending on new FDA approvals or unique needs of individual patients. Once NRC ascertains that licensees are qualified to handle radioactive material, the safety rules are the same regardless of nuclide or chemical and physical form. You and I discussed this problem several years ago with an early draft of the pharmacy regulatory guide.

May 27, 1997  
Hugh L. Thompson, Jr.  
Page -2-

Larry understands this issue, and I have asked him to indicate specifically in the regulatory guide that broad categories are permitted. Remember Bill Briner's license, "Atomic no. 1-83 in any chemical/physical form, consistent with the possession limits of Duke University". Mine is essentially the same. Why not?

We did not discuss why NRC wants to have a separate distribution license for manufacturers instead of including this in their main license. Presumably Sam Jones will answer this in the written response Larry says he is providing.

Larry and I also made arrangements to discuss DG-0009 (Medical Licensees) on 28 May 97; this should be easy to fix.

We also discussed some of the major problems with DG-0006 (nuclear pharmacies). Many of the problems are old, some onerous new ones are present, and I believe a complete redo is in order. It cannot be fixed with a few changes. An overall change in NRC's understanding of the activities involved, and their low, rather than high risk, will be needed before a sensible and scientifically valid document is ready for public comment. Larry suggested a public meeting of commercial and academic nuclear pharmacists and those who have a stake in their regulation, and I think this is a good idea so long as the meeting doesn't start with unacceptable "givens" and NRC does not impose new requirements not in the regulations.

Frankly, as an aside, I don't see why any regulatory guides are needed for medical licensees or pharmacists at all. We need to redo the regulations along the lines recommended by SNM, ACNP, ACMUI, and NAS-IOM, all of whom are basically in agreement. The resulting simplified performance standards for qualified professionals would require no licensing guides and a license in most cases no longer than half a page. Then, you could use most of your medical programs people for other purposes, such as the regulation of DOE. The decreased regulatory costs will result in decreased medical costs, and I believe that Larry understands the overwhelming need to decrease medical costs in today's managed care environment and in light of federal mandates necessitating cost decreases.

May 27, 1997  
Hugh L. Thompson, Jr.  
Page -3-

I want to thank you for seeing to it that our concerns regarding DG-0007 are being addressed, and I hope our other concerns are addressed as well.

Sincerely,



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Director, Nuclear Med. Outpt. Clinic  
and  
Professor of Radiological Sciences,  
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cc: Larry Camper  
Kathy Haney  
Samuel Z. Jones  
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CSM:sfd