

DOCUMENT SOURCE	University of California at Berkeley The Bancroft Library/The University Archives, Berkeley CA
RECORDS SERIES TITLE	Banc MS 87/Sec
BANCROFT/UMARC ID NO.	John A. Lawrence MD/23P
CARTON NO.	8
FOLDER NAME	Seeger, Eugene L
NOTES	P 1/2
FOUNDED/DATE FOUND	P. Hall 2/1/95

COPY

722602

UNIVERSITY OF CINCINNATI
COLLEGE OF MEDICINE

MAILING ADDRESS:
RADIOISOTOPE LABORATORY
CINCINNATI, OHIO 45229

Copied from originals in The Bancroft Library
 reference use only. Do not be deposited in
 other library. For more information, contact
 Facstaff, p. 100, University of California, Berkeley
 or contact the University of Cincinnati
 Head of Library and
 University of Cincinnati
 Head of Library, Cincinnati, Ohio 45221

1971
Hearing Clerk
Food and Drug Administration
Room 6452
5600 Fisher's Lane
Rockville, Maryland 20852

Dear Sir:

I refer to my earlier comments concerning the regulations of the Food and Drug Administration concerning radioactive pharmaceuticals I have discovered a paper by Robert A. Tucker of the Office of Legislative Services, Food and Drug Administration entitled "Present Status of Pending Legislation Regarding the Safety of Medical Devices," Trans. N.Y. Acad. Sciences, Series II, 32: 832-836, November, 1970. In describing the work of a task force on medical devices he makes the following statement:

"First, there was a general recognition that devices ought to be handled in a different way from drugs because of the inherent differences in their respective mechanisms and modes of action, as well as in the ways by which each may initially be developed."

Whether his viewpoint represents "official" thinking of the FDA or not it does represent a peculiar dichotomy of thinking within an agency where some consistency of viewpoint would be highly desirable. This viewpoint is certainly not represented in the proposed regulations for radiopharmaceuticals, teletherapy devices and interstitial radiation sources.

In the Federal Register, Vol. 36, No. 99, p. 4368 of March 5, 1971, there is a statement from the Atomic Energy Commission concerning the use of technetium 99 pertechnetate for scanning of blood pools and the salivary glands. There is nothing wrong with the regulation but conceptually it is extremely difficult to understand how the ordinary practicing physician or even a relatively small radiopharmaceutical supplier could keep up with several different agencies all issuing directives and suggestions and regulations and notices in a field in which he elects to work.

1162656

Seeger

DOCUMENT SOURCE	
University of California at Berkeley The Bancroft Library/The University Archives, Berkeley CA	
RECORDS SERIES TITLE	
John H. Lawrence Contest	
BANCROFT/UMARC ID NO.	COPY
Bancroft MISS 87/8a	
CARTON NO.	
FOLDER NAME	
Saenger, Eugene L.	
NOTES	
p. 2/2	
FOUND BY/DATE FOUND	
P. New 2/1/75	

Hearing Clerk, FDA

-2-

March 11, 1971

Copied from originals in The Bancroft Library for
 reference use. This material is deposited in
 other library. Do not express per-
 mission to reproduce.

In my recent summary comments at the Radiological Health Seminar on "Current Problems in the Regulation of Ionizing Radiation" on January 27, 28, and 29, 1971, I recommended the establishment of single unit within the Federal Government which would deal with matters of the appropriate quality control for the pharmaceutical aspects of radiopharmaceuticals and would incorporate the appropriate regulations concerning the safe use in regard to radiation. At the moment, the FDA concerns itself with matters of radiation safety (e.g., teletherapy and brachytherapy devices) and the AEC is involved in matters of medical practice (e.g., salivary gland and heart pool scanning). According to my understanding of the responsibility of these two agencies, their roles should be reversed.

All pertinent aspects of radiopharmaceuticals should be combined into one office, board, service, agency or division. The radiation safety of devices used in teletherapy and roentgen diagnosis should be combined into another. This latter function is already represented within the Bureau of Radiological Health. Whether the various groups within the Departments of HEW and the AEC individually and severally are involved in such cooperative efforts is immaterial. What is distressing is to see these efforts wasted upon the medical profession and American public in the guise of useful development when their eventual impact is to increase the complexity and cost of services rendered to the sick patient. There have been other examples in the past where various government groups have cooperated over a period of many years to produce a useful public service and such examples should not be lost in these rapidly growing fields.

Sincerely,

Eugene L. Saenger

Eugene L. Saenger, M.D.
Professor of Radiology

ELS/ml

1162657