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Remarks by
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THE REGULATION OF RADIATION MEDICINE:
BACK TO BASICS

Good morning, ladies and gentlemen! I want to thank you for affording me this opportunity to elaborate on the concerns that prompted me and my fellow Commissioners to turn to you for assistance as we reexamine our regulatory mission with respect to radiation medicine.

Let me note at the outset that I will be using the term, "radiation medicine," to refer to the overall use of ionizing radiation for medical purposes, whether the procedure involved is diagnostic or therapeutic, and whether the radiation is machine-produced (for example, from an accelerator or X-ray machine) or originates from radioactive materials (for example, cobalt in a remote afterloader, or radioiodines used in nuclear medicine). When speaking specifically of radioactive material subject to the Atomic Energy Act, I will use the term, "byproduct material." This, of course, includes only reactor-produced isotopes.

Over the last few years, the Commission has devoted increased attention to the area of radiation medicine. In part, this increased attention has been stimulated by external events such as public and Congressional concern over incidents that have led to injury, and even death, due to problems in radiation medicine. While relatively few such incidents have occurred over the course of many years, they can be dramatic, and they inevitably raise questions as to how well the regulators are doing their jobs.

This increased attention has also stemmed from the Commission's efforts to reevaluate its regulation of byproduct material used in medicine, efforts that reached fruition with the January

1992 Quality Management Program Rule, and from the reactions to that rule within the regulated community. One fortunate result of all this increased attention is that it presents the Commission with an opportunity to take a fresh look at some very fundamental questions such as "Why should radiation medicine be regulated?" "What areas of radiation medicine need to be regulated?" "Assuming regulation is needed, who should the regulator be?" and "What criteria should be used to determine success?" The search for answers to these questions is what brings me here this morning.

The Atomic Energy Act assigns responsibility to the Nuclear Regulatory Commission for the regulation of certain areas of radiation medicine, namely areas that involve radiation from byproduct material. This is not the whole universe of radiation medicine, nor even a large part, but it is the only area for which we have statutory responsibility. As long as this is the case, we, of course, want to fulfill that statutory responsibility in the best way we can and we welcome your suggestions as to how we can improve what we presently do.

But I personally am looking for a good deal more than ways to fine-tune the present system. This is an opportunity to reexamine the system itself. This is the time to ask whether the present statutory approach to the regulation of radiation medicine is the wisest public policy approach to take in attaining the goal of protecting people from possible harm. Answering such a question requires a broad perspective of the nature of the risks involved, and addresses, in effect, the first of my fundamental questions: "Why should radiation medicine be regulated?" My hope is that the report you will ultimately provide us will enable us to better see, from a public policy perspective, what makes sense in the regulation of radiation medicine.

Assuming that the risks associated with radiation medicine suggest that regulation is needed or desirable, the obvious second question is: "What areas of radiation medicine, if not all, should be regulated?" This leads us to the NRC's interest in a critical re-assessment of the current framework for the regulation of radiation medicine, including byproduct material. In other words: "Assuming regulation is needed, who should the regulator be?"

Let's stop at this point to examine the question of risk. Protecting workers and the public from risks inherent in the beneficial uses of nuclear energy and nuclear materials is the fundamental purpose of nuclear regulation. But, since humans live their lives in a world full of risk, including radiation risk, the key question becomes, "What is the desired level of protection from radiation?" Put another way, "What is the acceptable or tolerable level of this risk?" These questions take on an added dimension in the medical arena because clearly what may be a tolerable level of risk for a patient who derives a benefit from radiation medicine may not be tolerable for hospital workers or the patient's relatives, and the regulatory system must afford reasonable protection to all.

Risk-based decision-making has recently become a matter of considerable interest. It seems that no piece of environmental legislation can work its way through Congress without attracting debates on whether risk assessment should be a mandated part of the proposed regulatory program. Even the newest member of the Supreme Court, Justice Stephen Breyer, has focused

attention on the issue with his book, Breaking the Vicious Circle,[1] which points out that the risks that have attracted the attention of the public and of the Congress often are not those deemed to be of significant concern by scientists, and that society as a whole must decide what resources are worth spending on what risks. It may be that some risks are totally unacceptable and must be avoided no matter what the associated benefits. However, I don't think a policy-maker can, or should, make decisions that will involve the expenditure of resources to eliminate or lower risk without being aware of how these risks compare with other risks that society accepts, the associated costs, and the benefits to be derived. In other words, decision-makers need to be mindful of balancing risk, cost, and benefit.

To place the risks from radiation medicine into an overall context, let's examine, for a moment, the major causes of death for the general population in the United States. About 33% of the general population dies of heart disease, and about 23% dies of cancer. Non-cancerous lung disease, strokes, and accidents also figure strongly as major causes of death.[2]

Comparing these causes of death, all of which carry a risk of greater than 1%, with the elective or accidental risks faced by selected groups or by the general population adds perspective to the complexity of adding societal choice to risk-based decision-making. Smoking one pack of cigarettes daily will result in death from a related cause for about 28% of smokers, and a motorcyclist has about an 11% chance of dying in a motorcycle accident. About 1% of motor vehicle users will die in a traffic accident.[3] By comparison, one's risk of dying in an air accident is several orders of magnitude lower, at about 0.02%.[4]

While we have some understanding of how the risk from radiation medicine compares with other risks, we don't have a lot of confidence in the accuracy of the data at our disposal. However, the statistics we do have are illuminating, based on the context I have just established. I have already shown that the chance of dying from cancer, for a member of the U.S. population, is about 23%. For those cancer patients who opt for no treatment at all, the risk of dying from cancer is greater than 95%. The mortality risk from various cancer treatments themselves differs considerably based on the mode of treatment. The mortality risk from cancer surgery itself varies from 1% to 23%, depending on the type of cancer and the corresponding type of surgery required.[5] Chemotherapy carries with it a mortality risk of about 1%,[6] while, for purposes of

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[1]Harvard UP, Cambridge, Mass., 1993.

[2]*Cancer*, Jan./Feb. 1994: 12.

[3]V.T. Covello, P. M. Sandman, and P. Slovik. *Risk Communication, Risk Statistics, and Risk Comparisons: A Manual for Plant Managers.* Chemical Manufacturer's Association, 1988.

[4]National Safety Council. *Accident Facts, 1993 Edition.* Itasca, IL.

[5]V.T. DeVita, Jr., S. Hellman, and S. A. Rosenberg. *Cancer Principles and Practice of Oncology.* J. B. Lippincott Co.: Philadelphia, 1982. (see also G. Chodak, "Treatment of Early Prostatic Cancer," *Acta Oncologica* 30: 243-5, 1991.)

[6]J. Porter and H. Jick. "Drug-Related Deaths Among Medical Inpatients," *JAMA* 237: 879-81, 1977.

comparison, the risk of dying from general anesthesia is about 0.1%.[7]

But the most significant insight that can be gleaned from this chart lies in comparing the mortality risk from correctly administered radiation therapy using byproduct materials, which is about 1%,[8] to the risk of death from what the NRC defines as a misadministration of the use of byproduct materials, which, to the best of our knowledge, is about 0.0006%.[9] Therefore, assuming these data are in the right ballpark, even if all misadministrations were successfully eliminated--so that, as an incoming cancer patient about to undergo radiation therapy, I could be positively assured that my therapy would be properly administered--my risk of death due to the procedure itself would remain essentially unchanged, or about 1%.

Several other points should be made here. First, you will note that this chart does not give a mortality risk for diagnostic procedures. That is because, to the best of our knowledge, there have been no reported deaths linked to the diagnostic uses of byproduct material.

Second, note that so far in these slides we have only been concerned with mortality. Clearly, not all misadministrations result in death. Based on the data available to us,[10] therapeutic misadministrations of byproduct material occur at a rate of about 40 per every 100,000 administrations. Out of these, about 30 will result in significant side effects, or morbidity, and 0.6 out of every 100,000 will result in death (which converts to the estimate in the previous figure of a 0.0006% risk of death by therapeutic misadministration). As a

caveat, we should remember that it is frequently difficult to determine whether the death was indeed caused by the misadministration.

Third, I should point out again that these data only relate to misadministrations involving byproduct material. In fact, to the best of our knowledge, about 4/5 of present radiation therapy

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[7]S. G. Pauker and J. P. Kassirer, "Therapeutic Decision Making: A Cost-Benefit Analysis," *New England Journal of Medicine* 293: 229-34, 1975.

[8]Internal NRC Memoranda dated February 1, 1993, March 8, 1993, and April 19, 1993, from Myron Pollycove, M.D., NRC Visiting Medical Fellow, to John E. Glenn, Chief, Medical, Academic, and Commercial Use Safety Branch, Division of Industrial & Medical Nuclear Safety, NRC. Based on personal communication of David J. Flynn, M.D., Professor of Radiation Oncology, Harvard and Boston U. Schools of Medicine, U.S. NRC Consultant and ACMUI member: Significant (moderate to severe) post-radiation-therapy complication occurrence rate is approximately 10%. Approximately one-tenth of these complications lead to death. Due to biologic variability, this mortality rate of 1% occurs following correctly prescribed and delivered radiation doses. The prescribed dose is optimized to achieve the lowest morbidity and mortality results in the face of a more than 95% mortality of untreated malignancy within 5 years, and for palliation of incapacitating dysfunction of incurable widespread malignancy.

[9]Personal data of Myron Pollycove, M.D.

[10]NRC: Misadministration and Abnormal Occurrence Data. See Internal NRC Memoranda dated February 1, 1993, March 8, 1993, and April 19, 1993, from Myron Pollycove, M.D., NRC Visiting Medical Fellow, to John E. Glenn, Chief, Medical, Academic, and Commercial Use Safety Branch, Division of Industrial & Medical Nuclear Safety, NRC.

procedures are conducted using linear accelerators.[11] To gain a balanced medical risk perspective, it would be extremely helpful to have data, for comparison, for mortality and morbidity rates resulting from the proper administration of radiotherapy using linear accelerators, as well as resulting from the equivalent misadministration of such therapy. It is possible that burdensome regulation of a relatively safe modality of radiotherapy encourages practitioners to use one that is less safe.

So what do all these data mean? First, we can say that, if the general principle applies here--that, as risks get larger, more attention should be given to their regulation, and as they get smaller, they deserve less attention--then it should be evident at this point why the NRC is re-examining this area. The reason should also be evident as to why we have asked for a verifiable "comparison of the frequency of errors and consequences therefrom (mortality and morbidity) from the use of licensed byproduct materials and the rate of mortality and morbidity of properly carried out administrations of licensed byproduct materials." This information, together with the perspective of the Institute, will help the Commission in achieving sensible, risk-based decision-making.

The next major issue that I want to address, taken from the charge given to the Institute, concerns NRC's interest in a critical assessment of the current framework for regulating radiation medicine--or, as I stated earlier, "Who should the regulator be?" As you may be aware, at the Federal level two agencies, the NRC and the Food and Drug Administration, have been assigned statutory responsibility over certain types of radiation uses--the NRC over byproduct material and the FDA over machines and drugs that incorporate radiation derived from any source. While this division of responsibility is workable, it results in some peculiar outcomes.

For example, both remote afterloaders, which contain byproduct material, and linear accelerators, which are not regulated by the NRC, are used by medical practitioners to administer radiation therapy. The FDA must certify both machines. However, FDA's role ends at the point of certification. When using a remote afterloader, a medical practitioner must observe NRC's regulations. However, if the same medical practitioner uses a linear accelerator to accomplish essentially the same purpose, the NRC has no authority to regulate. The usage of the linear accelerator is either regulated by the State or not regulated at all. Interestingly enough, as I stated earlier, the data available to us indicate that about 4/5 of present radiation therapy procedures are conducted using linear accelerators. It would be useful to know your views on whether this scheme of regulation makes sense.

To further complicate matters, the Atomic Energy Act has a provision, Section 274, under which a State that wishes to itself be the regulator of byproduct material can become an "Agreement State" for that purpose. The NRC then relinquishes its authority over the use of byproduct material and the State becomes the regulatr. This has led to two difficult issues which have not yet been satisfactorily resolved by the Commission. First, to what extent should the Commission

[11]Ibid.

require that a State's regulatory program be identical to the program of the NRC? Second, to what degree must the Commission continue to exercise a supervisory role over an Agreement State even after it has relinquished its authority? The statute contemplates some type of supervisory role because it provides for the possible unilateral revocation of an agreement in certain undefined circumstances but it is not clear just how much leeway is to be given to the States to decide for themselves the level of risk at which they may choose to regulate.

It is not, of course, my intent to ask the Institute for advice on how to deal with the knotty problems caused by the Agreement State provision of the Atomic Energy Act, since these problems extend beyond the field of medical regulation. It is my intent, however, to ask for your advice on whether the existing regulatory framework for radiation medicine makes sense and, if not, to ask that you make suggestions for a more rational framework. Presumably, your advice would depend, in part, on your views as to the degree of uniformity necessary or desirable in regulating radiation medicine, as well as your view of what needs to be regulated and by whom. Within this area, I would also ask for an answer to the last of my fundamental questions: "What criteria should we use to determine the success or failure of either the existing, or a different, regulatory framework?" Under any regulatory scheme, there will inevitably be mishaps. Human error, for example, can almost never be completely eliminated, and it often seems to be the cause of misadministration. What is important to the regulator is not solely the mishap itself but what it might say about the success or failure of the regulatory program. Useful criteria for judging the effectiveness of the regulatory program would be criteria that place a single mishap in proper context.

This brings me to my final point. In addition to the government regulators to whom I have already referred, there are numerous "private regulators" such as hospital review boards or the medical malpractice system. Is government involvement in regulating radiation medicine an anomaly, or is government similarly involved in regulating other medical procedures that involve risk--for example, chemotherapy? If it is an anomaly, are there unusual dangers surrounding radiation risk in the medical area that warrant government involvement? Could the regulation of radiation medicine be safely left in the hands of private parties? These are questions of judgment and philosophy and your advice on these issues would be most helpful.

In conclusion, I assure you that the end-product of your endeavors is eagerly anticipated and should be extremely useful to me and my fellow Commissioners in bringing to us the broad perspective that will enhance our ability to make sound regulatory decisions, and will hopefully provide us with a firm basis as to whether or not radiation medicine should be regulated by government. In particular, I look forward to your assessment of how radiation medicine risks compare with other similar risks, and what that might say about what areas of radiation medicine need to be regulated. I also look forward to your assessment of who it is that should be doing the regulating, and your suggestions for criteria by which to judge the success or failure of a regulatory framework.

These are certainly complex issues, but society needs and deserves the answers to these questions in order to have confidence that its resources are being used rationally and effectively to protect

people at a cost commensurate with the risk, and without denying them the benefits they may seek. I wish you success in what I expect will be difficult deliberations. I thank you for taking the time to hear the views of myself and my fellow Commissioners on these matters, and most especially for the time and effort you are giving in service to our mission.