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Medical Radiation: An Overview of the Issues

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Chairman Pallone, Ranking Member Deal, and members of the Health Subcommittee, thank you for this opportunity to testify today. I am Dr. Rebecca Smith-Bindman, Professor of Radiology, Epidemiology and Biostatistics, at the University of California San Francisco School of Medicine. I am a clinical radiologist and I conduct research focused on assessing the risks and benefits of medical imaging. I recently published a paper in the Archives of Internal Medicine focused on safety of diagnostic CT and I have included a copy of this paper with my testimony.

My testimony today focuses on computed tomography – CT – because it is one of the most common imaging tests that we use in medical diagnosis, and the test with the greatest potential for causing harm.

CT uses x-rays to obtain extremely detailed images of internal organs, and the development of CT is widely considered among the most important advances in medicine. It is a simply an extraordinary test, allowing the more accurate diagnosis of disease across nearly every area of medicine. In part because it is so useful, the utilization of CT has risen dramatically and currently 1 in 5 individuals in the U.S. undergoes a CT every year.

Although CT is useful, it delivers much higher doses of radiation than do conventional x-rays, and exposure to radiation can lead to the development of cancer. To help put this into context, when you go to the dentist and you are offered dental x-rays, you may pause, in order to consider the potential harm associated with getting x-rays. The most common type of CT scan patients undergo in the U.S. – a CT of the abdomen – delivers approximately the same radiation as getting 1500 dental x-rays. Additionally, newer applications of CT, such as those used to assess the heart, or to assess the blood vessels in the brain, require even higher doses of radiation – as much as 5,000 or more dental x-rays.

The increase in the number of CT tests that are done each year, and the higher dose per CT test, has resulted in a very large increase in the population's exposure to radiation from medical imaging. The National Council on Radiation Protection, a group dedicated to ensuring that the US population is as safe as possible in relation to

radiation exposures, has estimated that the US population's exposure to radiation from medical imaging has increased 6 times since the 1980s.

Risks

Exposure to radiation increases a person's risk of getting cancer. The National Academy of Sciences' National Research Council reviewed all of the published literature related to health risks of radiation. They found people who received doses in the same range as a *single* CT scan were at increased risk of developing cancer. Further, some patients receive multiple CT scans over time – and their risks are even higher. Thus the doses that we experience every day as part of routine CT scanning are potentially dangerous. The cancers may not develop for 5, 10 or 20 years. Even though we can't see the harms immediately, we must take them seriously.

Oversight

Oversight for CT radiation dosing is currently very fragmented. The FDA oversees the approval of the CT scanners, as medical devices, but does not regulate how the test is used in clinical practice. Radiologists determine how the CT tests are performed. However, there are few national guidelines on how these studies should be conducted and therefore there is great potential for practice variation that could introduce unnecessary harm from excessive radiation dosing. Furthermore, since information on radiation is reported differently across the different types of CT machines, it is difficult for radiologists to standardize their practice. The American College of Radiology has established a voluntary accreditation process to try to standardize practice, and collects dose information but only on a very small sample of tests. This approach is promising, but at this point in time the data collection is extremely limited, making it difficult if not impossible for the College to monitor if facilities comply with their recommendations. The manufacturers of CT equipment have begun work to establish standards of how radiation dose information should be measured

and reported. These steps could lead to collection, standardization and reporting of dose information that would improve the safety of CT. But, the manufacturers have not adopted or implemented these standards. As a result of this fragmentation, information on CT dose is extremely limited.

My research team at UCSF conducted a research study to assess the doses associated with typical CT scans. We collected radiation dose information on over 1000 patients and found that for nearly all types of CTs, the radiation doses were much higher than commonly reported, that the radiation dose varied substantially between different facilities, and that *even within the same facility*, that the doses varied dramatically between patients evaluated for the same clinical problem. For example, we found that one patient had 20-times the radiation dose as another patient for a routine head CT when both studies were done at the same institution.

As part of this study, we also quantified the risk of CT. We found that for some patients, the risk of a *single test* could be as high as 1/ 100. That means of 100 patients who undergo a CT, one of them could get cancer from that test. This is an extremely high risk for a test that is supposed to find cancer, not cause it.

There are private businesses that currently offer full body CT *screening* to healthy individuals. The FDA and professional organizations have voiced concerns that using CT as a screening test could cause more cancers than they find. For *diagnostic* CT- tests that are done in patients who have a clinical problem - it has generally been thought that if a patient is sick enough to get a CT scan, the benefit of the test outweighs any risk. However, we have started to use CT so often, and in patients who really are not very sick, that we need to think about whether the test is really necessary and whether it could cause more harm than benefit. Neither physicians nor patients are aware of the risks associated with CT, nor the importance of limiting exposures.

What Needs to Happen to Improve the Safety of CT Imaging

Given the importance of CT and yet its potential for causing cancer, it's imperative that we make CT scanning is as safe as possible. To do this, we need to do two things: first, we need to lower the radiation dose of routine CT scans; and second, we need to ensure we use CT only when necessary.

To lower the doses, several steps are important. We need very clear standards for what are acceptable levels of radiation exposure associated with CT and there should be regulatory oversight for setting of these standards. There is evidence that for many types of CTs the radiation dose can be reduced 50% or more without reducing quality.

Dose used in actual patients needs to be monitored. Despite the potentially high radiation doses CT can deliver, there is no regulation of CT practice in the United States, as the FDA does not have a legislative mandate to do so.

The default settings set by the manufacturers should be ones that yield the lowest possible doses and this dose information should be prominently displayed when CTs are done so that technologists can easily make adjustments as needed if the doses are too high.

And lastly, the dose associated with each CT examination should be documented and recorded in each patient's medical record and this information should be tracked over time. Recording and tracking this

information would help educate patients and providers about radiation exposure and would lead to activities to minimize dose.

Summary

In summary, consensus is growing that efforts are needed to minimize radiation exposure from CT, and to ensure patients receive the minimum dose necessary to produce a medical benefit. These efforts must include reducing unnecessary studies, reducing the dose per study, and reducing the variation in dose across patients and facilities. Despite the frequency and importance of CT imaging, there are no resources available to the research community to study or improve the quality of CT imaging. Creation of an academic consortium to study CT and to make it as safe as possible would go along way toward improving its utilization and safety.

Thank you for allowing me to contribute to this discussion and I would be happy to answer any questions.