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EDWARD J. MARKEY  
7TH DISTRICT, MASSACHUSETTS

2108 RAYBURN HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515-2107  
(202) 225-2836

**Congress of the United States**  
**House of Representatives**  
Washington, DC 20515-2107

DISTRICT OFFICES:

5 HIGH STREET, SUITE 101  
MEDFORD, MA 02155  
(781) 396-2900

188 CONCORD STREET, SUITE 102  
FRAMINGHAM, MA 01702  
(508) 875-2900

<http://markey.house.gov>

November 23, 2010

The Honorable Margaret Hamburg  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Commissioner Hamburg:

I am writing to gather more information about the research that has been performed to evaluate the safety and health impacts of general-use full-body x-ray screening systems that are currently used for airport security. In April, a letter generated by several UCSF (University of California-San Francisco) scientists and medical professionals sent to Dr. John Holdren, Assistant to the President for Science and Technology, highlighted potential concerns about the long term health impacts of these scans, particularly for vulnerable populations such as pregnant women, children and the elderly. Other groups<sup>1</sup> also have raised issues with respect to whether the safety of these devices has been adequately demonstrated, particularly for frequent fliers, pilots and flight attendants.

As you know, in response to these concerns, the FDA replied to UCSF scientists Drs. John Sedat, David Agard, Marc Shuman and Robert Stroud on October 12, 2010, via a letter to Dr. John Holdren. The letter highlighted several studies, dating back to the 1990's, performed by various expert groups and panels, which have served to support the approval and roll out of these machines for use as a screening tool by the Transportation Security Administration (TSA) and assure the traveling public of the machines' safety. After reading this response from the FDA, there are several items that require more clarity. Accordingly, I request that the FDA respond to the following questions and provide supporting data, documents and other relevant information by close of business Monday, December 6, 2010.

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<sup>1</sup> For example see news report: <http://healthland.time.com/2010/11/17/should-we-worry-about-radiation-exposure-from-new-airport%C2%A0scanners/> and <http://www.npr.org/2010/11/19/131447056/are-airport-scanners-safe>

1. In the October 12<sup>th</sup> letter, the FDA mentions that the assumed skin dose of x-rays that was used to grant approval for the use of these machines was an estimate based on theoretical modeling. Additionally, the FDA mentions that it has in place survey teams that are collecting radiation dose data with mounted dosimeters placed within the inspection zone of the x-ray scanner. Where in the “inspection zone” will these dosimeters be placed? When will the data collection be completed? Does the FDA plan on making this data publicly available? If yes, when? Please describe what the FDA hopes to accomplish by collecting this data. Will the FDA use this data to validate its theoretical model using the actual measurements for passengers screened with these machines? If so, when will these efforts be completed and if not, why not?
2. Has the FDA, either through modeling or measurement, determined the dose that would be received by the eyes, which are covered by a thinner layer of skin than most other organs? If so, what was the outcome and if not, why not?
3. Were the population risk assumptions initially made regarding the use of these machines that they would be used for secondary screening only? Since, general-use full-body x-ray machines are now being used as a primary screening tool. In FDA’s view, do the individual and population risk assumptions that were made in the study of these machines and in their approval process change as a result of their actual use? If yes, how? If not, why not?
4. In the October 12<sup>th</sup> letter, the FDA states that the dose modeling revealed that a typical screening delivers approximately 69  $\mu$ rem of radiation to the testes—higher than the 25  $\mu$ rem per scan standard for general-use x-ray screening systems that was published by a FDA and the National Institute of Standards and Technology (NIST) working group in 2009. This per scan limit was defined on the basis that a general use x-ray screening system should deliver less than 1/1000 of the annual dose limit of 25 mrem, which is the national dose limit for radiation received by the general public from security screening systems. Has the FDA attempted to determine how the higher projected dose received by the testes may impact any localized risk for this particular organ? If yes, please describe what was found. If not, why not? Are there other organs that are also expected to receive a greater dose than the effective dose for the deployed product? Please provide all relevant information.
5. There exists a subset of females, such as those who carry mutations in the breast cancer susceptibility gene BRCA, who have defects in DNA repair mechanisms and as a result are more sensitive to the damaging effects of ionizing radiation. Has the FDA investigated the effect that the low level x-ray radiation produced by this scanning equipment may have on this subset of the female population or on other individuals who might be more inclined to experience adverse health effects from lower doses of radiation? If yes, please describe what you found. If not, why not?

6. Young children and developing fetuses are another subset of the population that have increased sensitivity to the damaging effects of radiation. Has the FDA determined the cumulative risk of multiple exposures to the radiation emitted by the security scanning equipment for children and pregnant women? If yes, please describe what you found. If not, why not?
7. Is the scanning motion on the full-body x-ray screening systems uniform for the entire body or are particular areas of the body scanned at slower rates? Please describe. Is it possible for the scanning motion to be adjusted by the operator of the machine a) during scans or b) in between scans?
8. What enforcement strategy does the FDA have in place to ensure that all screening systems and protocols in use remain in compliance with the general-use dose-per screening limit of 25  $\mu$ rem?
9. Does the responsibility of monitoring the safe use of this equipment lie solely with the FDA or is it shared with the TSA? Please describe the monitoring plan(s) that are in place.
10. What policies does the FDA have to ensure that any inappropriate dosage that occurs as a result from either human error or malfunctioning of the equipment is promptly reported to the FDA and the individual(s) who are likely to have received a higher dose, and that the machines are repaired?
11. It has been reported that the millimeter wave security systems uses non-ionizing radiation — a safer alternative to the ionizing radiation used in x-ray scanners—in smaller quantities than the backscatter x-ray screening equipment to create a black and white three dimensional image for screening purposes. In FDA's view would replacement of backscatter x-ray security systems with millimeter wave security systems pose less risk for travelers and airport employees being screened?

Thank you for your assistance and cooperation in responding to this request. Should you have any questions, please have your staff contact Dr. Avenel Joseph or Dr. Michal Freedhoff of my staff at 202-225-2836.

Sincerely,



Edward J. Markey  
Member of Congress