



HOUSE OF REPRESENTATIVES  
WASHINGTON, D.C. 20515

March 28, 2013

The Honorable John P. Holdren  
Director, White House Office of Science & Technology Policy  
Executive Office of the President  
725 17th Street Room 5228  
Washington, DC 20502

Dear Dr. Holdren:

We write to urge you to overturn the decision of your predecessor that effectively blocked the implementation of a 2002 law requiring the distribution of potassium iodide to public facilities such as schools and hospitals as well as to the people who live within 20 miles of nuclear power plants in order to protect them against the effects of a radioactive iodine release. We believe that a failure on your part to do so would be tantamount to a rejection of both sound science and the opportunity to learn important lessons from the 2011 nuclear meltdowns in Japan.

Potassium iodide, known by its chemical symbol KI, protects the thyroid gland by flooding it with stable iodine so that the gland cannot take up the cancer-causing radioactive form that can be released during melt-downs of nuclear reactors.<sup>1</sup> If an earthquake, terrorist attack, or accident caused a radiation release in the United States, one of the greatest risks to health comes from radioactive forms of the chemical element iodine. Children are the most vulnerable because their thyroid glands concentrate more iodine on a per unit mass basis than adults and are more sensitive to radiation because of their rapidly dividing cells.

Timing of KI distribution is critical as the drug is most effective if used within 3-4 hours of exposure.<sup>2</sup> According to the Food and Drug Administration (FDA), inhalation of radioactive iodine is a significant contributor to exposure and is of particular concern for those residing in the immediate area of a nuclear accident or otherwise directly exposed to the radioactive plume. This means that it is critical to distribute KI to residents and local authorities *before* a radiation release happens, rather than scrambling to try to do it afterwards as happened during the 1979

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<sup>1</sup>[http://www.birdflumanual.com/resources/Self\\_Defense/files/Guidance%20for%20use%20of%20KI%20for%20nuclear%20emergency%20USG.pdf](http://www.birdflumanual.com/resources/Self_Defense/files/Guidance%20for%20use%20of%20KI%20for%20nuclear%20emergency%20USG.pdf)

<sup>2</sup> <http://www.fda.gov/Drugs/EmergencyPreparedness/BioterrorismandDrugPreparedness/ucm072265.htm>

Three Mile Island accident, or at Fukushima when its distribution was only ordered five days after the nuclear accident commenced<sup>3</sup>.

Section 127 of the Bioterrorism Preparedness and Response Act of 2002 directed the President to establish a program to make KI available free to State and local governments for distribution to residents living within 20 miles of a nuclear power plant. Previously, distribution was limited to just those within 10 miles, and only to States that requested it from the Nuclear Regulatory Commission (NRC).

The Congress' choice of a minimum 20-mile KI distribution radius was driven by its recognition that radiological exposure during a nuclear emergency could exceed the "intervention level", set by the NRC to be 5 rem to a child's thyroid gland, at distances greater than 10 miles from the event. Despite the 2002 law and a multitude of studies and other endorsements related to the use of KI<sup>4</sup>, your predecessor, the late Dr. John Marburger, in a January 22, 2008<sup>5</sup> memorandum (hereafter referred to as the Marburger memo), chose to invoke a novel and erroneous interpretation of Section 127(f) of the law, previously rejected by the Department of Health and Human Services, to prevent KI distribution. Section 127(f) was included in the law to allow halting of KI distribution only if superior radiation protection was achieved in the future with a newly-developed drug or method. However, instead of citing a new prophylaxis, Dr. Marburger declared that evacuation and removal of contaminated foodstuffs were "more effective... than the administration of KI." He used as a basis for his decision an analysis prepared at his request by the Federal Radiological Preparedness Coordinating Committee (hereafter referred to as the FRPCC analysis)<sup>6</sup>.

In recent months, and in the context of the Fukushima meltdowns, we have reviewed the Marburger memo, the FRPCC analysis, numerous documents related to the response to the Japanese catastrophe, and other government and academic publications related to the use and benefits associated with the administration of KI in the event of a nuclear emergency. We have concluded based upon this review that Dr. Marburger's original decision was predicated on unrealistic assumptions that were flawed at the time it was issued. When viewed through the lens of the Fukushima meltdowns, these assumptions seem nothing short of absurd. What follows is a summary of our assessment:

1. **The decision assumes that catastrophic nuclear events are unlikely to occur in the U.S. because of the robust design of U.S. nuclear power plants.**

The Marburger memo<sup>7</sup> states that "A nuclear power plant accident that creates public health risks beyond the 10 mile range would be a highly unusual catastrophic event," and

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<sup>3</sup> See September 29 2011 article in the Wall Street Journal entitled "Japan Officials Failed to Hand Out Radiation Pills in Quake's Aftermath"

<sup>4</sup> Please see <http://markey.house.gov/document/2011/march-16-2011-markey-sec-sebelius-reagrding-ki> for a description of some of these.

<sup>5</sup> Decision Memorandum from John H. Marburger, III, Director of Office of Science and Technology Policy, January 22, 2008

<sup>6</sup> October 23 2007 Paper entitled "Interagency Technical Evaluation Paper for Section 127(f) of the Bioterrorism Act of 2002" prepared by the Federal Radiological Preparedness Coordinating Committee, October 23 2007.

<sup>7</sup> See page 6 of the Marburger memo

that “for the types of nuclear reactors in use in the United States, there are very few accident scenarios that produce [the sort of effects that would require the use of KI]”. The FRPCC analysis further states that “because of the construction of nuclear power plants in the U.S., the release of radioactive materials including I-131 as a result of either a highly unlikely successful terrorist attack or failure of multiple reactor safety systems would be a very rare event and would evolve over many hours or days...<sup>8</sup>”

The Mark 1 design of the Fukushima Daiichi reactors is utilized in 23 nuclear reactors in the U.S. Not only did a catastrophic failure occur at multiple reactor units at the Fukushima Daiichi power plant within hours of the loss of offsite power, but additionally, so did the first radioactive releases<sup>9</sup> from these facilities. It has also become clear<sup>10</sup> that initial estimates of the radiation released were lower than what actually occurred, which raises questions about whether the protective measures that were ordered were adequate.

We agree that catastrophic releases of radiation are likely to be rare events in any country. We do not believe, however, that the design of U.S. nuclear reactors renders these events to be impossible within the U.S., or that their small likelihood justifies a failure to prepare adequately.

**2. The nuclear accident scenario used as a basis for the Marburger decision is unrealistic.**

The FRPCC analysis modeled a nuclear accident scenario that assumed a “design basis” accident<sup>11</sup> containment leakage, or in other words, the sort of radiation release that would occur under a “design basis” accident scenario.<sup>12</sup> This artificial constraint should not be used as the basis for any policy that is designed to be protective of human health in case a beyond design basis accident such as that at the Fukushima Daiichi nuclear power plant should occur.

In an April 15, 2011 letter<sup>13</sup> to the Nuclear Regulatory Commission (NRC), Rep. Markey asked whether any of the nineteen events (i.e. stronger than expected earthquakes and tsunamis, hydrogen explosions, etc.) believed to have occurred at the Fukushima Daiichi nuclear power plant are currently within the NRC’s “design basis.” The NRC’s response<sup>14</sup> indicated that only three of these nineteen events were fully considered to be

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<sup>8</sup> See page 8 of the FRPCC analysis

<sup>9</sup> See, for example, page 230 of <http://pbadupws.nrc.gov/docs/ML1117/ML11175A277.pdf> which is one of many such timelines obtained by NRC officials from TEPCO, the owner of the Fukushima Daiichi nuclear power plant, that indicate that the earthquake occurred at 2:46 PM Japan time on March 11 and that a radiation release was suspected about 11 hours later. Additionally, the November 2011 “Special Report on the Nuclear Accident at the Fukushima Daiichi Nuclear Power Station” by INPO notes that radiation levels of 50-120 mrem/hour were measured at the Unit 1 doors about 9 hours after the earthquake.

<sup>10</sup> <http://www.businessweek.com/news/2011-10-27/fukushima-station-discharged-more-radiation-than-estimated.html> and <http://mainichi.jp/english/english/newsselect/news/20130222p2a00m0na009000c.html>

<sup>11</sup> See page 16 of the FRPCC analysis

<sup>12</sup> <http://www.nrc.gov/reading-rm/doc-collections/cfr/part050/part050-appj.html>

<sup>13</sup> <http://markey.house.gov/document/2011/april-15-2011-letter-nrc-reagrding-fukushima-inspections>

<sup>14</sup> <http://markey.house.gov/document/2011/august-11-2011-nrc-response-inspection-questions>

within its design basis, meaning that one cannot assume that either U.S. nuclear reactors' designs or NRC regulations protect against any of the other sixteen from occurring.

It is also worth noting that the ground motion at the North Anna nuclear plant due to the 2011 Virginia earthquake exceeded the design basis for that plant.<sup>15</sup>

Continuing to base any decision on whether to distribute KI on a model that assumes that natural disasters, terrorist attacks or other accidents will never exceed the design-basis severity for those events flies in the face of recent history.

### **3. The Marburger decision is based on unrealistic accident timing and evacuation scenarios.**

The FRPCC analysis<sup>16</sup> states that “for dominant scenarios, the offsite release of fission products may be delayed for 24 hours or longer from the start of an event,” and that the scenario analyzed does not result in a large release of radiation for more than 20 hours<sup>17</sup>. The analysis thus concludes that if evacuations are initiated within 12 hours of the event, that the populations that might be impacted by radioactive iodine would be able to be relocated before the plume (which is assumed to be traveling at 5 miles per hour) arrives. Finally, the analysis assumes that 99 percent of those directed to evacuate would do so as directed, and uses a KI-efficacy assumption that expects that when populations were ordered to be evacuated, they might stop at KI stockpiling centers along the way in order to obtain any recommended dosages.

In stark contrast to the theoretical scenario devised by the FRPCC, what actually occurred in Japan was quite different: The area had been devastated by the earthquake and tsunami, making evacuation and communication difficult. Radiation releases began within about 11 hours of the earthquake, the accident proceeded to intensify thereafter<sup>18</sup> and the radioactive releases continued for some time until the reactors were brought under control.

Moreover, it took the NRC five days to order the evacuation of U.S. citizens within 50 miles surrounding the stricken reactors<sup>19</sup>. The Japanese government first ordered a mere 1.8 mile evacuation zone about 7 hours after the earthquake<sup>20</sup>, instructed those living

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<sup>15</sup> See for example <http://www.virginiabusiness.com/index.php/news/article/nrc-inspectors-say-earthquake-did-not-cause-significant-damage-to-north-ann/314466/>

<sup>16</sup> See page I0 of the FRPCC analysis

<sup>17</sup> See page I4 of the FRPCC analysis

<sup>18</sup> See, for example, page 230 of <http://pbadupws.nrc.gov/docs/ML1117/ML11175A277.pdf> which is one of many such timelines obtained by NRC officials from TEPCO, the owner of the Fukushima Daiichi nuclear power plant, that indicate that the earthquake occurred at 2:46 PM Japan time on March 11 and that a radiation release was suspected about 11 hours later. Additionally, the November 2011 “Special Report on the Nuclear Accident at the Fukushima Daiichi Nuclear Power Station” by INPO notes that radiation levels of 50-120 mrem/hour were measured at the Unit 1 doors about 9 hours after the earthquake.

<sup>19</sup> <http://www.nrc.gov/reading-rm/doc-collections/news/2011/11-050.pdf> Other countries ordered similar measures. Please see, for example, page 257 of <http://pbadupws.nrc.gov/docs/ML1128/ML11285A009.pdf>

<sup>20</sup> <http://www.tepco.co.jp/en/press/corp-com/release/11031106-e.html>

between 1.8 miles and 6.2 miles to stay indoors after about nine hours<sup>21</sup>, ordered all living within 6.2 miles to evacuate after about 16 hours<sup>22</sup>, and only broadened that to a 12.4 mile evacuation zone about 26 hours after the earthquake, which was also several hours after the first hydrogen explosion occurred<sup>23</sup>. In fact, a recent article<sup>24</sup> indicated that “in one area, the level of radiation had surged to more than 700 times the normal level, indicating that many local residents were exposed to high levels of radiation before they evacuated.”

Japan also failed to order the distribution of KI until five days after the accident began,<sup>25</sup> which may well have lead to an increased future risk of thyroid cancer and other thyroid disorders for the exposed population. This possibility is borne out by projected dose analysis: In May 2012, the Japanese Ministry of Education released<sup>26</sup> a map of the projected dose of radioactive iodine to infants under a year old, which indicates that a greater than 5 rem dose may have been experienced tens of miles away from the reactors. Problems with evacuation and communications during a crisis are not unique to Japan; The mass confusion and failures of the U.S. federal, state and local governments during Hurricane Katrina led to unnecessary deaths and other harm. And a 2003 report by former FEMA Commissioner James Lee Witt, entitled “Review of Emergency Preparedness of Areas Adjacent to Indian Point and Millstone<sup>27</sup>”, concluded that the NRC’s emergency response plans assumed that people would comply with directions they were provided with and “do not consider the reality and impacts of spontaneous evacuation,” meaning that individuals ordered to evacuate might not do so in the manner they were directed and that others directed to stay in their homes would choose to evacuate anyway. This could lead to greater than expected traffic flow and a failure to execute a timely evacuation of the area before radiation reached it.

Recent experience related to the evacuation of large populations faced with a pending emergency – or even a severe snowstorm - makes clear that these events never go as they should. Assuming otherwise ignores this history, and places these populations at unnecessary risk of harm.

#### 4. **The Marburger decision ignores the most rational scenario for KI use.**

The FRPCC analysis models two basic scenarios<sup>28</sup> to evaluate the effectiveness of KI distribution: 1) the population is evacuated and *does not* take KI or 2) the population is not evacuated and *does* take KI.

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<sup>21</sup> <http://www.tepco.co.jp/en/press/corp-com/release/11031203-e.html>

<sup>22</sup> <http://www.tepco.co.jp/en/press/corp-com/release/11031211-e.html>

<sup>23</sup> <http://www.tepco.co.jp/en/press/corp-com/release/11031227-e.html>

<sup>24</sup> <http://mainichi.jp/english/english/newsselect/news/20130222p2a00m0na009000c.html>

<sup>25</sup> See September 29 2011 article in the Wall Street Journal entitled “Japan Officials Failed to Hand Out Radiation Pills in Quake's Aftermath”

<sup>26</sup> Please see the maps linked at <http://ex-skf.blogspot.com/2011/05/ministry-of-education-quietly-released.html>

<sup>27</sup> <http://www.nirs.org/reactorwatch/emergency/epwitrpt2003.pdf>

<sup>28</sup> See, for example, Figure 1.1 of the FRPCC analysis

Scenario 1 ignores the possibility (discussed above) that communication failures, a more rapidly developing radiation release than anticipated, or other problems could severely hinder any ordered evacuation. KI must be taken within a few hours of exposure to be most effective. Thus, if a radioactive plume moves more quickly than an evacuation for any reason, the exposed populations will not gain the same benefit from simply taking the medication later if they do not have access to it at the time at which they are exposed.

Scenario 2 assumes that it is possible that a release of radioactive iodine severe enough to require the administration of KI could occur but that an evacuation would not also be ordered. Since KI does not protect against the effects of any radioisotopes other than radioactive iodine, and since a release of radioactive iodine would likely be accompanied by a release of other dangerous radionuclides, this scenario seems somewhat unlikely.

Our belief is that neither of the scenarios contemplated in the FRPCC analysis is the one that should have been analyzed. Rather, we believe it should have analyzed the scenario assumed throughout the 2004 National Academy of Sciences (NAS) report *'Distribution and Administration of Potassium Iodide in the Event of a Nuclear Incident'* that "the need for administration of KI is necessary only once to protect the thyroid gland against inhalation of radioiodine from a passing plume (cloud) and that further protection from radioiodine will be accomplished by evacuation and control of contaminated milk and other foods."

In other words, people at risk of exposure to radioactive iodine could be directed to take KI as they evacuated, not as a substitute for evacuation. We believe the Marburger decision failed to analyze the benefits associated with this most rational scenario for KI use.

##### **5. The Nuclear Regulatory Commission staff supports pre-distribution of KI – at least to themselves**

NRC staff members who were sent to Japan to assist with the response efforts were all given KI in case it was needed, even though the majority of them were not expected to get closer to the stricken reactors than Tokyo<sup>29</sup>. The decision to pre-distribute KI to these individuals was a prudent measure, since it was unclear at the time how severe the radiation releases could get. The same logic should be applied to protective measures for residents surrounding nuclear power plants in this country.

In its October 3 paper number SECY-11-0137 entitled "Prioritization Of Recommended Actions To Be Taken In Response To Fukushima Lessons Learned," NRC staff

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<sup>29</sup> See for example page 91- 95 of <http://pbadupws.nrc.gov/docs/ML1124/ML11244A167.pdf> According to private communications between Congressman Markey's staff and NRC staff, a small number of the roughly two-dozen U.S. NRC personnel deployed to Japan since the earthquake did leave Tokyo. One toured a staging area 12 miles away from the reactor in early April, and subsequently took van tours to the Fukushima site in both early May and mid-July. This individual spent about 10 minutes inside the undamaged units 5 and 6 reactors. Another two individuals also toured the staging area 12 miles away in mid-June and took a van tour of the Fukushima site, but did not leave the vehicle they were in. These three individuals wore full protective gear, including respirators, during their tours.

recommended to the NRC Commissioners that “pre-staging of potassium iodide beyond 10 miles” be added to the list of potential regulatory changes being considered for the future.

While we believe the 2002 law already requires such pre-staging, we nevertheless commend the NRC staff for their recognition that the current 10 mile distribution zone may not be sufficient when confronted with Fukushima-scale radiation releases and Fukushima-caliber evacuation and communications challenges.

**6. Many scientific and public health experts believe KI should be more widely distributed**

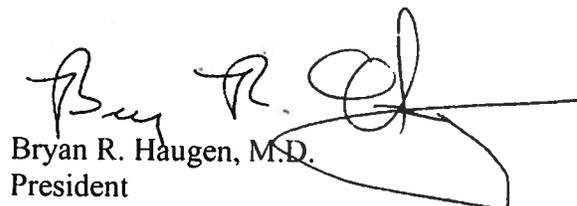
Section 127 of the 2002 Bioterrorism law required a study by the National Academy of Sciences on the use of potassium iodide. In 2004, its report, *Distribution and Administration of Potassium Iodide in the Event of a Nuclear Incident*, concluded that “KI should be available to everyone at risk of significant health consequences from accumulation of radioiodine in the thyroid in the event of a radiological incident... To be most effective, KI must be taken within a few hours before or after exposure to inhaled or ingested radioiodine... KI distribution should be included in the planning for comprehensive radiological incident response programs for nuclear power plants. KI distribution programs should consider pre-distribution, local stockpiling outside the emergency planning zone (EPZ), and national stockpiles and distribution capacity.”

The American Thyroid Association (ATA), the leading worldwide organization dedicated to the advancement, understanding, prevention, diagnosis and treatment of thyroid disorders and thyroid cancer recommends the pre-distribution of KI to residents located within 50 miles of a nuclear reactor<sup>30</sup>.

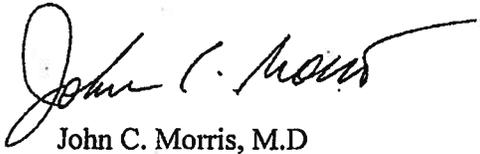
We believe that the decision made by your predecessor to assert that the wider distribution of potassium iodide directed in Section 127 of the Bioterrorism Act is not needed because evacuation and contaminated food interdiction are more effective at mitigating the potential health effects associated with exposure to radioactive iodine was based on flawed science and assumptions that have been shown by the events of Fukushima to be highly unrealistic. To perpetuate this decision would require a willful effort to ignore the lessons that should be learned from the Japanese catastrophe. We urge you in the strongest possible terms to overturn it.

Sincerely,

  
Edward J. Markey  
Member of Congress

  
Bryan R. Haugen, M.D.  
President  
American Thyroid Association

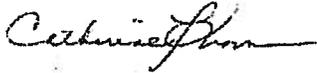
<sup>30</sup> [http://www.thyroid.org/professionals/advocacy/documents/2011\\_03\\_30\\_ATA\\_Kloos\\_Holdren.pdf](http://www.thyroid.org/professionals/advocacy/documents/2011_03_30_ATA_Kloos_Holdren.pdf)



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