September 25, 2007

Dear Dr. Marburger:

The following comments are submitted on behalf of national, state and local public interest groups urging implementation of the Bioterrorism Act’s Section 127 – stockpiling KI out to 20 miles from a reactor site.

The nuclear industry, the Nuclear Regulatory Commission and the Administration have attempted to block the pre-distribution of Potassium Iodide (KI) out to 20 miles from a reactor site. We implore you to place the public’s interest first in this matter and support the implementation of the Bioterrorism Act’s Section 127.

We understand and deeply regret that President Bush has moved to nullify Section 127 of the 2002 Bioterrorism Act law that would have improved protection for the public in case of nuclear terrorism. The Nuclear Regulatory Commission and the nuclear power industry fought the legislation; however it passed almost unanimously and was signed into law by the president. The White House hailed the result, declaring that henceforth, this "crucial" drug would be available where needed in an emergency.

More than five years after the law's passage, however, the broader distribution of KI has yet to take place due to the NRC’s adroit maneuvers. The Department of Health and Human Services, with initial authority over the statute, tried to make the bill a reality; however, it was frustrated at every turn by the NRC, working behind the scenes with the White House staff. Please note that the NRC Staff involved in blocking this is not medical doctors.

The NRC's argument against the guidelines was based on a provision of the statute that permits the president to forgo expanded KI stockpiling if he identifies a more effective alternative means of thyroid protection. The NRC contends that this allows the president to decide that neither KI
nor any other protective measure is needed - a legally frivolous claim, that is contradicted by our top medical professionals, and a slap in the face to Congress and American citizens.

President Bush signed an order stripping HHS of its responsibilities for KI under the law and transferring them to the NRC. The White House retained the authority to decide whether KI was needed. The NRC is reportedly drafting that decision.

One of the Lessons from Katrina is that we must be prepared and have a plan. The government’s response to it has become a major embarrassment to the Administration and the nation, and a tragedy for its citizens. We are all aware that accidents can happen due to mechanical failure, human error or acts of malice, and that the government’s response may not be adequate or timely. It is, therefore, imperative that we continue to follow the recommendation of our health experts and prioritize the safety of our children with the most proactive means we have available to us. We must anticipate the need and be prepared by distributing KI into the hands of parents and caregivers. We must stockpile KI in institutions such as schools, groups homes, and nursing facilities without hesitation as a precautionary measure to be used, if deemed appropriate, in the context of a nuclear accident or act of malice.

In an accident radioactive iodine will be released; be absorbed by the human thyroid; and in sufficient quantity cause thyroid cancer, thyroid disease and/or growth disorders in those exposed – especially the unborn and children, our most important and vulnerable citizens. This can be prevented by taking a potassium iodide tablet - an over-the-counter FDA approved and recommended substance – before or shortly after exposure. Because it is time dependent, it must be stockpiled and in place.

There is a need to stockpile KI beyond 10-miles, as appreciated by Congress and ironically by NRC in their very own studies.

1. Federal studies indicate that the consequences of an accident can spread well beyond 10-miles. Calculation of Reactor Accident Consequences U.S. Nuclear Power Plants (CRAC-II), Sandia National Laboratory, 1982 states: The consequences of a core melt at Pilgrim NPS, for example, would result in a 20 miles peak 1st year fatal radius; a 65 miles peak 1st year injury radius; and 23,000 peak cancer deaths.
These estimates are conservative. The federal study, CRAC II (colon deleted) used census data from 1970; assumed the entire 10-mile EPZ would be evacuated within at most six hours after the issuance order; assumed aggressive medical treatment for all victims of acute radiation exposure in developing numbers for early fatalities and used a now obsolete correlation between radiation dose and cancer risk that underestimated the risk by a factor of 4 relative to current models; sampled only 100 weather sequences out of over eight thousand (an entire year’s worth), a method that underestimates the peak value over the course of a year by 30%.

2. NRC’s site specific consequence plume models are inaccurate because they use a steady-state straight-line Gaussian plume distribution model when instead variable trajectory models are needed due to the complexity of winds at reactor sites resulting from the sea-breeze or lake effect and wind variability resulting from hills, river valleys, and building clusters. Use of the appropriate variable trajectory models would demonstrate that plumes and consequences extend further than currently projected, thereby justifying KI distribution beyond 10 miles.

3. The reason to provide KI in the 10-20 mile zone is because of the possibility of inhalation during an accident of significant consequence. For example, Dr. Temeck (FDA representative to NRC’s KI Core Group Meeting, Tempe Arizona, March 4, 1999) stated that exposure to children after Chernobyl resulted from “a combination of inhalation and ingestion.”

4. NRC’s NUREG-1633 points out that radioactive iodide can travel hundreds of miles on the winds. An increase in cancer caused by Chernobyl was detected in Belarus, Russia and Ukraine. Notably, this increase, seen in areas more than 150 miles from the site, continues to this day and primarily affects children who were 0-14 years old at the time of the accident…the vast majority of the thyroid cancers were diagnosed among those living more than 31 miles from the site. The 2001 figures showed 11,000 thyroid cancers at 31 miles. Again, “Exposure to children after Chernobyl resulted from “a combination of inhalation and ingestion.”

5. NRC’s NUREG/CR 1433 said that for children, the following dangers might occur from the inhalation of nuclear materials after a massive core-melt atmospheric accident (like Chernobyl):
Approximate Dangers of a Core-Melt Atmospheric Accident for Children

<table>
<thead>
<tr>
<th>Distance in Miles</th>
<th>Mean Thyroid Dose (rem) for Exposed Children Outdoors*</th>
<th>Probability of Thyroid Damage to Exposed Children Located Outdoors if not Protected by Stable Iodine (like KI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>26,000</td>
<td>100%</td>
</tr>
<tr>
<td>5</td>
<td>11,600</td>
<td>100%</td>
</tr>
<tr>
<td>10</td>
<td>6,400</td>
<td>100%</td>
</tr>
<tr>
<td>25</td>
<td>2,200</td>
<td>80%</td>
</tr>
<tr>
<td>50</td>
<td>760</td>
<td>26%</td>
</tr>
<tr>
<td>100</td>
<td>200</td>
<td>7%</td>
</tr>
<tr>
<td>150</td>
<td>72</td>
<td>2%</td>
</tr>
<tr>
<td>200</td>
<td>32</td>
<td>1%</td>
</tr>
</tbody>
</table>

6. Terrorism: The Guidance is part and parcel of the Bioterrorism Act. Nuclear reactors are known terrorist targets. The Administration owes our citizens better preparation; and stockpiling KI is an important step.

Stockpiling KI is endorsed by health professionals across the nation and world.

KI is recommended, for example, by: U.S. Food and Drug Administration; World Health Organization; American Thyroid Association; American Academy of Pediatrics; International Agency Atomic Scientists; National Academy of Sciences; National Council on Radiation Protection; Federation of American Physics; Physicians for Social Responsibility; Union of Concerned Scientists; and locally for example the Massachusetts Medical Society (MMS) July 22, 2002 adopted a policy which calls for providing thyroid-blocking agents to all Massachusetts communities for protection against radioiodine. Further we know that nations around the world have routinely stockpiled potassium iodide for many years.

Stockpiling KI is not difficult to implement.

Is stockpiling and distributing KI really all that difficult? No. Each state has an emergency management structure already in place – from the state down to the local community. Some states and some local communities have existing KI Plans and Procedures out to 10 miles; it is not difficult to extend the plan an additional 10 miles. The Commonwealth of Massachusetts already passed legislation to stockpile communities on Cape Cod, the Islands and Cape Ann – located outside the 10-mile Emergency Planning Zones of Pilgrim NPS and Seabrook NPS.
States already provide KI to emergency workers and institutionalized populations—so a procedure is already in effect that triggers who shall make the “official” call to administer KI, when and how.

Schools and other institutions have medical release forms that permit administering medication to minors in the absence of a guardian/parent. They simply have to add KI to that permission form. A master list can be created of the names of public school children at the same time the medical permission form is completed and a procedure established to obtain consent from non-public school minors. Files can be kept up-to-date and ready to transfer to shelters and Reception Centers, if needed.

It is not difficult to determine where to stockpile: schools, shelters, correctional facilities, group homes, Reception Centers, other institutions and finally, to provide a stockpile for citizen’s personal use and for workers at their place of work. The stockpile for personal use can be kept at the local Fire Station, for example. It is open 24-hours a day. The workplace stockpile can be sent, quite obviously, to the place of work.

Public education is the key to any public health program. We all agree it is work that must be done in a healthy society for the benefit of all. While others have lost the will to stay on course, we continue to have the will to implement this critical section on our behalf.

The NRC is the wrong agency for Office of Science and Technology Policy to go to for advice:

The NRC opposed the enactment of Section 127; NRC staff consistently has opposed stockpiling potassium iodide going back decades; and worse NRC staff has provided misinformation to another Government agency and to the public on the subject of potassium iodide (KI). This is the reason why Congress in the Bioterrorism Act directed authority to the National Academy of Sciences and to HHS for assessment and implementation and not to NRC.

For example: On November 1, 2005, William F. Kane, Deputy Executive Director for Reactor and Preparedness Programs, sent a letter to Dr. Robert Claypool of the Department of Health and Human Services. It seriously distorted the findings of the report on KI issued in 2004 by the National Research Council of the National Academies of Science (NAS).
The essence of the NRC letter to HHS was that in the event of a radiological emergency that releases radioiodines, the only pathway of concern beyond the 10-mile radius is the ingestion pathway, that this can be addressed by testing and interdiction of milk and other foods, and that distribution of KI beyond the 10-mile radius is therefore unnecessary. The NRC letter claims to base its conclusions on the NAS report, and even declares that "the Academy raised questions about the usefulness of expanded distribution of KI."

The NRC letter quoted with approval one sentence from the NAS report, from page 159, while omitting the four preceding sentences, which were essential if the meaning of the quoted sentence was to be understood correctly. NRC’s letter quoted simply,

"KI is also effective for protection against the harmful thyroid effects of radioiodine ingested in contaminated milk and other food, but food testing and interdiction programs in place throughout the United States are more effective preventive strategies for ingestion pathways."

The four preceding sentences in the NAS report that NRC artfully omitted read,

"In the event of nuclear accidents or as a result of nuclear terrorism, radioiodine could be released to the environment. Because iodine concentrates in the thyroid gland, exposure to radioiodine by inhalation of contaminated air or ingestion of contaminated milk and other foods can lead to radiation injury to the thyroid, including risk of thyroid cancer and other thyroid diseases. Thyroid radiation exposure from radioiodine can be limited by taking stable iodine. KI is a chemical compound that contains iodine and can be used to protect the thyroid gland from possible radiation injury by reducing the amount of radioiodine concentrated by the thyroid after inhalation of radioiodine."

Far from having "raised questions regarding the usefulness of expanded distribution of KI," as the NRC letter claims, the NAS report made clear that depending on site-specific factors, KI might be desirable beyond the 10-mile EPZ, since the 10-mile radius does not necessarily correspond to the actual risk presented. See Recommendation 2, from p. 160, of the section on "Benefits of and Risks Posed by Potassium Iodide Distribution":

"..."
"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." [Boldface in the original.]

And, from p. 161 of the NAS report, is its conclusion on "Implementation Issues Related to Potassium Iodide Distribution and Stockpile Programs":

“Conclusion: A strategy is needed whereby local planning agencies could develop geographic boundaries for a KI distribution plan based on site-specific considerations because conditions and states vary so much that no single best solution exists. [Boldface in the original.] KI distribution planning in the United States has focused on the Nuclear Regulatory Commission's early-phase Emergency Planning Zone (EPZ) of a 10-mile radius. However, the EPZ provides only a basis for planning. A specific incident might call for protective actions to be restricted to a small part of the EPZ or require that they be implemented beyond the EPZ as well. See Chapters 5 and 7 for details."

By saying "no single best solution exists," the NAS report is stating, in unmistakable terms, that applying the standard 10-mile radius to all situations is inappropriate. But the NRC letter strives to give exactly the opposite impression.

Similar NRC deception is shown in the use of the quotation from page 81 of the NAS report. (This is the passage in the letter beginning with “Exposure to radioactive iodine is possible through the ingestion pathway..." and ending with "... “That also eliminates the need for the use of KI by the general public as a protective action.”) The last sentence of the quoted passage sounds dispositive indeed, but what the NRC letter neglects to mention is that this is from a section of the report, beginning on p. 79, that is entitled "Intermediate Phase Planning," and refers only to the period after the plume has passed, when inhalation is no longer an issue.

This sort of game-playing with words on an issue affecting the health and safety of American children, has been repeated time again by Patricia Milligan, Senior Advisor for Emergency
Preparedness, US Nuclear Regulatory, at stakeholder meetings on emergency planning and most recently at public hearings on re-licensing in Plymouth, Massachusetts.

This deception goes back a long way. For example, at a public meeting on November 5, 1997, a senior NRC staff official apologized to FEMA officials for having "misrepresented" FEMA's position on KI.

It will likewise be recalled that the NRC Commissioners, after authorizing publication of "NUREG-1633," a staff analysis of KI, in the summer of 1998, ordered it withdrawn from circulation after scathing comments from state health officials alerted the Commissioners to its numerous misstatements and distortions. This NRC document, 40 pages long, managed not to mention the FDA’s finding that KI was "safe and effective." The staff twice attempted to secure Commission approval of a revised version of the document, and twice failed, after which the Commissioners ordered work on the document to stop.

No doubt those Commissioners who were around at the time also recall that the Commission was forced to apologize to a Member of Congress for having supplied him with an inflated number for the cost of a nationwide KI program. Supposedly it was an honest mistake of multiplication, though it is baffling that anyone who succeeded in completing elementary school could have multiplied 70 (the number of nuclear sites) by 80,000 (the average number of residents in the EPZ) by $.50 (the estimated cost of two KI pills) and come up with a figure of $3,250,000.

The foregoing is not a complete list of NRC’s deceptions.

**Summary:** Dr. Marburger, we urge you not to allow President Bush to flip-flop on this and instead to stick to his initial decision supporting distribution out to 20 miles; this follows the mandate of Congress and advice of America’s top scientists, medical professionals and interests of the American public.

Sincerely,

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