EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20502

July 23, 2010

Mr. Jeff Duncan
Chief of Staff
Congressman Edward Markey
United States House of Representatives
2108 Rayburn House Office Building
Washington, D.C. 20515-2107

Re: Implementation of the waiver provision of section 127(f) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Dear Mr. Duncan:

You requested information from the Office of Science and Technology Policy ("OSTP") regarding the proper interpretation and implementation of section 127(f) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, § 127, 116 Stat. 594, 615 (codified at 42 U.S.C. § 247d-6b). In 2008, OSTP undertook a careful legal analysis of that waiver provision in consultation with the Department of Justice and concluded that its intended implementation of that section was based on a permissible interpretation of the statute. Specifically, OSTP concluded that: (1) OSTP did not need to identify "alternative and more effective prophylaxis or preventive measures" that were not available at the time of enactment; (2) section 127(f) did not require that the "alternative and more effective prophylaxis or preventive measures" be medical or pharmaceutical in nature; and, (3) OSTP's definition of "more effective" satisfied the statutory requirements of section 127(f). We have recently reviewed those legal conclusions in consultation with the Department of Justice and believe that they remain sound.

BACKGROUND ON SECTION 127(F)

Section 127(a) states that the President shall make potassium iodide ("KI") tablets available to state and local governments for stockpiling and for distribution as appropriate and in quantities sufficient to provide adequate protection for the population within 20 miles of a nuclear power plant. Pub. L. No. 107-188, § 127(a). Subsection (d) directs the President to inform state and local governments of that program. *See id.* § 127(d). Section 127(f) authorizes the President to waive the requirements of subsections (a) and (d) upon a determination that "there is an alternative and more effective prophylaxis or preventive measures for adverse thyroid conditions that may result from the release of radionuclides from nuclear power plants." *Id.* § 127(f).

President Bush delegated his authority to make the section 127(f) waiver determination to the Director of OSTP. *See* Memorandum on Assignment of Certain Functions Relating to Nuclear Energy Facilities, 43 Weekly Comp. Pres. Doc. 910 (July 3, 2007).

LEGAL ANALYSIS

OSTP'S INTERPRETATION AND IMPLEMENTATION OF SECTION 127(F)'S WAIVER PROVISION

1. **OSTP does not need to identify "alternative and more effective prophylaxis or preventive measures" that were not available at the time of enactment in 2002.**

Section 127(f) provides that the provisions requiring the President to make KI tablets available for stockpiling and to inform state and local governments of the program "cease to apply . . . if the President determines that there is an alternative and more effective prophylaxis or preventive measures for adverse thyroid conditions that may result from the release of radionuclides from nuclear power plants." Pub. L. No. 107-188, § 127(f). "Prophylaxis" is defined as "measures necessary to preserve health and prevent the spread of disease: protective, preservative, or preventive treatment." Webster's Third New International Dictionary 181 (1993). "Preventive," means "making or aiming to make unlikely or impossible: devoted to or concerned with prevention." *Id.* at 1798. The plain terms of section 127(f) thus permit OSTP to waive subsections (a) and (d) if it determines that there is an "alternative" to KI that is "more effective" at "preserv[ing] health and prevent[ing] the spread of" or "making or aiming to make unlikely or impossible" "adverse thyroid conditions that may result from the release of radionuclides from nuclear power plants."

Based on these provisions, OSTP concluded that section 127(f) does not require that the "alternative and more effective prophylaxis or preventive measures" be ones developed after the provision's enactment. Nothing in the language of the provision suggests such a limitation. The statute establishes no minimum period before a determination can be made, suggesting that the waiver determination could be made soon after enactment based on then-existing alternatives. The language of the provision, which requires a determination whether "there *is* an alternative and more effective prophylaxis or preventive measures," focuses on the alternatives available at the time the decision is made, and says nothing about alternatives available at the time of enactment. Nothing in the legislative history suggests such a limitation.

For these reasons, OSTP does not need to identify "alternative and more effective prophylaxis or preventive measures" not available at the time of enactment in 2002.

2. **Section 127(f) does not require that the "alternative and more effective prophylaxis or preventive measures" be medical or pharmaceutical in nature.**

The President is authorized under section 127(f) to invoke the waiver upon a determination that "there is an alternative and more effective prophylaxis or preventive measures for adverse thyroid conditions that may result from the release of radionuclides from nuclear power plants."

Although the term 'prophylaxis' ordinarily may be understood to denote medical measures or treatment, it does not appear to be limited exclusively to that meaning. Rather, it also may be understood to include non-medical preventive measures. *See, e.g.*, I.R. Reid et al., 'Prophylaxis Against Vitamin D Deficiency in the Elderly by Regular Sunlight Exposure,' 15 Age & Aging 35 (1986) (concluding that '30 minutes spent outdoors each day . . . provides a safe and inexpensive method for the prevention of osteomalacia in frail elderly subjects'); Edwin O. Jordan, *A Textbook of General Bacteriology* 377 (6th ed. 1918) (identifying "avoidance of . . . infected vermin" as a "[p]rophylaxis" against typhus); *cf.* 3 International Dictionary of Medicine and Biology 2315-16 (1986) (noting that '[t]hough [the term 'prophylaxis' is] often used as synonymous with *preventive*, it has been suggested that *prophylaxis* be applied to substances and *preventive* to actions').

This reading of the word "prophylaxis" draws some support from the fact that in other contexts, Congress has referred specifically to "medical" or "pharmaceutical" prophylaxis where that narrower meaning is intended. *See, e.g.*, 50 U.S.C. § 1523(a)(2) (2000) (requiring Secretary of Defense to include description of "requirements for . . . medical prophylaxis" in annual report on chemical and biological warfare defense); 22 U.S.C. § 7631(e) (Supp. V 2005) (authorizing funding for "post-exposure pharmaceutical prophylaxis" related to HIV/AIDS); *cf.* 7 U.S.C. § 8401(a)(1)(B)(i)(III) (Supp. V 2005) (requiring Secretary of Agriculture to consider the "availability and effectiveness of pharmacotherapies and prophylaxis" to counteract certain biological agents or toxins)." Because Congress did not use such a qualifier here, OSTP concluded that it did not intend to limit "prophylaxis" in section 127(f) to medical measures.

Even if "prophylaxis" were understood to be limited to medical measures, the statute also allows the waiver determination to be made based on the presence of alternative and more effective "preventive measures." "Preventive measures" is different from "prophylaxis." In light of the ordinary meaning of "preventive," the statute only requires that OSTP determine if there is a measure or measures that that "mak[es]" or aim[s]" to make adverse thyroid conditions "unlikely or impossible" in the wake of the release of radionuclides from a nuclear power plant. Webster's Third New International Dictionary at 1798. Because each term in a statute should be given independent meaning, if possible, "preventive measures" can be reasonably interpreted to encompass measures other than "prophylaxis." *See Duncan v. Walker*, 533 U.S. 167, 174 (2001) ("It is our duty to give effect, if possible, to every clause and word of a statute. We are thus reluctan[t] to treat statutory terms as surplusage in any setting.") (internal quotation marks and citations omitted, brackets in original). Further, "preventive measures" commonly encompass

non-medical procedures undertaken to reduce the risk of injuries or disease. *See, e.g.*, *The Merck Manual of Medical Information* 27 (2d home edition; Mark H. Beers, M.D., ed., 2003) (listing the following as "Preventative Measures" to reduce the risk of the following conditions: diet and exercise as "Preventative Measures" for "heart disease"; avoidance of smoking and eating low-fat, high-fiber diets for cancer; avoidance of smoking, diet and exercise for stroke; exercise and diet for diabetes; drinking alcohol in moderation to avoid liver disease; and wearing a seatbelt to avoid injuries in automobile accidents). Measures to avoid exposure to disease-causing agents are squarely within the ordinary meaning of "preventive measures." *See id.*; *see also* Yvonne Geissbühler et al., *Interdependence of domestic malaria prevention measures and mosquito-human interactions in urban Dar es Salaam, Tanzania*, 6 MALARIA J. 126 (2007) (describing "bed nets and insecticides" as "preventive measures" for malaria), *available at* http://www.malariajournal.com/content/6/1/126.

Finally, OSTP determined that reading the statute to encompass non-medical measures was supported by the Act's legislative history. The original House of Representatives bill specifically stated that the waiver authority would apply only if an alternative and more effective "*medical* treatment" was available. H.R. 3448, 107th Cong. (as introduced in House, Dec. 11, 2001) (emphasis added). However, the Senate version of the bill omitted a KI program provision entirely, and the broader language in the passed Act was adopted in conference. Although the conference report offers no explanation for the change, it is consistent with the conclusion that Congress deliberately rejected a strictly "medical" formulation in favor of a broader category of "prophylaxis or preventive measures" that could support a waiver determination.

For these reasons, OSTP concluded that the "prophylaxis and preventive measures" undertaken pursuant to section 127(f) are not required to be "medical or pharmaceutical in nature."

3. The definition of "more effective" adopted by OSTP satisfies section 127(f).

OSTP noted that section 127(f) conditions waiver authority on the determination that there is an 'alternative and more *effective* prophylaxis or preventive measures for adverse thyroid conditions that may result from the release of radionuclides from nuclear power plants.' A measure is "effective" if it is "capable of bringing about an effect: productive of results." Webster's Third New International Dictionary at 724. Thus, a measure is "more effective" under section 127(f) if it is more "capable" than KI of producing the desired result of reducing adverse thyroid conditions that may result from the release of radionuclides from nuclear power plants.

In late 2007, OSTP defined a prophylaxis or preventive measure as being more effective if it was (1) "expected to result in an averted thyroid dose of radioiodine . . . *greater* than that obtained by making potassium iodide available"; (2) likely to result in an averted thyroid dose equal to that of

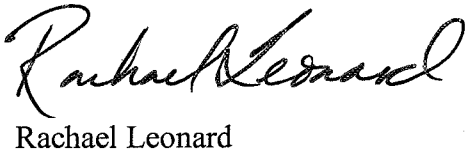
KI distribution, but is "more likely to be effectively used by [the target] population"; or (3) likely to result in an averted dose of radioiodine equal to that of KI distribution but "is likely to cause less harm." *See* Decision Memorandum from John H. Marburger, III, *Re: Decision on Delegation of Section 127(f) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002* at 5 (December 3, 2007) ("Decision Memorandum").

Insofar as a "greater" averted dose of radioiodine will reduce the "adverse thyroid conditions" that an individual will develop as compared to KI distribution, measures falling under the first category would clearly be "more effective" at producing section 127(f)'s intended result. Similarly, an equal reduction in radioiodine exposure delivered to a larger number of individuals under the second category would satisfy section 127(f) because it will reduce "adverse thyroid conditions" across the affected population more than KI.

Regarding the third category, measures that are likely to result in an averted dose of radioiodine equal to that of KI distribution but likely to cause less harm, also satisfy the requirements of section 127(f) insofar as the "harm" meant by OSTP would be sufficiently related to the "adverse thyroid conditions" addressed in section 127(f). That is, OSTP believes the better reading of the statute's provisions permit consideration of negative side-effects when determining if an alternative is more effective. For instance, if KI were found to have a fatal side effect in some populations, common usage would consider an alternative measure free of such a risk "more effective" in achieving the general goal of reducing adverse thyroid conditions. OSTP recognizes that consideration of harms unrelated to adverse thyroid conditions from released radionuclides in the waiver determination might give rise to challenges to its interpretation of "more effective measures." But it did not rely on such harms in making its waiver determination, because the measures OSTP considered (evacuation and interdiction of contaminated food) fell within the first category of more effective measures.

For these reasons, OSTP's definition of "more effective measures" satisfies the requirements of section 127(f) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and is a permissible interpretation of that provision.

Sincerely,



Rachael Leonard
General Counsel