

ONE HUNDRED FOURTEENTH CONGRESS
Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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June 12, 2015

The Honorable Howard Shelanski, J.D., Ph.D.
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

The Honorable Stephen Ostroff, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Dear Administrator Shelanski and Commissioner Ostroff:

We commend the Food and Drug Administration (FDA) for its review of the risks associated with indoor tanning beds, which confirms that sunlamp products are not being properly regulated to protect the public health.

As you know, the March 2010 General and Plastic Surgery Devices Advisory Panel recommended an age restriction for indoor tanning. The experts on that panel concluded unanimously that the current classification of tanning beds as Class I medical devices — a category of devices that also includes band-aids and tongue depressors — was insufficient to address the dangers they present. The panel also recommended enhanced education, training, and testing of tanning bed operators and improved labeling of tanning beds. Some 42 states now regulate indoor tanning for minors, including 11 that ban the use of ultraviolet (UV) tanning devices by anyone under the age of 18.¹ In our own

¹ National Conference of State Legislatures, *Indoor Tanning Restrictions for Minors - A State-by-State Comparison* (online at <http://www.ncsl.org/research/health/indoor-tanning-restrictions.aspx#Tanning>) (updated March 2015)

respective home states, New Jersey prohibits those under 17 from using tanning beds² and Michigan requires in-person parental consent for a minor's use of a tanning device.³

The public health risks associated with tanning beds are well documented and significant. A study in *JAMA Dermatology* found that in the United States there are almost 420,000 cases of skin cancer attributable to indoor tanning, of which more than 6,000 cases are melanoma. Young people may be especially vulnerable to cancer risk associated with tanning bed use. Results from a recent study in *Pediatrics* suggest that early exposure to indoor tanning increases the risk of developing melanoma at a young age.

We note that the Office of Information and Regulatory Affairs (OIRA) Unified Agenda lists two proposed rules with action dates of March 2015. One would apply additional device restrictions to sunlamp products (RIN 0910-AH14⁴) and the other would update the performance standard for sunlamp products (RIN 0910-AG30⁵). These rules will be a critical step to improve safety, better reflect new scientific information, and correspond with international standards.

We urge OIRA to publish these proposed rules immediately. Any further delay is not in the interest of the public health.

Thank you for considering our views.

Sincerely,



Fred Upton
Chairman



Frank Pallone, Jr.
Ranking Member

² *Id.*

³ Section 333.13405 of Act 368 of Michigan Public Health Code (online at [http://www.legislature.mi.gov/\(S\(sfx0mskqb3hhmlogcpfmodi3\)\)/mileg.aspx?page=getObject&objectName=mcl-333-13405](http://www.legislature.mi.gov/(S(sfx0mskqb3hhmlogcpfmodi3))/mileg.aspx?page=getObject&objectName=mcl-333-13405)).

⁴ Office of Information and Regulatory Affairs, Office of Management and Budget, Executive Office of the President, *General and Plastic Surgery Devices: Sunlamp Products* (online at <http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201410&RIN=0910-AH14>) (2014).

⁵ Office of Information and Regulatory Affairs, Office of Management and Budget, Executive Office of the President, *Sunlamp Products; Proposed Amendment to the Performance Standard* (online at <http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201410&RIN=0910-AG30>) (2014).