AGENDA ITEM 8C
April 12, 2016
Action

MEMORANDUM

April 8, 2016

TO: County Council

FROM: Amanda Mihill, Legislative Attorney

SUBJECT: **Action:** Bill 5-16, Tanning Facilities – Amendments

Health and Human Services Committee recommendation (3-0): enact Bill 5-16 with an amendment to modify the definition of "tanning facilities" to make it consistent with state law and other technical amendments. The Committee recommended that the Council adopt a Board of Health regulation that would mirror Bill 5-16.

Bill 5-16, Tanning Facilities - Amendments, sponsored by Lead Sponsor Councilmember Hucker, and Co-Sponsors Council President Nancy Floreen, Councilmembers Leventhal, Katz, Navarro, and Rice, Council Vice-President Berliner, and Councilmembers Riemer and Elrich was introduced on March 1, 2016. A public hearing was held on March 22 at which several speakers, including Dr. Tillman on behalf of the County Executive, supported Bill 5-16. A Health and Human Services Committee worksession was held on April 4.

Bill 5-16 would prohibit minors from using indoor tanning devices; require tanning facilities and customers to adhere to certain duties; and require tanning facilities to provide certain warning statements and post certain signs.

Background

Health concerns associated with tanning devices According to the Centers for Disease Control and Prevention (CDC), there are several dangers associated with indoor tanning. These include increased risk of skin cancer, premature skin aging, and eye diseases (if eye protection is not used). Although these risks can affect people of all ages, the CDC notes that indoor tanning is particularly dangerous for young users and states that people who begin using tanning devices during adolescence or early adulthood have a higher risk of getting melanoma, which is the deadliest type of skin cancer. (See the Surgeon General's call to Action to Prevent Skin Cancer on ©15-20 and the CDC fact sheet on ©21-23. See also an "Evaluation of Indoor Tanning Health Claims" prepared for the New York State Office of the Attorney General on ©24-61.)

Federal law Federal law regulates tanning devices as "sunlamp products" and Bill 5-16 is consistent with existing federal regulations. Council staff notes, that the Food and Drug Administration recently proposed two new relevant rules. One regulation requires sunlamp manufactures and tanning facilities to take additional safety measures, some of which are similar to Bill 5-16. The second regulation would prohibit minors from using sunlamp products. See ©62-63 for an FDA News Release that summarizes these two proposed rules. The comment period for these proposed rules closed on March 21. It is unclear when (or if) the FDA will issue a final rule or what that final rule may require or prohibit.

State law Maryland does not comprehensively regulate the use of tanning facilities or tanning devices. Section 20-106 of the Health-General Article of the Maryland Code prohibits minors from using tanning devices unless the minor's parent or legal guardian provides written consent (©80-82).

Action in other jurisdictions According to the National Conference of State Legislatures, 12 states and the District of Columbia ban the use of tanning beds for minors. Many other states regulate the use of tanning devices by minors. See map on ©64. Since 2009, Howard County, Maryland prohibits minors from using tanning devices unless they have a written prescription from a physician.

Public Comments Received

At the public hearing, several individuals supported Bill 5-16. The Council has also received correspondence from residents supporting Bill 5-16. Select correspondence and testimony is on ©65-78.

The Council also received correspondence from Bruce Bereano on behalf of the Maryland Indoor Tanning Association opposing Bill 5-16 and arguing that Bill 5-16 is preempted by State law (©79).

Issues/Committee Recommendation

Preemption As noted above, Mr. Bereano argued that the County is preempted from banning minors from using tanning devices. House Bill 1358, which added §20-106 to the Health-General Article of the Maryland Code, included an uncodified provision that states that the Act "may not be construed to preempt a county or municipal government from enacting and enforcing more stringent measures to regulate the use of tanning devices by minors." Mr. Bereano argued that this language expressly permits minors to use a tanning device if their parent provides parental consent.

Council attorneys and the County Attorney disagree with Mr. Bereano's analysis. We do not believe that Bill 5-16 is preempted by State law. The purpose of the state law is to protect minors from the harmful effects of tanning devices. Because Bill 5-16 furthers this purpose, it does not conflict with the State law and is therefore not preempted. The case law cited in the County Attorney memorandum on ©88-90 supports this conclusion.

County Attorney amendments The County Attorney's Office proposed a number of technical amendments, of which the Committee recommended approval. Those amendments are included in the attached Committee bill. In addition, the Committee supported the County Attorney's Office recommendation that the County retain the existing definition of "tanning device" which mirrors the state definition. The existing definition is broader and easier to understand. See ©2, lines 12-21:

> [(4)] *Tanning device*[:
>
> a. Means any equipment that emits radiation used for tanning of the skin, such as a sunlamp, tanning booth, or tanning bed; and
>
> b. Includes any accompanying equipment, such as protective eyewear, timers, and handrails.] means equipment that emits [[electromagnetic]] radiation [[having wavelengths in the air between 200 and 400 nanometers and that is]] used for tanning of [[human]] the skin, such as a sunlamp, tanning booth, or tanning bed. *Tanning device* includes any accompanying equipment, including protective eyewear, timers, and handrails.

Other Committee comments The Committee was also concerned regarding outreach to the tanning facilities in the County. The Committee asked the Department of Health and Human Services to reach out to impacted facilities to ensure they are aware of the changes required by Bill 5-16. In addition, the Committee recommended that the Council adopt a Board of Health Regulation that mirrors Bill 5-16 to ensure that tanning facilities within municipalities are subject to the same requirements as other tanning facilities throughout the County. That Board of Health Regulation is scheduled to be introduced on April 12.

Bill No. 5-16
Concerning: Tanning Facilities – Amendments
Revised: 4/6/2016 Draft No. 4
Introduced: March 1, 2016
Expires: September 1, 2017
Enacted:
Executive:
Effective:
Sunset Date: None
Ch. _____, Laws of Mont. Co. _____

COUNTY COUNCIL
FOR MONTGOMERY COUNTY, MARYLAND

Lead Sponsor: Councilmember Hucker
Co-Sponsors: Council President Nancy Floreen, Councilmembers Leventhal, Katz, Navarro, and Rice, Council Vice-President Berliner, and Councilmembers Riemer and Elrich

AN ACT to:

(1) prohibit minors from using indoor tanning devices;
(2) require tanning facilities and customers to adhere to certain duties;
(3) require tanning facilities to provide certain warning statements and post certain signs; and
(4) generally amend the law regarding tanning facilities.

By amending and renumbering
Montgomery County Code
Chapter 51A, Tanning Facilities
Sections 51A-1, 51A-2, 51A-3, 51A-4, 51A-5, 51A-6, 51A-7, 51A-8, 51A-9, 51A-10, 51A-11, 51A-12, 51A-13, 51A-14, and 51A-15

Boldface	*Heading or defined term.*
Underlining	*Added to existing law by original bill.*
[Single boldface brackets]	*Deleted from existing law by original bill.*
Double underlining	*Added by amendment.*
[[Double boldface brackets]]	*Deleted from existing law or the bill by amendment.*
* * *	*Existing law unaffected by bill.*

The County Council for Montgomery County, Maryland approves the following Act:

Sec. 1. Chapter 51A is amended by amending and renumbering Sections 51A-1, 51A-2, 51A-3, 51A-4, 51A-5, 51A-6, 51A-7, 51A-8, 51A-9, 51A-10, 51A-11, 51A-12, 51A-13, 51A-14, and 51A-15:

51A-1. Definitions.

In this Chapter the following words have the meanings indicated:

[(1)] *Department* means the Department of Health and Human Services.

[(2)] *Director* means the Director of the Department of Health and Human Services or the Director's designee.

[(3)] *Tanning facility* means any place where a tanning device is used [for a fee, membership dues, or any other compensation] regardless of whether a fee is [[charge]] charged for access to the tanning device.

[(4)] *Tanning device*[:

a. Means any equipment that emits radiation used for tanning of the skin, such as a sunlamp, tanning booth, or tanning bed; and

b. Includes any accompanying equipment, such as protective eyewear, timers, and handrails.] means any equipment that emits [[electromagnetic]] radiation [[having wavelengths in the air between 200 and 400 nanometers and that is]] used for tanning of [[human]] the skin, such as a sunlamp, tanning booth, or tanning bed. *Tanning device* includes any accompanying equipment, including protective eyewear, timers, and handrails.

[51A-2. Scope.]

[This chapter does not apply to a licensed health care professional who uses a tanning device.]

[51A-4] 51A-2. License required.

(a) [It is unlawful for any person to] A person must not operate a tanning facility without a valid license issued by the [department] Department under this [chapter] Chapter.

(b) A license authorizes a person to operate a tanning facility only at the location identified in the license.

(c) A license issued under this [chapter] Chapter is not transferable. However, a new owner may continue to operate a tanning facility under the terms of the previous license if:

(1) [The] the new owner has applied for a license under this [chapter] Chapter; and

(2) [The] the license of the previous owner has not expired or been suspended or revoked.

[51A-5] 51A-3. Application for license.

(a) *In general.* A person who wants to operate a tanning facility must:

(1) [Submit] submit an application to the [department] Department on the form that the [department] Department requires; and

(2) [Pay] pay to the [department] Department a license fee in the amount that the [county executive] County Executive determines by regulation adopted under [method] Method (3).

(b) *Contents of form.* The application must include:

(1) [The] the name and address of the applicant;

(2) [The] the location and telephone number of the tanning facility for which the application is made;

(3) [The] the name, description and year of manufacture of each tanning device used by the tanning facility; and

(4) [Any] any other information that the [department] Department requires.

(c) *New equipment.* A person who operates a tanning facility must notify the [department] Department of the name, description, and year of manufacture of any new equipment it uses within [thirty (30)] 30 days after installing the new equipment for use.

[51A-6] 51A-4. Issuance of license; inspection.

(a) *Issuance.* The [department] Department must issue a license to any person who:

(1) [Submits] submits an application under [section 51A-5] Section [[51A-4]] 51A-3;

(2) [Pays] pays the license fee required under [section 51A-5] Section [[51A-4]] 51A-3; and

(3) [Meets] meets all other requirements of this [chapter] Chapter.

(b) *Inspection.* Before issuing a license [under this chapter], the [department] Department must inspect a tanning facility to determine whether it meets the requirements of this [chapter] Chapter.

[51A-7. License.]

[(a)] (c) *Contents of license.* A license must include:

(1) [The] the name of the licensee;

(2) [The] the location of the tanning facility for which the license is issued;

(3) [The] the date that the license expires; and

(4) [Any] any other information that the [department] Department requires.

[(b)] (d) *Term of license.* A license is valid for [one (1)] 1 year after its date of issuance.

[(c)] (e) *Display.* A licensee must display the license conspicuously in the tanning facility.

[51A-8. Renewal] 51A-5. License renewal.

(a) *Application.* A licensee may renew a license if, [thirty (30)] 30 days before the license expires, the licensee:

(1) [Submits] submits to the [department] Department a renewal application on the form that the [department] Department requires;

(2) [Pays] pays a renewal fee equal to the license fee established under [section 51A-5] Section [[51A-4]] 51A-3; and

(3) [Meets] meets all other requirements of this [chapter] Chapter.

(b) *Extension.* An existing license continues in effect until the [department] Department acts on the renewal application if:

(1) [The] the licensee meets the requirements of subsection (a); and

(2) [The] the existing license has not been suspended or revoked.

(c) *Term.* A license is valid for [one (1)] 1 year after its date of renewal.

[51A-11] 51A-6. Standard for tanning devices.

Any tanning device used by a tanning facility must meet performance standards based on applicable federal law and regulations for the protection of the public health as established by the [county executive] County Executive.

[51A-13] 51A-7. [Use requirements] Duties; prohibition of use by minors.

(a) *Tanning facility.* A tanning facility must:

(1) [Have] have a trained attendant on duty whenever the facility is open for business;

(2) [a.] (A) [Provide] provide each customer with protective eyewear that meets the standards for tanning devices established under this [chapter] Chapter; and

[b.] (B) [Not allow] prohibit a person [to use] from using a tanning device if that person does not use the protective eyewear.

(3) [Show] show each customer how to use suitable physical aids, such as handrails and markings on the floor, to maintain proper exposure distance as recommended by the manufacturer;

(4) [Limit] limit each customer to the maximum exposure time as recommended by the manufacturer;

(5) ensure that a timing device that is accurate [[with]] within 10% of any selected timer interval is used and is remotely located so customers cannot set their own exposure time;

(6) [Control] control the interior temperature of a tanning facility so that it does not exceed [the temperature that the county executive determines by regulation under method (3)] 100 degrees Fahrenheit;

(7) ensure that each tanning device is equipped with a mechanism that allows a customer to turn the tanning device off;

(8) prohibit a customer from using a tanning device in the facility more than once every 24 hours;

(9) sanitize each tanning device after each use;

(10) provide a written warning as required in Section [[51A-9]] 51A-8; and

(11) maintain records as required in Section [[51A-10]] 51A-9.

(b) *Customer.*

(1) Either each time a person uses a tanning facility, or each time a person executes or renews a contract to use a tanning facility, the person must sign a written statement that the person:

[a.] (A) [Has] has read and understood the warnings before using the device; and

[b.] (B) [Agrees] agrees to use the protective eyewear that the tanning facility provides.

(2) When using a tanning device, a person must use the protective eyewear that the tanning facility provides.

[(3) A person under the age of eighteen (18) must be accompanied by a parent or legal guardian when using a tanning device.]

(3) A person under the age of 18 must not use a tanning device.

[51A-12] 51A-8. Warnings.

(a) *Warning Statement.* A tanning facility must give each customer a written statement warning that:

(1) [The] the customer must use the protective eyewear that the tanning facility provides to avoid damage to the eyes;

(2) [Overexposure] overexposure causes burns;

(3) [Repeated] repeated exposure may cause premature aging of the skin and skin cancer;

(4) [Abnormal] abnormal skin sensitivity or burning may be caused by certain:

[a. Foods] (A) foods;

[b. Cosmetics] (B) cosmetics;

[c. Tranquilizers] (C) tranquilizers;

[d. Diuretics] (D) diuretics;

[e. Antibiotics] (E) antibiotics;

[f. High] (F) high blood pressure medicines; and

[g. Birth] (G) birth control pills; and

(5) Any person taking a prescription or over-the-counter drug should consult a physician before using a tanning device[.];

(6) it is a violation of County Code §51A-8 for a person under the age of 18 to use a tanning device.

(b) In the warning statement required under subsection (a), a tanning facility must tell its customers:

(1) [How] how much liability insurance it carries for the kinds of injuries listed in subsection (a); or

(2) [That] that it does not carry liability insurance for the kinds of injuries listed in subsection (a).

(c) *Warning Sign.* A tanning facility must post a warning sign in any area where a tanning device is used. The [county executive] Executive must determine the content and size of the warning sign by regulation under [method] Method (3). However, at a minimum, the sign must state that it is a violation of County Code §51A-13 for a person under the age of 18 to use a tanning device.

(d) A tanning facility must not claim, or distribute promotional materials that claim, that using a tanning device is safe or free from risk.

(e) The liability of a facility operator or a manufacturer of a tanning device is not changed by giving the warning under this [section] Section.

[51A-14] 51A-9. Injury report; records.

(a) *Injury report.*

(1) *Tanning facility.* A tanning facility must:

[a.] (A) [Report] report any injury, or any complaint of injury, to the [department] Department on the form that the [department] Department requires; and

[b.] (B) [Send] send a copy of the injury report to the person who is injured or complains of an injury.

(2) *Department.* The [department] Department must send to the [food and drug administration] Food and Drug Administration a report of all injuries in a tanning facility.

(b) *Records.* A tanning facility must keep a record of each customer's use of a tanning device. The [county executive] Executive must determine by regulation a reasonable length of time and the manner that records must be kept.

[51A-9] 51A-10. Right of entry.

The [department] Department may inspect any tanning facility whenever it is open to the public for business to determine whether the tanning facility meets the requirements of this [chapter] Chapter.

[51A-3] 51A-11. Administration; regulations.

The Department [of Health and Human Services is responsible for administering and enforcing] must administer and enforce this Chapter. The County Executive must issue regulations for administering this Chapter under [method] Method (2). These regulations should include standards for hygiene, injury reports, training of attendants, and the meaning of health care professional.

[51A-10] 51A-12. Enforcement.

(a) *Order to comply.* The [director] Director may order a licensee to comply with the provisions of this [chapter] Chapter. The [county attorney] County Attorney may file an action in any competent court to enforce an order under this [section] Section or to enjoin any violation of this [chapter] Chapter.

(b) *Denial, suspension, revocation.* The [department] Director may deny, suspend, or revoke a license under this [chapter] Chapter if the

[director] Director finds, after a hearing for which written notice has been given, that an applicant or licensee has:

(1) [Made] made a material false statement on an application for an initial or renewal license;

(2) [Obtained] obtained a license by fraud or deceit;

(3) [Failed] failed to conform to the provisions of this [chapter] Chapter;

(4) [Refused] refused lawful entry to any person authorized to enforce this [chapter] Chapter; or

(5) [Failed] failed to comply with an order under this [section] Section.

(c) *Summary closing.*

(1) The [director] Director may summarily suspend or revoke a license under this [chapter] Chapter if the [director] Director finds that the tanning facility presents an immediate threat to the public health or safety.

(2) If the [director] Director summarily suspends or revokes a license under this [section] Section, the [director] Director must:

[a.] (A) [Give] give the licensee written notice as soon as possible; and

[b.] (B) [Hold] hold a hearing within [forty-eight (48)] 48 hours after receiving a written request for a hearing from the licensee.

(d) *Reinstatement.* Any person whose license has been suspended or revoked under this [section] Section may apply to the [director] Director for reinstatement of the license. Upon receipt of an application for reinstatement, the [director] Director must inspect the tanning facility

and must reinstate the license if the tanning facility conforms to the provisions of this [chapter] Chapter.

(e) *Notice.* Notice to an applicant or licensee under this [section] Section is effective if:

(1) [Served] served personally on the applicant or licensee;

(2) [Mailed] mailed by certified mail to the applicant or licensee; [or]

(3) [Posted] posted on the door of the residence of the applicant or licensee[,]; or

(4) posted on the door of the tanning facility.

(f) *Appeal.* Any person aggrieved by a denial, suspension, or revocation under this [section] Section may file an appeal with the Montgomery County Board of Appeals within [ten (10)] 10 days after receipt of the denial, suspension, or revocation. An order to comply is not appealable under this subsection. The filing of an appeal does not stay an action under this [section] Section unless the action expressly provides for a stay upon appeal.

[51A-15. Penalty] 51A-13. Penalties.

[A person who does not comply with the provisions of this chapter or the regulations adopted under this chapter may be punished for a class A violation under section 1-19] Any violation of this Chapter or any regulation adopted under it is a Class A violation. Each day a violation continues is a separate offense.

LEGISLATIVE REQUEST REPORT

Bill 5-16
Tanning Facilities - Amendments

DESCRIPTION: Bill 5-16 would generally update County law related to tanning facilities and prohibit minors from using tanning facilities.

PROBLEM: The current laws related to tanning facilities were originally established in 1987 and infrequently amended since then. There have been increased knowledge about the risks of indoor tanning facilities since that time.

According to the Centers for Disease Control and Prevention, the use of tanning facilities is particularly dangerous for younger users because people who begin indoor tanning during adolescence or early adulthood have a higher risk of getting melanoma, the deadliest form of skin cancer.

GOALS AND OBJECTIVES: To protect public health by updating the general laws related to tanning facilities and prohibit minors from using tanning facilities.

COORDINATION: Department of Health and Human Services

FISCAL IMPACT: To be requested.

ECONOMIC IMPACT: To be requested.

EVALUATION: To be requested.

EXPERIENCE ELSEWHERE: To be researched.

SOURCE OF INFORMATION: Amanda Mihill, 240-777-7815

APPLICATION WITHIN MUNICIPALITIES: Not applicable.

PENALTIES: Class A violation.

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MONTGOMERY COUNTY COUNCIL
ROCKVILLE, MARYLAND

TO: Councilmembers
FROM: Councilmember Tom Hucker
DATE: March 1, 2016
RE: Tanning Safety Bill

Today I am introducing legislation that will provide several key health and safety updates to existing Montgomery County law on the operation and use of indoor tanning facilities. One of these updates is to prohibit the use of indoor tanning facilities by minors under the age of 18. I hope you will consider co-sponsoring.

In 2009 indoor tanning devices such as tanning beds, tanning booths, and sun lamps were classified by the World Health Organization as Class I human carcinogens (the same category as cigarettes) on the basis of strong evidence linking indoor tanning to increased risk of skin cancer. Skin cancer is the most commonly diagnosed cancer in the U.S., with melanoma being one of the most common types found in adolescents and young adults. Beginning indoor tanning at a young age increases exposure to harmful ultraviolet radiation and is clearly linked to a higher lifetime risk of cancer. As a result of the indoor tanning industry marketing heavily to young women, a 2011 CDC study showed that 20.9% of all U.S. female high school students had indoor tanned with female 17-year old students at 27.9%.

Montgomery County's tanning regulations were put into place in the 1980's and have not been updated since. I worked with the American Cancer Society to craft this bill to update the existing County law on indoor tanning facilities, taking guidance from the latest scientific research as well as their model statute regulating indoor tanning facilities. Currently minors in Montgomery County under the age of 18 are permitted to use indoor tanning devices when accompanied by a parent or legal guardian. Since indoor tanning has been conclusively shown to increase the risk of skin cancer, our bill would change this, so that minors under the age of 18 can no longer use indoor tanning facilities under any circumstances. This legislation would also supplement the existing County law by requiring tanning devices to have an "off" button that the customer can reach during use, have a remotely located timer so that customers cannot set their own exposure time, and prohibit use by the same customer more than once every 24 hours. This bill would not cover spray tanning facilities or products, so for teens who insist on artificial tanning, that option would still be available.

As of May 2015, 12 states (California, Delaware, Hawaii, Illinois, Louisiana, Minnesota, Nevada, New Hampshire, Oregon, Texas, Vermont, Washington) and the District of Columbia had adopted legislation prohibiting the use of indoor tanning facilities by minors. Many European and Scandinavian countries have laws preventing minors from using indoor tanning

facilities while Brazil and New South Wales, Australia have passed complete bans on all indoor tanning. In 2009, Howard County, Maryland became the first local jurisdiction in the country to ban indoor tanning by minors, followed by Chicago and many others.

Surely we will hear from our County's indoor tanning facilities operators that this change will hurt their businesses. However, scientific research points clearly to the conclusion that indoor tanning devices are dangerous and contribute to higher incidences of skin cancer and that it is especially harmful when initiated at a young age. By law we attempt to shield our children and teenagers under the age of 18 from the harmful health effects of tobacco and non-tobacco smoking products, and we should do same here.

U.S. Department of Health & Human Services www.hhs.gov

SURGEON GENERAL

The Surgeon General's Call to Action to Prevent Skin Cancer

Executive Summary

The Surgeon General's Call to Action to Prevent Skin Cancer calls on partners in prevention from various sectors across the nation to address skin cancer as a major public health problem. Federal, state, tribal, local, and territorial governments; members of the business, health care, and education sectors; community, nonprofit, and faith-based organizations; and individuals and families are all essential partners in this effort. The goal of this document is to increase awareness of skin cancer and to call for actions to reduce its risk. The *Call to Action* presents the following five strategic goals to support skin cancer prevention in the United States: increase opportunities for sun protection in outdoor settings; provide individuals with the information they need to make informed, healthy choices about ultraviolet (UV) radiation exposure; promote policies that advance the national goal of preventing skin cancer; reduce harms from indoor tanning; and strengthen research, surveillance, monitoring, and evaluation related to skin cancer prevention.

Skin Cancer as a Major Public Health Problem

Skin cancer is the most commonly diagnosed cancer in the United States, and most cases are preventable.[1–3] Skin cancer greatly affects quality of life, and it can be disfiguring or even deadly.[1,4–6] Medical treatment for skin cancer creates substantial health care costs for individuals, families, and the nation. The number of Americans who have had skin cancer at some point in the last three decades is estimated to be higher than the number for all other cancers combined,[7] and skin cancer incidence rates have continued to increase in recent years.[1,8]

Each year in the United States, nearly 5 million people are treated for all skin cancers combined, with an annual cost estimated at $8.1 billion.[9] Melanoma is responsible for the most deaths of all skin cancers, with nearly 9,000 people dying from it each year.[10] It is also one of the most common types of cancer among U.S. adolescents and young adults.[11] Annually, about $3.3 billion of skin cancer treatment costs are attributable to melanoma.[9]

Despite efforts to address skin cancer risk factors, such as inadequate sun protection and intentional tanning behaviors, skin cancer rates, including rates of melanoma, have continued to increase in the United States and worldwide.[1,12–16] With adequate support and a unified approach, comprehensive, communitywide efforts to prevent skin cancer can work. Although such success will require a sustained commitment and coordination across diverse partners and sectors, significant reductions in illness, deaths, and health care costs related to skin cancer can be achieved.

Although genetic factors, such as being fair-skinned or having a family history of skin cancer, contribute to a person's risk,[17–23] the most common types of skin cancer are also strongly associated with exposure to UV radiation.[3,24–29] As many as 90% of melanomas are estimated to be caused by UV exposure.[24,30] UV exposure is also the most preventable cause of skin cancer. The *Call to Action* focuses on reducing UV exposure, with an emphasis on addressing excessive, avoidable, or unnecessary UV exposures (such as prolonged sun exposure without adequate sun protection) and intentional exposure for the purpose of skin tanning (whether indoors using an artificial UV device or outdoors while sunbathing).

UV radiation is a type of electromagnetic radiation emitted by the sun and from some man-made lights, with wavelengths longer than X-rays but shorter than visible light.[31,32] UV exposure stimulates melanocytes to produce melanin, often resulting in a tan or sunburn, both of which indicate overexposure and damage to the skin, skin cells, and DNA within those skin cells.[33,34] This damage can lead to cancer. The degree to which UV exposure increases a person's risk of skin cancer depends on many factors, such as individual skin type, the amount and types of sun protection used, whether exposure is constant or intermittent, and the age at which the exposure occurs.[14,30,35–40] By reducing intentional UV exposure and increasing sun protection, many skin cancer cases can be prevented.[3,24–29]

For most people in the United States, the sun is the most common source of exposure to UV radiation. UV radiation from indoor tanning devices is a less common but more easily avoidable source of UV radiation exposure than from the sun. Indoor tanning devices, such as tanning beds, tanning booths, and sun lamps, expose users to intense UV radiation as a way to tan the skin for cosmetic reasons. Although reducing UV overexposure from the sun can be challenging for some people, UV exposure from indoor tanning is completely avoidable.

In 2009, the World Health Organization (WHO) classified indoor tanning devices as Class I human carcinogens on the basis of strong evidence linking indoor tanning to increased risk of skin cancer.[26] A 2014 meta-analysis estimated that more than 400,000 cases of skin cancer may be related to indoor tanning in the United States each year: 245,000 basal cell carcinomas, 168,000 squamous cell carcinomas, and 6,000 melanomas.[41] Initiating indoor tanning at younger ages appears to be more strongly related to lifetime skin cancer risk, possibly because of the accumulation of exposure over time from more years of tanning.[42–45]

The relationship between outdoor UV exposure, vitamin D, and human health is complex. The amount of outdoor sun exposure needed for meaningful vitamin D production depends on many factors, including time of day, time of year, latitude, altitude, weather conditions, a person's skin type, amount of skin exposed to the sun, other individual circumstances, and reflective surfaces, such as snow, water, and sand. Adequate vitamin D can be obtained safely through food and dietary supplements without the risks associated with overexposure to UV radiation.[46,47] Although all UV exposures can affect skin cancer risk, entirely avoiding UV rays from the sun is neither realistic nor advisable for most Americans. Spending time outdoors is associated with positive health benefits, such as increased levels of physical activity and improved mental health.[48–50]

Reducing the Risk of Skin Cancer

Most skin cancers are at least partially caused by UV exposure, so reducing exposure reduces skin cancer risk. However, one out of every three U.S. adults has been (15) sunburned in the past year, and most do not take recommended actions to protect themselves from the sun.[51,52] In addition, indoor tanning rates are high among some

groups, such as young, non-Hispanic white females, and skin cancer incidence rates are increasing. These facts show a need to take action to improve sun protection behaviors and address the harms of indoor tanning.

Individuals can take steps to reduce their risk of developing skin cancer. Sun protection helps prevent the harmful effects of sun exposure, including sunburn, skin cancer, premature skin aging, and eye damage. When used as part of a comprehensive approach, well-tailored, individual-focused strategies may be effective for reaching specific subpopulations.[53,54] According to WHO's International Agency for Research on Cancer, ideal sun protection involves several behaviors, including wearing tightly woven protective clothing, wearing a hat that provides adequate shade to the whole head, seeking shade whenever possible, avoiding outdoor activities during periods of peak sunlight (such as midday), and using sunscreen (in conjunction with other sun protection behaviors).[55]

There are barriers to using sun protection. Many Americans lack a general knowledge or awareness about the risks associated with sun exposure, or they think they are at low risk of developing skin cancer or sunburn.[56–58] Social norms regarding tanned skin as attractive and healthy create barriers to reducing intentional exposure to UV radiation, whether indoors or outdoors. Intentional tanning, which includes both indoor tanning and seeking a tan outdoors, is strongly associated with a preference for tanned skin and other appearance-focused behaviors.[59–62] Women in particular may experience greater social pressure to tan and have tanned skin, which likely explains the higher rates of indoor tanning observed among women than men.[59,63–67]

Sunburns in childhood are a clear risk factor for skin cancers later in life, and building healthy habits early when children are more receptive can lead to increased sun protection into adulthood.[68,69] Given the amount of time children spend in school settings, much of the skin cancer prevention efforts for children have focused on sun-safety education in schools and changes to the school environment to promote sun-safe behaviors.

Similar to schools, outdoor work settings are an important setting for efforts to prevent overexposure to the sun and reduce skin cancer risk. Research has shown that skin cancer prevention interventions designed to reach outdoor workers can be highly effective at increasing sun protection behaviors and decreasing sunburns.[70] The Guide to Community Preventive Services (The Community Guide[a]) states that sufficient evidence exists to recommend multicomponent, communitywide interventions,[b] as well as interventions designed for certain settings (specifically, child care centers, primary and middle schools, outdoor recreational and tourism settings, and outdoor occupational settings).[70]

Intervention strategies that address social and contextual factors have the potential for broad public health impact by making the healthy choice the easy or default choice.[71] Policies, legislation, and regulation are examples of such interventions, reaching wide segments of communities while requiring minimal individual effort compared with interventions directed at individuals.[71]

Policies that address skin cancer prevention vary across the country. Only a few states, such as California and New York, have passed legislation requiring that schools allow students to use sun-protective clothing (California) or sunscreen (California and New York) on campus.[72,73] California law also urges employers to identify and correct workplace hazards connected to UV radiation.[74]

A few states have passed legislation to support sun-safety education programs and skin cancer prevention awareness. Laws in Arizona and New York mandate instruction on skin cancer prevention as part of the health education curriculum in public schools.[75,76] Kentucky passed a law encouraging skin cancer education in schools.[77] Some states have policies that reach beyond children as the audience for education and awareness. New York mandates sun-safety education for all state employees that spend more than 5 hours per week outdoors.[78]

Some states and municipalities in the United States have regulations relating to use of indoor tanning devices. Considerable variation exists throughout the country in the strength and enforcement of indoor tanning restrictions, as well as compliance with these restrictions. In October 2011, California passed the most stringent youth access law in the country, which took effect on January 1, 2012, and prohibits indoor tanning for anybody younger than age 18 years.[79] Since then, Vermont, Nevada, Oregon,[c] Texas, Illinois, Washington,[c] Minnesota, Louisiana, and Hawaii have also adopted prohibitions on indoor tanning for minors younger than age 18 years.[79–81] Currently, at least 44 states and the District of Columbia have some kind of law or regulation related to indoor tanning, including bans on indoor tanning for minors under a certain age (ranging from 14 to 18), laws requiring parental accompaniment or parental permission, or regulations that otherwise reduce harms (such as requiring eye protection).[79–85] Indoor tanning laws, particularly those that include age restrictions, appear to be effective in reducing indoor tanning among female high school students, who have the highest rates.[86]

Federal policies, legislation, and regulations can help prevent skin cancer. The U.S. Department of Health and Human Services (HHS) and its agencies play important roles in skin cancer prevention at the federal level. These agencies include the National Cancer Institute in the National Institutes of Health, the Centers for Disease Control and Prevention (CDC), the U.S. Food and Drug Administration (FDA), and the Agency for Healthcare Research and Quality. CDC supports Comprehensive Cancer Control Programs in states, tribes, and territories, many of which conduct activities related to skin cancer prevention. Federal entities outside HHS also address skin cancer prevention, including the Federal Trade Commission, the U.S. Environmental Protection Agency, the National Park Service, and the Occupational Safety and Health Administration.

Sunscreens sold in the United States are governed by FDA as over-the-counter drugs. Regulations identify acceptable active ingredients and dosage strengths, provide language and format for product labels, and establish standardized test methods for determining a product's sun protection factor (SPF), among other requirements. Products that satisfy regulatory conditions are considered to be safe, effective, and truthfully labeled and may be marketed without premarket review and approval by FDA. Products that vary from regulatory conditions may be sold only after FDA review and approval.[87] Under the FDA regulations, all sunscreen products are labeled for use to help prevent sunburn, and they must state the product's SPF. Sunscreens that pass a separate test for broad spectrum (UVA and UVB) protection may also be labeled as "broad spectrum." In addition, broad spectrum sunscreens with SPF levels of 15 or higher may be labeled as reducing the risk of skin cancer and premature skin aging when used together with other sun protection measures, including limiting time in the sun and wearing long-sleeved shirts, pants, hats, and sunglasses.[87]

FDA also regulates indoor UV tanning devices under separate authorities, both as medical devices and as radiation-emitting electronic products. On May 29, 2014, FDA reclassified indoor tanning devices to Class II medical devices (moderate to high risk).[88,89] Once the reclassification order is effective, manufacturers will have to include a warning that people younger than age 18 years should not use these devices, receive premarket notification 510(k) clearance from FDA for newly marketed devices, and meet other requirements.[90]

The Surgeon General's Call to Action to Prevent Skin Cancer is informed by international efforts to prevent skin cancer. Other countries have taken a variety of approaches to prevent skin cancer, including community-based, multicomponent interventions, which are recommended by The Community Guide.[70,91] Data from efforts in Australia provide evidence that sustained funding for a community-level skin cancer prevention initiative can improve health outcomes and result in long-term savings in health care costs.[92]

Many countries have laws specifically addressing indoor tanning. Brazil and New South Wales, Australia, have passed complete bans on indoor tanning.[93,94] In addition, as of January 2014, France, Spain, Portugal, Germany, Austria, Belgium, the United Kingdom, Australia, Iceland, Italy, Finland, and Norway prohibit indoor tanning for youth younger than age 18 years.[93,94]

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Gaps in Research and Surveillance

Important strides have been made in skin cancer prevention in the United States, but they have not been sufficient to curb the rising rates of skin cancer incidence. Social and behavioral research can help us better understand some issues, such as ongoing high rates of sunburn despite improvements in sun protection and ongoing high rates of indoor tanning despite evidence that it is a human carcinogen. More information is needed regarding effective message framing and effective policies to promote behavior change. Reliable data are also needed to measure the effect of prevention efforts. Many skin cancer cases are not being captured by current surveillance systems, and current behavioral surveillance systems may not be adequate to track the effect of state and local initiatives, such as indoor tanning legislation for minors.

Calls to Action

This section presents five strategic goals to support skin cancer prevention in the United States. Federal, state, tribal, local, and territorial governments; businesses, employers, and labor representatives; health care systems, insurers, and clinicians; early learning centers, schools, colleges, and universities; community, nonprofit, and faith-based organizations; and individuals and families are all essential partners in this effort. Strategies that change the context or environment to support healthy choices generally have greater reach and are more effective at the population level than strategies focused on individual behavior.[71] This section also provides education and communication strategies, which will likely be most effective if used in conjunction with changes to the social context and environment. Involving partners across disciplines, sectors, and institutions will be essential to addressing the rising incidence of skin cancers in the United States.

Goal 1: Increase Opportunities for Sun Protection in Outdoor Settings

Strategies

- Increase shade in outdoor recreational settings.
- Support sun-protective behaviors in outdoor settings.
- Increase availability of sun protection in educational settings.
- Increase availability of sun protection for outdoor workers.

Goal 2: Provide Individuals with the Information They Need to Make Informed, Healthy Choices About UV Exposure

Strategies

- Develop effective messages and interventions for specific audiences.
- Support skin cancer prevention education in schools.
- Integrate sun safety into workplace health education and promotion programs.
- Partner with health care systems and providers to implement and monitor use of recommended preventive services for provider counseling on skin cancer prevention.
- Establish partnerships between public and private sectors to disseminate effective messages about skin cancer prevention.
- Enhance ongoing engagement of federal partners to advance our nation's skin cancer prevention efforts.

Goal 3: Promote Policies that Advance the National Goal of Preventing Skin Cancer

Strategies

- Support inclusion of sun protection in school policies, construction of school facilities, and school curricula.
- Promote electronic reporting of reportable skin cancers and encourage health care systems and providers to use such systems.
- Incorporate sun safety into workplace policies and safety trainings.
- Support shade planning in land use development.

Goal 4: Reduce Harms from Indoor Tanning

Strategies

- Monitor indoor tanning attitudes, beliefs, and behaviors in the U.S. population, especially among indoor tanners, youth, and parents.
- Continue to develop, disseminate, and evaluate tailored messages to reduce indoor tanning among populations at high risk.
- Support organizational policies that discourage indoor tanning by adolescents and young adults.
- Enforce existing indoor tanning laws and consider adopting additional restrictions.
- Address the risks of indoor tanning with improved warning labels and updated performance standards.

Goal 5: Strengthen Research, Surveillance, Monitoring, and Evaluation Related to Skin Cancer Prevention

Strategies

- Enhance understanding of the burden of skin cancer and its relationship with UV radiation.
- Evaluate the effect of interventions and policies on behavioral and health outcomes.
- Build on behavioral research and surveillance related to UV exposure.
- Quantify the prevalence of tanning in unsupervised locations.

Conclusion

With this *Call to Action,* the U.S. Surgeon General emphasizes the need to act now to solve the major public health problem of skin cancer. To reduce skin cancers in the population, people must get the information they need to make informed choices about sun protection, policies must support these efforts, youth must be protected from harms of indoor tanning, and adequate investments need to be made in skin cancer research and surveillance.

Achieving these goals will not be a small task. It will require dedication, ingenuity, skill, and the concerted efforts of many partners in prevention across many different

sectors. Many of these partners are already enthusiastically involved, but greater coordination and support are needed to increase the reach of their efforts. The goals and strategies outlined in the *Call to Action* are the next steps. We must act with urgency to stop the ever-increasing incidence of skin cancers in the United States.

Footnotes

[a] The Community Guide is a website that houses the official collection of all Community Preventive Services Task Force findings and the systematic reviews on which they are based.

[b] Multicomponent, communitywide interventions are defined as interventions that include at least two distinct components that are implemented in at least two different types of settings (e.g., schools, recreation areas) or that reach the entire community (e.g., mass media campaigns).

[c] State laws in Oregon and Washington allow minors younger than age 18 years to use indoor tanning facilities with a doctor's prescription.

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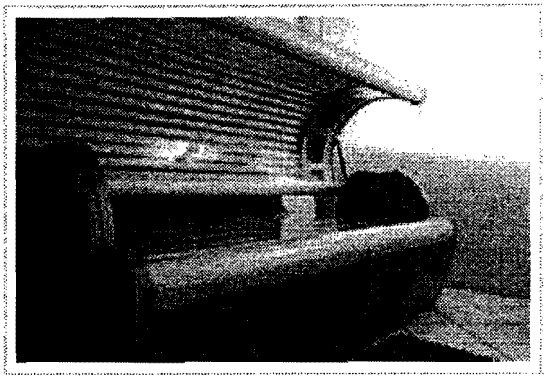
Indoor Tanning Is Not Safe



Using a tanning bed, booth, or sunlamp to get tan is called *indoor tanning.* Indoor tanning can cause skin cancers including melanoma (the deadliest type of skin cancer), basal cell carcinoma, and squamous cell carcinoma. Exposure to ultraviolet (UV) radiation also can cause cataracts and cancers of the eye (ocular melanoma).

Dangers of Indoor Tanning

Indoor tanning exposes users to two types of UV rays, UVA and UVB, which damage the skin and can lead to cancer. Indoor tanning is particularly dangerous for younger users; people who begin indoor tanning during adolescence or early adulthood have a higher risk of getting melanoma. This may be due to greater use of indoor tanning among those who begin tanning at earlier ages.

Every time you tan you increase your risk of getting skin cancer, including melanoma. Indoor tanning also—

- Causes premature skin aging, like wrinkles and age spots.
- Changes your skin texture.
- Increases the risk of potentially blinding eye diseases, if eye protection is not used.

Facts About Indoor Tanning

Tanning indoors is not safer than tanning in the sun.

Indoor tanning and tanning outside are both dangerous. Although indoor tanning devices operate on a timer, the exposure to UV rays can vary based on the age and type of light bulbs. Indoor tanning is designed to give you high levels of UV radiation in a short time. You can get a burn from tanning indoors, and even a tan indicates damage to your skin.

A base tan is not a safe tan.

A tan is the body's response to injury from UV rays. A base tan does little to protect you from future damage to your skin caused by UV exposure. In fact, people who indoor tan are more likely to report getting sunburned.

The best way to protect your skin from the sun is by using these tips for skin cancer prevention.

Indoor tanning is not a safe way to get vitamin D.

Although it is important to get enough vitamin D, (http://ods.od.nih.gov/factsheets/vitamind/) the safest way

:o do so is through what you eat. Tanning harms your skin, and the amount of UV exposure you need to get enough vitamin D is hard to measure because it is different for every person and also varies with the weather, latitude, altitude, and more.

Statistics

Studies have shown consistently that indoor tanning increases a person's risk of getting skin cancer, including melanoma.

- A *meta-analysis (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3049418/)* (a research study that looks at data from other studies) by Boniol and colleagues in 2012 (http://www.ncbi.nlm.nih.gov/pubmed/22833605) combined findings from studies conducted in Europe, Australia, and the United States. The meta-analysis shows a link between indoor tanning and melanoma.
- Another meta-analysis published in 2014 by Colantonio and colleagues (http://www.ncbi.nlm.nih.gov/pubmed/24629998) reconfirmed the association between indoor tanning and melanoma, and also found that newer tanning beds were not safer than older models.
- A 2014 study by Wehner and colleagues (http://www.ncbi.nlm.nih.gov/pubmed/24477278) estimated that more than 400,000 cases of skin cancer may be related to indoor tanning in the United States each year—causing 245,000 basal cell carcinomas, 168,000 squamous cell carcinomas, and 6,000 melanomas.
- A 2010 study by Lazovich and colleagues (http://www.ncbi.nlm.nih.gov/pubmed/20507845) in the United States found that the risk of getting melanoma increased the more years, hours, or sessions spent indoor tanning.

According to the data from the 2013 Youth Risk Behavior Surveillance System, (http://www.cdc.gov/yrbss/) many teens are indoor tanning, including—

- 13% of all high school students.
- 20% of high school girls.
- 27% of girls in the 12th grade.
- 31% of white high school girls.

According to the 2010 National Health Interview Survey, (http://www.cdc.gov/nchs/nhis.htm) indoor tanners tended to be young, non-Hispanic white (NHW) women. A closer look at the data showed the following rates of indoor tanning among NHW women—

- 32% of those aged 18 to 21 years.
- 30% of those aged 22 to 25 years.
- 22% of those aged 26 to 29 years.
- 17% of those aged 30 to 34 years.

Healthy People 2020 Objectives for Indoor Tanning

Healthy People (http://healthypeople.gov/2020/) provides science-based, 10-year national objectives for improving the health of all Americans. Healthy People 2020 has 20 cancer objectives.

http://healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=5) including—

- Reduce the proportion of adolescents in grades 9 through 12 who report indoor tanning to 14.0%.
- Reduce the proportion of adults aged 18 years and older who report indoor tanning to 3.6%.

Indoor Tanning Policies

ndoor tanning is restricted in some areas, especially for minors.

Jnited States

California, Delaware, Hawaii, Illinois, Louisiana, Minnesota, Nevada, New Hampshire, North Carolina, Oregon,* Texas, Vermont, Washington,* and some cities and counties have banned indoor tanning by minors younger than 18 years. For the latest information, see the National Conference of State Legislatures' Tanning Restrictions for Minors: A State-by-State Comparison http://www.ncsl.org/IssuesResearch/Health/TanningRestrictionsforMinorsstatelawssummary/tabid/14391/) and AIM at Melanoma's 2014 Indoor Tanning Legislation. (http://www.aimatmelanoma.org/en/aim-for-a-cure/legislative-accomplishments-in-melanoma/2014-indoor-tanning.html)

*The state laws in Oregon and Washington contain an exemption which allows people younger than age 18 to tan with a doctor's prescription.

CDC research (http://www.ncbi.nlm.nih.gov/pubmed/24524515) shows that states with indoor tanning laws that include age restrictions had lower rates of indoor tanning among minors.

The U.S. Food and Drug Administration has proposed a rule http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm350790.htm) to protect youth from the risks of indoor tanning devices by restricting use by minors younger than 18 years. This proposed rule also would require indoor tanning facilities to inform adult users about the health risks of indoor tanning and to obtain a signed risk acknowledgement from these users. The agency also is proposing a second rule that would require manufacturers and indoor tanning facilities to take more actions to help improve the overall safety of indoor tanning devices to protect adult consumers.

nternational

- Brazil and Australia have banned indoor tanning.
- Austria, Belgium, Finland, France, Germany, Iceland, Italy, Norway, Portugal, Spain, and the United Kingdom have banned indoor tanning for people younger than age 18.

Page last reviewed: January 5, 2016

Page last updated: January 5, 2016

Content source: Division of Cancer Prevention and Control, (http://www.cdc.gov/cancer/dcpc/about/) Centers for Disease Control and Prevention (http://www.cdc.gov/)

Evaluation of Indoor Tanning Health Claims

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March 2015

Table of Contents

This report was prepared for the New York State Office of the Attorney General. It examines the risks associated with indoor tanning and evaluates the veracity of health claims presented by the indoor tanning industry to promote indoor tanning. The report is jointly authored by Sophie Julia Balk, M.D.; David E. Fisher, M.D., Ph.D.; Alan C. Geller, MPH, RN; and Martin A. Weinstock, M.D., Ph.D. This report is based upon their knowledge and expertise as well as the materials referenced herein.

Introduction

1. "Indoor tanning" is the use of tanning beds or tanning booths to tan the skin for cosmetic purposes.[1] Over the past several decades, indoor tanning has become increasingly popular. Each day, over one million people in the United States indoor tan.[2] Tanning salons are ubiquitous; they now outnumber Starbucks or McDonalds in large U.S. urban areas.[3]

2. Tanning beds contain sunlamps, which expose users to ultraviolet (UV) radiation that is much stronger than natural sunlight—up to fifteen times more intense than the sun, frequently resulting in burning.[4] The U.S. Food and Drug Administration (FDA) has approved sunlamps for a very narrow purpose—"to tan the skin."[5] The FDA has *not* approved tanning beds for "health" purposes.

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[1] Tanning beds are designed to be used lying down, while tanning booths are designed to be used standing up. Tanning beds are often called sunbeds in Europe.

[2] Jody A. Levine et al., *The Indoor UV Tanning Industry: A Review of Skin Cancer Risk, Health Benefit Claims, & Regulation*, 53 J. Am. Acad. Dermatology 1038, 1039 (2005); S. Elizabeth Whitmore et al., *Tanning Salon Exposure & Molecular Alterations*, 44 J. Am. Acad. Dermatology 775, 775 (2001).

[3] Katherine D. Hoerster et al., *Density of Indoor Tanning Facilities in 116 Large U.S. Cities*, 36 Am. J. Preventive Med. 243 (2009).

[4] World Health Org., Int'l Agency for Research on Cancer, Working Group on Artificial Ultraviolet (UV) Light & Skin Cancer, *The Ass'n of Use of Sunbeds With Cutaneous Malignant Melanoma & Other Skin Cancers: A Systemic Review*, 120 Int'l J. Cancer, 1116 (2006); Beat Gerber et al., *Ultraviolet Emissions Spectra of Sunbeds*, 76 Photochemistry & Photobiology 6, 666 (2002).

[5] 21 C.F.R. § 878.4635 (2014).

3. As will be explained in more detail below, indoor tanning significantly increases the risk of skin cancer including melanoma, the type of skin cancer responsible for the most deaths. The harmful effects of UV exposure increase over time. Thus, indoor tanning devices pose a greater risk for children and teens by boosting overall lifetime exposure. Indoor tanning also increases the risk of eye damage and wrinkles, changes skin texture, and can be addictive.

4. Despite the serious and well-established health risks, however, indoor tanning salons and trade associations continue to aggressively market and promote indoor tanning as safe, often focusing their advertising on teenage girls and young women.[6] What is more, many salons and trade associations assert an array of purported health benefits in their advertising, including on websites and social media. This is true in New York State where tanning salons, including Total Tan, Inc. and Portofino Sun Center, have claimed that indoor tanning is a safe way to obtain vitamin D and prevent and treat cancer. These salons have also asserted that indoor tanning has physiological and psychological benefits, reduces blood pressure, and treats asthma. As detailed below, these and other health benefit claims are not supported by generally accepted science.

Prominent Organizations Deem Indoor Tanning a Cancer Risk and Advocate Banning Minors from Indoor Tanning

5. Recognizing the high cancer risk associated with indoor tanning, in 2009, the World Health Organization's International Agency for Research on Cancer reclassified indoor

[6] U.S. House of Representatives Comm. on Energy & Commerce Minority Staff, *Investigative Report False & Misleading Health Info. Provided to Teens By the Indoor Tanning Industry* at 1, 13, 15 (2012) *available at* http://democrats.energycommerce.house.gov/sites/default/files/documents/False-Health-Info-by-Indoor-Tanning-Industry-2012-2-1.pdf (last visited Jun. 10, 2014); *see also* Scott Freeman et al., *UV Tanning Advertisements in High School Newspapers*, 142 Archives of Dermatology 460 (2006), *available at* http://archderm.jamanetwork.com/article.aspx?articleid=404557 (last visited Jun. 10, 2014).

tanning devices from "probable carcinogen" (Group 2A) to its highest risk level of "carcinogenic to humans" (Group 1) placing tanning beds in the same category as cigarettes.[7]

6. In July 2014, the U.S. Surgeon General issued a call to action to various sectors across the nation to address skin cancer as a major public health problem.[8] A key goal of the call to action is to reduce the harm caused by indoor tanning, which is causing an estimated 400,000 cases of skin cancer per year and is an entirely preventable method of exposure.[9]

7. The leading national dermatological organization, the American Academy of Dermatology, supports the World Health Organization and also calls for an outright ban on the production and sale of indoor tanning equipment for non-medical purposes.[10] The American Academy of Pediatrics, an organization of more than 60,000 pediatricians, pediatric surgeons and pediatric subspecialists, calls for banning minors from tanning indoors.[11] The American Medical Association calls for banning minors from tanning indoors.[12]

8. The following leading national medical organizations recognize the high cancer risk associated with indoor tanning: [13]

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[7] Fatiha El Ghissassi et al. on behalf of the World Health Org., Int'l Agency for Research on Cancer, *Special Report: Policy, A Review of Human Carcinogens—Part D: Radiation*, 10 Lancet Oncology 751, 752 (2009) *available at* http://download.thelancet.com/pdfs/journals/lanonc/PIIS147020450970213X.pdf?id=eaa-jLrN5V-s-hFRlmmAu (last visited Jun. 11, 2014).

[8] U.S. Dep't of Health & Human Servs. Office of the Surgeon General, *The Surgeon General's Call to Action to Prevent Skin Cancer* (2014), http://www.surgeongeneral.gov/library/calls/prevent-skin-cancer/call-to-action-prevent-skin-cancer.pdf (last visited Aug. 8, 2014).

[9] *Id.* at 57.

[10] Am. Acad. of Dermatology, *Indoor Tanning*, http://www.aad.org/media-resources/stats-and-facts/prevention-and-care/indoor-tanning (last visited Feb. 2, 2015).

[11] Am. Acad. of Pediatrics, *AAP Recommendations on Limiting Sun Exposure in Children and Supporting Legislation to Prohibit Salon Tanning by Minors*, http://www.aap.org/en-us/about-the-aap/aap-press-room/pages/AAP-Recommendations-on-Limiting-Sun-Exposure-in-Children-and-Supporting-Legislation-to-Prohibit-Salon-Tanning-by-Minors.aspx (last visited Aug. 6, 2014).

[12] Carolyne Krupa , *Cancer Prevention Efforts Target Tanning Salons*, http://www.amednews.com/article/20110321/health/303219947/4/ (Mar. 21, 2011)

[13] Am. Acad. of Dermatology, *Nat'l Health Care Orgs. Unite to Warn the Public About the Dangers of Indoor Tanning*, http://www.aad.org/stories-and-news/news-releases/national-health-care-organizations-unite-to-warn-the-

American Medical Association	American Osteopathic Association
Centers for Disease Control and Prevention	Melanoma Research Foundation
American Cancer Society	National Council on Skin Cancer Prevention
American Academy of Dermatology	American College of Physicians
American Academy of Pediatrics	The Skin Cancer Foundation
American Academy of Ophthalmology	American Congress of Obstetricians and Gynecologists

Risks of Indoor Tanning

Indoor Tanning Increases Skin Cancer Risk

9. Skin cancer, which includes melanoma, basal cell carcinoma, and squamous cell carcinoma, is the most common of all cancers in the United States with more than 3.5 million skin cancers in over 2 million people diagnosed annually.[14] Over the past 30 years, more people have been diagnosed with skin cancer than all other cancers combined.[15] Over the course of their lifetimes, it has been estimated that one in five Americans will develop skin cancer.[16] Every year in New York State alone, approximately 3,500 people are diagnosed with melanoma and 100,000 people are diagnosed with basal or squamous cell carcinoma.[17]

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public-about-the-dangers-of-indoor-tanning (May 3, 2011) (last visited Jun. 10, 2014); Ctrs. for Disease Control & Prevention, *Is Indoor Tanning Safe?*, http://www.cdc.gov/cancer/skin/basic_info/indoor_tanning.htm (last visited Jun. 10, 2014).

[14] Howard W. Rogers, Martin A. Weinstock, Ashlynne R. Harris, Michael R. Hinckley, Steven R. Feldman, Alan B. Fleischer & Brett M. Coldiron, *Incidence Estimate of Nonmelanoma Skin Cancer in the U.S., 2006*, 146 Archives of Dermatology 283 (2010), *available at* http://archderm.jamanetwork.com/article.aspx?articleid=209782 (last visited Jun. 10, 2014).

[15] Robert S. Stern, *Prevalence of a History of Skin Cancer in 2007 Results of an Incidence-Based Model*, 146 Archives of Dermatology 279 (2010), *available at* http://archderm.jamanetwork.com/article.aspx?articleid=209761 (last visited Jun. 10, 2014).

[16] *Id.*

[17] N.Y. State Dep't of Health, N.Y. State Cancer Registry, *Skin Cancer in N.Y. York State Sixth Ann. Rep. to the Governor of N.Y., the Temporary President of the Senate, & Speaker of the Assembly* (2013) *available at* http://www.health.ny.gov/statistics/diseases/cancer/skin/report/docs/2013_report.pdf (last visited Jun. 10, 2014).

10. Melanoma is responsible for about 75% of skin cancer deaths.[18] One American dies from melanoma every hour.[19] About 600 New Yorkers die from skin cancer each year and 77% of those deaths are attributed to melanoma.[20] Melanoma is the most common cancer for young adults 25-29 years old and the second most common cancer for adolescents and young adults 15-29 years old.[21]

11. Non-melanoma (also called keratinocyte) skin cancers such as basal cell and squamous cell carcinoma are very common, but generally not fatal. They can lead to facial deformity, disfigurement, and scarring, and can be costly to treat when they recur. Non-melanoma skin cancers place burdens on our healthcare system, costing the United States $650 million annually.[22]

12. In New York State, more than 10,000 outpatient surgeries for melanoma and non-melanoma skin cancer are performed each year.[23] In 2012 alone, Medicaid patients in New York State diagnosed with skin cancer cost $10.7 million.[24] Treatment of all types of skin cancer can lead to scarring, large lesions, and particularly disfiguring treatments. Recognizing that indoor

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[18] Am. Cancer Soc'y, *Cancer Facts & Figures 2014* at 4, http://www.cancer.org/acs/groups/content/@research/documents/webcontent/acspc-042151.pdf (last visited Jun. 12, 2014).

[19] *Id.* at 4.

[20] *Skin Cancer in N.Y. State, supra* footnote 17, at 18.

[21] Cynthia Herzog et al., *Chapter 5 Malignant Melanoma* in CANCER EPIDEMIOLOGY IN OLDER ADOLESCENTS & YOUNG ADULTS 15 TO 29 YEARS OF AGE, INCLUDING SEER INCIDENCE & SURVIVAL: 1975-2000 at 53-57 (W. Archie Bleyer et al. eds., 2006), *available at* http://seer.cancer.gov/archive/publications/aya/aya_mono_complete.pdf (last visited Jun. 10, 2014).

[22] Tejaswi Mudigonda et al., *The Econ. Impact of Non-Melanoma Skin Cancer: A Review*, 8 J. Nat'l Comprehensive Cancer Network 888 (2010). *See also* Burak Ömür Cakir at al., *Epidemiology & Econ. Burden of Nonmelanoma Skin Cancer*, 20 Facial Plastic Surgery Clinics of North Am. 419 (2012); Kun Kim et al., *Econ. Burden of Resected Squamous Cell Carcinoma of the Head & Neck in a U.S. Managed-Care Population*, 14 J. Med. Econ. 421 (2011), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3219567/ (last visited Nov. 25, 2013).

[23] *Skin Cancer in N.Y. State, supra* footnote 17, at 17.

[24] N.Y. State Office of the Attorney General, Medicaid Database (accessed Jan. 28, 2014).

tanning leads to health care costs, Congress included a 10% tax on indoor tanning in the Affordable Care Act.[25]

13. A systematic review estimated the years of potential life lost and the value of productivity loss from morbidity and premature mortality resulting from melanoma and non-melanoma skin cancer.[26] After extracting data from 16 relevant studies, the review estimated that the average number of years of potential life lost per death was approximately 15 years for melanoma and 10 years for non-melanoma skin cancer. The indirect costs attributable to melanoma and non-melanoma skin cancer in one year were $76.8 million for morbidity (including lost workdays, caregiver lost workdays, and restricted activity days), and ranged from $1 billion to $3.3 billion for premature mortality. Therefore, skin cancer leads to significant years of potential life lost and indirect costs associated with premature mortality and morbidity.

14. Overwhelming evidence shows that indoor tanning **causes** skin cancer, and the causal link between indoor tanning and skin cancer is generally accepted in the scientific community. In a recent review of published studies, about 6,200 melanomas per year in the United States were attributed to tanning beds along with nearly 245,000 basal cell cancers and 165,000 squamous cell cancers.[27] Another recent review estimated a 1.8% increase (95% confidence interval of 0% to 3.8%) in risk of melanoma for each additional session of tanning bed use per year.[28] Within that same review, based on 13 informative studies, individuals who

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[25] 26 U.S.C. § 5000B; 155 Cong. Rec. S13,745 (Dec. 22, 2009) (statement of Senator Jack Reed).

[26] Gery P. Guy & Donatus U. Ekwueme, *Years of Potential Life Lost & Indirect Costs of Melanoma & Non-Melanoma Skin Cancer: A Systematic Review of the Literature*, 10 Pharmacoeconomics 863-74 (2011).

[27] Mackenzie R. Wehner et al., *Int'l Prevalence of Indoor Tanning, A Systematic Review & Meta-Analysis*, 150 JAMA Dermatology 390, 398, Table 2 (2014). "[T]he extremely high incidence of skin cancer means that there are more skin cancer cases attributable to indoor tanning than lung cancer cases attributable to smoking." *Id.*

[28] Mathieu Boniol et al., *Cutaneous Melanoma Attributable to Sunbed Use: Systematic Review & Meta-Analysis*, 2012 BMJ 1, 3 (Jul. 24, 2012), *available at* http://www.bmj.com/content/345/bmj.e4757 (last visited Apr. 20, 2015).

first used tanning beds before the age of 35 had an estimated 59% greater risk of melanoma compared to those who did not use tanning beds.[29]

15. Both animal studies and epidemiological studies show the link between UV exposure and melanoma.[30] Many melanomas occurring in indoor tanners—even in a country with large populations exposed to intense sun such as Australia—were more attributable to indoor tanning than to the sun.[31] Use of cutting edge genome sequencing technology has indicated that the genomic DNA of human melanomas is riddled with thousands of "UV signature" mutations, which represent chemical errors within melanoma cells that are known to be caused by UV radiation (di-pyrimidine mutations).[32] This constitutes direct experimental evidence showing the link between UV exposure and skin cancer.

16. It should be noted that multiple genetic and environmental factors have been implicated in the development of skin cancer. There are several known genetic conditions that predispose a person to develop melanoma, and there are individuals who develop melanoma on non-UV exposed areas, such as inside the mouth or in the genital areas. In addition, certain individuals may be predisposed to melanoma because of immunosuppression, preventing them

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[29] *Id.*; Mathieu Boniol et al., *Corrections, Cutaneous Melanoma Attributable to Sunbed Use: Systematic Review & Meta-Analysis*, 2012 BMJ (Dec. 13, 2012), *available at* http://www.bmj.com/content/345/bmj.e8503 (last visited Apr. 20, 2014).

[30] World Health Org., Int'l Agency for Research on Cancer, *Solar & Ultraviolet Radiation: Summary of Data Reported & Evaluated*, 55 IARC Monographs on the Evaluation of Carcinogenic Risks to Humans at 5-6, *available at* http://monographs.iarc.fr/ENG/Monographs/vol55/volume55.pdf (last visited Nov. 25, 2013); DeAnn Lazovich, Rachel Vogel, Marianne Berwick, Martin Weinstock, Kristen Anderson, & Erin Warshaw, *Indoor Tanning & Risk of Melanoma: A Case-Control Study in a Highly Exposed Population*, 19 Cancer Epidemiology, Biomarkers & Prevention 1557 (2010), *available at* http://cebp.aacrjournals.org/content/19/6/1557.long (last visited Jun. 11, 2014); Martin A. Weinstock & David E. Fisher, *Indoor Ultraviolet Tanning: What the Data Do & Do Not Show Regarding Risk of Melanoma & Keratinocyte Malignancies*, 8 J. Nat'l Comprehensive Cancer Network 867 (2010).

[31] Anne E. Cust et al., *Sunbed Use During Adolescence & Early Adulthood Is Associated With Increased Risk of Early-Onset Melanoma*, 128 Int'l J. Cancer 2425 (2011), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2993823/ (last visited Jun. 11, 2014).

[32] Eran Hodis et al., *A Landscape of Driver Mutations in Melanoma*, 150 Cell 251-63 (2012), *available at* http://ac.els-cdn.com/S0092867412007787/1-s2.0-S0092867412007787-main.pdf?_tid=a93493cc-aee7-11e3-862a-00000aab0f26&acdnat=1395179755_fa36879d742a45c9ea8b2cf908ad3c08 (last visited Jun. 11, 2014).

from mounting the normal immunologic defense against early tumor development. However, these predisposing factors do not negate the overwhelming evidence of the role of UV exposure in the development of most melanomas, and the role of indoor tanning in increasing that risk.

17. Sunlamp use also increases the risk of non-melanoma skin cancers. Exposure to indoor tanning was associated with a 67% higher risk for squamous cell carcinoma and a 29% higher risk for basal cell carcinoma in a review and meta-analysis.[33] In another study, individuals who indoor tanned were at least two and a half times more likely to develop squamous cell carcinoma and one and a half times more likely to develop basal cell carcinoma.[34]

Youth, and Young Women in Particular, Are Vulnerable

18. Efforts to market indoor tanning tend to target young women in particular, and the data show that these efforts have been successful—70% of the one million people who indoor tan each day are Caucasian females between 16 and 49 years of age.[35] Children are most susceptible to marketing efforts and are also at particular risk for disease, as the evidence clearly demonstrates that the earlier one indoor tans, the greater the risk for skin cancer in later years.[36]

19. According to the 2011 Youth Risk Behavior Study from the Centers for Disease Control and Prevention, 20.9% of all U.S. female high school students have indoor tanned in

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[33] Wehner et al., *supra* footnote 27; *see also* Leah M. Ferrucci et al., *Indoor Tanning & Risk of Early-Onset Basal Cell Carcinoma*, 67 J. Am. Acad. Dermatology 552 (2011) ("Ever indoor tanning was associated with a 69% increased risk of early-onset BCC [basal cell carcinoma].").

[34] Margaret R. Karagas, Virginia A. Stannard, Leila A. Mott, Mary Jo Slattery, Steven K. Spencer & Martin A. Weinstock, *Use of Tanning Devices & Risk of Basal Cell & Squamous Cell Skin Cancers*, 94 J. Nat'l Cancer Inst. 224 (2002); *see also* World Health Org., *supra* footnote 4; Marit B. Veierød et al., *Host Characteristics, Sun Exposure, Indoor Tanning & Risk of Squamous Cell Carcinoma of the Skin*, 135 Int'l J. Cancer 2, 413-22 (2014).

[35] Jody A. Levine et al., *The Indoor UV Tanning Industry: A Review of Skin Cancer Risk, Health Benefit Claims, & Regulation*, 53 J. Am. Acad. Dermatology 1038, 1039 (2005).

[36] *See, e.g.*, Wehner et al., *supra* footnote 27; Boniol et al., *supra* footnote 28.

2011 compared with 6.2% of males.[37] Rates were highest among female 17-year-old high school students (27.9%) and older students (31.5%).[38]

20. As indoor tanning has gained popularity, especially among young women who are targeted by tanning salons, there has been an associated increase in rates of melanoma. National Cancer Institute data was used to investigate changes in melanoma incidence between 1973 and 2004. During that time period, the age-adjusted annual incidence of melanoma among women increased by more than 2.5 times.[39] In contrast, during the same time period, the age-adjusted annual incidence of melanoma among young men only increased by 1.6 times. In the absence of data that shows marked differences in outdoor sun protection between high school males and females, the gender disparity in indoor tanning further supports the conclusion that high rates and frequent use of indoor tanning by women is the leading cause of increased melanoma rates in women relative to young men.

21. Because scientific evidence shows that indoor tanning is particularly dangerous for younger individuals, the American Academy of Pediatrics states, "Tanning salons are not safe and should not be used by teenagers or others."[40] The U.S. Preventative Task Force—an esteemed panel of independent national experts in prevention and medicine that works to improve the health of all Americans by making evidence-based recommendations about clinical preventive services—recommends counseling children, adolescents, and young adults (aged 10

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[37] Gery P. Guy et al., *Indoor Tanning Among High School Students in the United States, 2009 & 2011*, JAMA Dermatology (2014); *see also* Ctrs. for Disease Control & Prevention, *Youth Risk Behavior Surveillance - United States, 2011*, Morbidity & Mortality Weekly Report (June 8, 2012), *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/ss6104a1.htm (last visited Jun. 18, 2014).

[38] *Id.*

[39] Mark P. Purdue et al., *Recent Trends in Incidence of Cutaneous Melanoma Among U.S. Caucasian Young Adults*, 128 J. Investigative Dermatology 2908 (2008).

[40] Am. Acad. of Pediatrics, *Ultraviolet Radiation* in PEDIATRIC ENVIRONMENTAL HEALTH at 606 (Ruth A. Etzel & Sophie J. Balk eds., Oct. 2012).

to 24 years) who have fair skin about minimizing their exposure to UV radiation to reduce risk for skin cancer.[41]

22. Earlier exposure to sunlamps worsens later outcomes, and exacerbates the risk of later cancers.[42] Those who begin indoor tanning before they are 35 years old have an estimated 59% higher risk of melanoma than those who do not.[43] In one study from Australia, among 18 to 29 year olds who have ever indoor tanned and were diagnosed with melanoma, 76% of those melanoma cases were attributable to indoor tanning.[44] Indoor tanning at younger ages also affects basal cell carcinoma risk. A recent study shows that there is a significantly higher risk of developing basal cell carcinoma for individuals who used tanning beds during high school and college in comparison to the ages of 25 and 35 years.[45]

23. The number of teenage girls that use indoor tanning facilities is particularly alarming. Nearly all studies agree that about one third of white teenage girls use tanning beds, now far eclipsing cigarette use among the same age group.[46] Girls are six times more likely than boys to use tanning beds, and 40% of girls who use tanning beds used them 10 or more times in the past year.[47] The most typical adolescent indoor tanning patron is a teenage girl between the ages of 15 and 18 with a skin type that either usually burns and minimally tans or has a skin type

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[41] Virginia A. Moyer on behalf of the U.S. Preventive Servs. Task Force, *Behavioral Counseling to Prevent Skin Cancer: U.S. Preventive Servs. Task Force Recommendation Statement*, 157 Annals Internal Med. 59, 60 (2012), *available at* http://www.uspreventiveservicestaskforce.org/uspstf11/skincancouns/skincancounsrs.pdf (last visited Jun. 11, 2014).

[42] *See, e.g.*, Philippe Autier, *Perspectives In Melanoma Prevention: The Case Of Sunbeds*, 40 European J. Cancer 2367 (2004); Am. Acad. of Pediatrics, *Ultraviolet Radiation*, *supra* footnote 40.

[43] Boniol et al., *supra* footnotes 28, 29.

[44] Cust et al., *supra* footnote 31.

[45] Mingfeng Zhang, Abrar A. Qureshi, Alan C. Geller, Lindsay Frazier, David J. Hunter, & Jiali Han, *Use of Tanning Beds & Incidence of Skin Cancer*, 30 J. Clinical Oncology 1591 (2012).

[46] Guy et al., *supra* footnote 37.

[47] Boniol et al., *supra* footnote 28.

that sometimes burns and gradually tans.[48] According to a 2002 study of 10,000 children and adolescents, 7% of 14 year-old Caucasian girls indoor tan, 16% of 15 year-old Caucasian girls indoor tan, and 35% of 17 year-old Caucasian girls indoor tan.[49] Thus, the number of Caucasian girls who use indoor tanning facilities thus *doubles* from age 14 to age 15, and then *doubles again* from age 15 to age 17. Recent studies of adolescents report that rates of tanning bed use among females are more than double those for males.[50]

24. Concerns about indoor tanning among young women are echoed in a 2012 investigative report published by the U.S. Congress House Committee on Energy and Commerce.[51] The report is based on the results of telephone calls to 300 nationwide tanning salons from Congressional staff that identified themselves as 16-year-old girls interested in tanning for the first time. Some 90% of respondents employed by the tanning salons denied that indoor tanning poses health risks and, when asked about skin cancer specifically, more than half denied that indoor tanning would increase a fair-skinned teenager's risk of developing skin cancer, dismissing the notion as "a big myth," "rumor," and "hype." Some 78% of tanning salons claimed health benefits of tanning ranging from cancer prevention to providing vitamin D to weight loss. The report concluded that tanning salons deny known risks of indoor tanning, provide false information on the benefits of tanning, and fail to follow any recommendations on tanning frequency. The report also concluded that tanning salons target teenage girls with advertising and promotions such as student discounts and "prom," "homecoming," and "back-to-school" specials that often include "unlimited" tanning packages.

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[48] Alan C. Geller, Graham Colditz, Susan Oliveria, Karen Emmons, Cynthia Jorgensen, Gideon N. Aweh, A. Lindsay Frazier, *Use of Sunscreen, Sunburning Rates, and Tanning Bed Use Among More Than 10,000 U.S. Children and Adolescents*, 109 Pediatrics 1009, 1011-12 (2002).

[49] *Id.*

[50] Wehner et al., *supra*, footnote 27.

[51] U.S. House of Representatives, *supra*, footnote 6.

25. In response to the Congressional investigative report, the leading indoor tanning trade association admitted that "it does highlight the need for us to reevaluate how our industry can do a better job of ensuring that [trade association] member salons are providing accurate and consistent information to their customers nationwide."[52]

26. Recognizing the dangers associated with indoor tanning, New York State prohibits those under age 17 from indoor tanning and requires that 17 year olds obtain parental consent before tanning. California, Illinois, Nevada, Oregon, Texas, Vermont, Minnesota Louisiana, Hawaii, Delaware, Washington, the United Kingdom, Germany, Scotland, France, and several Canadian provinces have banned indoor tanning for youth under 18.[53] Brazil and Australia have banned indoor tanning beds for everyone, regardless of age.[54]

27. Likewise, the FDA recently placed additional restrictions on sunlamps, strengthening protections by reclassifying sunlamp products from a low-risk device (class I) to a moderate-risk device (class II).[55] Under this reclassification, effective September 2, 2014, sunlamp manufactures will need pre-market certification to demonstrate that their products meet certain performance testing requirements. In addition, the FDA is now requiring all sunlamp products to have the following warning placed in a black box: "Attention: This sunlamp product should not be used on persons under the age of 18 years." The FDA is also requiring that sales

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[52] Indoor Tanning Ass'n, *Report Misleads About Salon Claims* (Feb. 1, 2012) *available at* https://smarttan.com/news/index.php/report-misleads-about-salon-claims/ (last visited Jun. 11, 2014).

[53] Nat'l Conference of State Legislatures, *Indoor Tanning Restrictions for Minors - A State-by-State Comparison* (updated May 2014), *available at* http://www.ncsl.org/research/health/indoor-tanning-restrictions.aspx (last visited Jun. 11, 2014); Ctrs. for Disease Control & Prevention, *supra* footnote 13.

[54] Ctrs. for Disease Control & Prevention, *supra* footnote 13; Cancer Council Australia, *Position Statement Solariums*, http://wiki.cancer.org.au/prevention/Position_statement_-_Solariums#Regulation (last visited Jun. 11, 2014) (Table 1 lists Australian state and territory legislation covering solarium use).

[55] FDA, *FDA to Require Warnings on Sunlamp Products*, http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm399222.htm (May 29, 2014); *General & Plastic Surgery Devices: Reclassification of Ultraviolet Lamps for Tanning, Henceforth To Be Known as Sunlamp Products & Ultraviolet Lamps Intended for Use in Sunlamp Products*, 79 Fed. Reg. 31,205 (Jun. 2, 2014) (amending 21 C.F.R. part 878).

and promotional materials accompanying sunlamps contain the following warnings and contraindications:

(A) "Contraindication: This product is contraindicated for use on persons under the age of 18 years."

(B) "Contraindication: This product must not be used if skin lesions or open wounds are present."

(C) "Warning: This product should not be used on individuals who have had skin cancer or have a family history of skin cancer."

(D) "Warning: Persons repeatedly exposed to UV radiation should be regularly evaluated for skin cancer."

Indoor Tanning Can Lead to Premature Skin Aging, Immune Suppression, and Eye Damage, Including Cataracts and Cancer

28. In addition to increasing skin cancer risk, excessive exposure to UV radiation during indoor tanning can lead to premature skin aging, immune suppression, and eye damage, including cataracts and ocular melanoma.[56]

29. Indoor tanning leads to premature aging and wrinkles.[57] The immediate skin swelling and tanning induced by UV light are a known response to tissue and DNA injury.[58] Over time, UV exposure leads to severe collagen loss and a weakening of the skin's elasticity, resulting in sagging cheeks, deeper facial wrinkles, and skin discoloration.[59]

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[56] Lim et al., *Adverse Effects of UV Radiation From the Use of Indoor Tanning Equip.: Time to Ban the Tan*, 64 J. Am. Acad. Dermatology 893, 895 (2011).

[57] *See e.g.*, Ctrs. for Disease Control & Prevention, *supra* footnote 13.

[58] Denise K. Woo & Melody J. Eide, *Tanning Beds, Skin Cancer, and Vitamin D: An Examination of the Scientific Evidence and Public Health Implications*, 23 Dermatologic Therapy 61, 63 (2010); Yasuhiro Matsumura & Honnavara N. Ananthaswamy, *Toxic Effects of Ultraviolet Radiation on the Skin*, 195 Toxicology & Applied Pharmacology 298 (2004).

[59] Sophie J. Balk & Am. Acad. of Pediatrics Council on Envtl. Health & Section on Dermatology, *Technical Report – Ultraviolet Radiation: A Hazard to Children & Adolescents*, 127 Pediatrics 791, 792 (2011).

30. Indoor tanning leads to immune suppression.[60] The immune system protects the body against organisms or substances that might cause disease. Immune suppression is an impaired ability of the immune system to fight infection or disease.

31. Indoor tanning can cause eye damage including photokeratitis, and long-term exposure can increase the risk of developing cataracts.[61] Photokeratitis is a painful, but short-term, eye condition caused by exposure of insufficiently protected eyes to UV rays. Symptoms include eye tearing, pain, swelling of the eyelid, hazy or decreased vision and a feeling of having sand in one's eye. A cataract is a clouding of the eye's natural lens, causing blurry vision or, ultimately, blindness. Eye injuries, along with skin burns and syncope (fainting), caused by indoor tanning results in thousands of emergency room visits per year.[62]

Indoor Tanning Can Be Addictive

32. Studies increasingly indicate that tanning can be addictive, particularly in younger individuals. Early age of first indoor tanning use (between 13 and 17 years of age) was significantly associated with both the presence of tanning addiction disorder and problematic tanning behavior.[63] Excessive indoor tanning can be included in the spectrum of addictive behaviors. 90 of 229 study participants who tanned indoors met the Diagnostic and Statistical Manual of Mental Disorders criteria for addiction to indoor tanning.[64] Frequent tanners can distinguish between UV tanning beds and non-UV beds (which were the same in every respect

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[60] Lim et al., *supra* footnote 56.

[61] Am. Optometric Ass'n, *UV Radiation, Protecting Your Eyes from Solar Radiation*, http://www.aoa.org/patients-and-public/caring-for-your-vision/uv-protection (last visited Jun. 10, 2014).

[62] Gery P. Guy et al., *Indoor Tanning–Related Injuries Treated in a Nat'l Sample of U.S. Hospital Emergency Dep'ts*, JAMA Internal Medicine Letters (Dec. 15, 2014).

[63] Cynthia R. Harrington et al., *Addictive-Like Behaviours to Ultraviolet Light Among Frequent Indoor Tanners*, 36 Clinical & Experimental Dermatology 33, 35, 38 (2010).

[64] Catherine E. Mosher & Sharon Danoff-Burg, *Addiction to Indoor Tanning: Relation to Anxiety, Depression, & Substance Use*, 146 Archives of Dermatology 412 (2010).

except for UV radiation), indicating that UV produces perceived behavioral effects known as "reinforcing stimuli."[65] Some 21% of adolescents who tanned indoors more than one time in the past year reported "difficulty in quitting" indoor tanning.[66]

33. Indoor tanning's addictive qualities have been linked to increased tanning frequency[67] and endorphin release,[68] and individuals who stop abruptly can face withdrawal-like symptoms of nausea and jitters.[69] Exposure to UV radiation from a commercial tanning bed induced a response similar to nicotine, methamphetamine and cocaine.[70] A high percentage of frequent indoor tanners experience behaviors consistent with other addictive disorders.[71] In some individuals, indoor tanning has met Diagnostic and Statistical Manual criteria for a substance-related disorder.[72] For example, some individuals continue to tan past the point

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[65] Steven R. Feldman et al., *Ultraviolet Exposure Is a Reinforcing Stimulus In Frequent Indoor Tanners*, 51 J. Am. Acad. Dermatology 45 (2004).

[66] Sarah Zeller et al., *Do Adolescent Indoor Tanners Exhibit Dependency*, 54 J. Am. Acad. Dermatology 589-96 (2006).

[67] Lisham Ashrafioun & Erin E. Bonar, *Tanning Addition & Psychopathology: Further Evaluation of Anxiety Disorders & Substance Abuse*, J. Am. Acad. Dermatology (2014), *available at* http://dx.doi.org/10.1016 /j.jaad.2013.10.057 (last visited Mar. 26, 2014).

[68] Rutao Cui et al., *Central Role of p53 in the Suntan Response & Pathologic Hyperpigmentation*, 128 Cell 853-64, (2007); Gillian L. Fell, Kathleen C. Robinson, Jianren Mao, Clifford J. Woolf, & David E. Fisher, *Skin b-Endorphin Mediates Addiction to UV Light*, 157 Cell 1527-34 (2014).

[69] Mandeep Kaur et al., *Induction of Withdrawal-Like Symptoms in a Small Randomized, Controlled Trial of Opioid Blockade in Frequent Tanners*, 54 J. Am. Acad. Dermatology 709-11 (2006); Bridgit V. Nolan et al, *Tanning as an Addictive Behavior: A Literature Review*, 25 Photodermatology, Photoimmunology & Photomedicine 12-19 (2009).

[70] Cynthia R. Harrington et al., *Activation of the Mesostriatal Reward Pathway With Exposure to Ultraviolet Radiation (UVR) vs. Sham UVR in Frequent Tanners: A Pilot Study*, 17 Addiction Biology 680-86 (2012).

[71] Harrington et al. (2010), *supra* footnote 63; Cynthia R. Harrington et al., *Activation of the Mesostriatal Reward Pathway with Exposure to Ultraviolet Radiation (UVR) vs. Sham UVR in Frequent Tanners: A Pilot Study*, Addiction Biology 680, 681 (2011).

[72] Nolan et al., *supra* footnote 69; Molly M. Warthan et al., *UV Light Tanning as a Type of Substance-Related Disorder*, 141 JAMA Dermatology 963-66 (2005), *available at* http://archderm.jamanetwork.com/ article.aspx?articleid=398011 (last visited Mar. 26, 2014);

necessary to achieve their desired appearance.[73] Laboratory studies in mice have demonstrated UV addiction behavior.[74]

34. Research into the addictive effects of indoor tanning "provide[s] a fascinating potential explanation for the growth of the tanning bed industry despite the known health risk of excessive UV exposure."[75]

Lack of Health Benefits Associated With Indoor Tanning

Indoor Tanning Is Not a Safe Source of Vitamin D

35. Many tanning salons assert through consumer-facing materials (including websites and social media) that indoor tanning is a safe and efficient way to obtain vitamin D. A number of salons have provided links on their websites to the Vitamin D Council website, which asserts that vitamin D can be used to address a wide array of health conditions.[76]

36. As explained in detail above, the risks of indoor tanning are substantial. Although UV exposure of particular kinds, including some tanning beds, can increase production of vitamin D, it is generally accepted that a dietary supplement and healthy diet can address vitamin D deficiency or maintain adequate levels without the risks of indoor tanning. In June, the "FDA acknowledged that UV radiation stimulates the body's production of vitamin D, however, there are safer alternatives to obtain vitamin D other than the use of sunlamp products and UV lamps

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[73] Harrington et al. (2010), *supra* footnote 63.

[74] Gillian L. Fell, Kathleen C. Robinson, Jianren Mao, Clifford J. Woolf, & David E. Fisher, *Skin β-Endorphin Mediates Addiction to UV Light*, 157 Cell 1527-34 (2014), *available at* http://www.sciencedirect.com/science/article/pii/S0092867414006114 (last visited Aug. 7, 2014); Hugo A. Tejeda & Antonello Bonci, *Shedding "UV" Light on Endogenous Opioid Dependence*, 157 Cell 1500 (2014).

[75] Mary S. Brady, *Public Health & the Tanning Bed Controversy*, 30 J. Clinical Oncology 1571 (2012), *available at* http://jco.ascopubs.org/content/30/14/1571 (last visited Jun. 23, 2014).

[76] Vitamin D Council, *Health Conditions*, *available at* http://www.vitamindcouncil.org/health-conditions/ (last visited Jun. 11, 2014).

intended to be used in sunlamp products, for example, through an individual's diet."[77] Likewise, the American Academy of Pediatrics Policy Statement, authored by Dr. Balk, states that deliberate exposure to UV radiation should be avoided due to the associated skin cancer risk and "[g]uidance should be given about vitamin D adequacy obtained through the diet and supplements."[78]

37. Salons are not only asserting that customers can obtain vitamin D from tanning beds, but also claiming that vitamin D from sunlight or tanning beds is superior to vitamin D from supplementation. For example, Total Tan maintains on its website[79] a link to an article that claims:

> Sunlight exposure is the most reliable way to generate vitamin D in your own body. In a one-hour sunbath, the body can manufacture up to 10,000 units of vitamin D. That is more than five times the recently increased recommended daily allowance for the vitamin. This is another example of how wrong 'health authorities' can be about vitamins. It is impossible for your body to generate too much vitamin D from sunlight exposure: your body self-regulates and only produces what it needs.[80]

Similarly, Portofino's website claims that "[d]uring a typical tanning session your body naturally creates as much Vitamin D as you would get from drinking 100 glasses of milk or eating 25 servings of salmon."[81] Portofino asserts that "The benefit of regular UV exposure as the body's

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[77] 79 Fed. Reg. at 31,210, *supra* footnote 55.

[78] Am. Acad. of Pediatrics Council on Envtl. Health & Section on Dermatology, Sophie J. Balk (lead author), *Policy Statement on Ultraviolet Radiation: A Hazard to Children & Adolescents*, 127 Pediatrics 588-97 (2011), *available at* http://pediatrics.aappublications.org/content/127/3/588.full (last visited Jun. 23, 2014).

[79] Total Tan, *Tanning Industry News*, http://www.totaltancorp.com/articles-on-tanning (last visited Jun. 11, 2014). A print-out of http://www.totaltancorp.com/articles-on-tanning from June 11, 2014 is attached hereto as Exhibit A.

[80] A page from Total Tan's website, reproduced in Exhibit A, states "SUNSHINE ARTICLE 5-1-13" and links to *Vitamin D: The Sunshine Vitamin*, The Gleaner, http://jamaica-gleaner.com/gleaner/20130430/news/news6.html (Apr. 30, 2013). The article is attached as Exhibit B.

[81] Portofino, *We Make Sunshine*, http://www.portofinosun.com/tanning/we-make-sunshine/ (last visited Jun. 11, 2014). A print-out of http://www.portofinosun.com/tanning/we-make-sunshine/ from June 11, 2014 is attached hereto as Exhibit C.

only true natural source of sufficient vitamin D production easily outweighs the manageable risks associated with overexposure to sunlight."[82]

38. There is no evidence that supports indoor tanning as a "superior" method of producing vitamin D. Furthermore, there is nothing in the vitamin D obtained from UV exposure that cannot be obtained through dietary supplementation. In fact, dietary supplementation of vitamin D is identical to what is produced by UV exposure—all without the associated risk of cancer.[83] Thus, because UV exposure from indoor tanning presents health risks and does not provide superior delivery of vitamin D, vitamin D can be attained more safely with dietary supplementation. Indeed, the studies that demonstrate beneficial health effects of vitamin D almost always use oral vitamin D supplements to evaluate the effect of vitamin D.

39. In fact, there are significant limitations on the effectiveness of vitamin D production from indoor tanning. UVA and UVB are different wavelengths of UV light. The body produces vitamin D in response to UVB exposure—not UVA exposure—and the effectiveness of various indoor tanning devices at promoting vitamin D varies with the amount of UVB emitted by a sunlamp.[84] Modern tanning beds emit negligible UVB emissions and are therefore ineffective at stimulating the body to produce vitamin D.[85] Even with older sunlamps that emit UVB, only a limited amount of vitamin D can be obtained before levels plateau.[86] The

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[82] *Id.* (attributing the statement to Dr. William Grant).

[83] Deon Wolpowitz & Barbara A. Gilchrest, *The Vitamin D Questions: How Much Do You Need & How Should You Get It?*, 54 J. Am. Acad. Dermatology 301-17 (2006).

[84] Robert M. Sayre et al., *Variability of Pre-Vitamin D3 Effectiveness of UV Appliances for Skin Tanning*, 121 J. Steroid Biochemistry & Molecular Biology 331-33 (2010); Autier, *supra* footnote 42.

[85] Brian Diffey, *Sunbeds, Beauty & Melanoma*, 157 British J. Dermatology 215-16 (2007); Am. Acad. of Pediatrics, *Ultraviolet Radiation*, *supra* footnote 40, at 595; World Health Org., *supra* footnote 4.

[86] Elisabeth Thieden et al., *Sunbed Radiation Provokes Cutaneous Vitamin D Synthesis in Humans – A Randomized Controlled Trial*, 84 J. Photochemistry & Photobiology 1487-92 (2008); Deon Wolpowitz & Barbara A. Gilchrest, *The Vitamin D Questions: How Much Do You Need & How Should You Get It?*, 54 J. Am. Acad. Dermatology. 301 (2006); Jody A. Levine et al., *The Indoor UV Tanning Industry: A Review of Skin Cancer Risk, Health Benefit Claims, & Regulation*, 53 J. Am. Acad. Dermatology 1038-44 (2005).

amount of vitamin D synthesized in the body as a result of exposure to indoor UV tanning varies tremendously, depending on the details of the UV emitted by the particular tanning machine and the individual being exposed to that UV. For example, while some increases in vitamin D levels were observed after four, six-minute-long indoor tanning sessions, additional tanning yielded no significant increase in vitamin D.[87] Thus, modern tanning beds, particularly with repeated use, will not stimulate the production of vitamin D equivalent to 100 glasses of milk (10,000 international units of vitamin D) as asserted by Portofino.[88] In any event, this amount would exceed the upper limit of the recommended daily intake of vitamin D, which may itself be associated with adverse health effects.[89]

40. Portofino's assertions that the benefits of UV exposure outweigh the risks appear to rely on one article's critique of the World Health Organization's findings on indoor tanning's association with cancer: William B. Grant, *Critique of the International Agency for Research on Cancer's Meta-Analyses of the Association of Sunbed Use With Risk of Cutaneous Malignant Melanoma*, 1 Dermato-Endocrinology 294-99 (2009). That article, however, does not represent generally accepted scientific views or methodologies.[90] His study, funded by the indoor tanning industry, has many flaws including the exclusion of fair-skinned (Fitzpatrick skin type I) residents in the United Kingdom from his analysis, which biases and undermines his conclusions. Grant's conclusions are contradicted by many other studies such as *Exposure to Indoor Tanning Without Burning and Melanoma Risk by Sunburn History*, authored by Rachel

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[87] Thieden et al., *supra*, footnote 86.

[88] Exhibit C.

[89] A. Catharine Ross et al., *The 2011 Report on Dietary Reference Intakes for Calcium & Vitamin D from the Institute of Medicine: What Clinicians Need to Know*, 96 J. Clinical Endocrinology & Metabolism 53 (2011); *see also* Kaveri Korgavkar, Michael Xiong, & Martin A. Weinstock, *Review: Higher Vitamin D Status and Supplementation May Be Associated With Risks*, European J. of Dermatology (2014).

[90] *See, e.g.*, Weinstock & Fisher, *supra* footnote 30.

Vogel, Rehana Ahmed, Heather Nelson, Marianne Berwick, Martin Weinstock, and DeAnn Lazovich, in the Journal of the National Cancer Institute (2014). This study reports data from Minnesota showing that tanning is associated with melanoma risk, even when individuals with sunburns are excluded.

41. The vast majority of vitamin D-related health claims made by Total Tan and Portofino have not been proven and are not generally accepted in the scientific community. The Vitamin D Council website asserts that vitamin D can treat everything from acne to cancer to type II diabetes. Although vitamin D is an important nutrient for bone health, studies have not established a clear link between vitamin D and other health benefits. Particular health claims are discussed in more detail below.

Indoor Tanning Does Not Prevent or Treat Cancer or Heart Disease

42. In addition to linking to the Vitamin D Council's information, tanning salons claim that indoor tanning prevents and treats cancer and heart disease.[91] For example, Total Tan cites to an article that states:

> Contrary to the propaganda, sunlight does not cause cancer. In fact, compelling medical evidence indicates that vitamin D could prevent close to 80 per cent [sic] of all types of cancer. The research results clearly demonstrate that the lower your vitamin D levels in your blood, the higher your risk of developing several cancers. Fifteen cancers have been identified as vitamin D sensitive: colon, stomach, oesophagus, gallbladder, rectum, small intestine, bladder, kidney, prostate, breast, endometrium, ovary, Hodgkins and non Hodgkins lymphoma.[92]

[91] Vitamin D Council, *supra* footnote 76. For example, the Total Tan website (Exhibit A) states "Research from the Boston University School of Medicine," and links to *Increasing Vitamin D Level Improves Immunity & Lowers Cancer Risk*, Big News Network, http://www.bignewsnetwork.com/index.php/sid/213377328/scat/a1e025da3c02ca7c (Mar. 21, 2013). The article is attached as Exhibit D.

[92] Exhibit B.

Total Tan's website also links to information asserting indoor tanning prevents heart disease.[93] Portofino has similar information, stating "Getting enough vitamin D is linked to reductions in heart disease, diabetes, multiple sclerosis & many cancers—are you getting enough?"[94]

43. While there is some research suggesting a link between chronic (not intermittent) *sunlight* exposure and risk of colon, prostate, and breast cancers as well as non-Hodgkin's lymphoma, exposure to UV radiation in tanning beds has not been found to be protective.[95] Sunlamps produce intermittent UV exposure for just minutes at a time, and emit a different mix of UV radiation than the usual solar spectrum.[96] In short, indoor tanning is not the equivalent of sunlight exposure and there is no established link between indoor tanning and colon, prostate, and breast cancers or non-Hodgkin's lymphoma.

44. Even with respect to sunlight exposure, the data is still inconclusive. Acknowledging the studies that show links between prevention of some cancers and sunlight exposure, the U.S. Preventive Services Task Force reviewed the literature on the potential benefits of vitamin D.[97] In its review of 165 primary articles and 11 systematic reviews that incorporated over 200 additional primary articles, the Task Force noted inconsistent findings for colorectal and prostate cancer, and insufficient studies for pancreatic cancer. The study

[93] For example, the Total Tan (Exhibit A) website states "UK article on sunscreen or as they say suncream," and links to Lucy Elkins, *Worried Suncream Blocks Vitamin D? Here's Good News...*, MailOnline, http://www.dailymail.co.uk/health/article-2335478/Worried-suncream-blocks-vitamin-D-Heres-good-news-.html#ixzz34NKqrm4y (Jun. 3, 2013) ("Vitamin D is vital for strong bones and may have many other health benefits. Studies have linked it to heart health, and it may also have a role in preventing certain cancers."). The article is attached as Exhibit E.

[94] Portofino, https://www.facebook.com/permalink.php?story_fbid=10151437886708459&id=196996883458 (posted Feb. 28, 2013, last visited Jun. 11, 2014), attached as Exhibit F.

[95] Han van der Rhee et al., *Is Prevention of Cancer by Sun Exposure More Than Just the Effect of Vitamin D? A Systematic Review of Epidemiological Studies*, 49 European J. Cancer 1422-36 (2013) (addressing only the link between sun exposure and certain cancers, not indoor tanning).

[96] *See, e.g.*, Autier, *supra*, footnote 42.

[97] Mei Chung et al., *Vitamin D With or Without Calcium Supplementation for Prevention of Cancer & Fractures: An Updated Meta-Analysis for the U.S. Preventive Servs. Task Force*, 155 Annals Internal Med. 827 (2011), *available at* http://www.uspreventiveservicestaskforce.org/uspstf12/vitamind/vitdart.pdf (last visited Jun. 11, 2014).

examined the effect of both vitamin D and calcium on cancer, and concluded that synthesizing a dose-response relation between intake of either vitamin D, calcium, or both nutrients and health outcomes in this heterogeneous body of literature proved challenging.

45. Similarly, Dr. Clifford Rosen, a member of the vitamin D subcommittee for the Institute of Medicine, published in The New England Journal of Medicine that "despite the recent focus in the media on the potential role of vitamin D in reducing the risk of various chronic diseases, this hypothesis requires testing in large, randomized, controlled trials, and vitamin D cannot currently be recommended for the purpose of reducing the risk of heart disease or cancer."[98]

46. With respect to breast cancer specifically, no studies directly support the notion that sunshine or indoor tanning prevents breast cancer, and the evidence is inconclusive regarding the role of vitamin D in reducing the risk of breast cancer. Although some studies have found associations between increased vitamin D levels and decreased risk of breast cancer, a statistically significant inverse association between vitamin D levels and breast cancer remains unconfirmed.

47. Perhaps the most aggressively misleading claim on Total Tan's website is its inclusion of a lengthy "testimonial" from an individual with kidney cancer "published to keep you abreast of a current event related to UV light as well as to bring awareness to Kidney Cancer."[99] Despite Total Tan's statement that "[t]his information is not intended to be used by any party to make unwarranted health claims to promote sunbed usage," the testimonial explains the success of a kidney cancer patient who opted to indoor tan at Total Tan in lieu of taking his

[98] Clifford J. Rosen, *Vitamin D Insufficiency*, 364 New Engl. J. Med. 248, 253 (2011).

[99] Total Tan Corp., *Testimonials*, http://www.totaltancorp.com/testimonials (Last visited Jun. 18, 2013). A copy of the testimonial as of June 18, 2013 is attached as Exhibit G. It appears that this material has since been removed from the Total Tan website.

"prescribed [] monthly pill, which was 50,000 unit of a Vitamin D." Total Tan went on to explain:

> One's kidney and Vitamin D go hand in hand. . . . His level of Vitamin D after the surgery was as low as 13 and with the prescription it got as high as 24, in January of 2012. According to Kurt, the normal level for him should have been 30. When Kurt moved to the Albany area he learned about the benefits of UV light and its relationship to Vitamin D. Kurt began tanning at Total Tan in Malta and Saratoga NY. During his January 2013 check Kurt's vitamin D level was a 39. The staggering thing was Kurt has just been tanning once or twice per week and NOT taking the 50,000 unit of Vitamin D.

Indoor Tanning Has Not Been Shown to Treat Asthma

48. In addition to linking to the Vitamin D Council's information on asthma, Total Tan's website links to a BBC News article under the heading "Sunshine and Asthma."[100] But any implication that indoor tanning can treat asthma is unfounded. Neither the Vitamin D Council's discussion of asthma nor the BBC article mentions indoor tanning. Thus, even if there were asthma-related vitamin D benefits, dietary supplementation would be sufficient.

Indoor Tanning Is Not an Established or Safe Way to Lower Blood Pressure or Treat Hypertension

49. Total Tan's website links to a web article, "Blood pressure benefits of sun may outweigh cancer risks" under the heading "Sunshine and BP."[101] The article reports that researchers have found that UV rays release a compound that lowers blood pressure called nitric oxide, which is separate from the body's manufacture of vitamin D. The article's suggestion that UV exposure lowers blood pressure is based, however, on studies of relatively few subjects that

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[100] Vitamin D Council, *Health Conditions – Asthma, available at* http://www.vitamindcouncil.org/health-conditions/asthma/ (last visited Nov. 25, 2013); Total Tan's website (Exhibit A) states "Sunshine and Asthma" and links to James Gallagher, *Sunshine Vitamin 'May Treat Asthma'*, http://www.bbc.com/news/health-22570859 (May 13, 2013). The article is attached as Exhibit H.

[101] Total Tan's website (Exhibit A) states "Sunshine and BP" and links to *Blood Pressure Benefits of Sun May Outweigh Cancer Risks*, http://www.caribbean360.com/news/blood-pressure-benefits-of-sun-may-outweigh-cancer-risks#axzz2SzU2oh68 (May 10, 2013). The article is attached as Exhibit I.

have shown an effect of UVA irradiation on the lowering of systemic blood pressure. These studies, however, have not controlled for changes in diet, exercise, or medication management. It is likely that these changes could have the same—or greater—effect on blood pressure without cancer risk. Moreover unlike UV radiation, numerous safe medications exist, which are broadly successful at maintaining good blood pressure control without inherent carcinogenic risk.

50. As for hypertension (high blood pressure), vitamin D has not been shown to be effective in treating this medical condition. Even if it were effective, a dietary supplement would be a preferable way to obtain vitamin D, without the risks of indoor tanning, and the dose could be measured and adjusted as needed. Furthermore, various, carefully-tested and FDA-approved drugs can be used to control hypertension.

Indoor Tanning Does Not Prevent or Treat Diabetes

51. In addition to linking to the Vitamin D Council's information on diabetes, Total Tan and Portofino claim that indoor tanning treats diabetes.[102] The link between sunlight exposure, vitamin D, and diabetes is not generally accepted in the scientific community. In fact, the majority of randomized controlled trials fail to show impact of vitamin D on insulin resistance or diabetes incidence.[103] The largest randomized controlled trial from the Women's Health Initiative showed no decrease in diabetes risk over seven years after daily vitamin D

[102] Total Tan website (Exhibit A) links to Sophie Borland, *Tanned Women Live Longer (As Long As You Sunbathe Sensibly), Say Scientists*, MailOnline, http://www.dailymail.co.uk/health/article-1335364/Tanned-women-live-longer-say-scientists-Lund-University-Sweden.html (Dec. 3, 2013). The article is attached as Exhibit J and claims that women who tan live longer because the sun helps protect against diabetes in the colder months, a phenomenon attributed to a lack of vitamin D. *See also* Vitamin D Council, *supra* footnote 76; Exhibit B.

[103] Stefan Pilz et al., *Role of Vitamin D in the Development of Insulin Resistance & Type 2 Diabetes*, 13 Current Diabetes Reports 261 (2013); Mayer B. Davidson et al., *High-Dose Vitamin D Supplementation in People With Prediabetes & Hypovitaminosis*, 36 Diabetes Care 260-66 (2013), *available at* http://care.diabetesjournals.org/content/36/2/260.full.pdf (last visited Jun. 11, 2014).

supplementation.[104] Smaller randomized controlled trials involving several hundred subjects did not show glucose or insulin changes after daily vitamin D supplementation.[105]

Indoor Tanning Does Not Prevent Blood Clots

52. An article linked to on Total Tan's website titled "Tanned women live longer (as long as you sunbathe sensibly), say scientists" and information from the Vitamin D Council claim the sun helps protect against blood clots in the leg known as deep vein thrombosis.[106] There is some, but often conflicting and observational data, regarding the benefits of vitamin D for blood clots or thrombosis.[107] A recent extensive review found that

> Despite the wide-ranging experimental and epidemiological evidence . . . , a meta-analysis of 51 trials of vitamin D in the prevention of various cardiovascular outcomes showed no overall benefit. At present, it is unclear whether vitamin D supplementation can reduce the risk or consequences of CVD [cardiovascular disease], and it is not recommended for this indication.[108]

In short, the data is inconclusive even with respect to sunlight, and it certainly has not been shown or generally accepted in the scientific community that indoor tanning prevents blood clots.

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[104] Ian H. de Boer et al., *Calcium Plus Vitamin D Supplementation & the Risk of Incident Diabetes in the Women's Health Initiative*, 31 Diabetes Care 701-07 (2008), available at http://care.diabetesjournals.org/content /31/4/701.full.pdf+html (last visited Jun. 12, 2014).

[105] Siobhan Muldowney et al., *Incremental Cholecalciferol Supplementation Up to 15 ug/d Throughout Winter at 51-55 Degrees N Has No Effect on Biomarkers of Cardiovascular Risk in Healthy Young & Older Adults*, 142 J. Nutrition 1519 (2012); Adrian D. Wood et al., *Vitamin D3 Supplementation Has No Effect on Conventional Cardiovascular Risk Factors: A Parallel, Double-blind, Placebo-Controlled RCT*, 97 J. Clinical Endocrinology & Metabolism 3557 (2012).

[106] Vitamin D Council, *supra* footnote 76; Exhibit J.

[107] Peter Brøndum-Jacobsen et al., *Hydroxyvitamin D Concentrations & Risk of Venous Thromboembolism in the General Population With 18,791 Participants,* 11 J. Thrombosis and Haemostasis 423-31(2013), *available at* http://onlinelibrary.wiley.com/doi/10.1111/jth.12118/pdf (last visited Jun. 11, 2014) (showing higher rates of clots among those with lower rates of circulating Vitamin D).

[108] Paul Norman & Janet Powell, *Vitamin D & Cardiovascular Disease*, 114 Circulation Research 379-93 (2013).

Indoor Tanning Does Not Improve Muscle Efficiency

53. The Total Tan website linked to an article claiming a connection between vitamin D levels and muscle efficiency.[109] Likewise, Portofino claims "A recent study showed that vitamin D helps muscle growth & slows age-related muscle deterioration. Are you as strong as you'd like to be?"[110] There is no generally accepted scientific evidence to support this claim.

Indoor Tanning Does Not Help Prevent Alzheimer's

54. Total Tan links to an article claiming that Vitamin D and omega-3 may help the immune system's ability to clear the brain of amyloid plaques, which is linked to Alzheimer's disease.[111] There is no generally accepted scientific evidence to support this claim.

Indoor Tanning Is Not a Safe Way to Avoid UV Risks or Overexposure

55. The Surgeon General's call to action to prevent skin cancer is clear: "No evidence exists to suggest that indoor tanning is safer than tanning outdoors or confers any substantial protection from future sun exposure."[112]

56. Total Tan asserts, "Moderate tanning, for individuals who can develop a tan, is the smartest way to maximize the potential benefits of sun exposure while minimizing the potential risks associated with either too much or too little sunlight."[113] It further asserts that "The risks of UV light exposure, on the other hand, are mainly associated with sunburn and

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[109] Total Tan's website (Exhibit A) states "Improve Muscle Efficiency," and links to *Vitamin D Replacement Improves Muscle Efficiency*, http://www.sciencedaily.com/releases/2013/03/130317221446.htm (Mar. 18, 2013). The article is attached as Exhibit K.

[110] Portofino, https://twitter.com/Portofino3rdAve/statuses/295985160837554176 (posted Jan. 28, 2013, last visited Jun. 11, 2014), attached as Exhibit L.

[111] Total Tan's website (Exhibit A) states "Vitamin D may help prevent Alzheimer's," and links to *Vitamin D May Help Prevent Alzheimer's*, http://www.upi.com/Health_News/2013/03/05/Vitamin-D-may-help-prevent-Alzheimers/UPI-75631362465703/ (Mar. 5, 2013). The article is attached as Exhibit M.

[112] *Surgeon General's Call to Action*, *supra* footnote 8 at 16.

[113] Total Tan, *History of Tanning*, http://www.totaltancorp.com/history-of-tanning (last visited Jun. 11, 2014), attached as Exhibit N.

overexposure (particularly among individuals who are fair-skinned or genetically predisposed to skin damage) and are easily managed by practicing sunburn prevention."

57. Such assertions are false. First, the UV output of tanning devices is much greater than what is found in natural sunlight. Second, tanning devices have a wide variance in UV output. Third, tanning booth operators typically lack training and knowledge of UV exposures. In fact, according to the Centers for Disease Control and Prevention, in the United States, 1,800 injuries requiring visits to the emergency room are attributed to UV radiation from tanning beds each year.[114] Thus, it is very difficult to prevent overexposure when using a tanning device.

58. Whether you get sunburned or not, there is no safe tan. UV radiation exposure increases the risk of skin cancer. Tanning salons often use tanning beds with certain UV wavelengths, such as UVA, to avoid burning, but these tanning beds are still not safe. In fact, the link between UV exposure and cancer is very closely linked to the tanning process itself. Studies show that UV radiation damages the DNA within the nuclei of epidermis cells and produces skin pigment.[115] Tanning is thus a response to cellular injury, and if UV irradiation is capable of producing pigmentation, DNA damage has inevitably occurred. Therefore, regardless of whether the skin tans or burns, UV exposure can damage the DNA of the epidermis and increase the risk of skin cancer. Thus, the idea that indoor tanning can provide a "base tan" to protect against outdoor sun exposure is a misconception. As the FDA recently found, "there is no evidence that moderate non-burning UV exposure or attaining a 'base tan' provides any protection against premature aging of the skin or reduces the risk of skin cancer."[116]

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[114] Ctrs. for Disease Control & Prevention, *supra* footnote 13.

[115] John A. D'Orazio, Tetsuji Nobuhisa, Rutao Cui, Michelle Arya, Malinda Spry, Kazumasa Wakamatsu, Vivien Igras, Takahiro Kunisada, Scott R. Granter, Emi K. Nishimura, Shosuke Ito & David E. Fisher, *Topical Drug Rescue Strategy & Skin Protection Based on the Role of Mc1r in UV-Induced Tanning*, 443 Nature 340-44 (2006).

[116] 79 Fed. Reg. at 31,210, *supra* footnote 55. *See also* Balk, *Technical Report* at 799, *supra* footnote 59.

Indoor Tanning Does Not Safely Provide Psychological Benefits

59. Total Tan claims that "we know that clients come to facilities for more than just a good tan; they also enjoy the positive psychological and physiological effects of regular exposure to ultraviolet light" and that "there are known physiological and psychological benefits associated with UV light exposure."[117] Portofino claims "Feeling the winter blues or a little post-holiday stress? Nothing perks you up like a little vitamin D."[118]

60. Studies have shown that visible light therapy, not UV light therapy, can effectively treat seasonal mood problems, such as seasonal affective disorder (SAD). The light therapy boxes used for visible light therapy filter out UV light. Therefore, sunlamps are ineffective for such treatment.[119]

61. Indoor tanning also can be addictive as discussed above in "Indoor Tanning Can Be Addictive" in Paragraphs 32-34.

Indoor Tanning Is Not a Safe Way to Treat "Problem Skin"

62. Portofino contends that indoor tanning "can help clear up problem []skin,"[120] but this statement is not accurate. The concept that UV light can benefit certain skin conditions is true, but the optimal way to treat psoriasis, for example, involves exposure to narrow band UVB phototherapy under the direction of a trained physician that minimizes complications, including

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[117] Exhibit N.

[118] Portofino, https://mobile.twitter.com/PortofinoSun/status/292350910477246464 (posted Jan. 18, 2013, last visited Jun. 12, 2014), attached as Exhibit O.

[119] *Surgeon General's Call to Action, supra* footnote 8 at 21; Anne Harding, *Tanning No Cure for Seasonal Depression, available at* http://www.reuters.com/article/2009/01/22/us-seasonal-depression-idUSTRE50L4UW20090122 (last visited Jun. 24, 2014).

[120] Portofino, https://twitter.com/PortofinoSun/status/303636973548097536 (posted Feb. 18, 2013, last visited Feb. 12, 2015), attached as Exhibit P.

skin cancers.[121] For managing acne, the American Academy of Dermatology recommends staying out of the sun and away from tanning booths.[122] In addition, certain acne medications make the skin very sensitive to UV light from tanning beds.[123] Thus, self-treatment using indoor tanning beds is not a safe way to treat skin conditions, especially given the skin cancer risk.

Unlimited Packages Encourage Frequent Tanning

63. Tanning salons, including Total Tan and Portofino, encourage customers to tan more and more frequently—and continually increase their cancer risk—by offering low-priced, "unlimited" monthly tanning memberships.[124] On average, non-Hispanic Caucasian 17-year-olds tan indoors 24 times per year. By age 18, these high school students tan indoors 30 times per year.[125] At this rate, only three years of tanning amounts to an estimated 90 sessions, increasing one's cancer risk significantly.[126] While no amount of indoor tanning is safe, such "unlimited" packages imply that very frequent indoor tanning is safe. Further, low cost plans encourage more frequent indoor tanning despite the cumulative increase in cancer rates that occur with each salon visit. This practice should be discontinued.

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[121] *See, e.g.*, Nat'l Psoriasis Foundation, *Position Statement on Indoor Tanning*, http://www.psoriasis.org/about-psoriasis/treatments/statement-on-tanning-beds (Jul. 31, 2013); Thilo Gambichler et al., *Narrowband UVB Phototherapy in Skin Conditions Beyond Psoriasis*, 52 J. Am. Acad. Dermatology 660-70 (2005).

[122] Am. Acad. Dermatology, *Acne: Tips for Managing*, https://www.aad.org/dermatology-a-to-z/diseases-and-treatments/a---d/acne/tips (last visited Feb. 25, 2015).

[123] *Id.*

[124] *See, e.g.*, Total Tan, http://www.totaltancorp.com/monthlyspecials (last visited Jun. 11, 2014) ("30% OFF All One Week Unlimited Packages"), attached as Exhibit Q.

[125] Gery P. Guy et al., *Indoor Tanning Among Young Non-Hispanic White Females*, JAMA Internal Medicine (2013).

[126] Boniol et al., *supra* footnote 28 (an estimated 1.8% increase in risk of melanoma for each additional session of tanning bed use per year). The 1.8% increase in melanoma risk is the increase solely due to indoor tanning. Natural sun exposure further increases cancer risk.

Conclusions

64. Indoor tanning is carcinogenic. Numerous well-respected scientific organizations have concluded that indoor tanning raises the risk of developing skin cancer, including melanoma, the most commonly fatal type of skin cancer. Melanoma incidence is rising, especially among teenage girls and young women. Melanoma kills, and some of its victims are young people.

65. Indoor tanning can be physically addictive. Studies show that indoor tanning addiction is linked to tanning frequency and endorphin release. Among those addicted, stopping indoor tanning can lead to withdrawal symptoms.

66. Despite the fact that indoor tanning drastically increases skin cancer risk—and also causes premature aging of the skin and eye damage—indoor tanning is common, especially among young women. Salons aggressively market indoor tanning, targeting youth and women and promoting "unlimited" tanning packages.

67. Health claims made by tanning salons are not supported by scientific evidence. Without the need for indoor tanning, vitamin D supplements can more safely, more reliably, and less expensively supply vitamin D and achieve any vitamin D-related benefit. Indeed, most vitamin D-related health claims are unproven or false. In conclusion, indoor tanning causes skin cancer and is, therefore, not safe.

Author Background

Sophie Julia Balk, M.D.

68. Dr. Balk is a general pediatrician at Children's Hospital at Montefiore and Professor of Clinical Pediatrics at the Albert Einstein College of Medicine. She practices pediatrics and teaches in a community-based health center in the Bronx, New York. For the last

two decades, Dr. Balk's academic work has focused on educating clinicians about environmental health issues relevant to children. She was Chairperson of the American Academy of Pediatrics Committee on Environmental Health from 1999 to 2003. She is Associate Editor of the 1st, 2nd and 3rd Editions of Pediatric Environmental Health, a manual for clinicians published by the American Academy of Pediatrics. She founded and was Chairperson of the Academic Pediatrics Association Special Interest Group on Environmental Health and is co-chairperson of the National Council on Skin Cancer Prevention. Dr. Balk has published extensively and lectured regionally and nationally on smoking cessation, sun safety, and other environmental health issues. A graduate of Cornell University, Dr. Balk received her M.D. from the Albert Einstein College of Medicine. Dr. Balk's Curriculum Vitae is attached to the expert report as Exhibit R.

David E. Fisher, M.D., Ph.D.

69. Dr. Fisher is an internationally known researcher, clinician and academic, who currently serves as Chief of the Massachusetts General Hospital Department of Dermatology at Harvard Medical School in Boston, Massachusetts. He also serves as Director of the Massachusetts General Hospital Cutaneous Biology Research Center and Director of the Melanoma Center at Massachusetts General Hospital. A Professor of Dermatology and of Pediatrics at Harvard Medical School, Dr. Fisher came to the Massachusetts General Hospital from the Dana-Farber Cancer Institute, where he previously directed the Melanoma Program. Dr. Fisher's research has focused on understanding the molecular and genetic events which underlie formation of melanoma as well as skin pigmentation. As a clinician, he has worked to translate these understandings into advances in diagnosis, treatment and prevention of human diseases related to the skin and associated disorders. A graduate of Swarthmore College with a degree in Biology and Chemistry, Dr. Fisher received his Ph.D. under Nobel Laureate Gunter

Blobel at Rockefeller University and his Medical Degree at Cornell University Medical College under Dr. Henry Kunkel. Dr. Fisher's specialty training in Medicine, Pediatrics, and Oncology were carried out at Harvard Medical School. He recently served for three years as President of the Society for Melanoma Research, the largest international society dedicated to the study of melanoma. Dr. Fisher's Curriculum Vitae is attached to the expert report as Exhibit S.

Alan C. Geller MPH, RN

70. Professor Geller currently holds the positions of Senior Lecturer in the Department of Social and Behavioral Sciences at the Harvard School of Public Health; Director of Melanoma Epidemiology at Massachusetts General Hospital; and Adjunct Associate Professor (Research) in the Department of Dermatology at the Boston University School of Medicine. Professor Geller has been a Harvard faculty member since 2010. For more than 20 years, he was on staff and faculty at the Boston University School of Medicine and Public Health. In 2009, Professor Geller moved his research from Boston University's School of Medicine and Public Health to Boston University's Division of Public Health Practice. Professor Geller's research is focused on skin cancer screening, prevention, and treatment. Professor Geller has published over 190 manuscripts, 70 abstracts, and 25 book chapters, and holds a Master's degree in Public Health specializing in Epidemiology from Boston University and undergraduate degrees in Sociology and Nursing from the University of Buffalo and MassBay Community College, respectively. Professor Geller's Curriculum Vitae is attached to the expert report as Exhibit T.

Martin A. Weinstock, M.D., Ph.D.

71. Dr. Weinstock graduated from Williams College with a Bachelor of Arts Summa Cum Laude with Highest Honors in Mathematics. He earned his Ph.D. degree in Epidemiology at the Graduate School of Arts and Sciences and M.D. degree at the College of Physicians and

Surgeons, both at Columbia University in the City of New York. He completed his internship at the University of Pittsburgh Affiliated Hospitals (Presbyterian-University and Oakland V.A. Hospitals) and his residency in Dermatology at the Harvard University Affiliated Hospitals, followed by the Andrew W. Mellon Foundation fellowship in Clinical Epidemiology at Harvard Medical School. He is board certified in dermatology. His research has been supported by multiple research grants from the National Institutes of Health, the U. S. Department of Veterans Affairs Office of Research and Development, and non-profit foundations. Dr. Weinstock holds a dual appointment at Brown University in both the Department of Dermatology and the Department of Community Health. Dr. Weinstock's clinical interests include melanoma and nevi, and his research focuses on the epidemiology of cutaneous malignancies and dysplasias. He is author of over 350 publications and has delivered over 200 invited lectures in the United States and other countries on five continents. Dr. Weinstock's Curriculum Vitae is attached to the expert report as Exhibit U.

Submitted,

Sophie Julia Balk, M.D. — March 12, 2015

David E. Fisher, M.D., Ph.D. — March __, 2015

Alan C. Geller MPH, RN — March __, 2015

Surgeons, both at Columbia University in the City of New York. He completed his internship at the University of Pittsburgh Affiliated Hospitals (Presbyterian-University and Oakland V.A. Hospitals) and his residency in Dermatology at the Harvard University Affiliated Hospitals, followed by the Andrew W. Mellon Foundation fellowship in Clinical Epidemiology at Harvard Medical School. He is board certified in dermatology. His research has been supported by multiple research grants from the National Institutes of Health, the U. S. Department of Veterans Affairs Office of Research and Development, and non-profit foundations. Dr. Weinstock holds a dual appointment at Brown University in both the Department of Dermatology and the Department of Community Health. Dr. Weinstock's clinical interests include melanoma and nevi, and his research focuses on the epidemiology of cutaneous malignancies and dysplasias. He is author of over 350 publications and has delivered over 200 invited lectures in the United States and other countries on five continents. Dr. Weinstock's Curriculum Vitae is attached to the expert report as Exhibit U.

Submitted,

Sophie Julia Balk, M.D.	March __, 2015
David E. Fisher, M.D., Ph.D.	March 5th 2015
Alan C. Geller MPH, RN	March __, 2015

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Submitted,

Sophie Julia Balk, M.D.	March __, 2015
David E. Fisher, M.D., Ph.D.	March __, 2015
Alan C. Geller MPH, RN	March 4, 2015

Martin A. Weinstock, M.D., Ph.D.

4-2-15
March __, 2015

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

FDA News Release

FDA proposes tanning bed age restrictions and other important safety measures

For Immediate Release

December 18, 2015

Release

Español (/NewsEvents/Newsroom/ComunicadosdePrensa/ucm478029.htm)

Today, the U.S. Food and Drug Administration announced important proposed steps to protect public health by preventing the use of sunlamp products (also commonly known as indoor tanning beds) by minors and reducing the risk of using these devices for adults. The FDA is committed to protecting public health by informing consumers of the risks of indoor tanning.

"Today's action is intended to help protect young people from a known and preventable cause of skin cancer and other harms," said acting FDA Commissioner Stephen Ostroff, M.D. "Individuals under 18 years are at greatest risk of the adverse health consequences of indoor tanning."

Indoor tanning is a known contributor to skin cancer, including melanoma (its most deadly form), and other skin damage. Yet, 1.6 million minors indoor tan each year, increasing their risk of skin cancer and other damage (based on data in the 2013 National Youth Risk Behavior Survey).

According to the American Academy of Dermatology, those who have been exposed to radiation from indoor tanning are 59 percent more likely to develop melanoma than those who have never tanned indoors.

In addition, the effects of exposure to UV radiation add up over one's lifetime. Therefore, UV radiation exposure in children and teenagers puts them at a greater risk for skin and eye damage later in life.

The FDA is issuing two proposed rules today. The first proposed rule would restrict use of sunlamp products to individuals 18 and older. In addition, before their first tanning session and every six months thereafter, adult users over age 18 would have to sign a risk acknowledgement certification that states that they have been

(62)

informed of the risks to health that may result from use of sunlamp products. According to the Centers for Disease Control and Prevention, an average of more than 3,000 emergency department room visits occur for injuries related to indoor tanning each year in the U.S. (based on 2003-2012 data).

The FDA also issued a second proposed rule today that would require that sunlamp manufacturers and tanning facilities take additional measures to improve the overall safety of these devices. Specifically, some of the key proposed changes would include:

- making warnings easier to read and more prominent on the device;
- requiring an emergency shut off switch, or "panic button";
- improving eye safety by adding requirements that would limit the amount of light allowed through protective eyewear;
- improving labeling on replacement bulbs so tanning facility operators can make sure they are using the proper replacement bulbs, reducing the risk of accidental burns; and
- prohibiting dangerous device modifications, like installing stronger bulbs, without re-certifying and re-identifying the device with the FDA.

"The FDA understands that some adults may decide to continue to use sunlamp products," continued acting FDA Commissioner Stephen Ostroff, M.D. "These proposed rules are meant to help adults make their decisions based on truthful information and to ensure manufacturers and tanning facilities take additional steps to improve the safety of these devices."

The proposed device restriction would apply to manufacturers and tanning facility operators. There are approximately 18,000 to 19,000 indoor tanning salons and 15,000 to 20,000 other facilities, such as health clubs, spas, and other commercial establishments, that offer tanning services in the U.S. The FDA has information for consumers and businesses via the **Division of Industry and Consumer Education (DICE) (/MedicalDevices/DeviceRegulationandGuidance/ContactUs--DivisionofIndustryandConsumerEducation/ucm20041265.htm)**. Also, additional guidance and information for industry is included in the proposed rules.

The proposed restriction and updated performance standards are two of the latest steps the Department of Health and Human Services is taking to reduce the risks associated with skin cancer. In July 2014, the Office of the Surgeon General issued a **Call to Action to Prevent Skin Cancer (http://www.surgeongeneral.gov/library/calls/prevent-skin-cancer/)**, which included strategies for reducing indoor tanning among minors.

The proposed rules are available online at **www.regulations.gov (http://www.regulations.gov)** for public comment for 90 days.

How to Comment on the Proposed Rules

To comment on the Restricted Sale, Distribution, and Use of Sunlamp Products:

1. Read the **proposed rule (http://www.regulations.gov/#!documentDetail;D=FDA-2015-N-1765-0001)**.
2. Starting Tuesday, December 22, submit comments on the proposed rule on Regulations.gov.

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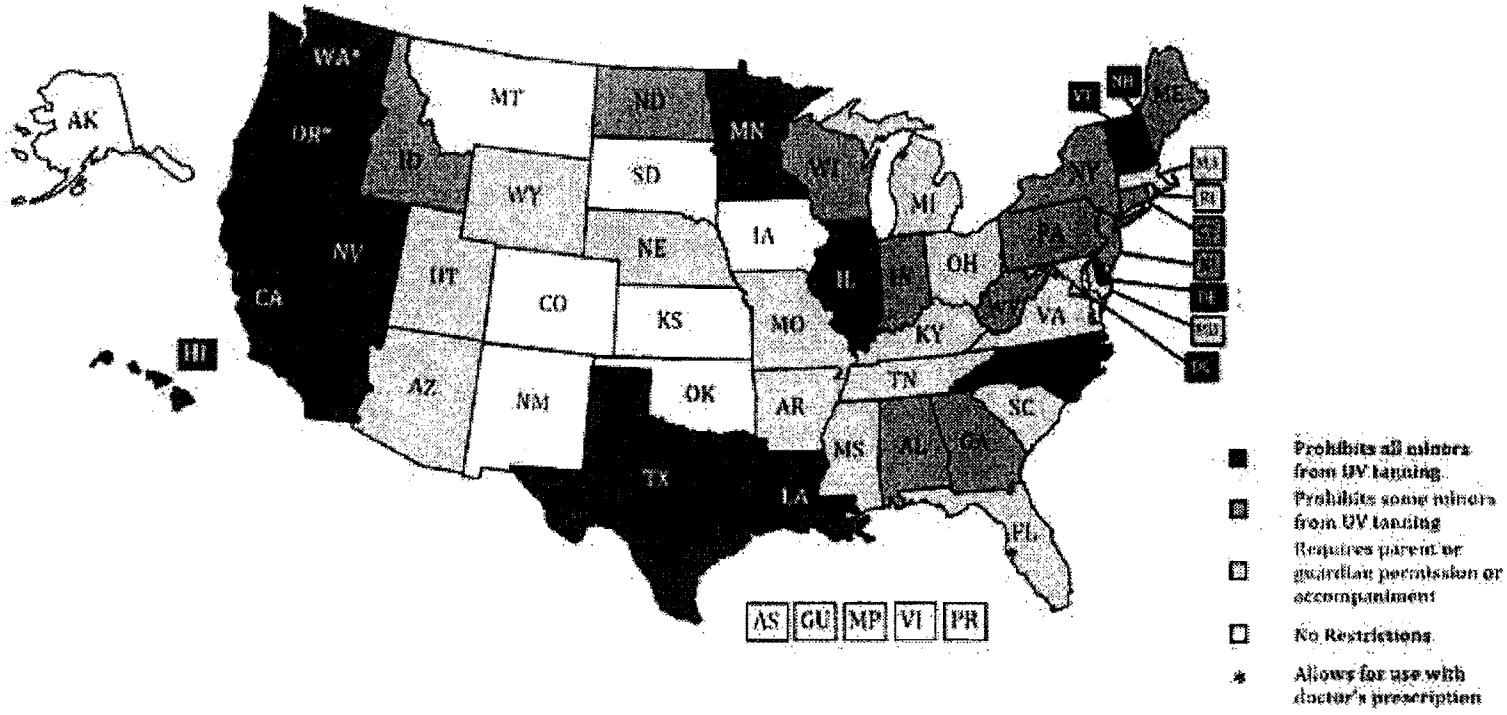
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DC
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VI
PR
Prohibits all minors from UV tanning
Prohibits some minors from UV tanning
Requires parent or guardian permission or accompaniment
No Restrictions
* Allows for use with doctor's prescription

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Testimony on behalf of County Executive Isiah Leggett
Bill 5-16, Tanning Facilities – Amendments

March 22, 2016

Good afternoon Council President Floreen and Councilmembers. I am Dr. Ulder Tillman, Montgomery County Health Officer, and I am here today to testify on behalf of the County Executive in support of Bill 5-16, which would place limits on the use of tanning facilities in the County.

The County Executive offers his support for this bill as it addresses a serious potential threat to the health of our residents, including minors. This bill prohibits minors from using indoor tanning devices; prohibits use of a tanning facility by anyone more than once in a 24-hour period; requires sanitization of the tanning device after each use; and requires the posting of certain warnings and maintenance records. Adding these additional restrictions and educational warnings to existing law makes public health sense.

While exposure to ultraviolet (UV) light is fairly consistent across age groups, research indicates that high-risk exposure happens more commonly in teens and that blistering sunburns and overexposure during childhood greatly increase the chances of developing skin cancer later in life. Because sun (and UV) exposure in childhood and the teenage years can be so damaging, policymakers in some states and territories are regulating minors' use of tanning devices (like tanning beds). Twelve states, including Delaware and the District of Columbia, ban the use of tanning beds for all minors under 18. Maryland regulates the use of tanning facilities by minors, allowing use only with "in-person" parental permission. Some counties and cities across the U.S. also regulate the use of tanning devices, including Howard County, Maryland, which was the first local jurisdiction to ban indoor tanning for all minors under age 18. (*National Conference of State Legislatures website - http://www.ncsl.org/research/health/indoor-tanning-restrictions.aspx*)

Montgomery County has a long history of being out in front of efforts to protect the health, safety, and well-being of our residents. In addition, this ban on underage use of tanning facilities furthers the state law's function to protect minors from the harmful effects of tanning devices which currently allows use with parental permission. The County Executive believes that this bill strengthens the County's commitment to the public's health and urges passage of this legislation.

The County Attorney has offered some suggestions for minor technical changes that we believe will clarify and improve the bill. A copy of that memorandum is also being submitted for the record. Executive staff will work with Councilmembers and their staff to address those suggestions.

Thank you for allowing me to testify this afternoon.

JAMIE RASKIN
Legislative District 20
Montgomery County

MAJORITY WHIP

Judicial Proceedings Committee

Chair
Executive Nominations Committee

Senate Chair
Joint Committee on Legislative Ethics

Joint Committee on the Chesapeake and Atlantic Coastal Bays Critical Area

Joint Committee on Federal Relations

The Senate of Maryland
ANNAPOLIS, MARYLAND 21401

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March 21, 2016

Dear Council President Floreen and Members of the Montgomery County Council:

Greetings. I am writing in strong support of Councilmember Tom Hucker's bill, 5-16, which would prohibit minors from using indoor tanning facilities in Montgomery County. I have introduced the statewide version of this legislation in the Maryland Senate five times over the last decade. At hearings, I have brought in the leading representatives of Maryland's official organizations for nurses, pediatricians, oncologists, dermatologists, and physicians, not to mention all of the relevant recommendations and warnings from the World Health Organization, the American Cancer Society and essentially every governmental and private entity on earth devoted to the cause of reducing and preventing cancer. They all testify that it is a scientific certainty that a minor's chances of contracting melanoma and other deadly forms of skin cancer go up dramatically with use of indoor tanning technology. They also testify that the cosmetic effects sought through tanning technology are easily replicable with tanning spray. A former Miss Maryland showed us dozens of scars on her body from surgical operations she had after being diagnosed with melanoma, a diagnosis she received after years of intensive tanning; we heard a lot of testimony like that, all of it from young women who got caught up in our dangerous commercial tanning culture. The force of this testimony is simply overwhelming.

However, in Annapolis, this powerful testimony has never been enough to overcome the statements of a handful of paid lobbyists for the tanning industry who question the scientific research and claim that the legislation is an interference with parental rights. We repeatedly came up one or two votes short of getting this bill out of the Senate Finance Committee, which always has a slight tilt towards the industry point of view. As a cancer survivor, this has been a profound frustration for me. Since I started introducing this legislation back in 2010, I have been able to help move through the Senate marriage equality, abolition of the death penalty, medical marijuana, a ban on military-style assault weapons, ignition interlock devices on the cars of repeat drunk drivers, and other dramatic policy changes. And, yet, a painfully simple public health measure to save minors from the carcinogenic effects of indoor tanning, which I thought would be the easiest of all, remains stymied by expert industry lobbying and politicking.

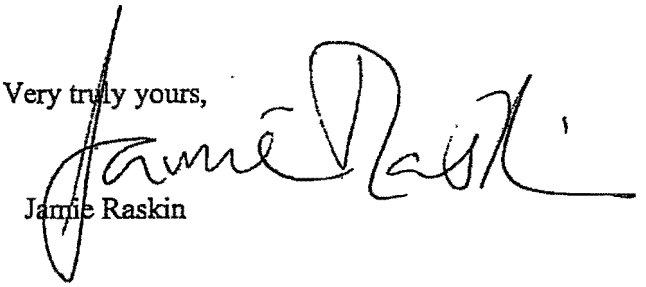
The adverse public health effects of indoor tanning for minors are well-known. The International Agency for Research on Cancer, a division of the World Health Organization (WHO), has ranked indoor tanning to be within the agency's highest cancer-risk category, which also includes asbestos, plutonium, and tobacco smoking. It recommends that indoor tanning be restricted only to those ages 18 and older, and even disfavors it for adults. An analysis of approximately 20 studies by Lancet Oncology concludes that the risk of skin cancer jumps by 75% when people start using tanning beds before age 30. The WHO has concluded that overexposure to all forms of UV radiation from the sun and artificial sources is known to substantially increase the risk of skin cancer, which remains the most common form of cancer in the United States. Indoor tanning is

responsible for increased rates of melanoma, the deadliest form of skin cancer and the second most common form of cancer for young people 15-29 years old.

Maryland restricts a minor's ability to access alcohol and tobacco products because it is widely recognized that the consumption of these products is inherently dangerous. We don't allow kids to smoke cigarettes if they can get a note from their parents. We don't allow kids to drink liquor if they get a note from their parents. This is because we recognize these habits to be deadly health risks and we recognize the public interest in categorically limiting young people's access until they are adults and fully understand the health risks they are accepting. Melanoma and other skin cancers are preventable forms of cancer. Let us help parents enforce healthy rules rather than arm short-sighted kids with the all-too-convenient argument that "if this were really dangerous, the government would not allow minors to do it."

Currently at least 42 states regulate tanning facilities. In Maryland, Howard County has a ban in effect. The Montgomery County Council can strike a major blow for young people's public health by passing Councilman Hucker's bill. I would feel very proud of Montgomery County taking this common-sense step towards public health and I strongly urge you to pass the bill. Thank you for your attention.

Very truly yours,



Jamie Raskin

KIRILL REZNIK
Legislative District 39
Montgomery County

Appropriations Committee
Chair
Health and Human
Resources Subcommittee
Vice-Chair
Montgomery County Delegation

THE MARYLAND HOUSE OF DELEGATES
ANNAPOLIS, MARYLAND 21401

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District Office
301-540-0054 · *Fax* 301-540-0911

March 17, 2016

County Council for Montgomery County Office Building
100 Maryland Avenue, 5th Floor
Rockville, MD 20850

Re: Bill 5-16: Tanning Facilities, Amendments
Recommendation: Favorable Report

Dear Honorable County Council Members,

I'm writing in strong support of Bill 5-16, introduced by Councilmember Tom Hucker, to ban minors from using indoor tanning devices. I applaud the Councilmember for his leadership on this issue and I encourage the Council to be proactive in protecting our Maryland youth by voting in favor of this bill.

The health risks associated with tanning devices are many. Indoor tanners are 2.5 times more likely to develop squamous cell carcinoma than non-indoor tanners, with more than 419,000 cases of skin cancer in the United States are linked to indoor tanning every year (National Cancer Institute & JAMA Dermatol). These risks are particularly damaging for youth. According to the British Medical Journal (2012), just minimal use of tanning beds before the age of 35 can increase one's risk of getting melanoma by 59%. Furthermore, the United States Surgeon General and the Food and Drug Administration have both cautioned against the use of indoor tanning devices, with specific warnings against tanning bed use by minors.

As elected officials, we have a special responsibility to protect all Marylanders. That is why I have sponsored legislation at the state level on this very issue. Bill 5-16 seeks to do the same at the county level and is a much needed measure to help protect our County youth.

I hope you will join me in supporting this bill and serving as an example for the rest of the state to take a stand and protect our children from the harmful consequences of artificial tanning.

Sincerely,

Delegate Kirill Reznik

March 18, 2016

Montgomery County Council
Council President, Nancy Floreen
100 Maryland Avenue
Rockville, MD 20850

Dear Members of the Montgomery County Council,

On behalf of the more than 13,500 U.S. members of the American Academy of Dermatology Association (AADA), I am writing to thank you for your leadership and share our support for Bill 5-16, which would join Howard County in prohibiting minors in Montgomery County from using indoor tanning beds. As dermatologists, we dedicate our lives to promoting habits in our patients that ensure healthy skin. The AADA is extremely concerned with the frequent patronage of indoor tanning facilities by adolescents, and urge you and your colleagues to take the necessary steps to protect Montgomery County's teens from the dangers of indoor tanning.

Tanning Device Use is as Carcinogenic as Tobacco Smoking

Ultraviolet (UV) radiation from tanning beds has been classified at the highest level as a known human carcinogen by the US Department of Health and Human Services, and is recognized as "carcinogenic to humans" by the World Health Organization's International Agency for Research on Cancer in the same category as tobacco and tobacco smoking, mustard gas, and asbestos.[1] In addition, the Centers for Disease Control and Prevention's Healthy People 2020 goals include the reduction of adolescent use of indoor tanning devices.[2]

The U.S. Food and Drug Administration (FDA) recognizes the dangers associated with tanning devices as demonstrated by recent actions on this issue. Most recently, the FDA proposed new regulations that would restrict minors under 18 from using indoor tanning beds and it would require all adults to sign a risk acknowledgement form before using indoor tanning devices. This follows action in 2014, when the FDA finalized changes to its regulation of tanning beds, including a strong recommendation against the use of tanning beds by minors under the age of 18. This order raises the classification for sunlamps and tanning beds to a Class II level, which institutes stricter regulations to protect public health. Additionally, the new order would require tanning bed and lamp manufacturers to label sunlamp products

[1] IARC Working Group. Special Report: Policy; A review of human carcinogens –Part D: radiation. *Lancet Oncology* 2009; 10: 751-52.
[2] US Department of Health and Human Services. Healthy People 2020. www.healthypeople.gov/hp2020/Objectives, accessed 22 Nov 2010.

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with a visible black-box warning that explicitly states that the sunlamp product should not be used on persons under the age of 18 years. Further, marketing materials must contain similar warnings and inform consumers of the risk of skin cancer.

In addition to actions taken by the FDA to address the dangers of indoor tanning, the U.S. Department of Health and Human Services' (HHS) Office of the Surgeon General issued a national call-to-action on skin cancer prevention. The national call to action identifies opportunities for the government, public and private organizations, health care providers and individuals to raise awareness of skin-protection practices. Specifically, the call to action recommends state and local policies and legislation to restrict minors' access. It recognizes that indoor tanning laws that restrict minors' access have been effective in reducing indoor tanning among the most at-risk populations.

There is no such thing as a "safe" tan. UV radiation damages the skin's DNA, which is the beginning stage of skin cancer. Use of indoor tanning beds has been linked to melanoma, basal cell carcinoma, squamous cell carcinoma, molecular damage of the skin, and other acute damage to the eyes and skin, and should be avoided.

Indoor Tanning Significantly Increases One's Risk of Developing Skin Cancer

Epidemiologic data suggest that most skin cancers can be prevented if children, adolescents, and adults are protected from UV radiation. However, the deadliest form of skin cancer, melanoma, is the most common form of cancer for young adults 25-29 years old and the second most common form of cancer for adolescents and young adults 15-29 years old. A study published in the International Journal of Cancer found that compared with study participants who had never used a tanning bed, the risk of melanoma was 41percent higher for those who had ever used a tanning bed, and was approximately doubled for those who reported more than 10 lifetime sessions.[3]

Indoor tanning is no longer only a risk factor for melanoma. New evidence demonstrates that ever-use of indoor tanning beds is associated with a 69 percent increased risk of early-onset basal cell carcinoma (BCC), the most common form of skin cancer. Risk of developing BCC was also higher in those who begin indoor tanning at earlier ages.[4]

Prohibiting use of indoor tanning for all minors under the age of 18 is critical to preventing future skin cancers. Survey data indicate use of these devices increases with each year of adolescence: indoor tanning rates among 14-, 15-, 16-, and 17-year-old girls in 2010 were 5 percent, 13.6 percent, 20.9 percent, and 26.8 percent, respectively.

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[3] Cust AE, Armstrong BK, Goumas C, Jenkins MA, Schmid H, Hopper JL et al. Sunbed use during adolescence and early adulthood is associated with increased risk of early-onset melanoma. Int J Cancer Jul 28, 2010.

[4] Ferruci LM, Cartmel B, Molinaro AM, Leffell DJ, Bale AE, Mayne ST. Indoor tanning and risk of early-onset basal cell carcinoma. *J Amer Acad Dermatol* Doi: 10.1016/j.jaad.2011.11.940. Published online December 8, 2011.

Tanning Industry Consistently Misleads Customers

In January 2010, the Federal Trade Commission charged the Indoor Tanning Association (ITA) with making false health and safety claims about indoor tanning. The ITA is now prohibited from making any false health claims, misrepresenting any tests or studies, and cannot provide deceptive advertisements to its members. Moreover, future advertisements from the association must contain disclosures regarding the risk of developing skin cancer and disclosures about vitamin D.

In February 2012, the US House of Representatives Energy and Commerce Committee released an investigative report detailing false and misleading health information provided by the indoor tanning industry. This investigation revealed that salons described the suggestion of a link between indoor tanning and skin cancer as a "myth," "rumor," or "hype." It also revealed that four out of five tanning salons falsely claimed that indoor tanning is beneficial to a young person's health. In fact, salons used many approaches to downplay the health risks of indoor tanning, including blaming the use of sunscreen as a reason for rising rates of skin cancer in the US. Many of the salons tried to validate the safety of indoor tanning by alluding to the fact that unsafe practices would not be allowed by the government. The Committee's report reconfirms that stronger state and federal laws are needed to provide oversight of this industry.[5]

Despite Legislative Gains, Increased Regulation Continues to be Necessary

Tanning advocates often argue that additional regulation of their industry is not necessary. Yet, despite some progress, the tanning industry remains highly unregulated and studies have indicated that state laws requiring only parental consent are ineffective at curbing this dangerous activity. Furthermore, commercial indoor tanning facilities are prevalent in the US, with an average of 42 tanning salons per major US city. This number exceeded the number of Starbucks and McDonalds in most locations.[6]

Although 43 states, including the District of Columbia, and ten local jurisdictions regulate indoor tanning facilities, more must be done. The AADA believes protecting the public, especially adolescents, and requiring appropriate oversight of the indoor tanning industry will have a profound effect on improving public health and reducing overall health care costs. Annually, about $3.3 billion of skin cancer treatment costs are attributable to melanoma.[7] Of course, this figure does not begin to account for the tragic loss of life from this menacing disease.

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[5] US House Committee on Energy and Commerce. False and Misleading Health Information Provided to Teens by the Indoor Tanning Industry Investigative Report. http://democrats.energycommerce.house.gov/sites/default/files/documents/Tanning%20Investigation%20Report%202.1.12.pdf, accessed 20 Feb 2012.

[6] Hoerster KD, Garrow RL, Mayer JA, Clapp EJ,Weeks JR, Woodruff SI, Sallis JF, Slymen DJ, Patel MR, Sybert SA. "Density of indoor tanning facilities in 116 large U.S. cities." *Am J Prev Med* 2009; 36 (3): 243-46.

[7] U.S. Department of Health and Human Services. The Surgeon General's Call to Action to Prevent Skin Cancer. Washington, DC: U.S. Dept of Health and Human Services, Office of the Surgeon General; 2014: page 1.

We urge you and your colleagues to support Bill 5-16 in order to reinforce the proposed actions taken on the federal level and increase the level of state protection for adolescents and young adults from the dangers of indoor tanning in Montgomery County. We appreciate the opportunity to provide written comments on this important public health issue. For further information, please contact Lisa Albany, associate director of state policy for the AADA, at LAlbany@aad.org or (202) 712-2615.

Sincerely,

Abel Torres M.D., FAAD

Abel Torres, MD, JD, FAAD
President
American Academy of Dermatology Association

American Cancer Society
Cancer Action Network
801 Roeder Road, Suite 800
Silver Spring, MD 20910
301.758.1255
www.acscan.org

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March 22, 2015

TO: George Leventhal, President
Members Montgomery County Council
FROM: Bonita M. Pennino, MS, Government Relations Director
RE: **Support 5-16 Tanning Facilities - Amendments**

Position:
The American Cancer Society Cancer Action Network (ACS CAN), the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, supports evidence-based policies and legislative solutions designed to eliminate cancer as a major health problem. ACS CAN advocates for public policies that will help reduce the risk of skin cancer associated with the use of indoor tanning devices, including **prohibiting minors from using indoor tanning devices.**

Background:
Skin cancer is the number one diagnosed cancer in the United States[i], with melanoma as one of the most common cancers diagnosed among young adults. Among young people aged 15-29 years melanoma is the fourth most commonly diagnosed cancer.[ii] The most avoidable risk factor for skin cancer is exposure to ultraviolet (UV) radiation through outdoor exposure to the sunlight or use of indoor tanning devices.[iii] UV radiation from indoor tanning and other sources is cumulative over time. The earlier a person starts tanning, the greater the risk of getting melanoma and other skin cancers later in life.[iv] In fact, using a tanning device before the age of 35 increases the risk of melanoma by 59 percent.[v] Using a tanning bed, even once, increases the risk of squamous cell carcinoma by 67% and basal cell carcinoma by 29%. The risk is higher when the tanning bed use begins before the age of 25.[vi]

Despite the risks and documented link to cancer, use of indoor tanning devices is on the rise among high school aged girls. The rate of indoor tanning device use increases drastically as high school girls grow older, from nearly 12 percent among freshman girls to nearly 27 percent among seniors.[vii]

In one study suggesting that parental consent is not effective, eighty percent (80%) of the teenage participants were able to purchase a tanning session without parental permission as required by law.[viii] A 2011 study published in the American Journal of Public Health found youth were 80% more likely to use a tanning device if they believed that their parents allowed them to use indoor tanning.[ix]

The high rates of indoor tanning, and the associated harms, have increased awareness and action at all levels of government, from local to state and federal. In 2014, the Surgeon General released a Call to Action to Prevent Skin Cancer calling for an increased effort to reduce exposure to UV radiation especially through the use of indoor tanning devices. In May 2014, the United States Food and Drug Administration reclassified tanning devices from a Class I to a Class II device. **As part of the additional restrictions, device manufactures will have to include a visible black box warning stating that people**

younger than 18 years should not use the devices. In addition, one of the Healthy People 2020 objectives is to "reduce the proportion of adolescents in grades 9 through 12 who report using artificial sources of ultraviolet light for tanning".

ACS CAN joins the World Health Organization and others in support of restricting access to tanning devices among young persons under the age of 18. States across the country are already beginning to protect youth by passing and implementing comprehensive laws which restrict minors' use of tanning devices.

Restricted access to tanning devices is consistent with other policies that protect youth from harmful devices substances like tobacco and alcohol. Parents do all they can to protect their kids when they are at home. The state also has a duty to protect our children when there are increased risks of harm.

ACS CAN supports Bill 5-16 to prohibit minors under the age of 18 from using indoor tanning devices, because the science demonstrates that tanning devices cause cancer.

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[i] Guy G, Machlin SR, Ekwueme DU, Yabroff KR, "Prevalence and Costs of Skin Cancer Treatment in the U.S., 2002–2006 and 2007–2011", American Journal of Preventive Medicine. 2014.

[ii] Calculations made using data from the North American Association of Central Cancer Registries. December 2014.

[iii] Lim HW, James WD, Rigel DS, Maloney ME, Spencer JM, Bhushan R. "Adverse effects of ultraviolet radiation from the use of indoor tanning equipment: time to ban the tan". J Am Acad Dermatol 2011;64:893–902.

[iv] American Cancer Society. "Melanoma of the Skin". Atlanta: American Cancer Society.

[v] Boniol B, Autier P, Boyle P, Gandini S. "Cutaneous melanoma attributable to sunbed use: systematic review and meta-analysis". British Medical Journal, 2012; 345:e4757. Correction published December 2012; 345:e8503

[vi] Wehner et al. "Indoor tanning and non-melanoma skin cancer:systematic review and meta-analysis." British Medical Journal. October 2012

[vii] Centers for Disease Control and Prevention. "Youth Risk Behavior Surveillance-United States, 2011". MMWR 2012;61(4):41.

[viii] Forster JL, Lazovich D, Hickle A, Sorensen G, Demierre MF. Compliance with restrictions on sale of indoor tanning sessions to youth in Minnesota and Massachusetts. J Am Acad Dermatol. Dec 2006;55(6):962-967.

[ix] Mayer, et al. (2011). "Adolescent's Use of Indoor-Tanning: A Large-Scale Evaluation of Psychosocial, Environmental, and Policy-Level Correlates." American Journal of Public Health, May 2011; 101:5.

Maryland Save Your Skin Coalition

4

March 22, 2015

TO: George Leventhal, President
Members Montgomery County Council
FROM: Maryland Save Your Skin Coalition
RE: **Support 5-16 Tanning Facilities - Amendments**

The below listed members of the Maryland Save Your Skin Coalition (MSYSC) support Bill 5-16:

- Maryland Academy of Family Physicians
- American Academy of Dermatology
- Advocates for Children and Youth
- American Cancer Society Cancer Action Network
- Center for a Healthy Maryland at Med Chi
- Maryland Dermatology Society
- Nurse Practitioners of Maryland (NPAM).
- The Society of Dermatology Physician Assistants

The most avoidable risk factor for skin cancer is exposure to ultraviolet (UV) radiation through exposure to sunlight or use of indoor tanning devices.[i] UV radiation from indoor tanning and other sources is cumulative over time. The earlier a person starts tanning, the greater the risk of getting melanoma and other skin cancers later in life.[ii] Using a tanning device before the age of 35 increases the risk of melanoma by 59 percent.[iii] Using a tanning bed, even once, increases the risk of squamous cell carcinoma by 67% and basal cell carcinoma by 29%. The risk is higher when the tanning bed use begins before the age of 25.[iv]

Despite the risks and documented link to cancer, use of indoor tanning devices is on the rise among high school aged girls. The rate of indoor tanning device use increases drastically as high school girls grow older, from nearly 12 percent among freshman girls to nearly 27 percent among seniors.[v]

To reduce the risk among Montgomery County youth of developing skin cancer later in life, MSYSC supports Bill 5-16 prohibiting minors under the age of 18 from using indoor tanning devices.

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[i] Lim HW, James WD, Rigel DS, Maloney ME, Spencer JM, Bhushan R. "Adverse effects of ultraviolet radiation from the use of indoor tanning equipment: time to ban the tan". J Am Acad Dermatol 2011;64:893–902.
[ii] American Cancer Society. "Melanoma of the Skin". Atlanta: American Cancer Society.
[iii] Boniol B, Autier P, Boyle P, Gandini S. "Cutaneous melanoma attributable to sunbed use: systematic review and meta-analysis". British Medical Journal, 2012; 345:e4757. Correction published December 2012; 345:e8503
[iv] Wehner et al. "Indoor tanning and non-melanoma skin cancer:systematic review and meta-analysis." British Medical Journal. October 2012
[v] Centers for Disease Control and Prevention. "Youth Risk Behavior Surveillance-United States, 2011". MMWR 2012;61(4):41.

MedChi
The Maryland State Medical Society

Your Advocate.
Your Resource.
Your Profession.

March 21, 2016

Ms. Nancy Floreen
President
Montgomery County Council
Council Office Building
100 Maryland Avenue, 5th Floor
Rockville, MD 20850

Sent via email to County.Council@montgomerycountymd.gov

Dear Council President Floreen:

MedChi, The Maryland State Medical Society, the largest physician organization in Maryland, supports Montgomery County Council Bill 5-16, Tanning Facilities - Amendments.

Bill 5-16 will preclude minors in Montgomery County from using tanning beds which - as all available medical evidence establishes - materially increases the prospect of skin cancer and particularly melanoma which is the deadliest form of skin cancer. Indoor tanning beds should be "off limits" to minors in the same way that we place cigarettes and alcohol "off limits" to them. We would also point out that a Howard County prohibition, which has been in effect since 2009, has been accepted and enforced by the tanning industry with no appreciable loss of business opportunity. We would expect the same outcome in Montgomery County.

The indoor tanning industry has argued, in other states, that there are "health benefits" from using indoor tanning beds. These claims are in direct violation of a January 2010 Consent Order that the Indoor Tanning Association and its affiliates entered into with the Federal Trade Commission which Consent Order forbids them from making health benefit claims in their advertisements without giving warnings about skin cancer. Indeed, the Consent Order requires them to give "Warnings" similar to the warnings which are required on cigarette packages. Despite this Consent Order, the tanning bed industry continues to provide false and misleading health information to teens as documented in the Investigative Report of the Minority Staff of the U.S. House of Representatives Committee on Energy and Commerce at http://www.medicine.uiowa.edu/uploadedFiles/Departments/Dermatology/Content/About_Us/Investigative%20report.pdf

Finally, MedChi doctors report that there are additional health problems besides the skin cancer episodes which are so well known. Dr. Steven Lenowitz, an OB-GYN, related to the MedChi Legislative Committee about the recent increases in cases of "molluscum contagiosum" that he was seeing in young girls using tanning beds. "I feel that these girls are tanning nude to avoid tan lines and this viral illness is being spread unsuspectingly to these innocent girls, many of whom are minors. The sterilization techniques are abominable involving a quick spray and a wipe of these fomites of infection. I can honestly say that I have not seen this infection except in girls that regularly frequent tanning salons. I

1211 Cathedral Street • Baltimore, MD 21201-5516 • 410.539.0872 • Fax: 410.547.0915 • 1.800.492.1056 • www.medchi.org

would be curious to see if Herpes or HPV could be spread this way as well. I think this is a cause for great concern in addition to the harmful carcinogenic ultraviolet ray."

MedChi strongly supports Bill 5-16 given the demonstrated and undisputed health issues relating to the use of indoor tanning beds.

Sincerely,

Gene M Ransom III

Gene M. Ransom, III
Chief Executive Officer

1211 Cathedral Street • Baltimore, MD 21201-5516 • 410.539.0872 • Fax: 410.547.0915 • 1.800.492.1056 • www.medchi.org

Testimony by Larry Green, MD
on behalf of the
American Academy of Dermatology Association and the Maryland Dermatologic Society

Montgomery County Council
In Support of Bill 5-16
Tuesday, March 22, 2016

Thank you, distinguished members of the council, for the opportunity to provide testimony in support of Bill 5-16. My name is Dr. Larry Green and I am a board-certified dermatologist from Rockville. I am here representing the American Academy of Dermatology Association and the Maryland Dermatologic Society.

No amount of UV exposure from tanning beds is safe. By definition, a tan is evidence of skin damage and a tan represents a scar/healing response.

The concept of prohibiting use of carcinogenic or dangerous products is not new. Governments often enact laws in the interest of educating the public and trying to preserve the health and wellbeing of its citizens, especially those such as minors who are easily influenced. Our Government restricts minors' use of tobacco and alcohol for this reason. We do not have parental consent permission for the use of cigarettes or alcohol for teenagers. For something that is classified as dangerous a substance as cigarettes, why do we make an exception for ultraviolet radiation exposure from indoor tanning? Moreover, the knowledge about the potentially disfiguring or even lethal danger of minors using tanning beds is not well known enough among parents and the general public, and we need your help to disseminate this message. Our message and recommendations cannot be heard without your help

I have performed examinations for skin cancer every working day in my office for the past 20 years. Countless times I have found and removed skin cancers from primarily women who used indoor tanning during their youth-and this is often without significant outdoor sun exposure. They just didn't at the time know and their parents didn't know to tell them that their earlier unhealthful behavior could lead to cancer later on in life. Time and time again they tell me that they wish someone had told them how dangerous indoor tanning can be to a teen's future.

In closing, if we wish to have an impact on the future incidence of skin cancer and melanoma, we have to reduce the amount of cumulative exposure our youth have to UV radiation – particularly intentional exposure via commercial indoor tanning.

AADA and the Maryland Dermatologic Society believe protecting the public, especially adolescents, and requiring appropriate oversight of the indoor tanning industry will have a profound effect on improving public health and reducing overall health care costs. Annually, about $3.3 billion of skin cancer treatment costs are attributable to melanoma. Of course, this figure does not begin to account for the tragic loss of life from this menacing disease.

From: Floreen's Office, Councilmember [Councilmember.Floreen@montgomerycountymd.gov]
Sent: Tuesday, March 22, 2016 11:15:28 AM
To: Council President
Subject: FW: From Bruce Bereano - Re: Bill 5-16 - Tanning Facilities - Amendments

---

From: lobbyannapolis@comcast.net [mailto:lobbyannapolis@comcast.net]
Sent: Tuesday, March 22, 2016 10:55 AM
To: Floreen's Office, Councilmember <Councilmember.Floreen@montgomerycountymd.gov>; Berliner's Office, Councilmember <Councilmember.Berliner@montgomerycountymd.gov>; Elrich's Office, Councilmember <Councilmember.Elrich@montgomerycountymd.gov>; Hucker's Office, Councilmember <Councilmember.Hucker@montgomerycountymd.gov>; Katz's Office, Councilmember <Councilmember.Katz@montgomerycountymd.gov>; Leventhal's Office, Councilmember <Councilmember.Leventhal@montgomerycountymd.gov>; councilmember.mavarro@montgomerycountymd.gov; Rice's Office, Councilmember <Councilmember.Rice@montgomerycountymd.gov>; Riemer's Office, Councilmember <Councilmember.Riemer@montgomerycountymd.gov>
Subject: From Bruce Bereano - Re: Bill 5-16 - Tanning Facilities - Amendments

I communicate to you in reference to Bill 5-16 - Tanning Facilities – Amendments, on behalf of my client the Maryland Indoor Tanning Association in very strong opposition to this legislation. Very regretfully do to commitments in Annapolis while the legislature is still in session I am unable to personally appear to voice my opposition. I am attaching for your reference a copy of current Maryland State Law enacted by State legislature in 2008 and currently in effect. This statute clearly and unequivocally gives Maryland parents and their minor children pursuant to the procedures and policies of an exacting consent form developed by the Maryland State Department of Mental Health and Hygiene to allow and permit minors to tan indoors with such exacting parental form executed and followed. While the 2008 legislation clearly gives County governments the authority to add further restrictions and conditions upon such State law and State right given, no County can ban or prohibit indoor tanning by minors with State Department of Health Parental Consent. A County cannot prohibit or take away a State legislative and given right. Any argument or point of view to the contrary is true politics and without any merit under the law. Accordingly, this legislation violates that State law by banning indoor tanning by minors in Montgomery County. That is in direct conflict of State law, and while the County can add additional conditions and requirements to the exercise of that right, but they cannot ban, prohibit or take that right away. I have spoken to the sponsor about this and have shown him the statute and he says that it doesn't say it. If you talk to any lawyer who is experienced in legislative law or any objective human being they will clearly see that is just bunk. I urge this Council without standing of your wishes or desires to respect State Law when each of you took oath of office and I do not mean this disrespectfully, you pledged that firmly to not only uphold the Constitution of the State of Maryland but its laws enacted thereof. Again I am sorry I cannot be with you. I look forward please to each of you giving me your response. Thank you in advance for your time.

Bruce

Office of Bruce C. Bereano
191 Duke of Gloucester Street
Annapolis, MD 21401
Phone 410-267-0410

79

CHAPTER 691

(House Bill 1358)

AN ACT concerning

Artificial Tanning Devices – Protection of Minors

FOR the purpose of prohibiting certain owners, employees, and operators of tanning facilities from allowing minors to use certain tanning devices unless ~~the minors have certain prescriptions or are accompanied by~~ certain individuals provide consent for the minors in a certain manner; requiring certain owners, employees, and operators of tanning facilities to require certain documentation before allowing certain individuals access to tanning facilities; authorizing the Secretary of Health and Mental Hygiene to impose certain penalties and adopt certain regulations; defining certain terms; providing for the construction of this Act; and generally relating to artificial tanning devices.

BY adding to
Article – Health – General
Section 20–106
Annotated Code of Maryland
(2005 Replacement Volume and 2007 Supplement)

Preamble

WHEREAS, The United States Food and Drug Administration and numerous leading national health care organizations estimate that, each year, approximately 1,000,000 Americans are stricken with skin cancer, a potentially deadly disease and the most common of all types of cancer; and

WHEREAS, The United States Food and Drug Administration and other organizations estimate that, on average, more than 1,000,000 people in the United States visit artificial tanning facilities each day and there is concern that consumers do not know that indoor, artificial tanning devices emit ultraviolet radiation, both UV–A and UV–B, that is similar to and sometimes more powerful than the ultraviolet radiation emitted by the sun; and

WHEREAS, More than 2,300,000 teenagers use artificial tanning devices each year, and more than 25% of American teenagers have used tanning booths three or more times; and

WHEREAS, The World Health Organization has declared that no person under the age of 18 years should use a tanning bed and the American Academy of

Dermatology has taken the position that no minor should be allowed to use artificial tanning devices; and

WHEREAS, It is in the public interest to protect children from the harmful effects of ultraviolet radiation through the use of artificial tanning devices by restricting minors' access to such devices unless authorized by a physician; now, therefore,

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article – Health – General

20–106.

(A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.

(2) "TANNING DEVICE" MEANS ANY EQUIPMENT THAT EMITS RADIATION USED FOR TANNING OF THE SKIN, INCLUDING SUNLAMPS, TANNING BOOTHS, OR TANNING BEDS.

(3) "TANNING FACILITY" MEANS ANY PLACE WHERE A TANNING DEVICE IS USED FOR A FEE, MEMBERSHIP DUES, OR OTHER COMPENSATION.

(B) AN OWNER, EMPLOYEE, OR OPERATOR OF A TANNING FACILITY MAY NOT ALLOW A MINOR UNDER THE AGE OF 18 YEARS TO USE A TANNING DEVICE UNLESS THE ~~MINOR:~~

~~(1) HAS A WRITTEN PRESCRIPTION FROM A PHYSICIAN AUTHORIZING USE OF A TANNING DEVICE; OR~~

~~(2) IS ACCOMPANIED BY A PARENT OR LEGAL GUARDIAN WHEN USING A TANNING DEVICE~~ MINOR'S PARENT OR LEGAL GUARDIAN PROVIDES WRITTEN CONSENT ON THE PREMISES OF THE TANNING FACILITY AND IN THE PRESENCE OF AN OWNER, EMPLOYEE, OR OPERATOR OF THE TANNING FACILITY.

(C) THE OWNER, EMPLOYEE, OR OPERATOR OF A TANNING FACILITY SHALL REQUIRE APPROPRIATE DOCUMENTATION TO VERIFY THE AGE OF AN INDIVIDUAL BEFORE ALLOWING THE INDIVIDUAL ACCESS TO A TANNING DEVICE.

(D) (1) THE SECRETARY MAY IMPOSE ON A PERSON WHO VIOLATES THIS SECTION:

(I) FOR A FIRST VIOLATION, A CIVIL PENALTY NOT TO EXCEED $250;

(II) FOR A SECOND VIOLATION, A CIVIL PENALTY NOT TO EXCEED $500; AND

(III) FOR EACH SUBSEQUENT VIOLATION, A CIVIL PENALTY NOT TO EXCEED $1,000.

(2) THE SECRETARY MAY ADOPT REGULATIONS TO IMPLEMENT AND CARRY OUT THIS SECTION.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act may not be construed to preempt a county or municipal government from enacting and enforcing more stringent measures to regulate the use of tanning devices by minors.

SECTION ~~2.~~ 3. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2008.

Approved by the Governor, May 22, 2008.

ROCKVILLE, MARYLAND

MEMORANDUM

March 24,2016

TO: Nancy Floreen, President, County Council

FROM: Jennifer A. Hughes, Director, Office of Management and Budget
Joseph F. Beach, Director, Department of Finance

SUBJECT: FEIS for Council Bill 5-16, Tanning Facilities-Amendments

Please find attached the fiscal and economic impact statements for the above-referenced legislation.

JAH:fz

cc: Bonnie Kirkland, Assistant Chief Administrative Officer
Lisa Austin, Offices of the County Executive
Joy Nurmi, Special Assistant to the County Executive
Patrick Lacefield, Director, Public Information Office
Joseph F. Beach, Director, Department of Finance
David Platt, Department of Finance
Rachel Silberman, Office of Management and Budget
Alex Espinosa, Office of Management and Budget
Naeem Mia, Office of Management and Budget

Fiscal Impact Statement
Council Bill 5-16 & Tanning Facilities-Amendments

1. Legislative Summary.

   Bill 5-16 would prohibit minors from using indoor tanning devices; require tanning facilities and customers to adhere to certain duties; and require tanning facilities to provide certain warning statements and post certain signs.

2. An estimate of changes in County revenues and expenditures regardless of whether the revenues or expenditures are assumed in the recommended or approved budget. Includes source of information, assumptions, and methodologies used.

   No changes in County revenue or expenditures are expected. Bill 5-16 is not expected to change the number of licensees, nor encourage or discourage new businesses. The bill is not expected to change the number or frequency of inspections.

3. Revenue and expenditure estimates covering at least the next 6 fiscal years.

   See response in #2

4. An actuarial analysis through the entire amortization period for each bill that would affect retiree pension or group insurance costs.

   Bill 5-16 does not affect retiree pension or group insurance costs.

5. An estimate of expenditures related to County's information technology (IT) systems, including Enterprise Resource Planning (ERP) systems.

   Bill 5-16 does not affect the County's IT systems.

6. Later actions that may affect future revenue and expenditures if the bill authorizes future spending.

   Bill 5-16 does not authorize future spending.

7. An estimate of the staff time needed to implement the Bill 5-16.

   No additional staff time is anticipated because the Department already conducts routine inspections of facilities and Bill 5-16 does not add a significant amount of additional work during those inspections.

8. An explanation of how the addition of new staff responsibilities would affect other duties.

   No additional staff time is anticipated because the Department already conducts routine inspections of facilities and Bill 5-16 does not add a significant amount of additional work during those inspections.

9. An estimate of costs when an additional appropriation is needed.

   No additional appropriation is needed.

10. A description of any variable that could affect revenue and cost estimates.

    There are no variables that would affect Bill 5-16's impact on revenue and cost estimates.

11. Ranges of revenue or expenditures that are uncertain or difficult to project.

    Bill 5-16 does not affect revenues or expenditures.

12. If a bill is likely to have no fiscal impact, why that is the case.

See response to question #2

13. Other fiscal impacts or comments.

14. The following contributed to and concurred with this analysis:

Clark Beil, Sr. Administrator, Licensure and Regulatory Services

Kenneth Welch, Environmental Health Manager, Licensure and Regulatory Services

Richard H. Harris, Office of Management and Budget

Jennifer A Hughes

Jennifer A. Hughes, Director
Office of Management and Budget

3/23/16
Date

Economic Impact Statement
Bill 5-16, Tanning Facilities – Amendments

Background:

This legislation would:

1. Prohibit minors for using indoor tanning devices,
2. Require tanning facilities and customers to adhere to certain duties, and
3. Require tanning facilities to provide certain warning statements and post certain signs.

1. The sources of information, assumptions, and methodologies used.

Since Bill 5-16 amends Chapter 51A with technical changes to definitions of a tanning facility and renumbering of Section 51A-1 through Section 51A-15 of current County Code.

Source of data include:

- American Community Survey (ACS), U.S. Census Bureau, and
- Centers for Disease Control (CDC), U.S. Department of Health and Human Services.

Bill 5-16 excludes spray tanning devices from the definition of a tanning device.

2. A description of any variable that could affect the economic impact estimates.

The variable that could affect the economic impact estimates are the number of customers under the age of eighteen (18), i.e., high school population, who are prohibited from using a tanning device. The ages of a high school population range from 14 to 18 years of age. Since Bill 5-16 prohibits the minors under the age of eighteen, the economic impact statement provides an estimate of the target population between the ages of 14 and 17.

Data from the ACS and CDC provide an estimate of minors under the age of eighteen likely to use such device. According to ACS, the County's population between the ages of 14 and 17 in 2014 was an estimated 27,500. Of those minors, CDC estimates that 13 percent of all high school students use indoor tanning devices. Therefore, the number of minors in the County who use tanning devices is approximately 3,600. However, the data from CDC do not differentiate between types of tanning devices. Because Bill 5-16 excludes spray tanning devices, the estimate of minors prohibited from using tanning devices as defined in the legislation would be less than 3,600.

3. The Bill's positive or negative effect, if any on employment, spending, savings, investment, incomes, and property values in the County.

Based on the lack of specific data on minors who currently use tanning devices and the exemption of spray tanning device, there is no reliable estimate on the loss of

business income to tanning facilities. Second, since spray tanning devices are excluded under Bill 5-16, minors who currently use tanning devices as defined in Bill 5-16 may choose the alternative device and therefore would have no economic impact on tanning facilities. Therefore, Bill 5-16 would likely have no economic impact on the County's employment, spending, savings, investment, incomes, and property values. The legislation provides technical amendments to current County Code.

4. **If a Bill is likely to have no economic impact, why is that the case?**

   Please see paragraph #3.

5. **The following contributed to or concurred with this analysis**: David Platt and Rob Hagedoorn, Department of Finance.

Joseph F. Beach, Director
Department of Finance

3/23/16
Date

Isiah Leggett
County Executive

Marc P. Hansen
County Attorney

OFFICE OF THE COUNTY ATTORNEY

MEMORANDUM

TO: Uma Ahluwalia, Director
Department of Health and Human Services

VIA: Edward Lattner, Chief, Division of Government Operations
Office of the County Attorney

FROM: Kristen M.K. Kalaria
Associate County Attorney

CC: Bonnie Kirkland
Assistant Chief Administrative Officer

DATE: March 10, 2016

RE: Review of Bill No. 5-16, Tanning Facilities- Amendments

Summary

Bill No. 5-16 ("the Bill") makes several changes to the existing Chapter 51A regulating tanning facilities, including: prohibits minors from using indoor tanning devices, requires use of a remotely located timers and tanning devices with an accessible off switch, prohibits use of a tanning facility more than once every 24 hours, requires sanitization of tanning device after each use, and requires posting of certain warnings and maintenance of records.

There are no significant legal concerns about the Bill. There appear to be some minor errors, primarily due to renumbering of Sections. All internal cross-references should be carefully reviewed before the Bill is finalized. Additionally, the Bill proposes a new definition for "tanning device" that should be reconsidered as it offers no apparent advantage over the current definition.

Legal Implications

I. Ambiguities

The following portions of the Bill contain potential errors or ambiguities, many of which relate to the new section numbers:

1. Section 51A-4 seems to refer to itself. It requires that a person submit the application required by Section 51A-4. I think this should be a reference to Section 51A-3
2. Section 51A-7(a)(5) "timing device that is accurate with 10% of any selected timer interval" should read "timing device that is accurate *within* 10% of any selected timer interval"
3. Section 51A-7(a)(10) should refer to Section 51A-8 not Section 51A-9
4. Section 51A-7 (a)(11) should refer to Section 51A-9 not Section 51A-10.
5. Section 51A-8(a)(6) should refer to Section 51A-7 not 51A-8.

To avoid confusion, all internal cross-references should be verified before the Bill is finalized.

II. Preemption

This Bill regulates subject matter already regulated by both the State and Federal governments. Neither government has indicated, expressly or implicitly, any intent to preempt local regulation of tanning facilities. In fact, the State law includes an uncodified provision that it "may not be construed to preempt a county or municipal government from enacting and enforcing more stringent measures to regulate the use of tanning devices by minors."

State law prohibits use of tanning facilities by minors except with written consent of a parent or guardian given on the premises. Md. Code, Health-General, §20-106. The Bill eliminates the written consent exception in Montgomery County. There is no conflict with the State law because Bill 5-16's ban on underage use of a tanning facility is in furtherance of the state law's function—protection of minors from the harmful effects of tanning devices. *Baltimore v. Hart*, 395 Md. 394, 408-10, 910 A.2d 463, 471-72 (2006).

The Food and Drug Administration (FDA) regulates tanning beds and other "sunlamp products." 21 CFR§1040.20. The Bill appears consistent with the existing Federal regulations and is, in some respects, duplicative. For instance, 21 CFR§1040.20(c)(3) already requires that all sunlamp products have an "off switch" as required by the proposed Section 51A-7(a)(7). It is worth noting, however, that the FDA recently published proposed regulations that would update and strengthen 21 CFR§1040.20. A summary of the proposed regulations may be viewed here: https://www.federalregister.gov/articles/2015/12/22/2015-32023/sunlamp-products-proposed-amendment-to-performance-standard. Public comments on the new regulations are due March 21, 2016.

III. Liability

The Bill does not expose the County to any significant potential for additional liability.

IV. Other Comments- Concerns About Definitions

The existing Chapter 51A-1 uses the same definition of "tanning device" found in the State law, §20-106 (a)(2), specifically: "any equipment that emits radiation used for tanning of the skin, such as a sunlamp, tanning booth, or tanning bed." The Bill would change the definition to: "any equipment that emits electromagnetic radiation having wavelengths in the air between 200 and 400 nanometers and that is used for tanning of human skin." The new definition is similar to that found in the federal regulations: "*Sunlamp product* means any electronic product designed to incorporate one or more ultraviolet lamps and intended for irradiation of any part of the living human body, by ultraviolet radiation with wavelengths in air between 200 and 400 nanometers, to induce skin tanning." 21 CFR§1040.20.

The State definition is broader, simpler, and easier to understand for a layperson. The FDA regulations target manufacturers, a more technical audience. In fact, the recently published proposed regulations referenced above would modify this definition to make it clear that tanning beds are included. If the County wishes to adopt the FDA's definition, however, there is no reason not to adopt the Federal definition in its entirety, complete with reference to the Code of Federal Regulations. This has the advantage of conveying simply that if the device is regulated as a sunlamp by the FDA, it comes within this statute. It is difficult to see any advantage to the current approach—adopting part of the FDA's more technical definition without reference to the original.

If you have any concerns or questions concerning this memorandum please call me.

kmkk

Enclosure (bill)

cc: Bonnie Kirkland, Assistant CAO
Marc P. Hansen, County Attorney
Amanda Mihill, Legislative Attorney