HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 113 Florida Drug and Cosmetic Act
SPONSOR(S): Roach
TIED BILLS: **IDEN./SIM. BILLS:** SB 172

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	8 Y, 5 N	Morris	McElroy
2) Local, Federal & Veterans Affairs Subcommittee	9 Y, 6 N	Rivera	Miller
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The federal Food Drug and Cosmetic Act (FDCA) and the Fair Packaging and Labeling Act (FPLA) regulate drugs and cosmetics in the U.S. The FDCA prohibits the introduction, receipt, and delivery of adulterated or misbranded drugs and cosmetics into interstate commerce, and requires the U.S. Food and Drug Administration (FDA) to regulate all prescription and over-the-counter (OTC) drug products marketed in the U.S., including sunscreen, to ensure that they may be used safely and effectively. The FPLA requires the Federal Trade Commission (FTC) and the FDA to issue regulations requiring all consumer commodities, including drugs and cosmetics, be labeled to disclose specific information including the identity of the commodity and the name and place of business of the product's manufacturer, packer, or distributor.

The Florida Drug and Cosmetic Act (FLDCA) regulates drugs and cosmetics within Florida and requires conformity with federal law. The Department of Business and Professional Regulation (DBPR) is responsible for administering the provisions of the FLDCA with the Division of Drugs, Devices and Cosmetics (DDC) overseeing the activities of companies manufacturing and/or distributing products within Florida. The DDC runs two programs: permitting certain companies, including OTC drug and cosmetics manufacturers, and permittee compliance with state and federal law.

The Florida Constitution grants counties and municipalities broad home rule authority. Specifically, municipalities have governmental, corporate, and proprietary powers necessary to perform their functions and provide services, and exercise any power for municipal purposes, except as otherwise provided by law. State legislation may preempt an area of law, precluding a local government from exercising authority in that particular area. Legislation preempting an area of law may be express, clearly stating the Legislature's intent to preempt the area, or implied, in that the legal regulatory scheme is so pervasive that local laws potentially would conflict with the state scheme if not found to be preempted.

Florida law does not currently preempt the regulation of OTC drugs or cosmetics to the state. Thus, local governments may pass ordinances regulating OTC drugs and cosmetics as long as such ordinances do not conflict with state or federal law.

HB 113 amends s. 499.002 to expressly preempt the regulation of OTC proprietary drugs and cosmetics to the state.

The bill has no fiscal impact on state and local governments.

The bill provides an effective date of July 1, 2020.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Over-the-Counter Drugs and Cosmetics – Federal Regulation

The U.S. Food and Drug Administration (FDA) regulates food, drugs, cosmetics, products[1], medical devices, biologic products, and tobacco products under the Food Drug and Cosmetic Act (FDCA) and the Fair Packaging and Labeling Act (FPLA).[2] The FDCA prohibits the creation, introduction, delivery for introduction, or receipt of adulterated and misbranded drugs or cosmetics into interstate commerce.[3]

The FPLA requires that packages and their labels provide consumers with accurate information about the quantity of contents to prevent consumer deception. Specifically, FPLA regulations require cosmetic product labels to disclose:[4]

- Identification of the product;
- Net quantity of contents in terms of weight, measure, or numerical count;
- Material facts about product and its use, such as directions for safe use;
- Name and place of business of the product's manufacturer, packer, or distributor;
- Warning and caution statements for products that are required to bear such statements by the FDCA and FDA regulations; and
- A list of ingredients in descending order of predominance.

Over-the Counter Drug Regulation

The FDCA defines the term drug to include an article (other than food) intended for use in diagnosing, curing, treating, or preventing human or animal diseases; or intended to affect the structure or any bodily function of a human or animal.[5] A drug is adulterated if it contains a substance that may cause injury to users under the conditions of use prescribed on the product's labeling, contains a soiled or decomposed substance, or is not manufactured pursuant to current good manufacturing practice (GMP) to assure the drug meets FDCA standards.[6] A drug is misbranded if the label is false or misleading, fails to contain the required information, fails to prominently display required items, fails to provide adequate instructions and warnings, is dangerous when used as directed or suggested, fails to comply with color additive laws, or creates the false impression that the registration number implies FDA approval.[7]

The FDA Center for Drug Evaluation and Research (CDER) regulates the safety and efficacy of drugs in the U.S.[8] The FDA Center for Food Safety and Applied Nutrition (CFSAN) houses the Office of Cosmetics and Colors which regulates cosmetics marketed within the U.S.[9]

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[1] Although the scope of the FDA's regulatory authority is very broad, it does not include the regulation of meat, poultry and some egg products. U.S. Food and Drug Administration (FDA), *What Does FDA Regulate?,* https://www.fda.gov/about-fda/fda-basics/what-does-fda-regulate (last visited Nov. 19, 2019).
[2] *See* FDA, *What Does FDA Regulate?,* https://www.fda.gov/about-fda/fda-basics/what-does-fda-regulate (last visited Nov. 19, 2019).
[3] 21 U.S.C. § 331.
[4] 15 U.S.C. § 1451-1460 (2009).
[5] *See* 21 U.S.C. § 321(g)(1).
[6] 21 U.S.C. § 351.
[7] 21 U.S.C. § 352; *see also* FDA, *Labeling Requirements – Misbranding*, https://www.fda.gov/medical-devices/general-device-labeling-requirements/labeling-requirements-misbranding (last visited Nov. 19, 2019).
[8] FDA, *Drugs*, https://www.fda.gov/drugs (last visited Nov. 8, 2019).
[9] FDA, *Regulatory Procedures Manual*, *Chapter 1 – Regulatory Organization*, available at https://www.fda.gov/media/71908/download (last visited Nov. 19, 2019).

The CDER regulates prescription and over-the-counter (OTC) drugs which include medicines and products such as fluoride toothpaste and sunscreen.[10] OTC drug products are drugs available without a prescription that are safe and effective for use by the general public without the need for treatment by a health professional.[11] For OTC drugs, the CDER must ensure that a drug's benefits outweigh its risks, the drug may be used safely in an unsupervised setting, and is properly labeled.[12]

Because there are more than 300,000 marketed OTC drugs, the CDER reviews the active ingredients[13] and labels for over 80 classes[14] of OTC drugs rather than for each individual drug. For each class, an OTC drug monograph[15] is developed and published in the Federal Register.[16]

The FDA ensures the quality of drug products by carefully monitoring drug manufacturers' compliance with its Current Good Manufacturing Practice (CGMP) regulations. The CGMP ensures a product is safe for use and its claims of quality and strength are reliable. The CGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. If a company does not comply with CGMP regulations, any drug it makes is considered "adulterated" under the law.[17]

Sunscreen Regulation

The FDCA treats sunscreens, and their active ingredients, as OTC drugs that are carefully regulated.[18] Currently, the FDA has approved 16 acceptable active ingredients, including octinoxate and oxybenzone, in products that are labeled as sunscreen.[19] Active ingredients in sunscreens protect the skin from the sun's ultraviolet rays, while inactive ingredients are all other ingredients.[20]

The FDA recently proposed a new rule addressing the list of acceptable sunscreen active ingredients.[21] The proposed rule re-assesses the safety and effectiveness of the active ingredients and dosage forms, updates sunscreen testing and recordkeeping requirements, and addresses new uses of sunscreens, including the sale of combination sunscreen-insect repellant products.

Significantly, the proposed rule will modify the status of the 16 acceptable active ingredients allowed in sunscreens, as follows:[22]

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[10] FDA, *Center for Drug Evaluation and Research (CDER)*, https://www.fda.gov/about-fda/office-medical-products-and-tobacco/center-drug-evaluation-and-research-cder (last visited Nov. 8, 2019).
[11] FDA, *Drug Applications for Over-the-Counter (OTC) Drugs,* available at: https://www.fda.gov/drugs/types-applications/drug-applications-over-counter-otc-drugs (last visited Nov. 8, 2019)
[12] FDA, *Office of Drug Evaluation IV: What We Do,* https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-drug-evaluation-iv-what-we-do (last visited Nov. 19, 2019).
[13] An active ingredient is any component that provides pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or animals. FDA, *Drugs@FDA Glossary of Terms,* https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms (last visited Nov. 18, 2019).
[14] Examples of these classes of drugs include those related to acne, allergy, cold and cough, laxative, insect repellant, nasal decongestant, and sunscreen. *See* FDA, *Status of OTC Rulemakings*, https://www.fda.gov/drugs/over-counter-otc-drugs/status-otc-rulemakings (last visited Nov. 8, 2019). *See also* FDA, *Division of Nonprescription Drugs*, https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/division-nonprescription-drugs (last visited Nov. 19, 2019).
[15] An OTC monograph establishes conditions under which certain OTC drugs may be marketed without approved new drug applications because they are "generally recognized as safe and effective" (GRASE) and not misbranded. *See* 21 C.F.R. § 330.1.
[16] FDA, *Drug Applications for Over-the-Counter (OTC) Drugs,* available at: https://www.fda.gov/drugs/types-applications/drug-applications-over-counter-otc-drugs (last visited Nov. 19, 2019)
[17] FDA, *Current Good Manufacturing Practice (CGMP) Regulations*, https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations (last visited Nov. 19, 2019).
[18] *See* 21 U.S.C. §§ 321(g) and 360fff; See also 61N-1.006 and 61N-1.009, F.A.C.
[19] The remaining acceptable active ingredients are: Aminobenzoic acid, Avobenzone, Cinoxate, Dioxybenzone, Homosalate, Meradimate, Octocrylene, Octisalate, Padimate O, Ensulizole, Sulisobenzone, Titanium dioxide, Trolamine salicylate, and Zinc oxide. FDA, *Sunscreen: How to Help protect Your Skin from the Sun,* https://www.fda.gov/drugs/understanding-over-counter-medicines/sunscreen-how-help-protect-your-skin-sun (last visited Nov. 8, 2019).
[20] *Id.*
[21] Federal Register, *Sunscreen Drug Products for Over-the-Counter Human Use,* https://www.federalregister.gov/documents/2019/02/26/2019-03019/sunscreen-drug-products-for-over-the-counter-human-use (last visited Nov. 19, 2019).
[22] FDA, *FDA advances new proposed regulation to make sure sunscreens are safe and effective,* https://www.fda.gov/news-events/press-announcements/fda-advances-new-proposed-regulation-make-sure-sunscreens-are-safe-and-effective (last visited Nov. 19, 2019).

- Zinc oxide and titanium dioxide will be categorized as generally recognized as safe and effective (GRASE);
- Para-aminobenzoic acid and trolamine salicylate will be categorized as no longer GRASE; and
- The remaining 12 ingredients will be identified as not having enough information to determine whether they are safe and effective and the FDA will request additional data from the industry. As stated by the FDA, this change and request for additional information "does not represent a conclusion by FDA that the sunscreen active ingredients …proposed here as Category III are unsafe for use in sunscreens."[23]

The FDA extended the 90-day comment period originally set to expire on May 28, 2019 to June 27, 2019. The proposed effective date for the amended rules was November 26, 2019.[24] The FDA does not expect the affected industry to fully comply with the new standards for at least a year.[25]

In other areas, Hawaii[26] and the U.S. Virgin Islands[27] are the only state and territory to pass legislation addressing sunscreen ingredients. The laws go further than the FDA rule and either ban the sale, distribution, or use of sunscreens containing two ingredients, oxybenzone and octinoxate, that the FDA determined needed more data. The Hawaii ban begins on January 1, 2021, and the U.S. Virgin Islands prohibition begins after March 30, 2020. Both laws contain findings referencing the chemicals' impacts on marine life and coral.

Cosmetic Regulation

The FDCA defines a cosmetic as an article intended to be applied to all or part of the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance, or any component of that article; except soap.[28] A cosmetic is adulterated if it contains a substance that may cause injury to users under the conditions of use prescribed on the product's labeling, contains a soiled or decomposed substance, was prepared in unsanitary conditions, or contains unsafe hair dyes when it is not a hair dye product.[29] A cosmetic is misbranded if its labeling is false or misleading, does not bear the required labeling information, if the container is made or filled in a deceptive manner, or does not comply with child resistant packaging requirements.[30]

Cosmetics are not required to be approved for marketing or sale, but the FDA is authorized to take action against a cosmetic on the market found to be adulterated or misbranded. Sanctions include seizing the offending products or seeking a court injunction against further distribution. The FDA also is authorized to take action, including criminal action, against the companies and individuals who market adulterated or misbranded products.[31] The FDA may not require a manufacturer to recall a cosmetic product from the marketplace but does permit companies to voluntarily remove or correct a product to avoid further FDA action.[32]

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[23] Federal Register, *Sunscreen Drug Products for Over-the-Counter Human Use,* at I.A., https://www.federalregister.gov/documents/2019/02/26/2019-03019/sunscreen-drug-products-for-over-the-counter-human-use (last visited Nov. 21, 2019).
[24] Despite the November 26, 2019 date, the rule is still in the final rule stage and has not been published in the Federal Register. Generally an agency rule is effective no less than thirty days (sixty days for certain significant or major rules) after the date of publication in the Federal Register. If the agency wants to make the rule effective sooner, it must cite "good cause" as to why this is in the public interest. Federal Register, *A Guide to the Rulemaking Process*, available at https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf (last visited December 3, 2019).
[25] *See* U.S. Regulations, Sunscreen Drug Products –OPEN, https://www.regulations.gov/docket?D=FDA-1978-N-0018 (last visited Nov. 8, 2019); *See also* 84 FR 6204.
[26] *See* HAW. REV. STAT. § 342D-21 (L 2018, c 104, §2, enacted July 2018), available at https://www.capitol.hawaii.gov/hrscurrent/Vol06_Ch0321-0344/HRS0342D/HRS_0342D-0021.htm (last visited Nov. 14, 2019).
[27] *See* U.S. Virgin Islands Bill No. 33-0043/Act No. 8185 (2019), available at http://legvi.org:82/ShowPDF.aspx?num=8185&type=Act (last visited Nov. 14, 2019).
[28] *See* 21 U.S.C. § 321(i).
[29] *See* 21 U.S.C. § 361.
[30] *See* 21 U.S.C. § 362.
[31] FDA, *FDA Authority over Cosmetics*. Available at: http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074162.htm (last visited Nov. 19, 2019).
[32] FDA, *FDA Policy for Cosmetics*. https://www.fda.gov/cosmetics/cosmetics-recalls-alerts/fda-recall-policy-cosmetics (last visited Nov. 12, 2019).

With the exception of color additives, the FDA does not require safety testing or premarket approval of the ingredients and chemicals used in cosmetic products.[33] Cosmetic products are also exempt from mandatory compliance with the FDA's drug CGMP[34] regulations unless the product is considered both a cosmetic and a drug.[35] The FDA publishes GMP guidelines for cosmetics, but failure to follow the guidelines will not result in a cosmetic being found adulterated by the FDA.[36]

Generally, a manufacturer may use any ingredient in the formulation of a cosmetic. Color additives are prohibited. However, the FDA prohibits or restricts the use of 10 other types of ingredients in cosmetic products including chloroform, bithioniol, methylene chloride, and mercury-containing compounds, and sunscreens in cosmetics. If a restricted ingredient is used in a cosmetic, the manufacturer may be required to place a warning statement on the cosmetic container.[37]

OTC Drugs and Cosmetics – State Regulation

Part I of ch. 499, F.S., the Florida Drug and Cosmetic Act (FLDCA), regulates drugs, cosmetics, and certain devices in Florida. Part of the purpose of the FLDCA is to promote uniformity between federal and state regulation.[38] As such, administration of the FLDCA must conform to the Federal Food, Drug, and Cosmetic Act[39] and the applicable portions of the Federal Trade Commission Act,[40] which prohibit the false advertising of drugs, devices, and cosmetics.[41]

FLDCA designates the Department of Business and Professional Regulation (DBPR), the agency charged with licensing and regulating businesses and professionals in the State of Florida, as the agency responsible for regulating the drugs, devices and cosmetics industries.[42] DBPR's Division of Drugs, Devices and Cosmetics (DDC) carries out this responsibility through two program areas:[43]

- The Permitting Program is responsible for the review and approval of applications for multiple permit categories including categories for over-the-counter drug manufacturers and cosmetic manufacturers;[44] and
- The Bureau of Compliance & Enforcement is responsible for initial permitting and compliance inspections for permitted facilities and investigation of complaints related to violations of the FLDCA.

In addition to the above, the FLDCA also provides:[45]

- Criminal prohibitions against distribution of contraband and misbranded prescription drugs;
- Regulations for the advertising and labeling of drugs, devices, and cosmetics; and

[33] FDA. *Facts about the Current Good Manufacturing Practices,* https://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm169105.htm (last visited Nov. 18, 2019).
[34] GMPs provide standards for product development, monitoring, and control of processes and facilities, providing assurance that products meet FDA quality and safety standards. U.S. FOOD AND DRUG ADMINISTRATION. *Facts about the Current Good Manufacturing Practices,* https://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm169105.htm (last visited Nov. 18, 2019).
[35] For example, an antidandruff shampoo is both a cosmetic and a drug and must comply with the requirements for both cosmetics and drugs. *See* FDA, *Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)*, http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074201.htm (last visited Nov. 19, 2019).
[36] FDA. *Is It a Cosmetic, a Drug, or Both (Or Is It Soap),* https://www.fda.gov/cosmetics/cosmetics-laws-regulations/it-cosmetic-drug-or-both-or-it-soap#Definecosmetic (last visited Nov. 18, 2019).
[37] FDA, *Prohibited and Restricted Ingredients*. http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm127406.htm (last visited Nov. 18, 2019).
[38] *See* s. 499.002(1), F.S.
[39] 21 U.S.C. ss. 301 *et seq*.
[40] *See* 15 U.S.C. §§ 41-58, as amended.
[41] S. 499.002(1)(b), F.S.
[42] S. 27, ch. 2010-161, Laws of Fla., shifted responsibility for operation and enforcement of the Florida Drugs, Devices, and Cosmetics Act from the Department of Health to the Department of Business and Professional Regulation.
[43] *Id.*
[44] S. 499.01, F.S., outlines 18 distinct permits based on the type of entity and intended activity, and includes permits for entities within the state, out of state, or even outside of the United States. These are: an out-of-state prescription drug wholesale distributor; a retail pharmacy drug wholesale distributor; a restricted prescription drug distributor; a complimentary drug distributor; a freight forwarder; a veterinary prescription drug retail establishment; a veterinary prescription drug wholesale distributor; a limited prescription drug veterinary wholesale distributor; an over-the-counter drug manufacturer; a device manufacturer; a cosmetic manufacturer; a third party logistics provider; or a health care clinic establishment.
[45] *See* ss. 499.0051, 499.0054, and 499.062, F.S.

- Enforcement authority for DBPR, including seizure and condemnation of drugs, devices, and cosmetics.

State and Local Sunscreen Regulation

DBPR regulates sunscreen as an OTC, or proprietary, drug because FDA regulation considers sunscreen a drug.[46] Florida defines an OTC or proprietary drug as a drug in its unbroken, original package, sold to the public by, or under the authority of, the manufacturer or primary distributor, purchased without a prescription and not misbranded.[47]

Some municipalities have passed or considered ordinances banning the sale and use of certain sunscreens as a result of the findings of recent studies[48] suggesting certain sunscreen chemicals could be linked to damage of coral reefs. In February 2019, the City Commission of Key West passed an ordinance making it unlawful to sell, offer for sale, or distribute for sale in the City of Key West any SPF[49] sunscreen protection personal care product that contains oxybenzone or octinoxate, or both, without a "medically-licensed" prescription.[50] A month later, the City of Miami Beach considered but did not pass similar legislation amid lawmakers' concerns that more research is needed.[51]

In passing the ordinance, the Key West City Commission cited significant harmful impacts from the two chemicals on the marine environment and residing ecosystems around the waters of Key West, including coral reefs that protect the shoreline of Key West and the Florida Keys. The first violation of the ordinance results in a written warning, unless there is a serious threat to public safety or an irreparable violation. Subsequent violations are punishable pursuant through the city's civil citation procedure, which could result in a maximum civil penalty of $500.[52] The city's sunscreen prohibition becomes effective January 1, 2021.[53]

Recent Research on Effects of Over-the-Counter Sunscreen Chemicals

Ultraviolet (UV) Radiation

Ultraviolet (UV) radiation is a form of energy most commonly produced by sunlight. There are three types of UV radiation produced by sunlight: UVA, UVB, and UVC. UVC and some UVB radiation is absorbed by the Earth's ozone layer. However, UVA and some UVB radiation comes into contact with

[46] *See* FDA*, Clover Custom Blending LLC MARCS-CMS 527994 Warning Letter,* February 28, 2018*,* available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/clover-custom-blending-llc-527994-02282018 (last visited November 14, 2019); *see also* U.S. Food and Drug Administration, *Sunscreen: How to Help protect Your Skin from the Sun,* https://www.fda.gov/drugs/understanding-over-counter-medicines/sunscreen-how-help-protect-your-skin-sun(last visited Nov. 8, 2019).
[47] S. 499.003(43), F.S.,
[48] *See* Danovaro, *et. al.*, *Sunscreens cause coral bleaching by promoting viral infections*, Environmental Health Perspectives, Vol. 116, April 2008, at 441, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2291018/pdf/ehp0116-000441.pdf (last visited November 13, 2019).
[49] Sun protection factor (SPF) is the value indicating the amount of UV radiation exposure it takes to cause a sunburn when using a sunscreen compared to when not using a sunscreen. The higher the SPF value (up to 50) the greater sunburn protection provided. FDA, *Sun protection factor (SPF)*, https://www.fda.gov/drugs/understanding-over-counter-medicines/sunscreen-how-help-protect-your-skin-sun#spf (last visited Nov. 14, 2019).
[50] Chapter 26, Article VII., Sec. 26-311, Code of Ordinances, City of Key West Florida (Ord. No.19-03, § 1, 2-5-2019, available at https://library.municode.com/fl/key_west/codes/code_of_ordinances?nodeId=SPAGEOR_CH26EN_ARTVIISU (last visited Nov. 13, 2019).
[51] *See* Gurney, Kyra, "Miami Beach considers banning the sale of sunscreens believed to harm coral reefs," Miami Herald, March 13, 2019, available at https://www.miamiherald.com/news/local/community/miami-dade/miami-beach/article227431294.html (last visited Nov. 14, 2019).
[52] Ch. 2, Art. VI, Div. 3, Code of Ordinances, City of Key West Florida.
[53] *See* City of Key West City Commission*, Action Details Amending Chapter 26 – Sunscreen,* available at http://keywest.legistar.com/LegislationDetail.aspx?ID=3763135&GUID=EFF5D76E-F043-4AFF-A898-42EB20A25953&Options=Advanced&Search= (last visited Nov. 19, 2019).

humans and can cause damage to the body. Short term[54] overexposure to UV radiation can cause a sunburn while prolonged exposure can cause skin cancer and premature aging.[55]

There are health benefits with exposure to UVB radiation which helps the skin produce vitamin D. Vitamin D plays an important role in the bone and muscle health. Additionally, some UV radiation therapies have been used to treat unresponsive and severe conditions such as psoriasis, rickets, and lupus.[56]

The Center for Disease Control (CDC) recommends the use of sunscreen or protective clothing as the best protection against UV damage from the sun. Sunscreens absorb, reflect, or scatter sunlight to help protect the skin from damaging UV effects. Sunscreens are assigned a sun protection factor (SPF) which measure their rate of effectiveness. The minimum SPF recommended by the CDC is SPF15, but the higher the number the more protection is provided. The CDC also recommends re-applying sunscreen if in the sun more than two hours or after swimming, sweating, or toweling off.[57]

Dermatological Efficacy of Sunscreen

According to the American Academy of Dermatology (AAD),[58] one in five Americans will develop skin cancer in their lifetime with nearly 20 Americans dying from melanoma[59] every day. The AAD's official position is that vitamin D should be obtained from a healthy diet and not unprotected exposure to the sun or indoor tanning beds. The AAD noted studies have shown that UV radiation from the sun and tanning devices can cause oncogenic mutations in skin cells,[60] and there is no scientifically safe level of UV exposure from either the sun or indoor tanning devices. To protect against skin cancer, the AAD recommends a photo-protective regimen including regular and proper use of broad-spectrum sunscreens.[61]

The Environmental Working Group (EWG) promulgates a sunscreen guide annually assessing the efficacy of sunscreens on the market. EWG found two-thirds of the non-mineral sunscreens[62] tested

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[54] The Center for Disease Control (CDC) estimates the sun's UV rays can damage the skin in as little as 15 minutes. *See* CDC, *Sun Safety*, https://www.cdc.gov/cancer/skin/basic_info/sun-safety.htm (last visited Nov. 18, 2019).
[55] FDA, *Prohibited and Restricted Ingredients*, available at https://www.fda.gov/radiation-emitting-products/tanning/ultraviolet-uv-radiation (last visited Nov. 18, 2019).
[56] *Id*.
[57] CDC, *Sun Safety*, https://www.cdc.gov/cancer/skin/basic_info/sun-safety.htm (last visited Nov. 18, 2019).
[58] *See* American Academy of Dermatology (AAD), *Detect Skin Cancer: How to Perform a Skin Self-Exam, available at* https://www.aad.org/skin-cancer-find-check and *Is Sunscreen Safe?*, https://www.aad.org/sun-protection/is-sunscreen-safe (last visited Nov.22, 2019).
[59] Melanoma is one of the rarer and more dangerous forms of skin cancer. It is much more likely to spread to other parts of the body if not caught and treated early. *See* American Cancer Society (ACS), *What is Melanoma Skin Cancer?,* https://www.cancer.org/cancer/melanoma-skin-cancer/about/what-is-melanoma.html (last visited Nov. 22, 2019).
[60] *See* D M Parkin, D Mesher and P Sasieni, *Cancers Attributable To Solar (Ultraviolet) Radiation Exposure in the UK in 2010,* British Journal of Cancer, Dec. 2011. At 105, available at https://www.nature.com/articles/bjc2011486 (last visited Nov. 22, 2019); International Agency for Research on Cancer, Working Group on artificial ultraviolet (UV) light and skin cancer, *The Association Of Use Of Sunbeds With Cutaneous Malignant Melanoma And Other Skin Cancers: A Systematic Review*, Jan. 2007, https://onlinelibrary.wiley.com/doi/full/10.1002/ijc.22453 (last visited Nov. 22, 2019); *See also* Jennifer S Lin, MD, MCR, Michelle Eder, PhD, Sheila Weinmann, PhD, Sarah P Zuber, MSW, Tracy L Beil, MS, Daphne Plaut, MLS, and Kevin Lutz, MFA, *Behavioral Counseling To Prevent Skin Cancer: A Systematic Review for the U.S. Preventive Services Task Force Recommendation*, Rockville (MD): Agency for Healthcare Research and Quality (US), Feb. 2011, available at https://www.ncbi.nlm.nih.gov/books/NBK53508/. (last visited Nov. 22, 2019).
[61] AAD, P*osition Statement on Vitamin D*, available at https://server.aad.org/forms/policies/uploads/ps/ps-vitamin%20d.pdf? (last visited Nov. 22, 2019); *See also See* Jolieke C. van der Pols, Gail M. Williams, Mirmala Pandeya, Valerie Logan, and Adèle C. Green, *Prolonged Prevention of Squamous Cell Carcinoma of the Skin by Regular Sunscreen Use*, Cancer Epidemiol Biomarkers Prevention, Dec. 2006, at 2546, available at https://cebp.aacrjournals.org/content/15/12/2546 (last visited Nov. 22, 2019) and Caroline G. Watts, MPH, PhD, Martin Drummond, MBiost, Chris Goumas, MPH, et al, *Sunscreen Use and Melanoma Risk Among Young Australian Adults,* JAMA Dermatol. July 2018, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6143037/ (last visited Nov. 22, 2019).
[62] Organic sunscreens, like those containing oxybenzone and octinoxate, are easy to apply and less likely to leave a visible film than their inorganic counterparts. However, organic sunscreens may trigger a sensitivity or allergic reaction in some users. Alternatively, inorganic sunscreens cover a broad spectrum of UV radiation and are associated with a reduced risk of allergic or irritant contact dermatitis. Although they may leave a thin, white film on the skin, they are cosmetically more acceptable than the thick, opaque pastes associated with older products. Oxybenzone is one of the few FDA-approved ingredients that provides safe and effective UV protection, and has been approved for use since 1978. Originally developed in 1950's as an organic filter that absorbs UV-B rays, octinoxate is today more commonly combined with other specialized ingredients to decrease skin absorption. *See* CDC, 2020 *Yellow Book: Health Information for International Travel, Chapter 3: Environmental Hazards & Other Noninfectious Health Risks,* available at

contained oxybenzone.[63] The EWG also found that the use of octinoxate was widespread within the sunscreens tested. The EWG found that eight FDA-approved active ingredients are rarely used in sunscreens including the chemicals Para-aminobenzoic acid (PABA) and trolamine salicylate. The FDA recommended these two chemicals be removed from the approved list in its proposed rule update.[64]

Office of Program Policy Analysis and Government Accountability (OPPAGA) Research Survey

As directed by the Legislature, the Office of Program Policy Analysis and Government Accountability (OPPAGA) compiled recent peer-reviewed research about the effects of oxybenzone and octinoxate on corals and marine life. In the overview of its findings presented to the Legislature in September 2019, OPPAGA recognized that "a small number of scientific studies have shown negative effects[65] of oxybenzone and octinoxate (active ingredients in some sunscreen products) on corals and marine life at concentration levels generally not observed in nature." OPPAGA noted that sunscreens were not the only source of these chemicals, but they were also found in wastewater effluent, plastics dumped in the ocean, and hull paint on ships.[66]

OPPAGA noted that the active ingredients in sunscreen fall into two categories: organic radiation absorbers and inorganic sun-blocking agents. Oxybenzone and octinoxate are organic absorbers used in sunscreens, shampoos, and other personal care products. While on the FDA's approved list, the chemicals are restricted to a maximum amount of 6% for oxybenzone and 7.5% for octinoxate in sunscreens sold in the U.S.[67]

OPPAGA reviewed 18 peer-reviewed studies from 2008 to the present and detailed the effects of the chemicals oxybenzone and octinoxate in the following chart:

https://wwwnc.cdc.gov/travel/yellowbook/2020/noninfectious-health-risks/sun-exposure; Personal Care Products Council (PCPC) *Sunscreen*, https://www.personalcarecouncil.org/sunscreen/; and U.S. National Library of Medicine National Center for Biotechnology Information (NCBI), *Compound Summary: Octyl methoxycinnamate*, https://pubchem.ncbi.nlm.nih.gov/compound/5355130 (last visited Nov. 25, 2019).

[63] In 2008, the Environmental Working Group (EWG) called on the FDA to review oxybenzone because of growing evidence that the chemical penetrates the skin and potentially disrupts the human hormone system. EWG, *EWG Sunscreen Guide: Executive Summary,* available at https://www.ewg.org/sunscreen/report/executive-summary/ (last visited Nov. 22, 2019).

[64] EWG, *EWG Sunscreen Guide: The Trouble with Ingredients in Sunscreens,* available at https://www.ewg.org/sunscreen/report/the-trouble-with-sunscreen-chemicals/ (last visited Nov. 22, 2019).

[65] Identified negative effects that may be occurring include the bleaching of coral fragments and coral cells from hard coral and damage to coral DNA and reduced reproductive success.

[66] Office of Program Policy Analysis and Government Accountability (OPPAGA)*, Summary of Peer-Reviewed Research on the Effects of Selected Sunscreen Chemicals on Corals and Marine Life, 2008 to Present* (Sept. 2019) (on file with House Local, Federal & Veterans Affairs Subcommittee).

[67] *Id.* at pages 1-2.

Exhibit 2

Detailed Effects of Oxybenzone and Octinoxate Exposure on Corals and Marine Life, by Concentration in Water

Effect	Organism(s)	Study
Chemical Concentrations of Parts Per Million		
Coral bleaching	Coral	Danovaro, 2008
Damage to coral planulae, coral bleaching, damage to coral DNA	Coral	Downs, 2015
Reduced reproductive success (flatworms and diatoms) and behavioral changes (anemones and coral)	Flatworms, diatoms, sea anemones, and coral	McCoshum, 2016
Reduced reproductive success	Marine phytoplankton Japanese medaka fish Green alga Aquatic midges	Tovar-Sánchez, 2013 Kim, 2014 Mao, 2018 Campos, 2019
Behavioral changes	Siamese fighting fish	Chen, 2016
Immobilization	Aquatic crustaceans	Jang, 2016
Larvae damage	Sea urchins	Corinaldesi, 2017
Mortality	Aquatic crustaceans	Gakowska, 2018
Chemical Concentrations of Parts Per Billion		
Bioaccumulation	Coral Fish including common carp, brown trout, Ebro barbel, and European Eel Zebrafish	He, 2019 Gago-Ferrero, 2015 Zhou, 2019
Reduced reproductive success	Fathead minnows[1]	Christen, 2011
DNA damage	Zebrafish[2]	Zucchi, 2011 Bluthgen, 2012 Zhang, 2017

[1] Fathead minnows are used in EPA testing to determine toxicity levels.

[2] Zebrafish are considered an excellent vertebrate organism for testing toxic effects of chemicals.

Source: OPPAGA analysis.

OPPAGA identified three main categories of deficiencies in current research. First, the lowest concentration of the tested chemicals that would have a negative impact on the marine environment cannot be determined because there is not enough data. Additionally, in Florida the concentration of the tested chemicals is not currently being recorded by any state agency and concentrations vary widely across different locations.

Next, the method of exposure addressed in the studies presents a research gap. Scientists interviewed by OPPAGA noted that the studies addressed short term acute exposure of the tested chemicals on marine life but did examine long term chronic exposure. Scientists also were concerned that the studies were conducted in laboratories absent real world factors affecting coral reefs and marine life such as the amount of organic material in the seawater.

Finally, the effects of multiple combined chemicals has not been sufficiently addressed by current research. Scientists noted that the studies do not examine the effects of combinations of ingredients as they might be found in nature nor do they examine how these chemicals could break down and interact with other compounds in the seawater.[68]

[68] *See* OPPAGA, *Summary of Peer-Reviewed Research on the Effects of Selected Sunscreen Chemicals on Corals and Marine Life, 2008 to Present* (Sept. 2019) 4-5 (on file with House Local, Federal & Veterans Affairs Subcommittee).

Local Government Authority

The Florida Constitution grants counties[69] and municipalities[70] broad home rule authority. Non-charter county governments may exercise those powers of self-government provided by general or special law.[71] Counties operating under a county charter have all powers of self-government not inconsistent with general law or special law approved by vote of the electors.[72]

Municipalities have those governmental, corporate, and proprietary powers necessary to conduct municipal government, perform their functions and provide services, and exercise any power for municipal purposes,[73] except as otherwise provided by law.[74]

Preemption

Counties and municipalities have broad authority to legislate on any matter that is not inconsistent with federal or state law. A local government enactment may be inconsistent with state law if (1) the Legislature "has preempted a particular subject area" or (2) the local enactment conflicts with a state statute. Where state preemption applies to a particular topic, it precludes a local government[75] from exercising authority in that particular area.[76]

Florida law recognizes two types of preemption: express and implied. Express preemption requires a specific legislative statement; it cannot be implied or inferred.[77] Express preemption of a field by the Legislature must be accomplished by clear language stating that intent.[78] In cases where the Legislature expressly or specifically preempts an area, the intent of the Legislature is readily ascertained.[79] In cases determining the validity of ordinances enacted in the face of state preemption, the effect has been to find such ordinances null and void.[80]

Implied preemption actually is a decision by the courts to recognize state preemption in the absence of an explicit legislative directive.[81] Preemption of a local government enactment is implied only where "the legislative scheme is so pervasive as to evidence an intent to preempt the particular area," and strong public policy reasons exist for finding preemption.[82] Implied preemption is found where the local legislation would present a danger of conflicting with the state's pervasive regulatory scheme.[83]

Proposed Changes

The bill amends s. 499.002, F.S., to expressly preempt the regulation of OTC proprietary drugs and cosmetics to the state. The law nullifies any local laws regulating OTC drugs and cosmetics, including any local regulation of sunscreen products.

B. SECTION DIRECTORY:

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[69] Counties are subdivisions of the state created by law. *See* art. VIII, s. 1(a), Fla. Const.
[70] Municipalities are created by general or special law or recognized pursuant to art. VIII, s. 2 or s. 6, Fla. Const. *See* s. 165.031(3), F.S. The term "municipality" may be used interchangeably with the terms "city," "town," or "village."
[71] Art. VIII, s. 1(f), Fla. Const.
[72] Art. VIII, s. 1(g), Fla. Const.
[73] A "municipal purpose" is any activity or power which may be exercised by the state or its political subdivisions. *See* s. 166.021(2), F.S.
[74] Art. VIII, s. 2(b), Fla. Const. *See also* s. 166.021(1), F.S.
[75] Including without limitation counties, municipalities, school districts, special districts, or any other subdivision of the state.
[76] Wolf, *The Effectiveness of Home Rule: A Preemption and Conflict Analysis*, 83 Fla. B.J. 92 (June 2009), available at https://www.floridabar.org/the-florida-bar-journal/the-effectiveness-of-home-rule-a-preemption-and-conflict-analysis/ (last visited Oct. 25, 2019).
[77] *See City of Hollywood v. Mulligan*, 934 So. 2d 1238, 1243 (Fla. 2006); *Phantom of Clearwater, Inc. v. Pinellas County*, 894 So. 2d 1011, 1018 (Fla. 2d DCA 2005), approved in *Phantom of Brevard, Inc. v. Brevard County*, 3 So. 3d 309 (Fla. 2008).
[78] *Mulligan*, *supra* at 934 So. 2d at 1243.
[79] *Sarasota Alliance for Fair Elections, Inc. v. Browning*, 28 So. 3d 880, 886 (Fla. 2010).
[80] *See, e.g., Nat'l Rifle Ass'n of Am., Inc. v. City of S. Miami,* 812 So.2d 504 (Fla. 3d DCA 2002).
[81] *Phantom of Clearwater, Inc.*, 894 So.2d at 1019.
[82] *Id*., quoting *Tallahassee Memorial Regional Medical Center, Inc. v. Tallahassee Medical Center, Inc.,* 681 So.2d 826, 831 (Fla. 1st DCA 1996), citing *Tribune Co. v. Cannella*, 458 So.2d 1075 (Fla. 1984).
[83] *Sarasota Alliance for Fair Elections, Inc.,* 28 So.3d at 886.

Section 1 Amends s. 499.002, F.S., to preempt the regulation of over-the-counter drugs and cosmetics to the state.

Section 2 Provides an effective date of July 1, 2020.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not Applicable. This bill does not appear to require counties or municipalities to spend funds or take action requiring the expenditures of funds; reduce the authority that counties or municipalities have to raise revenues in the aggregate; or reduce the percentage of state tax shared with counties or municipalities.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

The bill neither requires nor authorizes executive branch rulemaking.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES