

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	10 Y, 6 N	Morris	Calamas

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., including sunscreen, which is an over-the-counter (OTC) drug not requiring a prescription.

The Florida Drug and Cosmetic Act (FLDCA) regulates drugs and cosmetics within Florida, including sunscreen. The Department of Business and Professional Regulation (DBPR) is responsible for administering the provisions of the FLDCA within the Division of Drugs, Devices and Cosmetics (DDC). The DDC issues permits to OTC drug and cosmetics manufacturers, and enforces 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, F.S., 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, products¹, 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 FDA Center for Drug Evaluation and Research (CDER) regulates the safety and efficacy of drugs in the U.S.⁵ 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.⁶

Over-the-counter (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.⁷ The CDER regulates prescription and OTC drugs which include medicines and products such as fluoride toothpaste and sunscreen.⁸ 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.⁹

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 Jan. 24, 2020).

² See FDA, *What Does FDA Regulate?*, <https://www.fda.gov/about-fda/fda-basics/what-does-fda-regulate> (last visited Jan. 24, 2020).

³ 21 U.S.C. § 331.

⁴ 15 U.S.C. § 1451-1460 (2009).

⁵ FDA, *Drugs*, <https://www.fda.gov/drugs> (last visited Jan. 24, 2020).

⁶ FDA, *Regulatory Procedures Manual, Chapter 1 – Regulatory Organization*, available at <https://www.fda.gov/media/71908/download> (last visited Jan. 24, 2020).

⁷ 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 Jan. 24, 2020)

⁸ 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 Jan. 24, 2020).

⁹ 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 Jan. 24, 2020).

Because there are more than 300,000 marketed OTC drugs, the CDER reviews the active ingredients¹⁰ and labels for over 80 classes¹¹ of OTC drugs rather than for each individual drug. For each class, an OTC drug monograph¹² is developed and published in the Federal Register.¹³

Sunscreen Regulation

The FDCA treats sunscreens, and their active ingredients, as regulated OTC drugs.¹⁴ Currently, the FDA has approved 16 acceptable active ingredients, including octinoxate and oxybenzone, in products that are labeled as sunscreen.¹⁵ Active ingredients in sunscreens protect the skin from the sun's ultraviolet rays, while inactive ingredients are all other ingredients.¹⁶

The FDA recently proposed a new rule addressing the list of acceptable sunscreen active ingredients to make sure that over-the-counter sunscreens are safe and effective for human use.¹⁷ 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 repellent products. The rule is not yet effective¹⁸ and the FDA does not expect the affected industry to fully comply with the new standards for at least a year after it becomes effective.¹⁹

Significantly, the proposed rule will modify the safety and efficacy status of the 16 acceptable active ingredients currently allowed in sunscreens, as follows:²⁰

- Zinc oxide and titanium dioxide will be categorized as safe and effective;
- Para-aminobenzoic acid and trolamine salicylate will be categorized as unsafe and ineffective; 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 to help make a determination on safety and efficacy.

¹⁰An 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 Jan. 24, 2020).

¹¹ Examples of these classes of drugs include those related to acne, allergy, cold and cough, laxative, insect repellent, nasal decongestant, and sunscreen. See FDA, *Status of OTC Rulemakings*, <https://www.fda.gov/drugs/over-counter-otc-drugs/status-otc-rulemakings> (last visited Jan. 24, 2020) See also FDA, *Division of Nonprescription Drugs*, <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/division-nonprescription-drugs> (last visited Jan. 24, 2020).

¹² 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.

¹³ 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 Jan. 24, 2020)

¹⁴ See 21 U.S.C. §§ 321(g) and 360fff; See also 61N-1.006 and 61N-1.009, F.A.C.

¹⁵ 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 Jan. 24, 2020).

¹⁶ *Id.*

¹⁷ 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 Jan. 24, 2020).

¹⁸ Federal Register, *Sunscreen Drug Products for Over-the-Counter Human Use*, <https://www.federalregister.gov/documents/2019/04/18/2019-07710/sunscreen-drug-products-for-over-the-counter-human-use-extension-of-comment-period> (last visited Jan. 24, 2020). 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 Jan. 24, 2020).

¹⁹ See U.S. Regulations, *Sunscreen Drug Products –OPEN*, <https://www.regulations.gov/docket?D=FDA-1978-N-0018> (last visited Jan. 24, 2020); See also 84 FR 6204.

²⁰ 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 Jan. 24, 2020).

In January, 2020, the FDA released the results from their study²¹ showing evidence that some sunscreen active ingredients (avobenzene, oxybenzone, octocrylene, homosalate, octisalate, and octinoxate) may be absorbed through the skin into the body.²² However, the FDA stated that the results of this study does not mean the ingredients are unsafe, only that further information is needed to make such a determination.²³ The FDA has advised continued use of sunscreens.²⁴

In contrast to its sunscreen drug regulations, the FDA's cosmetic regulations exclude more ingredients as being unsafe. 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.²⁵

OTC Drugs and Cosmetics – State Regulation

Part I of ch. 499, F.S., the Florida Drug and Cosmetic Act (FLDCA), implemented by the DBPR, regulates drugs, cosmetics, and certain devices in Florida. Part of the purpose of the FLDCA is to promote uniformity between federal and state regulation.²⁶ As such, administration of the FLDCA must conform to the Federal Food, Drug, and Cosmetic Act²⁷ and the applicable portions of the Federal Trade Commission Act,²⁸ which prohibit the false advertising of drugs, devices, and cosmetics.²⁹

DBPR's Division of Drugs, Devices and Cosmetics (DDC) issues permits to over-the-counter drug manufacturers and cosmetic manufacturers and inspects permittees and enforces FLDCA.³⁰

In addition to the above, the FLDCA also provides:³¹

- Criminal prohibitions against distribution of contraband and misbranded prescription drugs;
- Regulations for the advertising and labeling of drugs, devices, and cosmetics; and
- Enforcement authority for DBPR, including seizure and condemnation of drugs, devices, and cosmetics.

State and Local Sunscreen Regulation

DBPR regulates sunscreen as an OTC drug because FDA regulation considers sunscreen a drug.³² Florida defines an OTC 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.³³ Florida law does not authorize the DBPR to determine if OTC drug ingredients are safe or unsafe for the environment or use by humans.

²¹ Journal of the American Medical Association, *Effect of Sunscreen Application on Plasma Concentration of Sunscreen Active Ingredients*, <https://jamanetwork.com/journals/jama/article-abstract/2759002> (last visited Jan. 30, 2020).

²² FDA, *FDA In Brief: FDA announces results from second sunscreen absorption study*, <https://www.fda.gov/news-events/fda-brief/fda-brief-fda-announces-results-second-sunscreen-absorption-study> (last visited Jan. 30, 2020).

²³ *Id.*

²⁴ FDA, *Shedding More Light on Sunscreen Absorption*, <https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/shedding-more-light-sunscreen-absorption> (last visited Jan. 30, 2020).

²⁵ FDA, *Prohibited and Restricted Ingredients*, <http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm127406.htm> (last visited Jan. 24, 2020).

²⁶ See s. 499.002(1), F.S.

²⁷ 21 U.S.C. ss. 301 *et seq.*

²⁸ See 15 U.S.C. §§ 41-58, as amended.

²⁹ S. 499.002(1)(b), F.S.

³⁰ *Id.*

³¹ See ss. 499.0051, 499.0054, and 499.062, F.S.

³² 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 Jan. 24, 2020); 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 Jan. 24, 2020).

³³ S. 499.003(43), F.S.,

Some municipalities have passed or considered ordinances banning the sale and use of certain sunscreens as a result of the findings of recent studies³⁴ 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 SPF³⁵ sunscreen protection personal care product that contains oxybenzone or octinoxate, or both, without a “medically-licensed” prescription.³⁶ A month later, the City of Miami Beach considered but did not pass similar legislation amid lawmakers’ concerns that more research is needed.³⁷

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 \$500.³⁸ The city’s sunscreen prohibition becomes effective January 1, 2021.³⁹

Hawaii⁴⁰ and the U.S. Virgin Islands⁴¹ 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.

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 humans and can cause damage to the body. Short term⁴² overexposure to UV radiation can cause a sunburn while prolonged exposure can cause skin cancer and premature aging.⁴³

³⁴ 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 Jan. 24, 2020).

³⁵ 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 Jan. 24, 2020).

³⁶ 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_ARTVIIISU (last visited Jan. 24, 2020).

³⁷ 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 Jan. 24, 2020).

³⁸ Ch. 2, Art. VI, Div. 3, Code of Ordinances, City of Key West Florida.

³⁹ 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 Jan. 24, 2020).

⁴⁰ 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 Jan. 24, 2020).

⁴¹ 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 Jan. 24, 2020).

⁴² 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 Jan. 24, 2020).

⁴³ FDA, *Prohibited and Restricted Ingredients*, available at <https://www.fda.gov/radiation-emitting-products/tanning/ultraviolet-uv-radiation> (last visited Jan. 24, 2020).

Exposure to UVB radiation helps the skin produce vitamin D. Vitamin D plays an important role in the bone and muscle health. Some UV radiation therapies have been used to treat unresponsive and severe conditions such as psoriasis, rickets, and lupus.⁴⁴

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.⁴⁵

Dermatological Efficacy of Sunscreen

According to the American Academy of Dermatology (AAD),⁴⁶ one in five Americans will develop skin cancer in their lifetime with nearly 20 Americans dying from melanoma⁴⁷ 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,⁴⁸ 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.⁴⁹

Environmental Effects of Sunscreen

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 effects⁵⁰ 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.⁵¹

⁴⁴ *Id.*

⁴⁵ CDC, *Sun Safety*, https://www.cdc.gov/cancer/skin/basic_info/sun-safety.htm (last visited Jan. 24, 2020).

⁴⁶ 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 Jan. 24, 2020).

⁴⁷ 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 Jan. 24, 2020).

⁴⁸ 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 Jan. 24, 2020); 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 Jan. 24, 2020).

⁴⁹ AAD, *Position 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 Jan. 24, 2020).

⁵⁰ 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.

⁵¹ 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 Health and Human Services Committee).

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.⁵²

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:

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	Tovar-Sánchez, 2013
	Japanese medaka fish	Kim, 2014
	Green alga	Mao, 2018
	Aquatic midges	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	He, 2019
	Fish including common carp, brown trout, Ebro barbel, and European Eel	Gago-Ferrero, 2015
	Zebrafish	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 not 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.⁵³

⁵² *Id.* at pages 1-2.

⁵³ 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 Health and Human Services Committee).

Local Government Authority

The Florida Constitution grants counties⁵⁴ and municipalities⁵⁵ broad home rule authority. Non-charter county governments may exercise those powers of self-government provided by general or special law.⁵⁶ 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.⁵⁷

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,⁵⁸ except as otherwise provided by law.⁵⁹

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 government⁶⁰ from exercising authority in that particular area.⁶¹

Florida law recognizes two types of preemption: express and implied. Express preemption requires a specific legislative statement; it cannot be implied or inferred.⁶² Express preemption of a field by the Legislature must be accomplished by clear language stating that intent.⁶³ In cases where the Legislature expressly or specifically preempts an area, the intent of the Legislature is readily ascertained.⁶⁴ 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.⁶⁵

Implied preemption actually is a decision by the courts to recognize state preemption in the absence of an explicit legislative directive.⁶⁶ 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.⁶⁷ Implied preemption is found where the local legislation would present a danger of conflicting with the state's pervasive regulatory scheme.⁶⁸

Effect of Proposed Changes

The bill amends s. 499.002, F.S., to expressly preempt the regulation of OTC proprietary drugs and cosmetics to the state. This nullifies the current City of Key West ordinance banning the sale of any SPF sunscreen product containing oxybenzone or octinonate and prevents local governments from enacting similar ordinances in the future.

⁵⁴ Counties are subdivisions of the state created by law. See art. VIII, s. 1(a), Fla. Const.

⁵⁵ 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."

⁵⁶ Art. VIII, s. 1(f), Fla. Const.

⁵⁷ Art. VIII, s. 1(g), Fla. Const.

⁵⁸ 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.

⁵⁹ Art. VIII, s. 2(b), Fla. Const. See also s. 166.021(1), F.S.

⁶⁰ Including without limitation counties, municipalities, school districts, special districts, or any other subdivision of the state.

⁶¹ 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).

⁶² 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).

⁶³ *Mulligan*, *supra* at 934 So. 2d at 1243.

⁶⁴ *Sarasota Alliance for Fair Elections, Inc. v. Browning*, 28 So. 3d 880, 886 (Fla. 2010).

⁶⁵ See, e.g., *Nat'l Rifle Ass'n of Am., Inc. v. City of S. Miami*, 812 So.2d 504 (Fla. 3d DCA 2002).

⁶⁶ *Phantom of Clearwater, Inc.*, 894 So.2d at 1019.

⁶⁷ *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).

⁶⁸ *Sarasota Alliance for Fair Elections, Inc.*, 28 So.3d at 886.

B. SECTION DIRECTORY:

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

