DECLARATORY RULING OF

THE ALABAMA STATE BOARD OF MEDICAL EXAMINERS

On July 18, 2024, the Alabama State Board of Medical Examiners ("the Board") considered a request submitted on behalf of the Alabama Board of Pharmacy ("Petitioner") for a declaratory ruling pursuant to Ala. Code § 41-22-11 and Ala. Admin. Code r. 540-X-1-.10, concerning the purchasing and compounding of Glucagon-like peptide-1 agonist (GLP-1) products by physicians.

FACTS PRESENTED

Petitioner presents the following factual background[1]:

Purchasing

Semaglutide powder is being advertised to physician offices and the public for purchase from innumerable sources. Much of this semaglutide is NOT prescription quality. The outlets are selling semaglutide salt forms and research grade powder. These salt forms and research grade powders are NOT approved by the FDA nor are they evaluated for safety. As such, the only powder that should be used in compounding is the prescription quality powder.

Pharmacists are required to purchase and use only prescription quality active pharmaceutical ingredients when compounding a drug for human consumption. Outlets attempting to sell GLP-1 powder or products to practitioners in Alabama must have the appropriate permit from the ALBOP. Physicians can validate a supplier has an active permit with ALBOP by utilizing the License Verification feature on the ALBOP website, www.albop.com.

Compounding

[1] A complete copy of Petitioner's petition is attached as Attachment A.

The Federal Food, Drug and Cosmetic Act (FDCA) expressly recognizes the United States Pharmacopeia (USP) quality standards for medicines. USP has extensive standards outlining the proper and safe processes for compounding sterile injectable products. USP explicitly states that the standards apply to all places where compounded sterile preparations (CSPs) are prepared, including physician offices, and enforcement falls on state regulatory bodies.

These standards expressly lay out requirements for sterility, stability, and beyond use dating as the industry standard to protect public safety in compounding products for prescription use. An abbreviated outline [appears in Attachment A].

The Board of Pharmacy is charged with regulating the safe and effective compounding of medications (§34-23-162). As such Rule 680-X-2-.43 states:

> 680-X-2-.43 Requirements For Compounding.
>
> All pharmacies that engage in the compounding of drugs or drug products shall comply with all applicable and current regulations of United States Pharmacopeia–National Formulary (USP)-NF. Section 34-23-11 applies.

While Rule 680-X-2-.43 specifically references 34-23-11 which exempts physicians from Chapter 23, Pharmacists and Pharmacies, of the Code of Alabama, it seems counterintuitive that exemption was intended to take away all the requirements for compounding from physicians that would ensure such compounding is done in a manner that is safe and effective for their patients.

We are aware some physicians may not consider themselves compounding because they are simply drawing unit dose syringes from a bulk vial to send home with the patient. However, this practice is regulated as a compounding action.

QUESTIONS PRESENTED

(1) Does the exemption of physicians under Ala. Code § 34-23-11 permit a physician to compound and dispense a drug using non-prescription quality ingredients?

(2) Are physicians required to ensure any prescription product or ingredient is purchased from an entity permitted by the Alabama State Board of Pharmacy?

(3) Are physicians required to comply with USP standards when compounding GLP-1 products?

ANSWER

(1) Alabama-licensed physicians are not permitted to compound or dispense a drug using non-prescription quality ingredients.

(2) Alabama-licensed physicians are required to purchase prescription products and ingredients only from an entity permitted by the Alabama State Board of Pharmacy.

(3) Alabama-licensed physicians are required to comply with USP standards when compounding GLP-1 products.

DISCUSSION

The Alabama State Board of Pharmacy ("ALBOP") regulates the practice of pharmacy, the importation of drugs, and the compounding and dispensing of drugs "in such a manner as to protect the public." Ala. Code § 34-23-2. Generally, no "person, firm, or corporation" can practice pharmacy, compound drugs, or dispense medications unless he or she possesses a license issued by ALBOP. Ala. Code § 34-23-50(a). However, Alabama-licensed physicians may compound, dispense, administer, or supply drugs to their patients for the patient's personal use without a license issued by ALBOP. Ala. Code § 34-23-11.

This exemption is referenced in Ala. Code § 34-23-70, which sets forth certain requirements and restrictions attaching to the operation of a pharmacy. In the midst of a list of requirements ALBOP is empowered to enforce, the Legislature clarified that ALBOP is not authorized to "promulgate or enforce any rule which governs, regulates, or restricts the professional practice of a physician licensed to practice medicine in this state." Ala. Code § 34-23-70(g)(3). It appears to the Board that the Legislature's intent is that ALBOP not impair an Alabama-licensed physician's medical practice or subject physicians to regulation by ALBOP. This accords with the broad definition of the practice of medicine and the exclusive authority of the Board and Medical Licensure Commission to license and regulate the practice of medicine in this state. *See* Ala. Code § 34-24-50; § 34-24-53; and § 34-24-311.

However, it is the opinion of the Board that this statute is <u>not</u> intended to exempt physicians from the public welfare and safety purposes accomplished by the licensing and regulation of pharmacists and pharmacies. Indeed, a primary goal of the regulation of the practice of medicine by the Board is "prioritize patient safety and wellness" and to "determine the medical practices" that achieve this goal. Ala. Code § 34-24-53.1(a)(2)-(3). Patient safety and wellness is not prioritized if physicians disregard the safety measures put in place and enforced by ALBOP. Instead, Alabama-licensed physicians should participate in and bolster ALBOP's efforts to combat unscrupulous actors who seek to introduce dangerous drugs to Alabama's citizens.

While it is true that nothing in the Alabama Pharmacy Act "shall prevent any licensed practitioner of the healing arts from personally compounding, dispensing, administering or supplying to his or patients drugs and medicines for their use," it is also true that "[n]o manufacturer . . . wholesale drug distributor . . . or [any other person or entity] identified in the supply chain of any legend drug or device shall ship, or cause to be shipped, into the state any

legend drug or device without a valid permit issued by [ALBOP]." Ala. Code §§ 34-23-11 and 34-23-32(g). It is the unambiguous intent of the Legislature that all drugs come into the state through licensed sources. Accordingly, it is the opinion of the Board that physicians must purchase prescription products and ingredients only from an entity permitted by ALBOP.[2]

Furthermore, ALBOP has determined that patient safety requires "[a]ll pharmacies that engage in the compounding of drugs or drug products" to comply with "all applicable and current regulations of the United States Pharmacopeia-National Formulary (USP)-NF." Ala. Admin. Code r. 680-X-2-.43. This directive requires pharmacists to adhere to USP 797, which sets the standards for compounding sterile preparations. USP 797 is a national standard utilized by the FDA, as well as many states.[3] It is intended to apply to "all persons who prepare [compounded sterile preparations] and all places where [these preparations] are prepared. . . . [including] physicians." USP 797 1.1.3. The Board agrees with ALBOP that these sterile practices promote the health and safety of Alabama patients. Indeed, many of the practices promoted in USP 797 accord with existing medical standards, including limitations on the use of bulk vials, garbing and cleanliness, sterilization, and prohibitions on reusing components. There is no evidence before the Board justifying any departure from these standards when a physician is compounding a GLP-1 product. In fact, the evidence before the Board overwhelmingly favors adherence to the USP 797 standards. Consequently, it is the opinion of the Board that Alabama-licensed physicians are required to comply with USP standards when compounding GLP-1 products.

Finally, it is the opinion of the Board that physicians must use prescription quality ingredients when compounding and dispensing a drug to their patients. Patient health and wellness

[2] ALBOP does not keep a list of 503-B permitted pharmacies on their website; however, physicians are invited to contact ALBOP for more information and to verify any source for prescription products and ingredients.
[3] https://www.usp.org/compounding/general-chapter-797

is best served when a physician uses quality ingredients intended for human use. In light of recent warnings by the United States Food and Drug Administration ("FDA"), the publication of adverse event data, the warnings of relevant drug manufacturers, and other state boards, it appears to the Board that a physician's patients are put at unjustifiable risk by non-prescription grade GLP-1 products.[4] Therefore, physicians are not permitted to compound or dispense a drug using non-prescription quality ingredients.

This ruling is based upon the precise facts presented and upon statutes and rules currently in existence. The Board specially notes that this decision accords with the actions of other medical boards as well as the FDA. Should any relevant statutes or rules be amended or repealed, this ruling may no longer be valid.

DONE this 8th day of August, 2024.

C.M.A. "Max" Rogers, IV, M.D.
Chairman
Alabama State Board of Medical Examiners

[4] See Attachment B

Attachment A

ALABAMA BOARD OF PHARMACY

Donna C. Yeatman, R.Ph., CISCI
Executive Secretary

Location:
111 Village Street
Birmingham, AL 35242

(205) 981-2280
www.albop.com

June 7, 2024

Mr. E. Wilson Hunter
General Counsel
Alabama Board of Medical Examiners
848 Washington Avenue (36104)
PO Box 946
Montgomery, AL 36101-0946

Mr. William M. Perkins
Executive Director
Alabama Board of Medical Examiners
Montgomery, Alabama 36104

Dear Mr. Hunter and Mr. Perkins,

As Executive Secretary of the Alabama Board of Pharmacy (ALBOP), I am requesting a Declaratory Ruling regarding Glucagon-like peptide-1 agonists (GLP-1) products. Numerous calls and complaints have been fielded by this office relative to GLP-1 physician compounding and dispensing. Please see attached complaint as one example. These calls and complaints are surrounded by two issues: purchasing and compounding.

Purchasing

Semaglutide powder is being advertised to physician offices and the public for purchase from innumerable sources. Much of this semaglutide is NOT prescription quality. The outlets are selling semaglutide salt forms and research grade powder. These salt forms and research grade powders are NOT approved by the FDA nor are they evaluated for safety. As such, the only powder that should be used in compounding is the prescription quality powder.

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Attachment A

Compounding

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These standards expressly lay out requirements for sterility, stability, and beyond use dating as the industry standard to protect public safety in compounding products for prescription use. An abbreviated outline is attached for your reference.

The Board of Pharmacy is charged with regulating the safe and effective compounding of medications (§34-23-162). As such Rule 680-X-2-.43 states:

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We are aware some physicians may not consider themselves compounding because they are simply drawing unit dose syringes from a bulk vial to send home with the patient. However, this practice is regulated as a compounding action.

Considering the above, the Alabama Board of Pharmacy requests a Declaratory Ruling on the following:

1) Does the exemption of physicians under Ala. Code 34-23-11 permit a physician to compound and dispense a drug using non-prescription quality ingredients?
2) Are physicians required to ensure any prescription product or ingredient is purchased from an entity permitted by the Alabama State Board of Pharmacy?
3) Are physicians required to comply with USP standards when compounding GLP-1 products?

Thank you for your consideration and advisement on these issues.

Sincerely,

Donna C. Yeatman

Donna C. Yeatman
Executive Secretary

Online Complaints

Attachment A

Submission Date :02/26/2024 **Status :**Processed

COMPLAINT DETAILS1

PHARMACY NAME [redacted]

PHARMACIST/TECHNICIAN COMPLAINT IS AGAINST: [redacted]

Address [redacted]

City [redacted] State [redacted] Zip [redacted] Phone [redacted]

Explain the incident in your own words

[redacted] conducted a virtual visit with me on Tues Feb 20,2024 for the purpose of prescribing Trizepatide for weight loss. On Wed Feb 21 my Rx was shipped over night. On Thursday, Feb 22 I receivd my shipment via UPS. It was a cardboard box without insulation. My Rx was wrapped in white paper and the small ice pack in the cardboard box was warm to the touch and completely thawed (not even cool). The package had a strong odor of cigarette smoke. I immediately administered the first injection which i now regret. After further inspection of the packaging, I became aware that the labels on the shipping box and the little plastic box the pre-drawn syringes were in had no information about the compound pharmacy and was not labeled by the pharmacy at all. All labels referred to [redacted]. there was no expiration date on the label. Thursday night, Feb 22nd after becoming concerned about the possible adulteration of the medication I took, I contacted the clinic. I left voice mails and sent messages through their Website and sent email with my concerns. Finally, on Monday, Feb 26th I spoke with [redacted], the office manager. She informed that the clinic obtains meds from a compound pharmacy and draws the meds into syringes and then re-distributes them to patients. She would not give me any information about the compound pharmacy where the medication originated from. She further denied that anyone at their clinic smokes so the package could not have been exposed to smoke. she further stated that they are not responsible for how the package is handled by UPS. She stated that the syringe was packed with an ice pack so being warm upon arrival should not have a negative impact on the meds even though it was not insulated for shipping. Although I regretfully injected the first syringe before realizing all the red flags, I now have concerns about what product I put in my body and the conditions it was drawn under. Please help

Complaint Filed By

First Name [redacted] Middle Name [redacted] Last Name [redacted]

Phone Type [redacted] Phone [redacted]

Alternate Phone Type Select Alternate Phone Phone

Business Name

Business Name

Email [redacted]

Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Attachment A

Attachment A

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pharmacists advancing healthcare®

USP <797>

KEY CHANGES

The following represents key changes from the currently enforceable version of USP Chapter <797> (last major revision in 2008) to the revised USP Chapter <797> (official as of November 1, 2023). The following are the major changes and are not meant to be an exhaustive list of the entirety of all changes made. Some changes will be reported as direct text excerpts from the respective chapter (notated by quotation marks), while others will be reported as a general comment describing the text or change. *Note: Bolding has been added to the text below for emphasis.*

Category	USP <797>, 2008[1]	USP <797>, 2023[2]
01. INTRODUCTION AND SCOPE		
"The use of technologies, techniques, materials, and procedures other than those described in this chapter … "	" … not prohibited so long as they have been proven to be equivalent or superior with statistical significance to those described herein."	" … not prohibited as long as they are **noninferior** to those described herein **and validated for the intended purpose" (e.g., USP <1223>, <1225>)**
Compounded sterile preparations (CSPs) affected	" … irrigations for wounds and body cavities … " " … aqueous bronchial and nasal inhalations … "	" … Irrigations for **internal** body cavities … [NOTE—irrigations for the mouth, rectal cavity, and sinus cavity **are not required to be sterile**.]" "Nasal dosage forms intended for local application are **not required to be sterile**."
Hazardous drugs	Covered within the chapter under section Hazardous Drugs as CSPs Allows preparation of a "low volume of hazardous drugs" outside of a negative pressure space as long as two tiers of containment are used (closed-system transfer device with containment primary engineering control)	Removed from chapter and references to follow USP <800> No longer allows preparation of a low volume of hazardous drugs outside of a negative pressure space.
Radiopharmaceuticals	Covered within the chapter under section Radiopharmaceuticals as CSPs	Removed from chapter and references to follow USP <825>
Personnel and settings affected	Largely refers to and addresses only compounding personnel	**"Any person entering a sterile compounding area**, *whether preparing a CSP or not*, must meet the requirements in **3. Personal Hygiene and Garbing."**
The designated person(s)	Not addressed	"The compounding facility must designate one or more individuals (i.e., **the designated person(s)) to be responsible and accountable** for the performance and operation of the facility and personnel in the preparation of CSPs and for performing other functions as described in this chapter." A complete list of the designated person responsibilities has been provided as a separate resource.

Category	USP <797>, 2008[1]	USP <797>, 2023[2]
Administration	Standards do not pertain to the clinical administration of CSPs to patients (e.g., implantation, infusion, inhalation)	"For the purposes of this chapter, 'administration' means the direct application of a sterile product or preparation to a single patient by injecting, infusing, or otherwise providing a sterile product or preparation in its final form."
Immediate-use CSPs	"Administration begins not later than 1 hour following the start of the preparation … " Does not involve > 3 commercially manufactured packages of sterile nonhazardous products	"Administration begins **within 4 h following the start of preparation.**" "The preparation involves **not more than 3 different sterile products.**" "Personnel are trained and demonstrate competency in aseptic processes as they related to assigned tasks and the facility's SOPs."
Preparation per approved labeling	Strictly following the manufacturers' approved labeling (product package inserts) is considered a CSP and the requirements of the chapter apply	"**Compounding does not include** mixing, reconstituting, or other such acts that are **performed in accordance with directions contained in approved labeling or supplemental materials** provided by the product's manufacturer." "The product is prepared as a **single dose** for an **individual patient** … " "Approved labeling includes information for the diluent, the resultant strength, the container closure system, and storage time."
Proprietary bag and vial system	Does not mention BUDs other than following the manufacturer's instructions for handling and storing	Docking of the proprietary bag and vial system for **future activation** • This is **considered compounding** and must be performed in accordance with this chapter (ISO Class 5 environment) • BUDs must not be longer than the manufacturer's labeling
CSP microbial categories	CSP Categories • Low Risk • Low Risk with 12-h BUD • Medium Risk • High Risk Factors that determine CSP Category • Type of manipulation • Complexity and length of preparation • If any nonsterile ingredient, component, or equipment is used • Number of sterile products and packages • Number of transfers into any single container • Number of doses being prepared • Following proper garbing • Exposure to lower than ISO class 5 air and duration	CSP Categories • Category 1 • Category 2 • Category 3 Factors that determine CSP Category • Primarily based on environment/conditions of where the CSP is compounded • Level of garbing • Environmental testing and monitoring • Frequency of application of a sporicidal • Based on BUD assignment "Category 1, Category 2, and Category 3 CSPs can be compounded by using only sterile starting ingredients, or by using some or all nonsterile starting ingredients." One (or more) component is non-sterile: sterility of the compound must be achieved through a sterilization process (e.g., terminal sterilization) and must be maintained if it is subsequently manipulated

Category	USP <797>, 2008[1]	USP <797>, 2023[2]
02. PERSONNEL TRAINING AND EVALUATION		
Who needs to be trained and how often	"Personnel who prepare CSPs shall be trained … " How often: • Low- and medium-risk level: at least annually • High-risk level: semi-annually	Compounders and those who have direct oversight of compounders • Initially and at least every 6 or 12 months (depends on the individual) Personnel who do not compound nor have direct oversight of compounders, but are associated with other tasks **(e.g., restock or clean/disinfect the SCA, only compound immediate-use CSPs)**: • Defined by facility SOPs
Initial garbing competency evaluations	Compounders need to pass garbing competency evaluations before beginning to prepare CSPs	Garbing competency evaluations include: • Visual observation • Gloved fingertip and thumb sampling (GFT) of both hands Compounders and those who have direct oversight of compounders • " … must complete an initial garbing competency evaluation **no fewer than 3 separate times. The 3 successful completions must be in succession** … " Remediation of failed competency • " … failure of any of the 3 initial garbing competency evaluations r**equires repeat testing until personnel successfully completes 3 evaluations in a row.**"
Ongoing garbing competency evaluations	Visual observation of hand hygiene and garbing • At least annually Gloved fingertip and thumb sampling • Low/medium risk – at least annually • High-risk – at least semiannually	Compounders • Category 1 and 2: **at least every 6 months** • Category 3: **at least every 3 month**s Those who have direct oversight of compounders • At least every 12 months
Initial aseptic manipulation competency evaluations	Compounders need to pass media-fill testing of aseptic manipulation skills before beginning to prepare CSPs	Aseptic manipulation evaluations include: • Visual observation • Media-fill testing with post-GFT • Surface sampling Compounders and those who have direct oversight of compounders • Must complete 1 successful aseptic manipulation competency evaluation Remediation of failed competency • "A failure in the media fill, gloved fingertip and thumb sampling, or surface sample constitutes an overall failure of the aseptic manipulation competency."

Attachment A

Category	USP <797>, 2008[1]	USP <797>, 2023[2]
Ongoing aseptic manipulation competency evaluations	Each person authorized to compound in a low-risk or medium-risk level environment: At least annually Each person authorized to compound in a high-risk level environment: At least semiannually	Compounders Category 1 and 2: **at least every 6 months** Category 3: **at least every 3 months** Those who have direct oversight of compounders: At least every 12 months
Gloved fingertip and thumb sampling incubation standards	Incubate sample at 30-35 C for 2-3 days	"Incubate the media device at 30-35 C for no less than 48 h **and** then at 20-25 C for no less than 5 additional days."
Media-fill testing incubation standards	Incubate sample at 20-25 C or 30-35 C for 14 days	"Incubate the final containers at 20-25 C **and** 30-35 C for a minimum of 7 days at each temperature band … " "The order of the incubation temperatures must be described in the facility's SOPs"
Action levels for gloved fingertip and thumb sampling	0 cfu	After garbing: >0 cfu After media-fill testing: >3 cfu Action levels based on total cfu count **from both hands**
03. PERSONAL HYGIENE AND GARBING		
Order of handwashing and garbing	Gave a specific order for garbing and handwashing Sterile gloves could be donned in the buffer room	Order of handwashing and garbing is determined by the placement of the sink Order of garbing must be described by facility's SOPs "Donning and doffing garb should not occur in the same area at the same time" "Sterile gloves must be donned in a classified room or SCA"
Hand hygiene	Allows use of hand dryers Does not mention soap containers	Hand dryers **must not** be used Disposable soap containers **must not** be refilled or topped off – need to be replaced
Sanitizing hands	" … perform antiseptic hand cleansing with an alcohol-based surgical hand scrub with persistent activity."	Do not need an agent with persistent killing
Reusing garb	Allows gown to be reused if used on the same work day	Category 1 and Category 2 • " … gowns may be reused within the **same shift by the same person** if the gown is **maintained in a classified area or adjacent to, or within, the SCA in a manner that prevents contamination.**" • Other garb cannot be reused and should be discarded or laundered before reuse Category 3 • "Disposable garbing items **must not be reused**, and laundered garb **must not be reused without being laundered and resterilized with a validated cycle.**" • "The facility's SOPs must describe disinfection procedures for reusing goggles, respirators, and other reusable equipment."

Category	USP <797>, 2008[1]	USP <797>, 2023[2]
Garbing for category 3	Not applicable	"If the facility compounds Category 3 CSPs, **additional garbing requirements must be continuously met in the buffer room in which Category 3 CSPs are prepared."** • No exposed skin (I.e., face and neck must be covered) • All low-lint outer garb must be sterile • Disposable garb cannot be reused • Laundered garb cannot be reused until it is laundered and re-sterilized • Facility's SOPs describe disinfection procedures for reusing goggles, respirators, and other reusable equipment
04. FACILITIES AND ENGINEERING CONTROLS		
ISO classification of particulate matter	Particle count listed as m^3 and ft^3	Particle count is only listed as **m^3**
Use of isolators	PECs shall be located within a restricted access ISO Class 7 buffer area, with exceptions for CAI/CACI which would allow for BUD's equivalent to a full cleanroom suite in a segregated compounding area when certain conditions are met	The exception for CAI/CACI's has been removed; to obtain Category 2 CSP BUD's, the CAI/CACI must be placed in an ISO Class 7 buffer room located within a cleanroom suite Alternatively, a pharmaceutical isolator (different type of engineering control than a CAI/CACI) can be placed in an ISO Class 8 environment without the need for an anteroom
Air exchange requirements	Does not address ISO Class 8 ACPH requirements	ISO Class 8 room: >20 ACPH
Cleanroom	Not addressed	Term to describe ISO-classified anteroom and buffer room
Cleanroom suites: access doors and seals	Not addressed	Seals should not be installed at doors between buffer rooms and anterooms Access doors should be hands-free
Precision and accuracy of pressure differentials	Listed as 0.02 (two decimal places), broad	Listed as 0.020 (three decimal places), narrow
Humidity requirements	Does not mention humidity	"… should be maintained at … a relative humidity of 60% or below … "
05. CERTIFICATION AND RECERTIFICATION		
Certification of PEC and SEC	"Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities shall be used."	All professional organizations have been removed: " … independently certified using the requirements in this chapter and when applicable, manufacturer specifications."
06. MICROBIOLOGICAL AIR AND SURFACE MONITORING		
Viable air sampling – timing and locations	At least every 6 months for all compounds	Category 1 and Category 2: • At least every 6 months Category 3 • Within 30 days before the start of any Category 3 compounding • At least monthly

Attachment A

Category	USP <797>, 2008[1]	USP <797>, 2023[2]
Viable air sampling – incubation standards	TSA: • 30-35 C for 48 to 72 h Fungal media: • 26-30 C for 5 to 7 days	Incubate at 30-35 C for no less than 48 h then incubate at 20-25 C for no less than 5 additional days **"To shorten overall incubation period, two sampling media devices may be collected for each sample location and incubated concurrently"** • Incubate one at 30-35 C for no less than 48 h and the other at 20-25 C for no less than 5 days
Surface sampling – timing and locations	"Surface sampling shall be performed in all ISO classified areas on a **periodic** basis"	Locations: • Equipment contained within the PEC • Staging or work area(s) near the PEC • Frequently touched surfaces Category 1 and 2 • At least monthly Category 3 • At least weekly • Prior to assigning a BUD longer than the limits established for Category 2 CSPs
Surface sampling – action levels	Action levels • ISO Class 5: >3 • ISO Class 7: >5 • ISO Class 8 or worse: >100	Action levels • ISO Class 5: >3 • ISO Class 7: >5 • ISO Class 8: **>50**
Identifying microorganisms and Corrective Actions	Identification of microorganisms (at least the genus level) is required regardless of cfu count Mention of **highly pathogenic microorganisms** (e.g., gram-negative rods, coagulase *Staphylococcus*, molds and yeasts) must be immediately remedied regardless of cfu count	If action levels specified for air and surface sampling are exceeded, **" … an attempt must be made to identify any microorganism recovered to the genus level … "** Does not mention highly pathogenic microorganisms "The extent of the investigation should be consistent with the deviation and should include an evaluation of trends" "Data collected in response to corrective actions must be reviewed to confirm that the actions taken have been effective." "The corrective action plan must be dependent on the cfu count and the microorganism recovered."
07. CLEANING, DISINFECTING, AND APPLYING SPORICIDAL DISINFECTANTS AND STERILE 70% IPA		
Minimum frequency for cleaning and disinfecting surfaces	Does not split up minimum frequency based on method (e.g., cleaning, disinfecting)	Minimum frequency for cleaning is broken down by cleaning, disinfecting, and applying sporicidal disinfectant

Category	USP <797>, 2008[1]	USP <797>, 2023[2]
Cleaning/disinfecting supplies	Does not specify the type of material	Cleaning and disinfecting supplies (e.g., wipers, sponges, pads, mop heads) • Must be low-lint • Should be disposable • Reusable cleaning tools must be dedicated for use and not be removed from classified areas or SCA and be made of cleanable materials (e.g., not wood or any other porous material) "Cleaning, disinfecting and sporicidal agents used within the PEC **must be sterile**." Sterile water must be used when diluting concentrated agents for use in the PEC.
08. INTRODUCING ITEMS INTO THE SEC AND PEC		
No major changes	--	--
09. EQUIPMENT, SUPPLIES, AND COMPONENTS		
No major changes	--	--
10. STERILIZATION AND DEPYROGENATION		
Biological indicators	Steam Heat – *Bacillus stearothermophilus* Dry Heat – *Bacillus subtilis*	Steam Heat – *Geobacillus stearothermophilus* Dry Heat – *Bacillus atrophaeus*
11. MASTER FORMULATION AND COMPOUNDING RECORDS		
Master formulation records (MFR)	Specific requirements not listed	• Must be created for all CSPs prepared for more than one patient or when using non-sterile components • Any changes or alterations must be approved and documented based on facility's SOPs • Requirements for MFR are listed out in section
Compounding records (CR)	Specific requirements not listed	• Must be created for all Category 1, Category 2, and Category 3 CSPs and for immediate-use CSPs when prepared for more than one patient • Requirements for CR are listed out in section
12. RELEASE INSPECTIONS AND TESTING		
Maximum batch size	Not addressed	"The maximum batch size for all CSPs **requiring sterility testing** must be limited to **250 final yield units.**"
Sterility testing	"A method not described in the *USP* may be used if verification results demonstrate that the alternative is at least as effective and reliable ... "	Specifies a *USP* chapter "... or a **validated alternative method (see <1223>) that is noninferior to <71> testing."**
Number of CSPs needed to send for sterility testing	Does not specify number of CSPs needed to be sent for sterility testing	Number of CSPs sent for sterility testing depends on **number of CSPs to be compounded in a single batch** • 1-39 CSPs – must send 10% of the number of CSPs prepared, rounded up to the next whole number • >40 CSPs – must use sample sizes specified in *<71>*, Table 3

Attachment A

Category	USP <797>, 2008[1]	USP <797>, 2023[2]
Sterility testing requirements	Required for high-risk level CSPs under certain circumstances: • >25 identical individual single-dose packages • Multiple-dose vials for administration to multiple patients • Exposed longer than 12 h at 2-8 C and longer than 6 h at warmer than 8 C before they are sterilized	Category 1 – not required Category 2 – based on BUD Category 3 – required
13. LABELING		
Compounding notification on label	Not addressed	**"The labeling on the CSP should indicate that the preparation is compounded."**
14. ESTABLISHING BEYOND-USE DATES		
Establishing a BUD for a CSP	Factors that determine a BUD for risk categories • Storage conditions • Information gathered from professional sources (e.g., sterility studies)	Factors that determine Category 1 BUDs • Storage conditions (e.g., controlled room temperature, refrigerator) Factors that determine Category 2 BUDs • Compounding method (e.g., aseptic process, terminally sterilized) • If sterility testing is performed • Starting component of compound (e.g., sterile, nonsterile) • Storage conditions Additional requirements needed for longer BUDs in Category 3 CSPs for: • Increase use of sporicidal disinfectants • Increase of environmental monitoring • Use of sterile garb • Stability determination • Personnel qualification
Non-preserved topical ophthalmic CSPs	Not addressed	"The beyond-use-date of a multiple-dose, aqueous, non-preserved CSP intended for topical, including **topical ophthalmic**, administration may be **assigned in accordance with *14.5 Multiple-Dose CSPs.***" Requirement for passing antimicrobial effectiveness testing in accordance with <51> is not required only if the preparation is: • Prepared as a Category 2 or Category 3 CSP • For use by a single patient • Labeled to indicate that once opened, it must be discarded after 24 h stored at controlled room temp or 72 h stored under refrigeration

Category	USP <797>, 2008[1]	USP <797>, 2023[2]
15. USE OF CONVENTIONALLY MANUFACTURED PRODUCTS AS COMPONENTS		
Use of conventionally manufactured single-dose containers	"Single-dose vials exposed to ISO Class 5 or cleaner may be used up to **6 h** after initial needle puncture."	"If a single-dose vial is entered or punctured only in an ISO Class 5 or cleaner air, **it may be used up to 12 h after initial entry or puncture as long as the labeled storage requirements during that 12-h period are maintained**."
Use of conventionally manufactured pharmacy bulk package	Not addressed	"The pharmacy bulk package must be used according to the manufacturer's labeling (see *<659>, General Definitions, Injection Packaging Systems*). The pharmacy bulk package must be entered or punctured only in an ISO Class 5 PEC."
16. USE OF CSPS AS COMPONENTS		
Use of compounded multiple-dose CSPs	Not addressed	When used as a component to compound additional CSPs • Required to meet criteria for antimicrobial effectiveness testing and requirements in *14.5* • Must be stored in conditions the BUD is based (e.g., refrigerator) • After punctured, must not be used longer than assigned BUD or 28 days, whichever is shorter. Remainder must be discarded
Use of compounded single-dose CSPs and CSP stock solutions	Not addressed	When used as a component to compound additional CSPs • Must be entered or punctured in ISO Class 5 or cleaner air • Must be stored in conditions the BUD is based (e.g., refrigerator) • May be used for sterile compounding up to **12 h** or its assigned BUD, whichever is shorter. Remainder must be discarded
17. SOPS		
Who needs training based on facilities SOPs	Not addressed	"All personnel who perform or oversee compounding or support activities must be trained in the SOPs"
18. QUALITY ASSURANCE AND QUALITY CONTROL		
Notification and recall of CSPs with out-of-specification limits	Not addressed except for notifying the patient and physician of potential risk	SOP for recall of out-of-specification limits must contain procedures • To determine severity of problem and urgency for implementation and completion of the recall • To determine distribution of any affected CSP • To identify patients who received the CSP • For disposal and documentation of recalled CSP • To investigate and document reason for failure
Redispensed CSPs	Unopened, unused, returned CSPs may be redispensed when certain conditions are met to ensure the CSP is sterile, pure, and stable	Not specifically addressed; however does not prohibit this practice. Would need to refer to state board of pharmacy for guidance.
19. CSP HANDLING, STORAGE, PACKAGING, SHIPPING, AND TRANSPORT		
No major changes	--	--

Category	USP <797>, 2008[1]	USP <797>, 2023[2]
20. DOCUMENTATION		
No major changes	--	--
21. COMPOUNDING ALLERGENIC EXTRACTS		
Compounding allergenic extract prescription sets	No mention of training or competency evaluation needed for compounders making allergenic extracts	Requirements for personnel who prepare allergenic extracts • Training must be done initially prior to compounding independently and annually • Gloved fingertip and thumb sampling on both hands no fewer than 3 separate times needs to be done prior to compounding independently and at least every 12 months • Sterile technique of compounders needs to be evaluated at least every 12 months • Personnel that have not compounded in 6 months need to be evaluated in all core competencies before resuming their duties

References

1. United States Pharmacopeial Convention. General chapter <797> pharmaceutical compounding—nonsterile preparations. USP43-NF38. Rockville, MD: U.S. Pharmacopeial Convention; 2019.

2. United States Pharmacopeial Convention. General chapter <797> pharmaceutical compounding—sterile preparations. USP-NF 2023, Issue 1, November 1, 2022, official as of November 1, 2023.

Special acknowledgment to **Sarah Hall, PharmD (candidate)**, *UNC Eshelman School of Pharmacy, and* **Kevin Hansen, PharmD**, **MS, BCSCP**, *Director of Pharmacy, Compounding Services and Data Analytics, Cone Health, for the development of this resource, and to* **Patricia Kienle, RPh, MPA, BCSCP, FASHP**, *Director, Accreditation and Medication Safety, Cardinal Health, and* **Michael Ganio, PharmD, MS, BCSCP, FASHP**, *Senior Director, Pharmacy Practice and Quality, ASHP, for peer-review.*

Kevin and Patti are members of the USP Compounding Expert Committee, but this resource is not affiliated with or endorsed by USP.

Attachment B

GUIDANCE REGARDING SEMAGLUTIDE-BASED MEDICATIONS FROM THE MISSISSIPPI STATE BOARD OF MEDICAL LICENSURE

The Board recognizes that Type 2 Diabetes and obesity are two of the most serious public health problems facing our state. The potential benefits for many Mississippi patients of new semaglutide-based medications like Ozempic® and Wegovy® are obvious.[1] However, because these drugs are in high demand and short supply, some providers have turned to the use of compounded versions that are represented to be safe substitutes for the patented drugs, but which are unproven. Public safety requires that the Board emphasize three points concerning this issue:

1. The off-label use of semaglutide-based legend drugs is prohibited by Board regulation;[2]

2. Compounded semaglutide products likely use as Active Pharmaceutical Ingredients (APIs) salt forms of semaglutide, chemically synthesized versions, or research-grade ingredients not intended for human use. Such APIs have not been proven to be safe and effective substitutes or equivalents for the patented drugs;

3. The Board strongly advises medical licensees to refrain from prescribing, dispensing, or administering any compounded semaglutide until further notice.

Ozempic® and Wegovy® are currently listed on the Food and Drug Administration (FDA) "shortage list." Generally, when a drug appears on the shortage list, compounded drugs can be made and distributed with fewer restrictions. However, the listing of Ozempic® and Wegovy® does not change the high standards for quality of ingredients and sanitary manufacturing conditions with which compounders must comply.

Board regulations prohibit off-label use of any non-FDA-approved medication solely for the purpose of weight loss. On March 22, 2023, the Board passed an emergency rule to permit waivers to be granted for the off-label use of diet medications on a per-medication or class of medications basis. The Board then granted an emergency waiver or exemption for Semaglutide-based legend drugs until July 1, 2023.[3] However, since that time the Board has received additional information on this issue from various sources, including the Food and Drug Administration (FDA) and the Mississippi Board of Pharmacy. Therefore, on July 27, 2023 the Board RESCINDED the exemption permitting off-label use

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[1] Saxenda® (liraglutide) is also FDA-approved for weight loss. Other non-semaglutide based medications showing promise for these conditions are also becoming available, such as Mounjaro™ (tirzepatide).

[2] *See* Part 2640, Chapter 1, Rule 1.5(F). "Off-label use of any medication that does not have Food and Drug Administration approval for use in the treatment of weight loss is prohibited if administered solely for the purpose of weight loss."

[3] On April 18, 2023, after the Board received information from the Mississippi Board of Pharmacy expressing concerns about the safety of compounded semaglutide based on FDA publications, the Executive Director emailed to all Board licensees a memorandum prepared by the Pharmacy Board and distributed to Mississippi pharmacists. That memo outlined problems with the use of semaglutide salt forms as APIs for compounding purposes.

of semaglutide-based medications, and REJECTED a new request for a waiver specifically authorizing the use of compounded semaglutide.[4]

Ozempic®, Wegovy®, Mounjaro™ and similar medications are already becoming important tools for treating and managing Type 2 Diabetes and obesity. However, the use of unproven and potentially unsafe compounded versions of these patented medications cannot be condoned by the Board under current circumstances.

CONCLUSION

1. Currently Wegovy® (semaglutide) and Saxenda® (liraglutide) are the only peptides approved by the FDA for weight loss. The off-label use of peptide-based legend drugs solely for weight loss is prohibited;

2. Compounded semaglutide products have not been proven to be safe and effective substitutes or equivalents for the patented drugs;

3. Licensees are advised to refrain from prescribing, dispensing, or administering compounded semaglutide at this time.

Kenneth E. Cleveland, M.D.
Executive Director
MISSISSIPPI STATE BOARD
OF MEDICAL LICENSURE

CC: All Board Licensees

[4] On July 27, 2023, the Board was asked to grant a waiver for compounded semaglutide. Susan McCoy, the Executive Director of the Mississippi Board of Pharmacy, appeared and provided current information concerning compounded semaglutides. The available compounded versions are likely being made with salt forms of semaglutide, chemically synthesized versions, or research-grade ingredients not intended for use in humans. Research-grade materials are not subject to the same strict manufacturing regulations as pharmaceutical-grade APIs, nor are they intended for human use. Director McCoy advised that the substitute ingredients, manufactured in China, have not been proven to be legitimate, effective, or manufactured under sanitary conditions. At least some such products appear to have been originally labeled as research-grade drugs and then relabeled as pharmaceutical grade after they were imported into the United States. Further, some compounding pharmacies appear to be using misleading or inaccurate information in their advertising. At least one out-of-state pharmacy actively marketing compounded semaglutide to Mississippi physicians has ever had a Mississippi compounding certificate, and therefore cannot legally sell any compounded products in this state. The video from July 27 Board meeting is available at: https://www.youtube.com/live/PaXqYWd2In0?si=G0LwcbzHHr3W1ve4&t=1976 The waiver request, comments, and discussion of this issue begin at the 21:20 mark.

Attachment B

July 16, 2024

Humayun J. Chaudhry, DO, MS, FACP, FACOI
President and Chief Executive Officer
Federation of State Medical Boards
400 Fuller Wiser Road, Suite 300
Euless, TX 76309
hchaudhry@fsmb.org

Dear Dr. Chaudhry:

The purpose of this letter is to bring to the attention of the Federation of State Medical Boards (FSMB) information related to injectable compounded drug products containing semaglutide or tirzepatide. We encourage you to share the information in this letter with your members for their awareness and consideration.

FDA is aware of increased interest in compounded semaglutide and tirzepatide products. Compounded drug products can serve an important medical need for certain patients. However, compounded drug products, including compounded semaglutide and tirzepatide products, are not FDA-approved. They do not undergo premarket review by FDA for safety, effectiveness, or quality.

FDA has received reports describing patients who experienced adverse events following the administration of compounded semaglutide or tirzepatide products in doses exceeding the recommended dosing or titration schedule for FDA-approved semaglutide and tirzepatide products. The adverse events described in the reports included nausea, vomiting, fatigue, stomach pain, shortness of breath, headache, heartburn, weakness, intestinal blockage, hypoglycemia, impacted bowels, electrolyte imbalances, bowel infection, ketoacidosis, pancreatitis, and rhabdomyolysis. Some of these are serious adverse events and some of the patients reported seeking medical attention for their symptoms.

FDA's ability to derive conclusions about safety concerns from these reports is limited because, for example, compounding pharmacies that are not registered with the FDA as outsourcing facilities generally do not submit adverse event reports to the FDA, and among the reports submitted, reported information varies. However, certain factors noted in the reports that may have contributed to the adverse events include the following:

- Prescribers started patients on doses that were approximately two to four times higher than the recommended starting doses of FDA-approved semaglutide and

tirzepatide products.
- Compounded semaglutide products were prescribed to be administered twice a week instead of once weekly, which is the recommended frequency of administration for FDA-approved semaglutide and tirzepatide products.
- Prescribers titrated the patients' doses every one to two weeks instead of every four weeks, which is the recommended titration schedule of FDA-approved semaglutide and tirzepatide products.

Health care providers and your members may consider information about the potential for adverse events when doses, dose frequencies, or titration schedules vary from those of the FDA-approved products, and when weighing the risks versus benefits and determining appropriate doses and titration and dosing schedules for patients.

FDA encourages health care professionals and compounders to report adverse events or quality problems experienced with the use of compounded drugs to FDA's MedWatch Adverse Event Reporting program:

- Complete and submit the report online at MedWatch: The FDA Safety Information and Adverse Event Reporting Program or

- Download and complete the form, then submit it via fax at 1-800-FDA-0178.

We are also sending this letter to the Alliance for Pharmacy Compounding, the National Association of Boards of Pharmacy, the National Council of State Boards of Nursing and the Outsourcing Facility Association, for your awareness.

We look forward to continuing to work with you on matters related to drug compounding. If you have questions, please contact the Office of Compounding Quality and Compliance at compounding@fda.hhs.gov.

Sincerely,

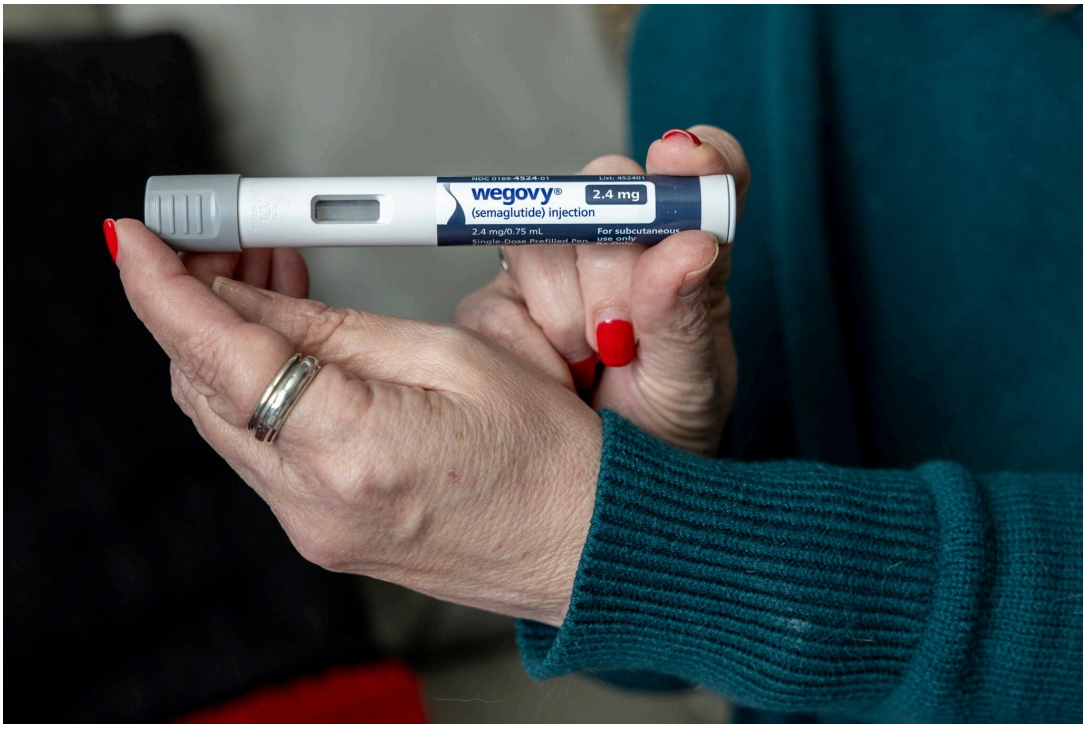
Shannon Glueck, Pharm.D.
Branch Chief, Compounding Branch 4
Division of Compounding II
Office of Compounding Quality and Compliance
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food & Drug Administration

HEALTH CARE

‘Compounded’ weight-loss drugs are a growing problem for state regulators

Some pharmacies and clinics are skirting rules meant to keep consumers safe.

BY: **ANNA CLAIRE VOLLERS** - JULY 8, 2024 5:00 AM



Wegovy and other injectable weight-loss medications have soared in popularity in the past two years. Supply issues and spotty insurance coverage have driven some patients to seek out compounded versions of the drug, which tend to be less expensive. Amanda Andrade-Rhoades/The Associated Press

Anna Wysock’s “aha” moment arrived in an Ohio amusement park, as she got ready to ride a roller coaster with her 7-year-old son: The safety bar across her lap would only click into place once. The attendant told her it had to click twice, or she couldn’t ride. She was mortified.

"I had to do the walk of shame and get off the roller coaster and let my 7-year-old ride it with his cousin," Wysock, an elementary school teacher and married mother of two, said of the 2022 incident. "I thought, 'Anna, you've got to get yourself together.'"

Three months after the roller coaster incident, Wysock got a prescription for Mounjaro, an injectable diabetes drug that can be used for weight loss. Her insurance didn't cover it, but a manufacturer's coupon cut the cost to $25 per month. In six months, combined with diet and exercise changes, it helped her shed nearly 60 pounds.

Then the discount ended, raising the price to about $1,000 per month. Friends told her about a local clinic that offered cheaper, compounded versions of weight-loss drugs, and she got a prescription costing $150 per month. She began losing weight again.

To create a compounded drug, pharmacists reformulate the active ingredients in a commercial drug to customize it for an individual patient. Wysock was concerned about making the switch, fearing that the compounded version would cause unfamiliar side effects, "but it was worth it to me to try."

> It's not a normal situation that a blockbuster drug immediately goes on shortage and meets criteria for compounding pharmacies to compound it. I don't think we've ever seen anything like this.
>
> *– Tenille Davis, chief advocacy officer for the Alliance of Pharmacy Compounding*

Drugs prescribed for weight loss such as Mounjaro, Ozempic, Wegovy and Zepbound are popular, expensive, and in short supply. To meet the demand, many physicians, medical spas, IV infusion clinics, telehealth entrepreneurs and pharmacies are jumping on the opportunity to provide compounded versions of the weight-loss medications, which haven't been on the market long enough to have generic equivalents.

State regulators are having trouble keeping up.

The U.S. Food and Drug Administration regulates commercial drugs, but the licensing and oversight of compounding pharmacies falls to states. States including Idaho and Tennessee have announced investigations into illegal dispensing by medical spas and other providers, while states such as California are looking to beef up their oversight.

“It’s not a normal situation that a blockbuster drug immediately goes on shortage and meets criteria for compounding pharmacies to compound it,” said Tenille Davis, an Arizona pharmacist and the chief advocacy officer for the Alliance of Pharmacy Compounding, an industry group representing compounding pharmacists.

“I don’t think we’ve ever seen anything like this.”

A cheaper alternative

Compounding pharmacies are allowed to make a medication that’s essentially a copy of a commercially available drug if its active ingredients are listed on the FDA’s drug shortage list. The active ingredient in weight-loss drugs such as Wegovy and Zepbound is either semaglutide or tirzepatide, and both are on the list.

“As the demand continues to grow, there continues to be a shortage of conventionally manufactured product, and compounding pharmacies are filling that need,” said Davis. “Compounding pharmacies have been able to step in and fill some of those gaps in the marketplace.”

Most states have similar compounding rules, though some states — including California and Texas — are stricter than others. Enforcement also varies.

In Mississippi, regulators have told doctors and other providers to stop prescribing compounded medications for weight loss — period. The state medical board has a rule that only medications that have been FDA-approved for weight loss can be prescribed for weight loss — meaning compounded drugs don’t qualify.

But many states and compounding pharmacies aren’t sure where the lines are. States including Kansas and New Jersey have had to issue statements clarifying their regulations. Last spring, North Carolina and West Virginia issued warnings that compounding weight-loss drugs wasn’t allowed — only to amend their statements after determining they had misinterpreted FDA guidance.

Attachment B

Pandemic Health Inequities Expose Need for Greater Obesity Prevention

The pandemic has thrust longstanding racial and economic health disparities into bold relief. Americans of color have died from COVID-19 at two to three times the rate of the rest of the population. A primary underlying cause is obesity. "The fact that obesity has proven to be such a significant risk factor for severe COVID-19 ... Continue reading

Stateline

Federal law requires most U.S. compounding pharmacies to make medications for specific patients. They aren't supposed to bulk manufacture medications unless they're registered with the FDA as "outsourcing facilities," which follow a stricter set of federal regulations.

But some states have found compounders breaking those rules.

In May, for example, Idaho's licensing agency announced that regulators had discovered videos of health professionals filling syringes of weight-loss medications that weren't compounded for specific patients, and then sending those syringes to patients, which is illegal under state law.

A compounding pharmacy in Nashville, Tennessee, that was producing tens of thousands of doses of compounded weight-loss medications shut down last year. It had been shipping its drugs nationwide. After state regulators inspected the facility and issued a disciplinary order requiring the company to make several changes

before it could resume compounding, an executive died by suicide and the pharmacy's owner chose to close.

And in Florida, a physician told the state pharmacy board he'd been approached by representatives from a multistate compounding pharmacy that wanted him to write prescriptions for their specific compounded semaglutide product — a form of prescription solicitation that's likely illegal, Carter said.

Compounders generally don't have to register with the FDA, and they aren't required to report which drugs they're compounding. That means there's no way to know exactly how much semaglutide or tirzepatide they are dispensing, said Davis.

'Like Whac-A-Mole'

To protect patients, the FDA enforces strict safety and quality requirements for drug manufacturers and for the small subset of compounding pharmacies registered as outsourcing facilities. The idea is that companies that are bulk manufacturing drugs need closer oversight than smaller compounding pharmacies that are merely customizing drugs for individual patients.

Compound pharmacies that bulk produce weight-loss drugs without FDA approval are doing so without that oversight. And because compounding pharmacies aren't required to report instances of patient harm involving their medications, problems may go undetected.

"It's kind of like 'Whac-A-Mole,'" said Al Carter, a pharmacist and executive director at the National Association of Boards of Pharmacy. He said state boards will only investigate when they receive a complaint.

"There are bad actors out there, purporting to be compounding pharmacies that are licensed in specific states or have the credentials to be able to compound when in actuality they don't," said Carter. "My understanding is most licensed, legitimate pharmacies aren't compounding" weight-loss medications.

Citing Cost to Taxpayers, Cities and States Tackle Obesity

© The Associated Press Kevin Durant of the Oklahoma City Thunder is greeted by students at the Oklahoma Capitol as part of an initiative to battle childhood obesity in Oklahoma City, one of a number of cities and states with plans to tackle obesity. More than 35 percent of Arkansas adults are obese, making it … Continue reading

Stateline

Most of the complaints that state regulators are hearing, he said, come from patients who tried to purchase their medications online. The National Association of Boards of Pharmacy recently released a report that found illegal online pharmacies – many operating outside the United States – sell substandard or fake weight-loss medications, or misrepresent the products they sell.

But even some domestic, legally operating clinics misrepresent the products they offer. Some clinics and online pharmacies advertise a "generic" form of semaglutide, even though the FDA hasn't approved a generic form of semaglutide or tirzepatide.

Meanwhile, pharmaceutical giants Novo Nordisk and Eli Lilly have gone on the offensive, filing dozens of lawsuits in multiple states against medical spas, weight-loss clinics and pharmacies. Many of the suits allege the companies falsely marketed their compounded products as commercial medications.

An Eli Lilly spokesperson told Stateline in a statement that "Lilly will continue to pursue legal remedies against those who falsely claim their products are Mounjaro, Zepbound, or 'FDA-approved' tirzepatide, including certain med-spas, wellness centers, online retailers, and compounding pharmacies."

Some states are focusing their investigations specifically on medical spas and IV infusion clinics that offer compounded weight-loss medications. The California State Board of Pharmacy recently discussed expanding its oversight of IV hydration clinics, noting that even when their drug products are from licensed compounding

pharmacies, clinic staff may not be giving them to consumers legally.

And in Texas, some physicians are pushing for legislation to tighten state oversight of medical spas following the death last July of a woman who died after receiving an IV infusion treatment.

But ultimately the burden rests on patients to figure out whether the medications they're taking were made by a licensed and reputable compounder.

For patients like Wysock, compounded versions of weight-loss medications have been life- changing. Wysock said her compounded tirzepatide has enabled her to continue to lose weight, to maintain a healthier lifestyle and to be present for her family and students.

"As a teacher you're on your feet all day long, and then coming home to two kids, I was exhausted by the weekend," she said. "I used to take naps every weekend. That was a 'nonnegotiable.' Now it's not a necessity anymore."

CALIFORNIA IDAHO MISSISSIPPI NORTH CAROLINA TEXAS

ANNA CLAIRE VOLLERS

Anna Claire Vollers covers health care for Stateline. She is based in Huntsville, Alabama.

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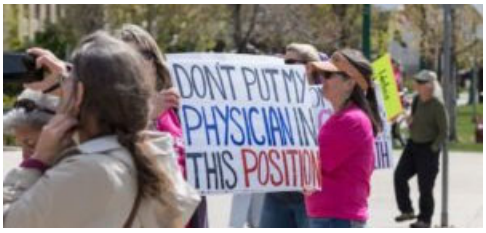
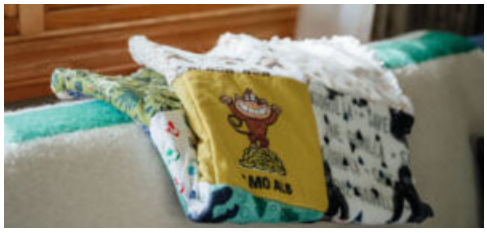


US Supreme Court sends Idaho abortion case back down to...

BY **KELCIE MOSELEY-MORRIS**

June 27, 2024



After an abortion for fetal anomalies, she hoped IVF would...

BY **KELCIE MOSELEY-MORRIS**

June 25, 2024

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STATES NEWSROOM

Attachment B

Via Email June 28, 2024

Donna Yeatman
Executive Director
111 Village St
Birmingham, AL 35242

Re: Request to Take Actions Regarding Compounded "Semaglutide" To Support Patient and Prescription Drug Safety

Dear Executive Director Yeatman,

I write on behalf of Novo Nordisk Inc. ("Novo Nordisk") regarding a serious concern for the public health and patient safety relating to compounded products claiming to contain semaglutide. To date, nine Boards of Pharmacy and Medicine, Food and Drug Administration ("FDA" or "Agency"), international regulators, and obesity advocacy groups have issued warnings about compounded "semaglutide." One key global regulator has taken steps to fully ban the compounding of "semaglutide" given the "clear risk to human health," posed by these "potentially unsafe and dangerous" compounded products.[28] We are respectfully urging your Board of Pharmacy to issue a statement warning patients and providers about the risks of compounded "semaglutide" and investigate and take enforcement action against pharmacies unlawfully and unsafely compounding "semaglutide," as appropriate.

Novo Nordisk is a healthcare company with a 100-year history of innovation in developing medicines to treat serious chronic diseases, like diabetes and obesity, and is the only company in the United States with FDA-approved medicines containing semaglutide. Semaglutide is the foundational molecule that serves as the primary ingredient for Novo Nordisk's well-known, prescription-only medicines: Rybelsus® (semaglutide) tablets as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes; Ozempic® (semaglutide) injection as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes and to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes and established cardiovascular disease; and Wegovy® (semaglutide) injection to reduce excess body weight and maintain weight reduction long term in patients 12 years or older with obesity or adults with overweight and at least one weight-related comorbidity and to reduce the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight.

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[28] Honorable Mark Butler MP, Ministers: Department of Health and Aged Care, *Protecting Australians from unsafe compounding of replica weight loss products* (May 22, 2024), https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/protecting-australians-from-unsafe-compounding-of-replica-weight-loss-products?language=en.

Driven by core values that prioritize patient safety, we have been taking actions to protect patients from unlawful sales and marketing of potentially dangerous compounded "semaglutide." Compounded products do not have the same assurances of safety, effectiveness, or quality as our FDA-approved products. We have seen several concerning safety, effectiveness, and quality issues with compounded drugs claiming to contain semaglutide, including peptide-related impurities, unknown impurities, inconsistent strengths compared to the labeled strength, and, in one case, no semaglutide at all in the product. As a company, Novo Nordisk shares the Board of Pharmacy's desire to support patient and prescription drug safety. In this regard, we are reaching out to you for your support in addressing unlawful and potentially dangerous compounded drugs purporting to contain semaglutide.

I. Actions Taken by Regulators and Advocacy Groups Concerning Compounded "Semaglutide"

At least nine state regulators have issued statements concerning compounding of products that claim to contain semaglutide.[29] For instance, the Executive Director of the Mississippi Board of Pharmacy advised the Mississippi State Board of Medical Licensure that "substitute ingredients" manufactured in foreign jurisdictions "have not been proven to be legitimate, effective, or manufactured under sanitary conditions."[30] The Mississippi State Board of Examiners "strongly advise[d] medical licensees to refrain from prescribing, dispensing, or administering compounded semaglutide until further notice," because such drugs are "unproven and potentially unsafe."[31] In addition, the

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[29] *See* N.J. Bd. Pharmacy, *Statement Concerning Semaglutide Compounding* (Nov. 6, 2023), https://www.njconsumeraffairs.gov/phar/Documents/Semaglutide-Compounding-Statement-04282023.pdf; N.C. Bd. Pharmacy, *Statement Concerning Semaglutide Compounding* (Apr. 2023), https://www.ncbop.org/downloads/SemaglutideCompounding.pdf; Miss. Bd. Pharmacy, *Compounded Products Due to Shortage or Due to Special Patient Needs*, https://www.mbp.ms.gov/sites/default/files/inline-images/Semaglutide.compoundguidance%20%28002%29.pdf; Ala. Bd. Pharmacy, *Compounding Semaglutide* (Nov. 2023), https:/nabp.pharmacy/wp-content/uploads/2023/11/November-2023-Alabama-State-Newsletter.pdf; Ky. Bd. Pharmacy, Newsletter (June 2023), https://pharmacy.ky.gov/Newsletters/June%202023.pdf; W. Va. Bd. Pharmacy, *Statement Concerning Semaglutide Compounding* (Apr. 2023), https://www.wvbop.com/admin/attachment/FINALSemaglutideCompoundingStatement21APR2023WVBoPdatedFV.pdf; Meg Farris, *Low-cost weight loss drug banned in La.*, 4WWL (Apr. 27, 2023), https://www.wwltv.com/article/news/health/weight-loss-wednesday/low-costweight-loss-drug-banned/289-d2608b63-f8c2-4eb4-9982-0530331d50ea (reflecting ban by Louisiana Board of Pharmacy); Ala. Bd. Med. Exam'rs & Med. Licensure Comm'n, *Concerns with Semaglutide and Other GLP-1 Receptor Agonists*, https://www.albme.gov/press-release/concerns-with-semaglutide-and-other-glp-1-receptor-agonists; Miss. State Bd. Med. Licensure, *Guidance Regarding Semaglutide-Based Medications From the Mississippi State Board of Medical Licensure* (Aug. 29, 2023), https://www.msbml.ms.gov/sites/default/files/news/Semaglutide%20Guidance%2008-29-23.pdf.

[30] Miss. State Bd. Med. Licensure, *Guidance Regarding Semaglutide-Based Medications From the Mississippi State Board of Medical Licensure*, 2 n.4 (Aug. 29, 2023), https://www.msbml.ms.gov/sites/default/files/news/Semaglutide%20Guidance%2008-29-23.pdf.

[31] *Id.* at 1-2.

Alabama Board of Medical Examiners has cautioned that semaglutide products other than those manufactured by Novo Nordisk "may be contaminated, improperly stored and transported, or adulterated."[32]

FDA also has issued statements and published a website related to the compounding of "semaglutide." On April 11, 2023, FDA Commissioner Califf cautioned the public about the use of unapproved compounded drugs for weight loss purposes.[33] In May 2023, FDA published a notice on its website warning patients and providers about the potential safety risks posed by compounded "semaglutide" products.[34] In October 2023, FDA sent a letter to the National Association of Boards of Pharmacy ("NABP") and the Federation of State Medical Boards ("FSMB") highlighting that it had received an increased number of adverse event reports and complaints concerning compounded drug products containing "semaglutide."[35] FDA is also actively monitoring the internet for fraudulent or unapproved products and has issued warning letters to stop the distribution of illegally marketed semaglutide.[36] The Agency warns that such unapproved products may be counterfeit; contain too little, too much, or no active ingredient at all; or contain other harmful ingredients.

The Australian government and Therapeutic Goods Administration ("TGA") recently took broad action to protect patients in Australia from potentially unsafe and dangerous compounded drugs purporting to contain semaglutide. On May 22, 2024, the government announced that to "protect Australians from the clear risk to human health

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[32] Ala. Bd. Med. Exam'rs & Med. Licensure Comm'n, *Concerns with Semaglutide and Other GLP-1 Receptor Agonists*, https://www.albme.gov/press-release/concerns-with-semaglutide-and-other-glp-1-receptor-agonists.

[33] *See* Meg Tirrell, *Health misinformation is lowering U.S. life expectancy, FDA Commissioner Robert Califf says*, CNBC (Apr. 11, 2023), https://www.cnbc.com/2023/04/11/us-life-expectancy-hurt-by-misinformation-fda-commissioner-robert-califf.html.

[34] FDA, *Medications Containing Semaglutide Marketed for Type 2 Diabetes or Weight Loss* (current as of Oct. 31, 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/medications-containing-semaglutide-marketed-type-2-diabetes-or-weight-loss.

[35] *See* Letter from F. Gail Bormel to Lemrey "Al" Carter (Oct. 10, 2023), https://www.fda.gov/media/173456/download.

[36] FDA, Warning Letter to www.semaspace.com (Oct. 2, 2023), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/wwwsemaspacecom-665848-10022023; FDA, Warning Letter to www.gorillahealing.com (Oct. 2, 2023), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/wwwgorillahealingcom-664245-10022023; FDA, Warning Letter to US Chem Labs (Feb. 7, 2024), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/us-chem-labs-669074-02072024; FDA, Warning Letter to Synthetix Inc. DBA Helix Chemical Supply (Feb. 7, 2024), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/synthetix-inc-dba-helix-chemical-supply-668918-02072024; FDA, Warning Letter to *www.dashpct.com* (Apr. 24, 2024), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/wwwdashpctcom-679727-04242024.

posed by the large-scale manufacture of compounded injections," they will issue new regulations that will remove GLP-1 RAs from the pharmacy compounding exemption.[37] While acknowledging the valid place for compounding in certain circumstances and recognizing the ongoing shortage of OZEMPIC® and WEGOVY® in Australia, the government determined that the "risk of not acting is far greater [than the consequences of banning GLP-1 RAs from compounding] . . . . You only have to look at the recent reports of individuals impacted by large scale compounding to realize the dangers posed."[38]

Other international regulators also have warned about the risks associated with compounded "semaglutide." The South African Health Products Regulatory Authority ("SAHPRA") has warned that "products claiming to contain semaglutide may not contain the active ingredient, semaglutide, as the SAHPRA registered product, which has been reviewed for quality, safety, and efficacy." The body further recommends that patients should use an SAHPRA-approved product if available over a compounded medicine claiming to contain semaglutide.[39] Relatedly, the Ontario College of Pharmacists explained that pharmacies should contact the prescribing physician to confirm that compounded "semaglutide" is appropriate because "differences may exist in the pharmacokinetics or pharmacodynamics of the compounded preparation" of semaglutide compared to Novo Nordisk's approved products that "could affect its efficacy."[40]

Organizations representing practitioners and patients, such as The Obesity Society, Obesity Medicine Association, and Obesity Action Coalition, echoed these warnings and issued a statement recommending that patients avoid compounded GLP-1 drugs. The groups warn that compounded drugs "are not the same as the drug provided by the manufacturers," and "may pose serious health risks because of impurities or other non-pharmaceutical additives."[41]

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[37] Honorable Mark Butler MP, Ministers: Department of Health and Aged Care, *Protecting Australians from unsafe compounding of replica weight loss products* (May 22, 2024), https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/protecting-australians-from-unsafe-compounding-of-replica-weight-loss-products?language=en.

[38] *Id.*

[39] *See* South African Health Products Regulatory Authority, *SAHPRA's Position On Semaglutide Compounded Products* (Dec. 13, 2023), https://www.sahpra.org.za/news-and-updates/sahpras-position-on-semaglutide-compounded-products/.

[40] Ontario College of Pharmacists, *Important guidance to pharmacists during the current Ozempic® shortage: Expectations when compounding semaglutide preparations to ensure quality and safe patient care* (Dec. 21, 2023), https://www.ocpinfo.com/important-guidance-pharmacists-ozempic-shortage/.

[41] *See* Obesity Medicine Association, *Leading Obesity Expert Organizations Release Statement to Patients on Compounded GLP-1 Alternatives* (Jan. 8, 2024), https://obesitymedicine.org/blog/leading-obesity-expert-organizations-release-statement-to-patients-on-glp-1-compounded-alternatives/.

II. Safety and Effectiveness Risks Posed by Compounded and Online "Semaglutide" Drugs

FDA has received adverse event reports related to compounded products purporting to contain "semaglutide." As of March 31, 2024, FDA's Adverse Event Reporting System ("FAERS") reports 442 cases of adverse events associated with compounded "semaglutide." Of those cases, 319 were classified as "serious" adverse events, 99 reported hospitalization, and seven involved deaths. The FAERS database also includes several reports on product quality issues, dosing issues, and lack of efficacy associated with these compounded drugs. Besides the reports in the FAERS database, there are recent reports highlighting administration errors associated with compounded "semaglutide," where patients self-administered doses up to 10 times greater than the correct amount.[42] Given the historic underreporting of the adverse events associated with compounded drugs,[43] Novo Nordisk is concerned that these 442 cases are just the tip of the iceberg and many more patients are experiencing adverse events from compounded "semaglutide" drugs.

Further heightening the potential risks to patients, Novo Nordisk has seen several entities sell compounded "semaglutide" in combination with other ingredients or in other dosage forms. For example, some entities sell compounded "semaglutide" with the peptide BPC-157, which FDA has placed on a list of bulk drug substances that raise significant safety risks in compounding.[44] Specifically, FDA has determined that BPC-157 "pose[s] risk for immunogenicity" and has "complexities with regard to peptide-related impurities and API characterization."[45] Additionally, a growing number of entities sell sublingual solutions, sublingual tablets, transmucosal films, or oral troches claiming to contain semaglutide. None of these dosage forms with these routes of administration has been studied in clinical trials or reviewed by FDA. Novo Nordisk has also observed that some entities now compound sublingual "semaglutide" products that are liposomal drug products, which FDA has proposed to include on a list of drug products that cannot be compounded because they are demonstrably difficult to compound and therefore present risks to patients that outweigh the benefits.[46]

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[42] Joseph E. Lambson et al., *Administration errors of compounded semaglutide reported to a poison control center – Case series*, 63 J. OF THE AM. PHARMACISTS ASS'N. 1643 (Sep. 25, 2023).

[43] *See* Janet Woodcock and Julie Dohm, *Toward Better-Quality Compounded Drugs — An Update from the FDA*, 377 NEW ENG. J. MED. 2509, 2510 (2017).

[44] *See* FDA, *Safety Risks Associated with Certain Bulk Drug Substances Nominated for Use in Compounding*, https://www.fda.gov/drugs/human-drug-compounding/safety-risks-associated-certain-bulk-drug-substances-nominated-use-compounding (last updated Dec. 12, 2023).

[45] *Id.*

[46] FDA, *Drug Products or Categories of Drug Products That Present Demonstrable Difficulties for Compounding Under Sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act*, 89 Fed. Reg. 19,776, 19,780 (Mar. 20, 2024), https://www.regulations.gov/document/FDA-2023-N-0061-0001; Comment from Novo Nordisk, No. FDA-2023-N-0061-0021 (Jun. 18, 2024), https://www.regulations.gov/comment/FDA-2023-N-0061-0021.

Novo Nordisk surveillance and testing offer a snapshot of the types of risks to patients associated with compounded "semaglutide." Testing results have revealed that some compounded "semaglutide" samples contain peptide-related impurities, including 24% total impurities in a sample from WellHealth Inc., 33% unknown impurities in a sample from Wells Pharmacy Network, amino acid additions and deletions, and dimers.[47] When these types of peptide-related impurities are present in compounded drugs administered to patients, they have the potential to stimulate an immune reaction upon repeated injections, which can lead to serious and life-threatening reactions like anaphylaxis for patients.[48]

In addition, testing results have shown that certain compounded "semaglutide" samples have substantially lower strengths than labeled (e.g., 12% reduction in strength in a sample from TruLife Pharmacy, 19% reduction in strength in a sample from Brooksville Pharmacy, and 20% reduction in strength in a sample from Medi-Oak Pharmacy),[49] rendering them potentially less effective than expected. To protect patients from compounded "semaglutide" products with these types of safety and efficacy issues, Novo Nordisk has filed several lawsuits against compounding pharmacies alleging that their drug products are adulterated and misbranded.

Novo Nordisk has also uncovered that some compounded products claiming to contain semaglutide do not have any semaglutide at all. Testing results for a sublingual "semaglutide" liquid solution sold by Midtown Express Pharmacy in Tennessee showed that the sample contained no semaglutide whatsoever.[50] The pharmacy also advertises that its product is comparable to Novo Nordisk's FDA-approved drug products and has better semaglutide absorption in the body than RYBELSUS® and that patients experience less nausea than those taking Novo Nordisk's injectable semaglutide products.[51] Novo Nordisk has filed a lawsuit against Midtown Express Pharmacy, alleging that its drug products are adulterated and misbranded and that the pharmacy has engaged in false advertising.

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[47] *See* Complaint, *Novo Nordisk Inc. v. Wells Pharmacy Network, LLC*, No. 5:23-cv-689 (M.D. Fla. Nov. 2023).

[48] Arne Staby et al., *Influence of Production Process and Scale on Quality of Polypeptide Drugs: A Case Study on GLP-1 Analogs*, 37 PHARM. RES. 120, 123 (2020); FDA, *Immunogenicity Assessment for Therapeutic Protein Products* 2 (Aug. 2014), https://www.fda.gov/media/85017/download.

[49] *See, e.g.*, First Amended Complaint, *Novo Nordisk Inc. v. Brooksville Pharm. Inc.*, No. 8:23-cv-01503-WFJ-TGW (M.D. Fla. Nov. 2023); Amended Complaint, *Novo Nordisk Inc. v. Live Well Drugstore LLC*, No. 3:23-cv-808 (M.D. Fla. May 2024); Complaint, *Novo Nordisk Inc. v. MediOAK Pharmacy LLC*, No. 4:24-cv-02032 (Dist. Ct. S.D. Tex. May 2024).

[50] *See* Complaint, *Novo Nordisk Inc. v. Dunklau Pharmacy Holdings LLC et al.,* No. 3:24-CV-00667 (M.D. Tenn. May 2024).

[51] *Id.*

In addition to the actions taken with respect to compounded "semaglutide," Novo Nordisk has initiated action against an unlawful, online retailer of "semaglutide" named Aesthetic Maison. The online-only site sold "semaglutide" powder intended for reconstitution and injection directly to patients without any prescription from a medical professional, claiming that it was for "research use only."[52] Aesthetic Maison also makes claims on its website about the safety and efficacy of its unapproved "semaglutide" powder and products based on research of Novo Nordisk's FDA-approved medicines containing semaglutide.[53] Novo Nordisk's lawsuit against Aesthetic Maison alleges that its sales of "semaglutide" drugs violate state unfair competition laws and that the entity has engaged in false advertising. This lawsuit is born out of patient safety concerns similar to the ones raised by NABP in its RogueRx report about online entities selling GLP-1 agonists for "research purposes only" to patients without holding required pharmacy licensure and without requiring a valid prescription.[54]

III. Requests for Action

We believe that your state's support is critical to protect patients and address unlawful and potentially dangerous compounding of "semaglutide" products. We urge your Board of Pharmacy to release a statement describing the potential safety concerns associated with compounded drugs purporting to contain semaglutide. We ask that the statement cover:

- Quality issues Novo Nordisk's testing has revealed about several compounded samples, including peptide-related impurities and inaccurately labeled "semaglutide" strength;
- Adverse events associated with compounded "semaglutide" drugs listed in FDA's FAERS database;
- Evidence that some entities sell compounded "semaglutide" in combination with other ingredients, such as the peptide BPC-157, or in dosage forms and with routes of administration that have not been studied in clinical trials or reviewed by FDA, such as dissolvable tablets and liposomal drug products for the sublingual route of administration;
- State regulator statements identifying concerns with compounding of products that claim to contain semaglutide, including concerns about "substitute ingredients"; manufacture in foreign jurisdictions; the lack of proof that the drugs are legitimate, effective, or manufactured under sanitary conditions; and the potential for contamination, improper storage and transportation, and adulteration;

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[52] Complaint, *Novo Nordisk Inc. v. Aesthetic Maison LLC*, No. 4:24-cv-2036 (S.D. Tex. May 2024).

[53] Complaint, *Novo Nordisk Inc. v. Aesthetic Maison LLC*, No. 4:24-cv-2036 (S.D. Tex. May 2024).

[54] *See* National Association of Boards of Pharmacy, *RogueRx Activity Report: Injectable Weight Loss Drugs: How Illegal Online Drug Sellers Are Taking Advantage of Patients* (2024), https://nabp.pharmacy/wp-content/uploads/2024/04/RogueRx-Activity-Report-Injectable-Weight-Loss-Drugs-2024.pdf.

- FDA's statements on compounded "semaglutide," including its concern that "illegally marketed semaglutide" could "contain too little, too much, or no active ingredient at all, or contain other harmful ingredients";
- Foreign regulator statements describing the concerns associated with compounded "semaglutide" drugs and the actions they have or intend to take, including Australia's plan to protect Australian patients from the clear risk to human health posed by the large-scale manufacture of compounded injections; and
- Statements from organizations like The Obesity Society, Obesity Medicine Association, and Obesity Action Coalition, which recommend that patients avoid compounded GLP-1 drugs like compounded "semaglutide."

We encourage the Board to remind pharmacists and practitioners that compounding with the active pharmaceutical ingredient ("API") semaglutide must comply with the Federal Food, Drug, and Cosmetic Act, including section 503A, and any applicable state laws and regulations. Federal law prohibits compounding using any non-pharmaceutical grade API, using API unaccompanied by a valid certificate of analysis, or using API produced by an establishment that is not registered with FDA.

Novo Nordisk will be reaching out soon to set up a meeting or call with your Board of Pharmacy to discuss patient safety, including the compounding of drug products purporting to contain "semaglutide" and associated risks. We look forward to hearing from you.

Sincerely,

RB Clark

Robert B. Clark
Vice President, Regulatory Affairs
Novo Nordisk Inc.