CONSUMER PROTECTION	*	**BEFORE ROBERT B. LEVIN,**
DIVISION, OFFICE OF THE	*	**AN ADMINISTRATIVE LAW JUDGE**
ATTORNEY GENERAL,	*	**OF THE MARYLAND OFFICE OF**
PROPONENT	*	**ADMINISTRATIVE HEARINGS**
v.	*	**OAH No.: OAG-CPD-04-18-33738**
INSYS THERAPEUTICS, INC.,	*	**CPD Case No.: 18-028-100480**
RESPONDENT	*	

* * * * * * * * * * * * *

PROPOSED RULING ON MOTION TO DISMISS STATEMENT OF CHARGES

STATEMENT OF THE CASE

On September 6, 2018, the Consumer Protection Division (CPD or Proponent) of the Maryland Attorney General's Office (OAG) filed a Statement of Charges and Petition for Hearing requesting an Order requiring Insys Therapeutics, Inc. (Insys or Respondent) to cease and desist from engaging in unfair and deceptive trade practices and granting relief as appropriate and necessary, based on alleged violations of the Maryland Consumer Protection Act (MCPA). Md. Code Ann., Com. Law §§ 13-101 through 13-501 (2013 & Supp. 2018).

On September 14, 2018, the Chief of the CPD issued an Order Granting Hearing and Notification of Hearing. The Order delegated authority to the Office of Administrative Hearings (OAH) to conduct a contested case hearing and to render proposed Findings of Fact and Conclusions of Law.

On September 14, 2018, the Chief of the CPD filed an Appointment of Designee, appointing Steve Sakamoto-Wengel to act as Chief of the CPD. Mr. Sakamoto-Wengel will conduct any exceptions hearing with respect to the OAH's Proposed Decision and issue a final administrative order. The CPD submitted a document from the Department of Assessments and Taxation, dated October 9, 2018, certifying that the aforementioned documents had been served on Insys on October 2, 2018. On October 17, 2018, Insys filed a Response to the Statement of Charges. On October 29, 2018, the OAG transmitted the matter to the OAH for a hearing.

On November 21, 2018, Insys filed a Motion to Dismiss Statement of Charges (Motion). On December 6, 2018, the CPD filed a Motion for an Extension of Time for Responding to Insys's Motion, requesting an extension to December 11, 2018. On December 6, 2018, I held a prehearing conference (PHC) at the OAH in Hunt Valley, Maryland. Brian T. Edmunds and Sara E. Tonneson, Assistant Attorneys General, represented the CPD. Jonathan Biran, Esquire, and Ty Kelly Cronin, Esquire, Baker Donelson, represented Insys. The parties each submitted PHC Statements.

On December 11, 2018, I issued a PHC Report and Scheduling Order, which set forth the matters discussed during the PHC and included a scheduling order that addressed, *inter alia*, dates for the submission of motions and responses thereto. The PHC Report and Scheduling Order stated that the CPD's Response to Insys's Motion was due on December 11, 2018, and Insys's Reply in further support of its Motion was due on December 18, 2018. On December 12, 2018, the CPD requested an additional extension of time to file a response to the Motion due to the illness of the attorneys and their children. On the same date, I granted CPD's request for a one-day extension of time for the filing of its response.

On December 13, 2018, the CPD filed a Response to the Motion, which included the following exhibits: A) SUBSYS® Patient Support Services, B) SUBSYS® "How to Talk to Your

Health Care Provider," C) Email from Vikram Malhotra re: "Syndros Launch Meeting," February 12, 2016, D) Email from Raimonds Dzelme re: "Update," April 22, 2016, E) Insys Partnership Plan with Avella Specialty Pharmacy, April 27, 2015, F) press release entitled "Hogan-Rutherford Administration Announces 2018 Anti-Opioid Initiatives," and G) Letter from Thomas V. Mike Miller, Jr., President of the Senate of Maryland, to Honorable Brian E. Frosh, Attorney General, August 3, 2017. On December 21, 2018, Insys filed a Reply in Support of Motion. On January 15, 2019, I held a hearing on the Motion at the OAH in Hunt Valley, Maryland.[1]

The contested case provisions of the Maryland Administrative Procedure Act, the CPD's procedural regulations, and the OAH's Rules of Procedure govern procedure in this case. Md. Code Ann., State Gov't §§ 10-201 through 10-226 (2014 & Supp. 2018); Code of Maryland Regulations (COMAR) 02.01.02; and COMAR 28.02.01.

ISSUE

Should the CPD's charges against Insys be dismissed?

DISCUSSION

Motion to Dismiss for Failure to State a Claim

COMAR 28.02.01.12 provides in pertinent part as follows:

> C. Motion to Dismiss. Upon motion, the judge may issue a proposed or final decision dismissing an initial pleading which fails to state a claim for which relief may be granted.

[1] A motions hearing on the Motion to Dismiss, as well as the CPD's Motion in Limine and Insys's Motion to Strike, was originally scheduled to begin on January 14, 2019, and extend, if necessary, to January 15, 2019. Due to inclement weather on January 14, 2019, liberal leave was in effect for the State and all scheduled hearings at the OAH were postponed. I conducted the motions hearing on January 15, 2019.
At the January 15, 2019 hearing, I denied on the record both the CPD's Motion in Limine and Insys's Motion to Strike on the grounds they each were premature, but did so without prejudice to or waiver of the parties' later assertions of their positions regarding the admissibility of evidence of Insys's alleged conduct that occurred outside of Maryland, which was the principal focus of both the Motion in Limine as well as the Motion to Strike.

An "initial pleading" is defined in COMAR 28.02.01.02B(7) as "a notice of agency action, an appeal of an agency action, or any other request for a hearing by a person." The CPD's Statement of Charges serves as the initial pleading in this matter, and is subject to dismissal by the OAH if the allegations therein fail to state a claim for which relief may be granted.

A motion to dismiss under COMAR 28.02.01.12C is comparable to a permissive motion to dismiss made under Maryland Rule of Civil Procedure 2-322(b)(2), which is applicable where a party to a civil action asserts that a complaint "fail[s] to state a claim upon which relief can be granted." Cases applying and interpreting Maryland Rule 2-322 are, thus, informative. When a party seeks dismissal under Rule 2-322(b)(2), the party must assert that, even if the allegations in the complaint were true, the complaining party would not be entitled to relief as a matter of law. *Lubore v. RPM Assoc., Inc.*, 109 Md. App. 312, 322 (1996). Further, in considering a motion to dismiss for failure to state a claim under Rule 2-322(b)(2), the court must "assume the truth of all well pleaded facts and all inferences that can reasonably be drawn from them." *Rossaki v. NUS Corp.*, 116 Md. App. 11, 18 (1997). Thus, the non-moving party here, the CPD, is entitled to all favorable inferences that can reasonably be drawn from the Statement of Charges. *See Gen. Motors Corp. v. Lahocki*, 286 Md. 714, 733 (1980).[2]

The Maryland Consumer Protection Act

The MCPA prohibits "unfair or deceptive trade practices" in a "variety of circumstances." *Scull v. Groover, Christie & Merritt, P.C.*, 435 Md. 112, 124 (2013). The MCPA's "declaration of findings and purpose" states, in part, as follows:

> The General Assembly of Maryland finds that consumer protection is one of the major issues which confront all levels of government, and that there has been mounting concern over the increase of deceptive practices in connection with

[2] The focus of a motion to dismiss is on the legal sufficiency of an initial pleading, here the Statement of Charges, Accordingly, in assessing the Statement of Charges, I did not consider it appropriate to consider the exhibits the CPD submitted with its Response to the Motion, as they are not a part of the Statement of Charges (which has not been amended), were not referred to in the initial pleading, and are thus outside the scope of the Statement of Charges.

> sales of merchandise, real property, and services and the extension of credit. The General Assembly recognizes that there are federal and State laws which offer protection in these areas . . . , but it finds that existing laws are inadequate, poorly coordinated and not widely known or adequately enforced.

Com. Law § 13-102(a)(1), (2) (2013).

The MCPA defines a "consumer" as an "actual or prospective purchaser, lessee, or recipient of consumer goods, consumer services, consumer realty, or consumer credit." *Id.* § 13-101(c)(1) (Supp. 2018). "Consumer goods," in turn, are defined as goods that are "primarily for personal, household, family, or agricultural purposes." *Id.* § 13-101(d)(1).

Section 13-104(1) of the MCPA provides that it does not apply to:

> (1) The professional services of a certified public accountant, architect, clergyman, professional engineer, lawyer, veterinarian, insurance company authorized to do business in the State, insurance producer licensed by the State, Christian Science practitioner, land surveyor, property line surveyor, chiropractor, optometrist, physical therapist, podiatrist, real estate broker, associate real estate broker, or real estate salesperson, or medical or dental practitioner . . . .

Physicians are exempt under the Act only when providing "actual professional services," as distinguished from "the commercial aspects of a medical practice." *Scull*, 435 Md. at 132.

The MCPA "is to be construed liberally to promote the protection of consumers." *Id.* at 125; *see also* Com. Law §§ 13-102(3), 13-105 (2013). The CPD is generally charged with administering the MCPA. The Court of Appeals, in its most recent pronouncement on the MCPA, stated that the "interpretation of the statute by the agency charged with administering it is entitled to *considerable* weight." *Scull*, 435 Md. at 129 (emphasis added).

The Statement of Charges

The CPD filed a Statement of Charges against Insys alleging that Insys committed "thousands of violations" of the MCPA in the marketing and sale of SUBSYS®, a fentanyl sublingual (*i.e.* applied under the tongue) spray, the only product it manufactured from 2012 to 2017. Statement of Charges ¶ 3 (Sept. 6, 2018). SUBSYS® is an "extremely potent opioid

medication" that was approved by the U.S. Food and Drug Administration (FDA) on January 4, 2012. *Id.* ¶ 15.

Opioids are "highly addictive narcotic medicines." *Id.* ¶ 5. The CPD averred that "Maryland is in the midst of an opioid crisis that has resulted in large part from the over-prescription of prescription opioids in the State and from the subsequent use of illicit opioids by people who initially became addicted to prescription opioids." *Id.* ¶ 4. Fentanyl is a Schedule II controlled dangerous substance and is "approximately 50 times more potent than heroin, and approximately 100 times more potent than morphine." *Id.* ¶¶ 6, 8.

In 1998, the FDA approved the first "transmucosal immediate release fentanyl (TIRF)" product for "breakthrough pain" in adult cancer patients. *Id.* ¶ 10. "Breakthrough pain" is "episodic spikes of pain" that break through a cancer patient's opioid treatment regimen. *Id.* ¶ 11. The FDA approved SUBSYS®, a TIRF product, *only for* "the management of breakthrough pain in adult cancer patients who are already receiving and are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain." *Id.* ¶ 15. The FDA requires all TIRF products to be prescribed through the TIRF REMS Access Program, a risk evaluation and mitigation strategy program. *Id.* ¶ 12. Insys acknowledged that SUBSYS®, a TIRF product, would be subject to the TIRF REMS Access Program. *Id.* ¶ 15.

The Statement of Charges alleges that Insys used inducements of money, personal or physical intimacy, and the SUBSYS® product to drive prescriptions of SUBSYS® for inappropriate patients. *Id.* ¶ 46. For example, the Statement of Charges alleges that:

- Insys "provided its sales representatives with target lists that overwhelmingly included pain management providers, not oncologists." *Id.* ¶ 26.

- Insys instructed its sales representatives to follow a "formula," which was to find the "one key player who could be induced to write SUBSYS® in high volumes." *Id.* ¶ 28.
- Insys instructed its representatives to move in or live with this prescriber and "own" them. *Id.*
- Sales managers and representatives earned up to hundreds of thousands of dollars in bonuses for targeted prescribers who wrote frequently and in high amounts. *Id.* ¶ 29.
- One prescriber, Roger Theodore, M.D., of Towson, Maryland, engaged in a sexual relationship with the Insys sales representative assigned to him and placed numerous "off-label" patients on SUBSYS® while dating and living with her. *Id.* ¶ 45.

According to the Statement of Charges, another inducement to prescribers was through the Insys Speaker Program, in which Insys paid Maryland doctors up to $5,400.00 for a single speaking engagement in exchange for "medically inappropriate and excessive prescriptions of SUBSYS®." *Id.* ¶¶ 33, 36. Insys representatives were instructed to have "difficult conversations" with the doctors in order to pressure them to write SUBSYS® prescriptions in exchange for the speaker program fees. *Id.* ¶ 35. The speaker programs were "often held at . . . strip clubs, restaurants with scantily-clad waitresses, and private hotel rooms" where "Insys would provide large quantities of alcohol and sales managers and representatives would also pay for lavish perks . . . on their personal cards." *Id.* ¶ 39.

Insys sometimes obtained agreements from its speakers for a percentage of its TIRF product prescriptions. *Id.* ¶ 38. Insys also invited local pharmacists to its events in order to obtain "cooperation" from pharmacists, who have "duties to report suspicious activities and can decline

to fill problematic prescriptions." *Id.* ¶ 40. Insys would remove prescribers from its speaker program if the prescriber did not write enough SUBSYS® prescriptions or did not write them in high enough doses or quantities. *Id.* ¶ 37.

Insys also continued to market SUBSYS® through a prescriber, Eva Dickinson, M.D., who received SUBSYS® from her patients for her own personal consumption. *Id.* ¶ 45. Insys continued to work with this physician until her arrest. *Id.* As a result of these activities, ninety percent of the SUBSYS® prescriptions in Maryland were for patients whose conditions did not warrant the use of a TIRF product, and "[m]any of these patients became addicted to SUBSYS® and suffered as a result of their addictions." *Id.* ¶ 46.

The Statement of Charges alleges that Insys also misled patients' insurance companies in order to ensure coverage for inappropriate prescriptions. Most insurance plans require "prior authorization" by an insurer for certain prescription drugs, such as SUBSYS®, before the prescription is filled by a pharmacy. *Id.* ¶ 51. The prior authorization requirements resulted in initial denials of coverage for SUBSYS® by patients' insurance providers. *Id.* ¶¶ 53, 56. In late 2012, Insys created the Insys Reimbursement Center (IRC) to circumvent insurance requirements. *Id.* ¶ 57. For example, Insys directed IRC employees to falsely claim to insurers that they were calling "with, for, from, or on behalf of the doctor's office." *Id.* ¶ 58. Insys also trained IRC employees to "provide insurers with false diagnoses of dysphagia, a medical term for patients with difficulty swallowing, in order to convince insurers that the patient needed" the SUBSYS® fentanyl spray rather than the less expensive, generic fentanyl "lollipop." *Id.* ¶ 59.

Insys also created and posted fake lists in the IRC of "tried and failed medications" that matched insurance payer's requirements. Employees were instructed to read them to the insurance company regardless of whether the patient had actually used them. *Id.* ¶ 60.

Moreover, Insys instructed its IRS employees to "misrepresent patient diagnoses" through the "Spiel, Statement 13, and Agent 14" to "give the false impression that the patient had breakthrough cancer pain without using the word 'cancer.'" *Id.* ¶¶ 61, 62. Insys encouraged the IRC employees to engage in these deceptions by providing biweekly bonuses connected to the number of insurance approvals. *Id.* ¶ 67.

If, despite these false statements, an insurer did not authorize a prescription for SUBSYS®, Insys provided free SUBSYS® to patients during the pendency of their appeal for the denial of coverage, creating dependence on SUBSYS®. *Id.* ¶ 65. During these appeals, Insys prepared a "template letter of medical necessity containing false statements" that it "disseminated to its prescribers" in order to "mislead reviewers." *Id.* ¶ 66.

The CPD asserts that SUBSYS® is a "consumer good" and Insys has violated section 13-303 of the MCPA in the sale and offer for sale of consumer goods and services. *Id.* ¶¶ 74-75. The CPD also argues that Insys has violated section 13-301(1) of the MCPA by making false and misleading statements regarding the appropriateness of SUBSYS® in certain amounts and doses for particular conditions and specific patients, thus deceiving and misleading consumers. *Id.* ¶ 76. Moreover, CPD contends that Insys's inducements to prescribers were unfair and deceptive trade practices in violation of section 13-301(2)(i) of the MCPA. *Id.* ¶ 77. The CPD also asserts that Insys failed to disclose material facts in order to deceive consumers, in violation of section 13-301(3) of the MCPA. *Id.* ¶ 78.

The CPD concludes that as a result of Insys's unfair and deceptive practices, it has "derived more than $20 million in revenue from more than 3,000 prescriptions it has had written in Maryland," leaving Maryland consumers with "extraordinary addictions to SUBSYS®." *Id.* ¶¶ 74-75. The CPD requests the following relief: 1) Insys cease and desist from engaging in unfair or deceptive trade practices under the MCPA, 2) Insys take affirmative action, including

restitution for money received in connection with its unfair or deceptive trade practices and creation of an adequate addiction treatment program for consumers who received SUBSYS®, 3) Insys pay the costs of this proceeding, including the costs of investigation, 4) Insys pay civil penalties under section 13-410 for each violation of the MCPA, 5) an award of economic damages, and 6) other relief as appropriate and necessary.

The Parties' Arguments

Insys asserts that it "does not sell SUBSY® directly to consumers" but rather sells to "distributors or to specialty pharmacies as *inventory*." Reply in Support of Mot., at 3. Insys maintains that "the alleged MCPA violations are based on the prescriptions written by medical practitioners, as opposed to any misrepresentations made by Insys directly to consumers." Mot. at 3.

First, Insys argues that SUBSY® is not a consumer good subject to regulation under the MCPA. Insys contends that the law in Maryland, as well as the law in other jurisdictions, "has determined that prescription drugs, such as SUBSY®, are ***not*** consumer goods as a matter of law." *Id.* at 5 (emphasis in original). Insys asserts that SUBSY® "must be selected and prescribed by a licensed physician before a pharmacy may dispense the medication to a patient." Reply in Support of Mot., at 1. It maintains that the CPD is "overreaching," and as a matter of statutory interpretation, Insys's interpretation of "consumer goods" as excluding prescription drugs from coverage under the MCPA is consistent with the statutory regime.

Second, Insys argues that it is exempt from the MCPA under the professional services exemption. Insys asserts that because the prescribing of SUBSY® is "inextricably linked to the professional services of those medical practitioners," Mot. at 7, the exemption applies "derivatively" to Insys. Insys argues that within the chain of distribution of its product that extends from the manufacturer (Insys), to the pharmacy or drug distribution firm, to the

doctor/prescriber, and finally to patients/consumers, the doctor standing at an intermediate point of the chain is statutorily immune from liability; therefore, as a matter of logic, a manufacturer in the beginning of the chain—even if (as the CPD alleges here) it improperly induced the doctor to prescribe the drug—is also immune.

The CPD responds that prescription drugs should not be "carved-out" from the scope of the MCPA. It argues that the plain language of the MCPA's definition of "consumer goods" is clear and unambiguous and the MCPA "reaches the conduct of pharmaceutical manufacturers who market prescription drugs through unfair and deceptive means." Response to the Mot., at 2. The CPD further argues from the case law that "the Maryland appellate courts would concur with the [CPD's] longstanding practice of applying the [MCPA] to unfair and deceptive trade practices in the marketing of prescription drugs, including opioids." *Id.* at 10 & 10 n.1 (noting approximately twenty prior Maryland Circuit Court cases in which it applied the MCPA to allegedly unfair and deceptive trade practices in the marketing of prescription drugs, and apparently entered into consent judgments or settlements with drug manufacturers or pharmacy benefit management companies).

The CPD rejects Insys's claim that it is exempt from the MCPA under the professional services exemption. *Id.* at 14. The CPD argues that "exemptions to remedial statutes must be narrowly construed," and "the Court of Appeals made clear that the professional services exemption applies only to the core 'professional services' . . . that are regulated by the professional boards." *Id.* at 15. The CPD concludes that "Insys is not a 'medical practitioner' regulated by a professional board that is providing 'professional services' when it markets and sells its product, and is not exempt from the [MCPA]." *Id.* at 17.

Pertinent Case Law

Neither the parties' nor my research has identified any Maryland appellate court decision that explicitly addresses whether a prescription drug is a consumer good under the MCPA. By contrast, the scope of the MCPA's professional services exemption has been addressed, most notably by the Court of Appeals in *Scull v. Groover, Christie & Merritt, P.C.*, 435 Md. 112 (2013), and the Court of Special Appeals in *Hogan v. Maryland State Dental Association*, 155 Md. App. 556 (2004).

In the discussion that follows, I will first review pertinent Maryland appellate decisions, as well as certain decisions from other courts that are relevant to the issues raised by the parties. Next, I will discuss the application of those decisions to the issues raised in the Motion.

In *T-Up, Inc. v. Consumer Prot. Div.*, 145 Md. App. 27, 40 (2002), the Court of Special Appeals addressed a claim under the MCPA for a company's unfair or deceptive trade practices in the marketing of a non-prescription, concentrated aloe vera extract as an "alternative medical treatment" for numerous diseases and conditions, including cancer, AIDS, and HIV. The aloe vera product could be purchased in liquid or other forms by calling a telephone number provided by the company in an audiotape mailed to consumers. *Id.* at 42. The purchase of the product did not require a prescription from a physician but did include a sterile form "sold for intravenous injection, which ostensibly was to take place under the care of a physician outside of the United States." *Id.* The Court of Special Appeals affirmed a $3,706,000 judgment against the company under the MCPA.

In an unpublished trial court decision, the Honorable Stuart R. Berger, then Associate Judge of the Circuit Court for Baltimore City (now Associate Judge of the Court of Special Appeals), dismissed an MCPA claim brought by private plaintiffs against the manufacturers of a childhood vaccine that contained thimerosal, a mercury-based preservative. *Agbebaku v. Sigma*

Aldrich, Inc., No. 24-C-02-004175, 2003 WL 24258219, at *1 (Cir. Ct. Md. Balt. City June 24, 2003). The plaintiffs, relying on *T-Up, Inc.*, argued that the thimerosal-containing vaccine was a "consumer good" and the manufacturer or distributor of the vaccine should be held liable under the MCPA. Finding that "the *T-Up, Inc.* case is wholly distinguishable from the issues present in this case," Judge Berger rejected the MCPA claim. *Id.* at *10. He explained:

> In the present case, Plaintiffs have not alleged that Defendants engaged in any such [unfair or deceitful] tactics for the purpose of profiting from the vaccine. Further, in *T-Up*, the defendants were directly dealing with the consumers and victims. *Here, Defendants were never in contact with Plaintiffs, nor did they directly market its products to the Plaintiffs. Defendants are bona fide manufacturers and distributors producing and providing an FDA-approved vaccine to knowledgeable physicians who professionally administer the vaccine. This Court finds that such a claim is not actionable under the Consumer Protection Act.*

Id. at *11 (emphasis added).

In an alternative holding, Judge Berger applied the MCPA's section 13-104 professional services exemption to the manufacturer of the vaccine. He reasoned as follows:

> Under the [MCPA], the physicians and other medical personnel who actually select, recommend, and administer the vaccine are exempt from liability should any injuries result. Accordingly, the manufacturer or distributor of the vaccine, an entity even more attenuated from the injured person than the medical practitioner who selected, recommended, and administered the vaccine, must also be exempt from liability under the [MCPA].
>
> For the above-mentioned reasons, *even if vaccines were consumer goods as defined by the CPA*, any manufacturer or distributer of the vaccines would be exempt from liability under section 13–104. Accordingly, this Court grants Defendants' motion to dismiss Count 14 of Plaintiffs' Complaint.

Id. (emphasis added).

In 2004, the Court of Special Appeals considered whether dental patients who had received dental fillings containing mercury stated an MCPA claim against the American Dental Association and the Maryland State Dental Association. *Hogan v. Md. State Dental Ass'n*, 155

Md. App. 556, 559 (2004). The court stated that the MCPA "allows consumers to recover from persons who engage in deceptive trade practices related to the sale or offering for sale of consumer goods," *id.* at 563, but held that the MCPA "was not intended to impose liability in factual situations such as the one before us" for the following reasons: 1) the state dental association was not a "merchant" that sold or offered to sell goods, 2) dental fillings are not "consumer goods," and 3) the claim fell within the express MCPA exemption applicable to the professional services of a "dental practitioner." *Id.* The court highlighted that "[d]ental fillings are not purchased by consumers as a good but are *selected and used* by a practitioner as part of a professional service." *Id.* at 564 (emphasis added).[3]

In an unpublished decision, Judge (now Chief Judge) James K. Bredar of the United States District Court for the District of Maryland found the reasoning in *Hogan* "persuasive" and applied it as the basis to dismiss a private plaintiff's MCPA claim alleging that the manufacturer of a prescription drug, Humira, engaged in unfair and deceptive practices in marketing, promoting, and creating warnings with respect to the drug. *Pease v. Abbott Laboratories, Inc.*, No. JKB-12-1844, 2013 WL 174478, at *2 (D. Md. Jan. 16, 2013). Holding that prescription drugs are not "consumer goods" under the MCPA, and that the MCPA's professional services exemption applies to the sale of prescription drugs, Judge Bredar stated:

> [The manufacturer] also argues that the MCPA is inapplicable to [its] sale of prescription drugs because prescription drugs are not "consumer goods" under the MCPA and because the MCPA's professional services exemption applies to it.

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[3] In *Rite-Aid Corp. v. Levy-Gray*, 391 Md. 608 (2006), the Court of Appeals held that because prescription drugs are goods subject to sale, they may potentially be the subject of an express warranty claim under the Uniform Commercial Code (U.C.C.). *Id.* at 621-22; *see also* U.C.C., §§ 2-105(1), 2-313. The court did not mention the MCPA. Interestingly, the *dissent* in *Rite Aid* stated, "[P]rescription drug sales are attributable to the advice of the patient's physician. Hence, the purchase of prescription drugs is fundamentally different from the purchase of other consumer goods. Because patients generally do not base their decision to purchase a prescription medication on the instructions for its consumption or use or any information contained in the informational pamphlet accompanying the prescription drug, such information is not part of the basis of the bargain, and, therefore, no express warranty is created thereby." 391 Md. at 639-40 (citation omitted).

> This argument is persuasive and serves as an alternative basis for the Court's dismissal of Count IX [the MCPA claim]. In *Hogan* . . . the Maryland Court of Special Appeals concluded that dental fillings were not consumer goods under the MCPA, which defines them as goods "which are primarily for personal, household, family, or agricultural purposes." The court reasoned that dental fillings are not purchased by consumers as a good but are selected and used by a practitioner as part of a professional service, and the MCPA expressly exempts professional services rendered by medical or dental practitioners. Similarly, the Humira used by [the party] was selected by [the parties'] physician and prescribed for [the party], not as a consumer good, but as part of her course of medical treatment. Thus, this would seem to fit into the statutory exemption.

Id. (citations omitted).

Judge Richard D. Bennett, also a Judge on the United States District Court for the District of Maryland, held in an unpublished decision that an unlicensed "medical healer" was not exempt from the MCPA under the professional services exemption. *Donnelly v. Rosas*, No. RDB-17-1486, 2018 WL 3862233, at *4 (D. Md. Aug. 14, 2018). The plaintiff in *Donnelly* sought treatment and bought products from a "medical healer" in order to alleviate her symptoms from Lyme Disease. *Id.* at *1. The plaintiff was eventually diagnosed with selenium toxicity and brought a claim under the MCPA against the medical healer. *Id.* Judge Bennett, in holding that the medical healer could not shield herself from the MCPA claim under the professional services exemption, stated that "[i]t is undisputed . . . that [the defendant] is not a licensed physician or licensed with any Maryland agency." Judge Bennett distinguished the non-prescription products at issue in *Donnelly* from the prescription drug (Humira) involved in *Pease* and quoted Judge Bredar's statement in *Pease* that "the [prescription] used by [the plaintiff] was selected by her physician and prescribed for her, *not as a consumer good*, but as part of her course of medical

treatment." *Id.* at *4 (quoting *Pease*, 2013 WL 174478, at *2 (emphasis added)). Accordingly, Judge Bennett denied the defendant's motion to dismiss the MCPA claim.[4]

Aston v. Johnson & Johnson, 248 F. Supp. 3d 43, 57 (D.D.C. 2017), noted that courts construing the consumer fraud statutes of Maryland, Pennsylvania, New York, and Illinois have held that those statutes did not apply to claims involving prescription drugs. For this proposition, *Aston* cited *Pease* (holding that prescription drugs are not consumer goods under the MCPA), as well as *Kester v. Zimmer Holdings, Inc.*, No. 210-CV-00523, 2010 WL 2696467, at *14 (W.D. Pa. June 16, 2010) ("[A] plaintiff does not have a viable [Pennsylvania Unfair Trade Practices and Consumer Protection Law] cause of action against a manufacturer of prescription drugs."); *Amos v. Biogen Idec Inc.*, 28 F. Supp. 3d 164, 173 (W.D.N.Y. 2014) ("[A]ny alleged deceptive act related to the issuance of those [drug] warnings is not a 'consumer oriented' act actionable under Section 349 of the New York General Business Law."); *Bober v. Glaxo Wellcome PLC*, 246 F.3d 934, 942 (7th Cir. 2001) (holding Illinois Consumer Fraud Act exempts "highly regulated" pharmaceutical companies from liability). *But see Watts v. Medicis Pharm. Corp.*, 365 P.3d 944, 953 (Ariz. 2016) ("[T]he [Arizona Consumer Fraud Act] applies to prescription pharmaceuticals."). *Id.* at 57.

In *Otis-Wisher v. Medtronic, Inc.*, 616 F. App'x 433 (2d Cir. 2015),[5] the Second Circuit affirmed the dismissal of a Vermont consumer protection act claim involving a prescription medical device, stating:

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[4] *McCormick v. Medtronic, Inc.*, 219 Md. App. 485 (2014) (Meredith, Berger, Arthur, JJ.), upheld certain claims under the MCPA that related to a prescription medical device, rejecting the manufacturer's argument that the claims were federally preempted. The court did not address whether the device was a consumer good under the MCPA, as that issue was apparently not raised in the appeal. *Boatel Industries, Inc. v. Hester*, 77 Md. App. 284 (1988), held that a yacht purchased from the manufacturer by a boat dealer for the latter's use as a "demonstrator" model was not a consumer good under the MCPA because it was used for business, rather than personal, purposes.

[5] *Otis-Wisher*, a summary order, was not selected for publication in West's Federal Reporter, and the decision bears a legend to the effect that "rulings by summary order do not have precedential effect."

> [T]he Vermont Consumer Protection Act . . . defines a "consumer" as a "person who purchases, leases, contracts for, or otherwise agrees to pay consideration for goods or services . . . for his or her use or benefit or the use or benefit of a member of his or her household." Plaintiff did not constitute a "consumer" under the statute because she did not, for her personal use, purchase Infuse, which in any event is not available for consumer purchase, but rather was prescribed the medical device by her doctor. Though Vermont has apparently not addressed this issue in the specific context of medical devices, the District Court's ruling here is consistent with that of courts in other jurisdictions interpreting similar consumer protection laws.[6]

Id. at 435 (quoting Vt. Stat. Ann. tit. 9, § 2451a(a)).

White v. Wyeth, 705 S.E. 2d 828 (W. Va. 2010), held that prescription medical products were not subject to a private cause of action under West Virginia's consumer fraud statute because of the restricted way in which they were distributed. "Prescription drug cases are not the type of private causes of action contemplated under the terms and purposes of the [statute] *because the consumer cannot and does not decide what product to purchase.*" *Id.* at 838 (emphasis added).

The following passage from *White* is fairly representative of the reasoning of courts that have excluded prescription drug products from private causes of action under state consumer protection statutes:

> A New Jersey appellate court in *New Jersey Citizen Action v. Schering–Plough Corporation* made a related observation in a consumer protection case involving a prescription drug when it said: "[T]he intervention by a physician in the decision-making process necessitated by his or her exercise of judgment whether or not to prescribe a particular medication[,] protects consumers in ways respecting efficacy that are lacking in advertising campaigns for other products." After generally noting the essential difference between the pharmaceutical industry and other companies, the New Jersey appellate court further ascertained that the high degree of federal regulation of prescriptive [sic] drug products attenuates the effect product marketing has on a consumer's prescriptive [sic] drug purchasing decision. This Court has previously taken into account the high degree of federal regulation when deciding a [West Virginia Consumer Credit and Protection Act] case. Additionally [, in an article in the Washburn Law Journal entitled, *"That's Unfair!" Says Who—The Government or the Litigant? Consumer Protection Claims Involving*

[6] The Second Circuit referred to the Appellee's Brief "collecting cases." The brief is publicly available on Pacer, the federal courts' online system for public access to court electronic records, as Case 14-3491, Document 49, 02/23/2015, at 63-64 n.24.

> *Regulated Conduct*, the authors] suggest[] that "[t]here is a strong argument that the scope of [consumer protection acts] was never meant to include FDA-approved drugs. The clear public policy behind these provisions is that consumer protection laws were meant to fill a gap by protecting consumers where product safety was not already closely monitored and regulated by the government." Accordingly, for the reasons stated above, we find that the private cause of action afforded consumers under West Virginia Code § 46A–6–106(a) does not extend to prescription drug purchases.

Id. (citations omitted).

Analysis

For the following reasons, I conclude (a) that SUBSYS® is a consumer good for purposes of this case brought by the CPD under the MCPA; and (b) that the Statement of Charges is not barred as a matter of law at the pleading stage by the MCPA's professional services exemption.

a. Consumer goods

The MCPA applies to "consumer goods," a term defined by the statute as goods "which are primarily for personal, household, family, or agricultural purposes." Com. Law § 13-101(d)(1) (Supp. 2018). This plain and unambiguous statutory definition does not exclude from its scope prescription drugs or other prescription medical products. As SUBSYS® is a product that is literally sprayed into the "person" of a patient for purposes of pain relief, it comes within the literal text of the statutory definition of a consumer good—*i.e.* SUBSYS® is primarily for personal use. The question becomes, however, whether prescription drugs have been deemed, through the process of judicial interpretation of the statutory text, not to be consumer goods.

The closest Maryland appellate decision on the question whether a prescription drug is a consumer good is *Hogan*, which held that dental fillings that a patient could only obtain through the judgment and intervention of a licensed health care provider (the patient's dentist) was outside of the MCPA's scope. 155 Md. App. at 561-62. There are important distinctions, however, between the facts in *Hogan* and those alleged in the Statement of Charges here. Dental

fillings are not purchased by a consumer in the marketplace *with or without a prescription.* Moreover, the dental association defendants in *Hogan* were not merchants that sold fillings, and the court noted that the fillings were *used—i.e.* applied—by the dentist as part of a professional service.

Insys, by contrast, is a merchant/manufacturer that sells the prescription "good" SUBSYS® to pharmacies or distributors. In addition, Insys acknowledged at the January 15, 2019 hearing on its Motion that typically the patient, not the physician, administers SUBSYS® by spraying the drug under the patient's tongue. Although both dental fillings and prescription drugs involve the intermediation of a health care provider between the manufacturer and the patient, based on these differences between dental fillings and prescription drugs, I conclude that *Hogan* does not foreclose a prescription drug from coverage under the MCPA as a matter of law.

There is another, fundamental distinction between the private consumer protection act cases principally relied upon by Insys (including but not limited to *Hogan, Pease, Agbebaku, Donnelly*, and *White*) and this case. This case was not, unlike those cases, instituted by a private plaintiff. This case was brought by the CPD of the OAG of the State of Maryland on behalf of the State. The significance of the distinction between private and State-initiated consumer protection actions was recognized in the unpublished decision in *West Virginia ex rel. McGraw v. Bristol Myers Squibb Co.*, No. 13-1603 (FLW), 2014 WL 793569 (D.N.J. 2014). There, the court refused to apply, in a consumer protection action brought against a pharmaceutical manufacturer by the State of West Virginia, the holding of *White v. Wyeth. White*, relied on by Insys here, was the 2010 decision of the Supreme Court of Appeals of West Virginia that held prescription medical products were not subject to a private cause of action under West Virginia's consumer fraud statute.

Bristol Myers Squibb was a *parens patriae* action,[7] in which the State of West Virginia, by its Attorney General, alleged that Bristol Myers Squibb and other defendants engaged in unfair and deceptive marketing practices relating to the efficacy of Plavix, an anti-clotting prescription drug. Judge Freda Wolfson of the United States District Court for the District of New Jersey rejected the defendants' argument, based on *White v. Wyeth,* that West Virginia's consumer fraud statute did not apply to the marketing of prescription drugs. 2014 WL 793569, at *6-*7.

The *Bristol Myers Squibb* court noted that *White* held that the state's consumer protection statute did not apply to *private* causes of action involving prescription drugs because doctors, rather than consumers, select which drugs to prescribe to an individual, and consumers are thereby protected by the doctor's medical judgment—which is known as the learned intermediary doctrine. The court concluded that *White's* holding should be limited to private consumer protection actions. The distinguishing feature was that the sole plaintiff in the *Bristol Meyers Squibb* case was the State of West Virginia, and that the state brought the suit to vindicate its quasi-sovereign interests under the that state's consumer protection statute. *Id.* at *6.

The court found instructive another West Virginia decision that allowed the West Virginia attorney general to sue a pharmaceutical manufacturer to redress violations of the consumer fraud statute for its allegedly deceptive and misleading promotion of its prescription drug products. The court explained in *Bristol Myers Squib* that the learned intermediary doctrine should not apply to a *parens patriae* action. It pointed out that when the State of West Virginia

[7] "*'Parens patriae'*, literally 'parent of the country,' refers traditionally to the role of the state as sovereign and guardian of persons under legal disability." *Black's Law Dictionary* at 1003 (5th ed. 1979). Under the *parens patriae* doctrine, a state may sue to protect what courts refer to as its "quasi-sovereign" interests, to include "the health and well-being–both physical and economic–of its residents in general." *Alfred L. Snapp & Son, Inc. v. Puerto Rico*, 458 U.S. 592, 607 (1982). In addition, a state may sue in "the exercise of [its] sovereign power over individuals and entities within the relevant jurisdiction-this involves the power to create and enforce a legal code, both civil and criminal." *Id.* at 601.

brings consumer fraud claims involving prescription drugs, it is not required under the statute to establish reliance or causation, which are required elements in *private* causes of actions brought by private individuals under the statute. "In the latter scenario, because individuals must prove damages 'as a result of' a defendant's deceptive act, the application of the learned intermediary doctrine is more appropriate." *Id.* at *10, n. 3.

Moreover, there was no provision in the West Virginia consumer fraud statute that exempted pharmaceutical companies from liability. Rather, the purpose of the statute was to protect consumers from unfair, illegal, and deceptive acts or practices by providing an avenue of relief for consumers who would otherwise have difficulty proving their case under a more traditional cause of action. *Id.* at *6.

I find that Judge Wolfson's analysis applies with equal force to the instant case. Though this action was not formally denominated a *parens patriae* action, neither is it a private action. The Statement of Charges confirms, at 1, that the CPD instituted this action "*on behalf of the State of Maryland* to enjoin Insys . . . from engaging in unfair and deceptive trade practices and to obtain relief for consumers victimized by Insys's unfair and deceptive trade practices." (emphasis added).

The CPD of the OAG is generally charged with the enforcement and interpretation of the MCPA under section 13-204 of the Commercial Law Article. The Maryland General Assembly granted the CPD standing to bring cases in order to fulfill the statute's purpose of protecting the interests of the State and its citizens in consumer protection and welfare. *See* Com. Law § 13-102 (2013) (legislative findings and statement of the MCPA's purpose). Thus, the Maryland legislature expressly granted the CPD authority under the MCPA that is the functional equivalent of *parens patriae* authority. *Hogan*, *Pease*, *Agbebaku*, *Donnelly*, and *White*, by contrast, are all private consumer protection lawsuits.

The observation in *Bristol Myers Squib* applies to the MCPA; namely, that the application of the learned intermediary doctrine is less appropriate than it may be in a private action whenever a state is not required under a consumer protection statute to establish reliance or causation. *See* 2014 WL 793569 at *9 n.3. Section 13-302 of the MCPA provides: "Any practice prohibited by this title is a violation of this title, whether or not any consumer in fact has been misled, deceived, or damaged as a result of that practice." As the Court of Appeals of Maryland noted in *Scull*, under section 13-302 of the MCPA, "[i]t is not necessary that a consumer actually have been misled or damaged as a result of the [unfair or deceptive trade] practice." 435 Md. at125.

Therefore, if (as alleged here), Insys engaged in unfair, abusive, or deceptive trade practices in marketing its prescription drug product, the State through the CPD has standing to sue to curtail the alleged violation, regardless whether consumers were misled, deceived, or damaged by the challenged conduct, and notwithstanding physician intermediation in the SUBSYS®'s chain of distribution.[8] This follows from the fact that "the [CPD] has authority, under § 13–403 of the Commercial Law Article, to conduct a cease and desist order hearing in the absence of consumer complaints." *Consumer Protection Div. Office of Atty. Gen. v. Consumer Pub. Co., Inc.*, 304 Md. 731, 795 (1985). Thus, if a prescription drug manufacturer launched an unfair, abusive, or deceptive marketing or promotional campaign, the State, through the CPD, may invoke the MCPA to *prevent* harm to consumer or State interests, notwithstanding the ostensible protection provided to patients by their doctors. The State would not have to wait for consumers to be harmed.

[8] Though the *CPD* need not establish that consumers were in fact misled, deceived, or damaged by an alleged unfair, abusive, or deceptive trade practice, in a *private* action under the MCPA a private plaintiff must prove actual injury or loss sustained by the MCPA violation in order to recover damages under the MCPA. Com. Law § 13-408(a) (2013). *See Citaramanis v. Hallowell*, 328 Md. 142 (1992) (plaintiff pursuing private action under section 13-408(a) of the MCPA must prove actual injury or loss sustained); *Galola v. Snyder*, 328 Md. 182 (1992) (tenant not entitled to damages under section 13-408(a) solely upon proof that the leased property was not licensed as required by law; rather, the tenant was required to prove actual loss or injury caused by the lack of licensure).

None of the cases relied upon by Insys to support its argument that the intermediation of the prescribing physician removes prescription drugs and devices from the class of consumer goods involved an allegation that the drug manufacturer improperly colluded with and wrongfully induced the "learned intermediary" physician to prescribe the product. Here, by contrast, the Statement of Charges includes particularized allegations that Insys used improper inducements of money, physical intimacy and SUBSYS® to drive prescriptions of SUBSYS® for inappropriate patients, misled patients' insurance companies in order to ensure coverage for inappropriate prescriptions, and engaged in other unfair or deceptive practices. Statement of Charges at 7, 13.

It would be incongruous to insulate Insys from liability as a matter of law at the pleading stage of the litigation based, without more, on the intermediation of physicians purportedly exercising independent, professional judgment in the prescription process, where the CPD has alleged that Insys corrupted or compromised the physicians' exercise of their independent judgment, by providing improper inducements to physicians to prescribe SUBSYS® to inappropriate patients.[9]

For the foregoing reasons, I conclude that Insys's argument that SUBSYS® is not a consumer good as a matter of law must fail.

b. Professional services exemption

The MCPA exempts certain activities of specified entities and individuals from its purview. The statute does not apply to "the professional services" of individuals in specified

[9] As the Court of Appeals declared in *Scull*, the "interpretation of the statute by the agency charged with administering it is entitled to *considerable* weight." 435 Md. at 129 (emphasis added). Here, the CPD has not only brought *this* action based on its interpretation that the MCPA covers prescription drugs, the CPD showed that it has previously entered into a number of consent judgments or settlements with prescription drug manufacturers based on its interpretation. Response to Mot. at 10 & 10 n.1. While Insys disparages the CPD's interpretation as merely the "practice" of an interested party litigant, the CPD's practice of bringing cases involving prescription drugs flows from its interpretation that those products are not excluded from the statutory definition of consumer goods. Moreover, unlike *Scull*, a private MCPA suit in which the CPD filed an *amicus* brief to convey its interpretation of the statute to the Court of Appeals, the CPD did not weigh in in *Hogan*, *Pease*, *Agbebaku*, or *Donnelly*, all of which were private MCPA actions.

professions.[10] Com. Law § 13-104(1) (2013). Pertinent to this case, that list includes "the professional services" of a "medical or dental practitioner." *Id.*

In 2013, the Court of Appeals addressed the MCPA's professional services exemption in the context of a claim that a medical practice's billing and collection activities violated the statute. *Scull*, 435 Md. at 118. Writing for the court, Judge McDonald stated that "medical billing is not a 'professional service' exempt from the Consumer Protection Act." *Id.* The court distinguished the "commercial and entrepreneurial aspects of a medical practice from the actual rendering of health care services" in finding that "not everything that a licensed professional does is a 'professional service.'" *Id.* at 129. The court held that the commercial or entrepreneurial aspects of a medical practice are not exempt from the MCPA. *Id.* at 132. Moreover, the court stated that "the exclusion is actually limited to 'professional services' rendered by medical providers." *Id.* at 127 n.14.

For purposes of considering Insys's motion to dismiss based on the statutory exemption, application of the statute as construed by *Scull* is straightforward. Insys is not a "medical provider" providing "medical services" and is not otherwise a member of the class of providers excluded by the statute. Nevertheless, Insys argues that because the prescribing of SUBSY® is "inextricably linked to the professional services of those medical practitioners," Mot. at 7, Insys claims that it effectively steps into the physicians' shoes such that the exemption should be applied "derivatively" to Insys.

Insys's argument is inconsistent with the legislative mandate that the MCPA "is to be construed liberally to promote the protection of consumers." *Scull*, 435 Md. at 125; *see also*

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[10] The statute reads in pertinent part:
This title does not apply to:
(1) The professional services of a certified public accountant, architect, clergyman, professional engineer, lawyer, veterinarian, insurance company authorized to do business in the State, insurance producer licensed by the State, Christian Science practitioner, land surveyor, property line surveyor, chiropractor, optometrist, physical therapist, podiatrist, real estate broker, associate real estate broker, or real estate salesperson, or medical or dental practitioner..

Com. Law §§ 13-105, 13-102(3) (2013). The argument is also at odds with the principle that exemptions from "remedial statutes" such as the MCPA are "strictly construed." *Saunders v. Md. Unemployment Comp. Bd.*, 188 Md. 677, 682-83 (1947). Accordingly, I conclude that Insys has not demonstrated that the professional services exemption bars the CPD as a matter of law, at the pleading stage, from stating a claim under the MCPA.[11]

PROPOSED CONCLUSION OF LAW

Based on the foregoing Discussion, I propose that the CPD should conclude as a matter of law that the CPD's charges against Insys should not be dismissed. COMAR 28.02.01.12C.

PROPOSED ORDER

I propose that the CPD should ORDER that the Respondents' Motion to Dismiss is **DENIED.**

January 31, 2019
Date Ruling Issued

Robert B. Levin
Administrative Law Judge

RBL/emh
#177621-v3

[11] I stress, however, the limited nature of the instant denial of Insys's Motion. I conclude only that the involvement of physicians in the prescription process is insufficient to bar the CPD's MCPA claims under the professional services exemption as a matter of law at the pleading stage. That does not mean that the nature and degree of physician involvement and judgment in prescribing SUBSYS® may not be relevant on the merits as the evidence unfolds.

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