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Chair's Message Goals For The Upcoming Term...

By: Everett Wilson



It is my honor to serve as Chair of the Section for the upcoming term. Our goal for the year can best be summed up by a simple statement – to permanently improve the value of the Section to our members.

We are fortunate in that a strong foundation has already been laid by prior leadership and all those members of the Section who have volunteered their time to further the Section's initiatives and programs. We are thankful for their efforts and the lasting impact they have made upon the Section. More importantly, though, they have set an example for our more recent members on what can be accomplished when diversely minded individuals with different skill sets are able to rally around issues of common interest to our collective membership. As we see newer members continuing to volunteer their time, I recognize that this is their true legacy.

In addressing how we will go about accomplishing our goal of improving value, allow me to summarize our current state of affairs. We are an "industry" focused Section comprised of practitioners of all types – regulatory, litigation, corporate, criminal, administrative, employment, tax, etc. The common denominator is that we service clients in the health care or health care insurance industry or are otherwise impacted by the same – an industry which represents almost 20% of the U.S. economy and employs one in every 8 individuals in the U.S. It is an industry comprised of many sectors and, thus, our respective clients and the matters we

assist them with are varied in type, size, and complexity.

Our clients (and we by extension), in turn, also share something in common. They operate in a highly regulated environment – which regulations impact almost every facet of their professions and businesses. More importantly, though, those government regulations and initiatives actually drive our clients' business models and are the cause of not just constant change, but opportunity. Further compounding the effect of new regulations, is that health care is ever changing. The evolution of technology, biological advances, and even changes in societal norms, far outpace the passage of laws and regulations. Thus, we are sometimes called upon to advise clients on scenarios for which existing laws provide inadequate guidance.

What all of this means is that in order for the Section to improve value for its members, it must go beyond its position of being the go-to source in Florida for CLE in health care law. The modern health care lawyer and our other members require more from their Section.

That being said, the Section will continue to offer first rate educational programs, but with a renewed and deliberate intent towards incorporating the latest trends in law and industry. Further, the Section will strive to make our programs more accessible to all of our members – both through geographic diversity of our in-person events and through technology and other media.

This term, the Section will also focus on professional and practice development for the benefit of our members. This will be

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CHAIR'S MESSAGE

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accomplished through more local and state-wide networking events and other opportunities for engagement amongst Section members. This includes taking affirmative steps towards the creation of a communication platform for the exchange of thoughts, information, and business opportunities. Because of the diversity of our varying practices, we will likely learn more from each other than from any CLE event we may attend. That same diversity of practices also creates an environment for the exchange of opportunities and for business development and referrals

amongst our members.

Further, since the value of a group may also be measured by what the group can accomplish collectively versus individually, you can look to the Section to take a more active role on issues that impact us collectively, particularly where the Section may be in the best position to advance those interests. In that regard, the Section will continue to monitor legislative issues. However, we encourage all of our members to engage with the Section so as to keep the rest of the Section's members informed as to other legal and industry issues as they encounter them.

The point cannot be stressed enough, though, that we need and are actively seeking the involvement of all of our

members to advance these value enhancing initiatives. Thus, I encourage all of our members to keep abreast of our emails, website, and to follow our new LinkedIn page www.linkedin.com/company/health-law-section-of-the-florida-bar and to participate and engage with the Section and its other members. I would also encourage all members to please feel free to reach out to me or Emily Young, the Section's program administrator, with any suggestions or other input on how the Section can best serve you.

I can be reached at everett.wilson@polsinelli.com. Emily may be reached at eyoung@floridabar.org.

We are looking forward to a great year.

Compounding Medications for Office Use

By: Deirdre Boling-Lewis



Medication compounding is the process of combining individual ingredients to create a customized medication for those segments of the population for which a commercially available product does not work. Commercially

available products are manufactured drugs for which the FDA has reviewed filings from the application sponsor that have been prepared by or on behalf of the drug manufacturer. These filings relate to the safety and efficacy of the proposed drug. During the review of these filings, the FDA determines the benefits as compared to the known risks of the proposed drug's intended use. Commercially available products may contain certain ingredients, like preservatives, to which patients may be allergic or sensitive. Or sometimes, the patient simply needs the commercially available drug in a different form or strength - for example, a cream for topical administration rather than a tablet or capsule or an ingredient at 7.5% potency rather than 5%. In those situations, many physicians prefer to keep prescription medications on-hand for office use. But from where does that compounded medication come?

Obtaining Compounded Medications

Traditionally, prescriptions for compounded medications would be sent to

compounding pharmacies on a patient-by-patient basis. However, in 2013, with the enactment of the Compounding Quality Act (Title I of the Drug Quality and Security Act, Pub. L. 113-54), Congress established a new section of the Federal Food, Drug and Cosmetic Act (FFDCA), Section 503B, thereby creating a new entity called an "outsourcing facility." Outsourcing facilities are a hybrid between a drug manufacturer and a traditional compounding pharmacy and are permitted to compound large quantities of medications. Like drug manufacturers, outsourcing facilities are required to comply with good manufacturing practices set out in 21 CFR Parts 210 and 211 (cGMP); unlike traditional compounding pharmacies, a patient-specific prescription is not required before an outsourcing facility can distribute the compounded medications to healthcare practitioners and facilities. "Under Section 503B, outsourcing facilities are permitted to compound medications in large quantities and without the patient-specific prescription prerequisite," states Lee Rosebush, Chairman of the Outsourcing Facilities Association. "Outsourcing facilities, therefore, create a pathway for physicians to obtain as office stock compounded medications." Because outsourcing facilities are subject to cGMP requirements and the FDA inspections, as well as specific adverse event reporting requirements "and other conditions that provide greater assurance of the quality of their compounded drug products, . . .

outsourcing facilities can compound and distribute sterile and non-sterile non-patient-specific drug products to hospitals, clinics, and health care practitioners for office use." (*Prescription Requirement* Guidance, page 14)

Traditional Compounding Pharmacies & the Patient-Specific Prescription Requirement

In contrast, federal law expressly limits traditional compounding pharmacies to providing compounded medications only to specific, individually identified patients. Section 503A(a) of the FFDCA exempts traditional compounding pharmacies from compliance with certain provisions of the FFDCA (namely, compliance with good manufacturing practices, providing adequate directions for use on the label, and requiring that the medications compounded by FDA-approved) "if the drug product is compounded for an identified individual patient based on the unsolicited receipt of a valid prescription order or notation." Under federal law, a compounding pharmacy either may compound a medication after receiving a patient-specific prescription or may compound a medication in anticipation of receiving the patient-specific prescription, but not allow the medication to leave the compounding pharmacy until receipt of the patient-specific prescription. (See FFDCA Section 503A(a); *State Oversight of Drug Compounding, A Report*

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COMPOUNDING MEDICATIONS

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from *The Pew Charitable Trusts and the National Association of Boards of Pharmacy* (February 2018) “Section 503A does not provide for distributing a compounded drug product before receiving a valid prescription order for an identified individual patient.” (“*Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act*,” page 8, Guidance for Industry (December 2016) at <https://www.fda.gov/media/97347/download>) “To meet the prescription requirement, a prescription must identify the patient for whom the drug has been prescribed. If the identity of the patient is not given or is not clear, it will not satisfy this requirement. For example, a prescription would not satisfy the requirement if it is written for the prescriber, when the prescriber is not also the patient.” (“*Prescription Requirement*” Guidance, page 10-11) As such, compounding pharmacies are prohibited from compounding medications for “office stock.”

Florida Law

In 2017, the Florida Board of Pharmacy revised Rule 64B16-27.700, *Florida Administrative Code*, to avoid “conflict with state and federal law and to make clear

that office use compounding of products intended for human use (sterile and non-sterile) shall require being registered as an Outsourcing Facility,” as defined by Section 465.003(19), *Florida Statutes*. (<https://floridaspharmacy.gov/Meetings/Agendas/2017/12-december/12122017-ccagenda.pdf>) As such, Rule 64B16-27.700, *Florida Administrative Code*, prohibits traditional compounding pharmacies not also registered with the FDA as an outsourcing facility from providing compounded medications as office stock.

Conclusion

Office stock plays a large role in patient care and with the ability to obtain from outsourcing facilities compounded medications that are customized to the needs of a certain segment of a practitioner’s patients, the importance of access to compounded medication for use as office stock is sure to grow. However, it is important to understand from where compounded medications can be obtained without running afoul of state and federal law because compounding pharmacies found to be releasing medications compounded without first receiving a patient-specific prescription have been found to be in violation of the FFCA. See <https://www.fdanews.com/ext/resources/files/2018/2/10-04-18-InnovativeIntrathecalSolutions.pdf?1538681087>; <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/custom-rx-llc-dba-custom-rx-pharmacy-and-wellness-concepts-559540-10182018>; and <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/raniers-compounding-laboratory-521003-03282017>) Failure to comply with this prohibition can result in permanent injunctions against the compounding pharmacy. (See <https://www.fda.gov/news-events/press-announcements/federal-judge-enters-consent-decree-against-texas-compounder-guardian-pharmacy-services>)

Deirdre Boling-Lewis is General Counsel of Sincerus Pharmaceuticals, Inc. where she has broad responsibilities for the operation of the legal department, compliance, and government relations. Previously, Ms. Boling-Lewis was with Kaiser Foundation Health Plan, Inc, where she provided strategic leadership for Kaiser’s national pharmacy program, and at Walmart Stores, Inc., where she spent 10-years in the Legal Department at Walmart Stores, Inc. in Bentonville, Arkansas, supporting Walmart’s Health & Wellness division.



Ethics Questions?

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