FDA Drug Compounding Law and What It Means for Dentists

by C.Scott Litch Chief Operating Officer and General Counsel

The FDA Modernization Act of 1997 **(DAMA)**[1] added Section 503A, providing that a drug product can be compounded by a licensed pharmacy or physician either: (1) based on the receipt of a valid prescription order for an identified individual patient; or (2) in limited quantities before the receipt of a valid prescription for an individually identifiable patient. The latter process is known an anticipatory compounding, which is permissible if:

- The compounding is based on a history of the licensed pharmacist or physician receiving valid prescription orders for the compounding of the human drug product; and
- The orders have been generated solely within an established patient-pharmacist or patient-prescriber relationship.

Due to a contaminated fungal meningitis outbreak involving 750 patients in 20 states and over 60 deaths,[2] in 2013 Congress enacted the Drug Quality and Security Act **(DQSA)**.[3] The DQSA clarified that Section 503A is still in effect (some advertising provisions had been declared unconstitutional in court cases) and established Section 503B which authorized FDA oversight of compounding pharmacies known as outsourcing facilities.[4] The FDA issued subsequent guidance in 2016 on the 503A provisions.[5]

The primary role of a 503B outsourcing facility is to produce large batches of sterile products with or without a prescription. These drugs are then procured by health care facilities for patient use. 503B outsourcing facilities differ from a traditional pharmacy. Most hospitals obtain their compounded drugs from an outsourcing facility.[6] This of course is not typical for a private dental practice, who usually work with a local pharmacist.

Is a dentist eligible for ordering compounded prescriptions via the Section 503A process?

In general, the answer should be yes. The Social Security Act definition of a "physician" includes dentists, and this definition is referenced in many federal laws:

> "(r) The term "physician", when used in connection with the performance of any function or action, means (1) a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action (including a physician within the meaning of section 1101(a)(7)), (2) a doctor of dental surgery or of dental medicine who is legally authorized to practice dentistry by the State in which he performs such function and who is acting within the scope of his license when he performs such functions . . ."[7]

In the FDA's 2016 guidance document referenced above (Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act), the following is stated:

> "For purposes of section 503A(a), a valid prescription order for a compounded drug product means a valid prescription order from a licensed physician or other licensed practitioner authorized by state law to prescribe drugs (prescriber)." P. 7

To be 100 percent certain, pediatric dentists should consult state law and state dental board regulations to confirm their authorization to prescribe drugs. For example in Illinois:

> "Licensed dentists in Illinois may write prescriptions only in connection with dental-related ailments or conditions. To write a prescription for any other non-dental condition is a violation of the Illinois Dental Practice Act and may make the dentist liable for license sanction."[8]

Consumers with questions about dentist prescriptions might do an internet search and come across this a blurb on WebMD:

> "There are a number of different drugs your dentist may prescribe, depending on your condition. Some medications are prescribed to fight certain oral diseases, to prevent or treat infections, or to control pain and relieve anxiety."[9]

There is also an entire national alliance that represents pharmacy compounding (*https://a4pc.org/*). For further information contact Chief Operating Officer and General Counsel C. Scott Litch at (312) 337-2169 ext. 29 or *slitch@aapd.org*.

This column presents a general informational overview of legal issues. It is intended as general guidance rather than legal advice. It is not a substitute for consultation with your own attorney concerning specific circumstances in your dental practice. Mr. Litch does not provide legal representation to individual AAPD members.

[1] *Pub. L. No.105-115. https://www.govinfo.gov/content/pkg/PLAW-105publ115/pdf/PLAW-105publ115.pdf*
[2] *https://www.cdc.gov/hai/outbreaks/meningitis/html*
[3] *Publ. L. No. 113-54 https://www.govinfo.gov/content/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf*
[4] *https://www.fda.gov/drugs/human-drug-compounding/compounding-laws-and-policies*
[5] *https://www.fda.gov/media/94393/download*
[6] *https://oig.hhs.gov/oei/reports/oei-01-17-00090.pdf*
https://www.fda.gov/drugs/human-drug-compounding/information-outsourcing-facilities
[7] *42 U.S. Code § 1395x, (r).*
[8] *https://www.isds.org/advocacy/il-dental-practice-act-rules/il-controlled-substance#:~:text=Prescription%20Writing%20Authority,dentist%20liable%20for%20license%20sanction.*
[9] *https://www.webmd.com/oral-health/medications-used-dentistry*

Several members of the Kellogg Leadership Institute cohort VI who attended POHAC pose with the AAPD's Issues Packet for Members of Congress. (L-R) Drs. Anthea Mazzawi (Canton, Ga.), Natalie Mansour (Glendale, Calif.), Jennifer Cully (Cincinnati, Ohio), Barrett Peters (Charlottesville, Va.), Jeffrey Rhodes (Rogers, Ark.), Bernard Larson (Mount Vernon, Wash.), Elise Sarvas (Minneapolis, Minn.), Suzanne Fournier (New Orleans, La.), and Hakan Koymen (Perry Hall, Md.). Mansour, Rhodes, Sarvas, and Fournier serves as Public Policy Advocates for their state chapters. Peters serves as Southeastern district representative on the Council on Government Affairs (CGA), and Larson serves as a consultant to CGA.