California State Board of Pharmacy Wins Ninth Circuit Appeal: Outsourcing Facilities Subject to State Regulation

By Jonathan Keller and Libby Baney

On June 17, 2020, the U.S. Ninth Circuit Court of Appeals issued its ruling in the case *Fusion IV Pharm., Inc. v. Sodergren*.[1] This case has been closely watched by boards of pharmacy as it addresses a state board's ability to concurrently regulate federally-registered outsourcing facilities. The June decision affirmed a lower court decision that California's state law regulating outsourcing facilities is not preempted by federal law.

Federal Regulation of Outsourcing Facilities

In 2013, Congress enacted the Drug Quality and Security Act (DQSA) which, among other things, established a new category of pharmaceutical entities known as "outsourcing facilities." Outsourcing facilities are required to register with the Food and Drug Administration (FDA) and comply with relevant federal regulations, including Current Good Manufacturing Practices, as such entities are permitted to engage in large scale compounding of drug products for interstate commerce.[2]

Subsequently in 2017, California passed its own law which, among other things, requires a facility registered as an outsourcing facility with FDA to be concurrently licensed by the California Board of Pharmacy.[3] These two laws set the stage for the dispute in Fusion IV v. Sodergren and the resulting decision by the Ninth Circuit.

Fusion IV v. Sodergren

Fusion IV Pharmaceuticals, Inc., also known as Axia Pharmaceuticals, and its owner, Navid Vahedi (collectively, "Fusion IV"), argued that California is prohibited from licensing outsourcing facilities because such state licensing is preempted by the federal DQSA and also violates the Commerce Clause of the U.S. Constitution.

Fusion IV was an FDA-registered outsourcing facility located in California that, pursuant to such registration, sought to compound and distribute its drug products in interstate commerce. Under the DQSA an outsourcing facility is not required to be a licensed pharmacy.[4] However, California law required FDA-registered outsourcing facilities to be concurrently licensed by the California Board of Pharmacy as an outsourcing facility if such facility compounds non-patient-specific drug products for distribution within or into California.[5] Fusion IV's activities clearly fell within this category.

In 2017, Fusion IV obtained its outsourcing facility registration from the FDA and then applied for state licensure with the California Board of Pharmacy. The California Board of Pharmacy, however, denied Fusion IV's state licensure application for its outsourcing facility because there was a pending board disciplinary action against Vahedi and another pharmacy facility he owed.

Unwilling to issue Fusion IV a state outsourcing facility license, the California Board of Pharmacy subsequently ordered Fusion IV to cease all operations as an outsourcing facility in California. In response, Fusion IV filed a lawsuit in early 2019 in federal district court challenging the board's authority to require it, as an FDA-registered outsourcing facility, to be concurrently licensed by the California Board of Pharmacy. The plaintiffs argued that the state

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regulation of outsourcing facilities by California was preempted by the DQSA and that such regulation was an impediment to interstate commerce, violating the Commerce Clause.

The district court rejected both of the plaintiffs' arguments. The court ruled that California's state law regulating outsourcing facilities is not preempted by the DQSA, whether by express or implied preemption. Instead, the district court found that the DQSA contemplates concurrent state regulation of federally-registered outsourcing facilities. As part of its reasoning, the district court explained that it was possible for Fusion IV to comply with both federal and state licensure regulations and thus, there was no conflict between the DQSA and California law. Lastly, the district court determined that California's concurrent licensure requirement of federally-registered outsourcing facilities did not violate the Commerce Clause.

Ninth Circuit Appeal and Decision

Having lost at the district court, the plaintiffs appealed the court's decision to the Ninth Circuit and raised the same two arguments – that California is prohibited from licensing outsourcing facilities because state licensure of outsourcing facilities is preempted by the DQSA and violates the Commerce Clause.

In a concise and clear ruling, the Ninth Circuit affirmed the district court's decision and wholly rejected Plaintiffs' arguments. As to the issue of preemption, the Ninth Circuit explained:

- There is *no express preemption* because the DQSA does not "explicitly manifest[] Congress's intent to displace state law" dealing with mass compounding…express preemption, by its very definition, cannot be implied.[6]
- There is also *no field preemption*, because "the scheme of federal regulation" at issue here is not "so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it…the DQSA clearly allows for "complementary state regulation."[7]
- There is *no conflict preemption*, because it is not "impossible for a private party to comply with both state and federal [compounding] requirements." Importantly, it is possible to obtain authorization under both the state and federal regulatory schemes, because California does not necessarily require anything more than registration with the FDA before a facility can acquire a state license.[8]

As to the Commerce Clause, the Ninth Circuit found that Fusion IV "failed to establish that the requirements impose a 'substantial burden' on interstate commerce" and thus, there was no violation of the Commerce Clause.

The Ninth Circuit's decision was clear. It unequivocally upheld the lower court's ruling and agreed that California's regulatory oversight of outsourcing facilities is not preempted by the DQSA and nor do such state regulations violate the Commerce Clause's protections against state laws imposing unreasonable burdens on federal law.

The Future of State vs Federal Regulation of Outsourcing Facilities

The *Fusion IV v. Sodergren* case raised interesting arguments regarding federal preemption of state law and the concurrent state regulation of an FDA registered outsourcing facility. But what will this mean for outsourcing facilities outside of California's jurisdiction and other state boards of pharmacy?

Approximately half of the states have regulations providing for a state license for facilities registered with FDA as an outsourcing facility. And given the clear ruling by the courts in California, it would not be surprising for these state boards of pharmacy to be emboldened in their future dealings with FDA registered outsourcing facilities. Additionally, the states without licensure requirements for an FDA outsourcing facility may now consider implementing such laws. One thing is clear – state boards of pharmacy now have a federal appellate court opinion ruling that outsourcing facilities are subject to state oversight and regulation.

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[1] No. 19-55791, 2020 WL 3265221 (9th Cir. June 17, 2020).

[2] *See* 21 U.S.C. § 353b.

[3] Cal. Bus. & Prof. Code § 4129.

[4] 21 U.S.C. § 353b(d)(4)(B).

[5] *See* Cal. Bus. & Prof. Code §§ 4129, 4129.1, 4129.2.

[6] *Fusion IV Pharm., Inc. v. Sodergren*, No. 19-55791, 2020 WL 3265221, at *1 (9th Cir. June 17, 2020) (emphasis added).

[7] *Id.*

[8] *Id.*