IN THE SUPREME COURT OF OHIO

STATE OF OHIO,	:	
	:	
Appellee	:	Supreme Court Case No. _____
v.	:	
	:	
JON TROISI,	:	Eighth District Court of Appeals
NICHOLAS TROISI,	:	Case Nos. 109871, 109874,
ANDREW STECK, and	:	109875, and 109876
MARTEK PHARMACAL CO.,	:	
	:	
Appellants.	:	
	:	

MEMORANDUM IN SUPPORT OF JURISDICTION OF APPELLANTS MARTEK PHARMACAL CO., ANDREW STECK, NICHOLAS TROISI, & JON TROISI

ON APPEAL FROM THE EIGHTH DISTRICT COURT OF APPEALS

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THIS CASE INVOLVES QUESTIONS OF PUBLIC OR GREAT GENERAL INTEREST

This case presents important questions of first impression. Wholesale pharmaceutical distributors and their employees typically are exempt from Ohio's drug trafficking laws because they are in the business of lawfully selling pharmaceuticals to healthcare providers. Can a prosecutor charge a licensed wholesale distribution company and its employees as drug traffickers for selling medications to doctors without specifying what statute they allegedly violated to lose their exemption from drug trafficking laws? Can a prosecutor charge a licensed wholesale distribution company and its employees as drug traffickers for violation of a regulation alone, without any statutory authorization or notice that said violation could be criminal? This case is the first time an Ohio court has answered yes.

This Court must decide whether the 2-to-1 opinion below is correct, because this case affects the entire pharmaceutical and medical industries in Ohio, including countless companies, employees, doctors, and patients. The majority's opinion below, if allowed to stand, would also allow for a dramatic increase in the power of prosecutors and administrative agencies to pursue legitimate businesses. These are quintessential questions of public or great general interest.

The State recognizes that this is a potential watershed case. It boasted to the trial court that no prosecutor had ever tried to prosecute a licensed wholesale distributor: "Yes, Judge, we are going after a distributor, hasn't been done before. So what?"

But under Ohio law, it very much matters ***who*** is distributing or selling a controlled substance. Drug trafficking laws "do not apply" to licensed wholesale distributors that comply with Chapter 4729 of the Revised Code. *See* R.C. 2925.03(B)(1). If prosecutors are going to start charging distributors and their employees with drug trafficking, the most critical question is ***how*** they failed to comply with Chapter 4729—*i.e.*, what section of Chapter 4729 did the company

and its employees violate? If it is a regulation, which statute explicitly authorizes that regulation to form the basis of a charge? That is what this case is about: Appellants have a right to know which statute under Chapter 4729 they allegedly violated so they can understand the charges they face and can adequately prepare a defense.

The State's answer is that it does not have to offer specifics. Its indictment alleged only that Appellants conduct was not "in accordance with Chapter 4729 of the Ohio Revised Code." That statement encompasses hundreds of possible crimes:

- Chapter 4729 contains more than **120 sections** (and a multitude more subsections);
- Just one section, R.C. 4729.99, the penalty provision, lists **43 different violations** that trigger criminal penalties; and
- The accompanying Administrative Code contains **more than 100 rules**, which the panel majority said were encompassed in the indictment.

The two-judge majority determined that the indictment complied with Due Process—Appellants should just guess which of these hundreds of provisions they violated. Two other judges—the trial court and the dissent—recognized that the indictment violated Due Process because it did not sufficiently specify the alleged regulatory violations that the company and its employees committed.

The indictment leaves companies and their employees guessing how their lawful business practices suddenly turned into crimes. The trial court recognized the unfairness of the State's actions and dismissed the charges because the State did not "give the defendants notice of the statute under Chapter 4729 which causes their conduct to fall outside of the exemptions accorded to wholesale distributors." (R. 41, *State v. Steck*, Cuyahoga C.P. No. CR-19-643493-A (July 28, 2020).) The dissent asked the majority, "So what code section of R.C. Chapter 4279 or [related] administrative code . . . applies to this case?" "How can the defendants in this case prepare and

defend when the specific statute under R.C. Chapter 4729 or regulation promulgated thereto is not specified in the indictment?" *State v. Troisi*, 8th Dist. Cuyahoga Nos. 109871, 109874–76, 2021-Ohio-2678, ¶ 26 [hereinafter "Op."] (Keough, J., concurring in part and dissenting in part).

If the Eighth District's split-decision stands, the "adequate notice" of the crime charged for a wholesale distributor and its employees, which is guaranteed under R.C. 2941.05, Crim.R. 7(B), and the United States and Ohio Constitutions, would be satisfied simply by referencing an entire ***Chapter*** of the Revised Code. A prosecutor's burden to give notice of the charges against a defendant may be relatively low, but this type of expansive "notice" is no notice at all. Even the State "struggled with identifying" any statute that applied. Op., ¶ 18. If the State cannot do so, how can a charged defendant? *See, e.g.*, *State v. Nucklos*, 121 Ohio St.2d 512, 2009-Ohio-792, 904 N.E.2d 512, ¶ 20 (explaining that "proof of compliance is not peculiarly within the knowledge of the accused").

In this case, there is a reason why the State did not specify the statutory basis for stripping Appellants of their drug-trafficking exemption—there is no legal support for this admittedly novel prosecution. Indeed, despite Appellants twice asking for a more specific bill of particulars and discovery, the State never identified any applicable statute or regulation that Appellants allegedly violated. That failure violated Appellants' right to know what crime they were being charged with and a fair chance to defend themselves. Perhaps that is why the State had never attempted a prosecution similar to this before. This Court should grant jurisdiction for this appeal and resolve this split decision involving public and great general interest.

STATEMENT OF THE CASE

Appellants—a company, its owner, and individual employees—are pharmaceutical wholesalers "with a focus on obesity treatments." Op., ¶ 4. Appellants sell and distribute medications that must "be prescribed or furnished only by authorized licensed health

professionals." *Id.* ¶ 3. Appellants do not prescribe medications—nor do they sell directly to patients. *Id.* Instead, they were a properly licensed "wholesale" distributor, so they sold controlled substances to doctors or health care professions, who then in turn distributed medications to individuals. *Id.* ¶¶ 2–3; *see also* R.C. 4729.01(K). Put more simply, Appellants were the middlemen between pharmaceutical companies and doctors. Appellants bought medications in large quantities, in "wholesale," and then distributed those medications in Ohio, creating lower costs for patients.

If these medications were sold on the street, it would constitute drug trafficking under R.C. 2925.03(A). *See* Op., ¶ 10 ("There is no dispute that the drugs at issue are controlled substances that fall under the ambit of R.C. 2925.03(A)."). But under R.C. 2925.03(B), drug trafficking laws "do not apply" to Appellants. Rather, as licensed wholesale distributors, Appellants are exempt from prosecution so long as they comply with R.C. Chapter 4729.

Appellants were charged with seven counts of drug trafficking.

The State charged Appellants with seven counts of drug trafficking. (R. 1.) In the indictment, each charge recited the statutory language in R.C. 2925.03(A)(1) and listed the relevant controlled substance, quantity, and timeframe (2014 to 2017). (*Id.* at 1–4.) But this information did not really matter. "There is no dispute that the drugs at issue are controlled substances that fall under the ambit of R.C. 2925.03(A) in general." Op., ¶ 10. "Further, there is no dispute that R.C. 2925.03 applies to the defendants." *Id.* Those facts are true for every pharmaceutical company, wholesale distributor, pharmacy, doctor, or other medical professional that legitimately sells, distributes, or prescribes controlled substances. *See Nucklos*, ¶ 19.

What matters is Appellants' exemption under R.C. 2925.03(B). For that, the indictment said the same thing for each count: Appellants' distribution of the substance was "not in

accordance with Chapter 4729 of the Ohio Revised Code." The indictment did not provide any additional details, facts, or explanation about how Appellants allegedly violated "Chapter 4729 of the Ohio Revised Code." *See* Op., ¶ 29 (Keough, J., dissenting in part).

Appellants sought more information and moved to dismiss the indictment when the State provided no statutory violation.

To try to figure out how they allegedly lost their exemption, Appellants sought a bill of particulars and discovery from the State. (R. 6, 8.) In response, the bill of particulars merely repeated the language from the indictment and did not identify any specific statute under Chapter 4729 that Appellant allegedly violated. (R. 11.) The discovery showed the volume of medications (and orders) that Appellants distributed to doctors, as reported by Appellant Martek. *See* Op., ¶ 5. (*See also* R. 10.) But the State never identified any specific statutory basis for how Appellants allegedly lost their exemption from prosecution. Still without answers, Appellants moved *again* for a "more specific" bill of particulars (R. 13), and when that also failed, Appellants moved to dismiss the indictment.

At multiple hearings, the State relied on different statutes and regulations, none of which applied to a wholesale distributor like Appellants.

At a March 9, 2020 hearing, the State finally "asserted that defendants' conduct was in violation of R.C. 4729.291." Op., ¶ 25 (Keough, J., dissenting in part). This statute "provides that a prescriber may not prescribe over 2,500 pills of a controlled substance in a one-month period." *Id.* Appellants are not a "prescriber." *See* R.C. 4729.01(I).

At that point, the State's "theory was that if prescribers cannot prescribe more than 2,500 pills of a substance per month, it must be illegal for wholesalers to sell more than that amount each month to the prescribers." *Id.* The State cited no authority for such an expansive reading of R.C. 4729.291. That is perhaps why, at the next hearing (on Appellants' motion to dismiss), the

State "abandoned that argument, conceding that R.C. 4729.291 does not apply to defendants because they are wholesalers of dangerous drugs, not prescribers." Op., ¶ 25 n.5 (Keough, J.).

The State then tried a new argument—this time focusing on the Ohio Administrative Code. The State "argued that Ohio Adm. Code 4729:6-3-05, regarding a distributor's duty to monitor and report orders of unusual size to the Ohio Pharmacy Board, applied to defendants." *Id.* Appellants objected to the State's attempt to bring charges based on a rule rather than a statute. Regardless, there was another problem with this rule. It "went into effect April 30, 2019," long after Appellants' indicted conducted that "occurred from 2013 to 2017." *Id.*

The trial court recognized this unfairness and dismissed the indictment.

The trial court dismissed the indictment because "it does not give the defendants notice of the statute under Chapter 4729 which causes their conduct to fall outside of the exemptions accorded to wholesale distributors." (R. 41.) Without giving notice of *any* statute within the chapter, the indictment violated the "well settled" rule that "an indictment must give defendants sufficient notice of the charges in order to prepare a defense." *Id.*

The trial court only did so after it gave the State additional time "to supplement the record with statutory provisions defendants allegedly violated," and which "are applicable to defendants." The State failed to do so. In dismissing the indictment, the trial court correctly explained that "this is not something that defendants should be surprised about at trial."

A split Eighth District Court of Appeals reversed.

The Eight District reversed with a split decision. Op., ¶¶ 1– 22 (Gallagher, J.); *id.* ¶¶ 23–33 (Keough, J., concurring in part and dissenting in part).[1] The majority recognized that an

[1] The dissent agreed that the case should have been dismissed without prejudice. But regardless, this Court's guidance is critical for determining what an indictment must include to satisfy Due Process in these drug-trafficking-exemption cases.

indictment must "contain[] the elements of the offense charged and fairly inform[] a defendant of the charge against him which he must defend," *id.* ¶ 14 (quoting *State v. Jackson*, 134 Ohio St.3d 184, 2012-Ohio-5561, 980 N.E.2d 1032, ¶ 13), but it said that the State is not "required to include the specific provisions of R.C. Chapter 4729 . . . in the indictment or the bill of particulars in order to satisfy constitutional due process requirements." *Id.* ¶ 7 (characterizing the statutory provision needed to strip Appellants' exemption as a "predicate element").[2] Applying the majority's logic, Appellants would have to wait until trial to discover which specific statute under Chapter 4729 of the Revised Code the State would present to the jury as the violation that stripped Appellants of their exemption. *Id.* ¶ 11, 15.

Worse still, the majority created an even heavier burden for Appellants by determining that Ohio law allows the State to indict a distributor and its employees for drug trafficking based on conduct that allegedly "*violated statutes or regulations*." *Id.* ¶ 18 (quoting *Nucklos*, ¶ 22). Ohio law does no such thing—nor does the text of R.C. 2925.03(B)(1), which preserves a distributor's exemption if its "conduct is in accordance with" Chapter 4729 of the Revised Code. R.C. 2925.03 says nothing about regulations the Board of Pharmacy may adopt. Yet the majority would leave Appellants guessing which statute *or* regulation, out of hundreds, the State might present at trial. *Id.* And if Appellants guessed incorrectly, the company's employees risked

[2] The majority also seemed confused about the real issue in the case. The majority viewed Appellants' argument as, "the state will be ***unable to demonstrate*** the inapplicability of R.C. Chapter 4729" at trial. *See* Op., ¶ 10 (emphasis added). Not so. Appellants did not make an evidentiary challenge. Indeed, Appellants had no idea if the State could demonstrate a violation at trial because it still had no idea which of the numerous potential violations of the sections, violations, and rules of Chapter 4729 the State would be trying to prove at trial. Armed with that misunderstanding, the majority excused the lack of specificity in the indictment because "it is purely speculation" whether the State will meet its burden at trial. *See id.* ¶¶ 10–11, 15, 18.

significant jail time. That is an overwhelming burden, especially when even "the state struggled with identifying the correct administrative code sections." *Id.*

The majority then speculated about what theory the State might present at trial. *Id.* ¶¶ 17–21. The majority found, *sua sponte*, O.A.C. 4729-37-03(C), which at the relevant time, required wholesale distributors to "report . . . drug transactions" to the Pharmacy Board. *Id.* ¶ 18. According to the majority, the State "intended to demonstrate at trial that the defendants failed to report the sales of the drugs to the board of pharmacy."[3] *Id.*

The majority also examined R.C. 4729.291 despite the State's concession that it did not apply. The majority ignored this concession—and the plain language of R.C. 4729.291—which does not apply to wholesale distributors. *See id.* ¶ 21. The majority also offered a new, alternative theory: "the defendants essentially conspired to violate R.C. 4729.291, which expressly limits the amount of dosages that any one prescriber can furnish to patients in a given 30-day period." *Id.* ¶ 21. Appellants were never charged with conspiracy. *See* R.C. 2923.01. In reaching this conclusion, the majority created a theory of criminal liability that, in light of the State's concession, *could not have been* presented to the grand jury.

The majority concluded by doubling-down on its errors. First, it concluded that whether Appellants violated Chapter 4729 is "not capable of determination without a trial on the general issue." *Id.* ¶ 22. In doing so, the majority ignored the State's legal obligation to first give Appellants notice of the alleged violation. Second, the majority miscited *Jackson* and misstated Ohio law, holding: "Under Ohio law, the state need not include the specific statutory sections that constitute the predicate element of a criminal charge." *Id.* (citing *Jackson*, 2012-Ohio-5561,

[3] The majority reached this conclusion without any examination of the State's grand jury presentation and after the State had switched theories of prosecution on the trial level. That is, at best, absolute speculation.

¶ 13). That is not the law in Ohio (nor does *Jackson* actually say that). *Id.* Rather, as this Court said in *Buehner*, even for "a predicate offense," an indictment must, at a minimum, make "reference ***to the statute number***." *State v. Buehner*, 110 Ohio St.3d 403, 2006-Ohio-4707, 853 N.E.2d 1162, ¶ 11 (emphasis added).

The dissent got it right, concluding that "the state's failure to specify the specific statutory section of R.C. Chapter 4729 or administrative code section that the defendants allegedly violated was prejudicial because it prevented them from adequately preparing or presenting a defense at trial." *Id.* ¶ 24 (Keough, J.). The dissent further noted that "[t]he record reflects that the state has continually changed its theory regarding how the defendants' conduct was allegedly 'not in accordance' with R.C. Chapter 4729." *Id.* ¶ 25. The dissent detailed how the State, when pressed for specifics, cited R.C. 4729.291. *Id.* But the State has now "expressly conceded . . . that the statute does not apply to the defendants." *Id.* ¶ 25 n.5. The dissent then explained how the State pivoted to O.A.C. 4729:6-3-05, until the State realized that the rule went into effect *after* the time period that it charged Appellants. *Id.* ¶ 25.

This analysis left the dissent with the same frustration that Appellants faced. It recognized that the majority's opinion created more questions than answers. "So what code section of R.C. Chapter 4729 [or related rule] applies to this case?" *Id.* ¶ 26. "Did the defendants' conduct involve overselling, as the state first alleged, or underreporting, as it now contends?" *Id.* "Will the state's theory of the defendants' alleged noncompliance with R.C. Chapter 4729 change yet again before the case goes to trial?" *Id.* And, most importantly, the dissent asked, "How can defendants in this case prepare?" *Id.*

These questions led the dissent to an important conclusion: "Under the state's ever-evolving theory of the case it is not clear that the facts relied upon by the state to support the

defendants' alleged violation of R.C. Chapter 4729 were those presented to the grand jury to obtain the indictment." *Id.* ¶ 27. The State cannot try Appellants for a crime that the grand jury did not indict them for. *Id.* (case citations omitted).

The dissent then dismissed the majority's speculation that this case is about O.A.C. 4729-37-03(C), which as the dissent noted, the State ***never mentioned***. *Id.* ¶ 31. As a result, "it is impossible to know what the state intended to demonstrate at trial with respect to this regulation." *Id.* This led to the dissent's conclusion, reaffirming a fundamental principle of Ohio law: "Due process requires the state to give a criminal defendant fair notice of the charges against him to permit adequate preparation of his defense for trial." *Id.* ¶ 32. The State "prejudicially misled" Appellants by failing to provide that notice.

PROPOSITIONS OF LAW AND ARGUMENTS IN SUPPORT

Proposition of Law I: The Ohio and United States Constitutions require notice of the statute that a wholesale distributor allegedly violated to lose its exemption from drug trafficking laws in order for the State to charge the distributor with drug trafficking.

The Ohio Constitution guarantees every criminal defendant the right to know "the nature and cause of the accusation against him." Section 10, Article 1, Ohio Constitution. So does the U.S. Constitution—an indictment must "fairly inform[] the defendant of the charge against which he must defend." *United States v. Bailey*, 444 U.S. 394, 414 (1980) (quoting *Hamling v. United States*, 418 U.S. 87, 117 (1974)). This "guarantees an accused that the essential facts constituting the offense for which he is tried will be found in the indictment by the grand jury." *Jackson*, 2012-Ohio-5561, ¶ 12. The purpose of this requirement is two-fold: (1) it identifies and defines the charged offenses, which protects a defendant from future prosecutions for the same offense, and (2) it compels the State to set forth "all material facts constituting the essential elements of an offense, thus affording the accused adequate notice and an opportunity to defend." *State v. Childs*, 88 Ohio St.3d 194, 198, 724 N.E.2d 791 (2000).

For the latter, an indictment is sufficient if it "tracks the language of the charged offense ***and*** identifies a predicate offense by reference to the statute number." *Buehner*, 2006-Ohio-4707, ¶ 11 (emphasis added). For example, this Court evaluated an indictment for "ethnic intimidation" under R.C. 2927.12. *Id.* ¶ 12. "An element of [that] offense . . . is that the accused violated one of the predicate offenses identified" in the statute. *Id.* The indictment, then, was sufficient because it specified one of the predicate statutes—R.C. 2903.21 (aggravated menacing). *Id.* In contrast, if the indictment had referenced only Chapter 2903, the defendant would have been left guessing which of the more than 20 crimes listed in that Chapter (ranging from murder, stalking, assault, and even hazing) he allegedly violated as the predicate offense.

The same is true here. As this Court already determined, the State cannot convict a licensed health professional for trafficking drugs under R.C. 2925.03(A) *unless* it shows how that professional lost his exemption under subsection (B). *Nucklos*, 2009-Ohio-792, ¶ 21. The State stipulated to this point in the trial court—Appellants are exempt from prosecution "as long as they complied with the requirements applicable to wholesale distributors pursuant to Chapter 4729 of the Ohio Revised Code." (R. 41.) That showing is "an element of the offense of drug trafficking." *Nucklos*, ¶ 21; *State v. Horner*, 126 Ohio St.3d 466, 2010-Ohio-3830, 935 N.E.2d 26, ¶¶ 8–9 (requiring sufficient notice "of all the elements of the offense"). As the majority below put it, Appellants' noncompliance is "a predicate element" of the crimes charged. Op., ¶ 12, 22. As a result, the State was required, at a minimum, to identify the "predicate offense by reference to the statute number." *Buehner*, 2006-Ohio-4707, ¶ 11.

Purportedly relying on *Jackson*, the majority wrote that "there is no constitutional mandate that the state present the specific provisions implicated by the predicate element under R.C. 2925.03(B)." Op., ¶ 12; *see also id.* ¶ 22. But *Jackson* said no such thing. Instead, this

Court correctly explained that an indictment "is not defective for failing to identify the ***elements*** of a predicate offense." *Jackson*, 2012-Ohio-5561, ¶ 14 (emphasis added). So while an indictment need not list all the elements of a predicate offense, it must still give notice of the specific predicate offense itself. *Id.* (citations omitted). That is all Appellants asked for here.

This result also tracks indictments for other crimes with predicate acts. For example, when charging a defendant with a pattern of corrupt activity, the indictment must include notice of the "predicate offenses comprising the pattern of corrupt activity." *State v. Siferd*, 151 Ohio App.3d 103, 2002-Ohio-6801, 783 N.E.2d 591, ¶ 23 (3d Dist.). This notice, including the "identification of the predicate acts in the indictment," "provides some assurance the defendant was indicted on the same essential facts on which he was tried and convicted." *Siferd*, ¶ 23; *see also State v. Childs*, 88 Ohio St.3d 194, 199, 724 N.E.2d 781 (2000) (explaining that "an indictment for conspiracy requires more than a mere recitation of the exact wording of the statute defining the offense of conspiracy," it must also allege "some specific, substantial, overt act," as found in a different statute, "performed in furtherance of the conspiracy").

The State has never articulated the essential elements of the drug trafficking charges. *See Nucklos*, 2009-Ohio-792, ¶ 21. Still today, the State has failed "to specify the specific statutory section of R.C. Chapter 4729 . . . that the defendants allegedly violated." Op., ¶ 24 (Keough, J.). Appellants, some of whom are facing significant jail time, do not know the violations they committed that turns them from legitimate wholesale distributors into drug-traffickers.

Proposition of Law II: For a wholesale distributor to lose its exemption from drug trafficking laws, its conduct must violate a statute in Chapter 4729 of the R.C.

Ohio has statutory offenses. R.C. 2901.03(A); *State v. Fremont Lodge of Legal Ord. of Moose*, 151 Ohio St. 19, 22 (1949). To determine whether certain conduct is (or is not) a crime, the Court "look[s] to the text of the statute." *State v. Pendergrass*, 162 Ohio St.3d 25, 2020-

Ohio-3335, 164 N.E.2d 306, ¶ 2. Like all statutes, the Court applies the plain language. *Id.* ¶¶ 5, 7. But for criminal statutes, like R.C. 2925.03, the Court is also "mindful of the rule of lenity," resolving any doubts in Appellants' favor. *Id.* Thus, to determine ***how*** a distributor can lose its statutory exemption, the Court should "begin with the statutory language." *Id.* ¶ 5.

R.C. 2925.03(A) lays out what constitutes a trafficking offense. For wholesale distributors, subsection (A) does not matter because their entire business involves selling controlled substances. R.C. 2925.03(B) provides the exemption:

> This section does not apply to any of the following:
>
> (1) Manufacturers, licensed health professionals authorized to prescribe drugs, pharmacists, owners of pharmacies, and other persons whose conduct is in accordance with Chapters 3719., 4715., 4723., 4729., 4730., 4731., and 4741. of the Revised Code . . . .

Wholesale distributors are not specifically mentioned in the exemption, so they fall under the final catchall, "other persons." Relevant here is Chapter 4729, which covers a "wholesale distributor" like Appellants. R.C. 4729.01(O). As a result, for Appellants to keep their exemption, their conduct must be "in accordance with ***Chapter***[] . . . 4729 . . . of the Revised Code." R.C. 2925.03(B)(1) (emphasis added). That is all the text says, and that should be the end of the analysis. *See Cleveland Elec. Illuminating Co. v. Cleveland*, 37 Ohio St.3d 50, 524 N.E.2d 441, 445 (1988) ("Courts are commanded to refrain from inserting or deleting words.").

Yet the majority determined that a wholesale distributor could lose its exemption simply by violating a rule adopted by the Ohio Pharmacy Board, located in the Ohio Admin. Code. Op., ¶ 18. But the text of R.C. 2925.03(B) says nothing about those rules. Rather, the "predicate element" must be rooted in Chapter 4729 of the Revised Code. To be sure, there are still more than 120 sections (and a multitude more subsections) under which the State may tether drug

trafficking charges against a distributer. But if a distributor is going to lose its exemption, it must be for a reason that the General Assembly said is sufficient. *See Pendergrass*, ¶ 15.

This does not mean that a violation of a regulation can never be the reason a wholesale distributor loses its exemption. But the General Assembly must first incorporate that regulation into a criminal statute and require compliance. For example, R.C. 3719.06 creates rules for licensed health professionals when prescribing drugs. And it requires drugs to be prescribed "in accordance with rules adopted by the state board of pharmacy." R.C. 3719.06(A)(1). R.C. 4729.16(C)(4) does the same thing, warning pharmacists that "unprofessional conduct" includes "[k]nowingly failing to maintain complete and accurate records of all dangerous drugs received or dispensed in compliance with . . . state laws ***and rules***." (Emphasis added.) *See also, e.g.*, R.C. 2903.04(B) (including "a regulatory offense" as a predicate act for involuntary manslaughter). As a result, those rules can justify a health professional losing his drug trafficking exemption because the General Assembly said the rules could.

In contrast, the majority relied on *Nucklos* to suggest that a violation of a regulation alone is enough for Appellants to lose their exemption. Op., ¶ 19. But this issue did not arise in *Nucklos* because there was a link between the applicable statute, R.C. 4731.052(B), and the relevant rule, O.A.C. 4731-21-02. *See* 2009-Ohio-792, ¶ 16. Here, the State has never provided that link. And if the State cannot root the "predicate element" to the text of a statute (which may or may not incorporate additional rules), the distributor cannot lose its exemption. *See State v. Hutton*, 6th Dist. Lucas No. L-00-1285, 2002 WL 252380, at *3–4 (Feb. 22, 2002). Yet that is exactly what the majority below did. *See* Op., ¶ 18.

The trial court recognized the problem with the majority's approach. Without some statutory hook, Appellants cannot be indicted for violation of a regulation. Moreover, without

such statutory authorization, distributors (and their employees) lack notice that a violation of some rule could risk turning their business into a criminal enterprise (resulting in significant jail time). Even the State agreed with the trial court that, "for purposes of a distributor knowing if they have violated the law, they would go to the statute to find the law." (R. 35.) Thus, for an indictment to pass constitutional muster, it must include "a statute that specifies that a violation of the Ohio Administrative Code subjects Defendants to criminal prosecution." (*Id.*) The State never provided that statute here.

CONCLUSION

This Court should grant jurisdiction and resolve these questions involving public and great general interest that affect the pharmaceutical and medical industries in Ohio, which includes countless companies and their employees, doctors, and patients across Ohio.

Respectfully submitted,

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CERTIFICATE OF SERVICE

This certifies that a copy of the above memorandum was served on the following on September 20, 2021, by email:

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