



ALAN WILSON
ATTORNEY GENERAL

February 11, 2022

The Honorable Shane Martin, Member
South Carolina Senate
211 Gressette Building
Columbia, SC 29202

The Honorable Bill Taylor, Member
South Carolina House of Representatives
416 Blatt Building
Columbia, SC 29201

Dear Senator Martin and Representative Taylor:

You have expressed concern that “hospitals across our state are refusing to allow doctors to prescribe, or their hospital pharmacies to dispense, ivermectin, hydroxychloroquine, or other 'off-label use medication' for the treatment or prevention of COVID-19.” In your letter, you cite South Carolina’s “Right to Try Act,” codified at S.C. Code Ann. § 44-137-10 et seq., as being possibly applicable to this situation, thereby permitting “these off label treatments to be used, so long as a treating physician has obtained the patient's informed consent, has not failed to check for contraindications, or has not engaged in any other professional misconduct.”

You further inquire that if a treating physician “has prescribed one of these so-called 'off label' treatments, and this patient's pharmacist has filled this prescription, under existing South Carolina law, including the provisions of our Right to Try Act and SCDHEC Regulation 61-4.100 et seq., is there any prohibition you see to this prescribed treatment then being taken to this hospital and administered to this patient?”

You also ask whether “a hospital licensed in South Carolina [may] refuse to render any off-label treatments to critically ill patients who, due to their health condition, are unable to leave those facilities voluntarily?” Also referenced is an opinion by the Attorney General of Nebraska regarding the prescription of Ivermectin as a treatment for COVID-19. You question the “constitutionality of Ivermectin suppression” by the CDC “and by extension hospitals in South Carolina who follow the CDC protocol.”

Law/Analysis

We advise that there are no easy answers to any of these questions. Each is fact -specific. Moreover, we generally do not advise with respect to questions concerning federal law. However, we note that the physician-patient relationship is given constitutional dimension by the courts and broad – if not absolute – deference in a doctor’s prescribing medications to his or her patient, whether such prescriptions relate to off-label use or not. Indeed, our Supreme Court has stated that only a licensed physician may decide what medication is to be given a patient, and in

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what dosage. Likewise, the North Carolina Court of Appeals has held that “a hospital has a duty to the patient to obey the instructions of a doctor, absent the instructions being obviously negligent or dangerous.”

In addressing your questions, we emphasize the following caveats. We do not undertake to address any particular relationship between a hospital and physicians who may be working there. Such is generally a matter of contract, varies widely from situation to situation, and thus would require factual determinations which cannot be made in an opinion of the Attorney General. Nor do we attempt to delve into questions related to the liability of a hospital for the conduct of a doctor. See generally McCord v. Laurens Co. Health Care System 429 S.C. 286, 295, 838 S.E.2d 220, 224-226 (Ct. App. 2020) [declining to impose a duty upon hospital to use due care in granting and monitoring hospital privileges].

Moreover, we do not comment upon whether the so-called “off label” medications mentioned in your letter are appropriate for the treatment or prevention of COVID-19. Such a determination is far beyond our expertise, and falls within the discretion and judgment of the treating physician. In short, we may comment generally upon the questions you raise, but only a court may rule thereupon with any degree of certainty, particularly with respect to the constitutional questions raised. Finally, we are unable to provide a legal opinion as to whether, in a given situation, a hospital possesses the right to take action against a physician who prescribes these “off label” medications for COVID-19. Again, the authority to take such action necessarily depends upon the particular facts involved and our opinion involves only a statement of the general law. See e.g. Bauman v. Mt. Sinai Hosp., 452 F.Supp. 490 (S.D.N.Y. 2006) [hospital’s summary suspension of doctor’s privileges for off-label use was reasonable, as against hospital protocol].

We first comment upon your question concerning the so-called “Right to Try” Act, codified at S.C. Code Ann. § 44-137-10 et. seq. Such Act permits the use of investigational drugs, biological products, or devices for a “terminal illness” attested to by a treating physician. Pursuant to the Act, a “terminal illness” will “result in death without life-sustaining procedures” [§ 44-137-10(3)(c)] and is an illness “not considered by a treating physician to be reversible even with administration of available treatments approved by the United States Food and Drug Administration. . . .” § 44-137-10(3)(b). The Act defines an “investigational drug, biological product, or device” as “a drug, biological product, or device that has successfully completed Phase I of a clinical trial but has not yet been approved for general use by the United States Food and Drug Administration and remains under investigation in a clinical trial approved by the United States Food and Drug Administration.” [§ 44-137-10(2)].

No previous decision of the South Carolina courts or an opinion of the Attorney General of South Carolina regarding the “Right to Try” statute has been found. However, a decision by the Court of Appeals of Texas addresses the applicability of a similar “Right to Try” statute in the context of COVID-19 and the use of Ivermectin. In Texas Health Huguley v. Jones, 2021

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WL 5405794 (2021), the Court concluded that the Texas Right to Try law was inapplicable to the use of the drugs mentioned in your letter. There, the Court explained its reasoning as follows:

First, it does not give a terminally ill patient the fundamental right to use a medicine off-label. By its own terms, the Act allows a terminally ill patient to use only an “investigational drug, biological product or device.” A medicine qualifies as an “investigational drug” if it “has successfully completed phase one of a clinical trial but has not yet been approved for general use by the [FDA] and remains under investigation in the clinical trial.” And while Mrs. Jones offered evidence that Ivermectin has already been approved by the FDA for unrelated illnesses, and that it may have an effective off-label use in the treatment of COVID-19, using a drug off-label is not the same thing as using it after a phase-one clinical trial while FDA approval is pending. . . .

Second, . . . the Right to Try Act is permissive. It authorizes terminally ill patients to use investigational drugs, and it protects the physicians and manufacturers that recommend or provide such drugs, but the Act does not require a physician to prescribe investigational drugs. . . . Thus, the Act operates to protect patients and physicians from adverse state action if they choose to prescribe such a drug. . . . In that way, this is yet another statute that provides a shield, not a sword.

We must assume that our courts would reach a similar conclusion, if and when such a question would be presented. Thus, we believe it is likely our courts would so rule similarly to the Texas decision.

Regardless of the applicability of our “Right to Try” statute, however, state law strongly protects the medical judgment of the physician in this circumstance. It is clear that an attending physician possesses especially broad discretion to prescribe what he or she deems the appropriate medication in a given situation. Courts typically afford such judgments made by the treating physician to be controlling, and rule that neither the hospital nor a court should interfere. Such appears to be the general law in other jurisdictions as well.

An earlier opinion of the Attorney General illustrates the exceedingly broad discretion given the physician in prescribing medication to the patient and concludes that a pharmacist cannot interfere in the doctor’s decision. In that opinion, Assistant Attorney General Karen L. Henderson, now a member of the D.C. Court of Appeals, stated the following:

[a] prescription by strict definition, is a physician’s written order to a pharmacist for medicinal substances for a patient. It includes directions to the pharmacist regarding the preparation and to the patient regarding the use of the medicine.

In reality, however, a prescription is infinitely more than can be simply defined. It is a summary of the physician’s diagnosis, prognosis, and treatment of the patient’s

illness. It brings to a focus on one slip of paper the diagnostic acumen and therapeutic proficiency of the physician. The prescription is an important practical phase in the application of pharmacology to clinical medicine, and combines the knowledge of the absorption, fate, excretion, action, toxicology, and dosage of drugs with the requirements for restoration of the patient's health. De Freese v. United States, 270 F.2d 730 at 733, footnote 5 (5th Cir. 1959).

Based upon this analysis, the 1976 Opinion concluded that “a regulation conferring upon a pharmacist the authority to substitute one drug for another necessarily broadens his powers in that it enables him to designate, i.e. prescribe a drug and, in effect, to replace the physician’s judgment with his own.” Op. S.C. Att’y Gen., 1976 WL 25250, No. 4408 (July 29, 1976).

Following this same reasoning, our Supreme Court has concluded that a pharmacy may not be held strictly liable for properly filling a prescription in accordance with the physician’s orders. According to the Court in Madison v. Am. Home Products Corp., 358 S.C. 449, 455, 595 S.E.2d 493, 496 (2004), “strict liability is inconsistent with the learned intermediary doctrine, which places the duty to warn on the prescribing physicians, and not pharmacists. . . .” The Madison Court proceeded to conclude that such liability “. . . would force pharmacists to refuse to stock necessary drugs because of risks involved, refuse to use less expensive generic drugs, or second guess the judgment of prescribing physicians. . . .”

The physician who prescribes a drug for “off-label” use is acting in accordance with generally accepted medical practice, as we understand it, and courts have so held. As the U.S. Supreme Court has noted, allowing physicians to prescribe for off-label use “is an accepted and necessary corollary of the FDA’s mission to regulate in this area without directly interfering with the practice of medicine.” Buckman Co. v. Plaintiffs’ Legal Comm., 531 U.S. 341, 350 (2001). And as recognized by one court,

[o]ff-label activity has been defined by the FDA as a “use for indication, dosage form, dose regimen, population or other use parameter not mentioned in the approved labeling.” [citation omitted]. . . . Off-label prescribing of drugs is both legal and ethical. The New Jersey Legislature declared “‘off-label’ use of an FDA-approved drug [to be] legal when prescribed in a medically appropriate way.” . . .

The FDA has long acknowledged that undue restrictions on off-label use could have adverse health consequences.

Bailey v. Wyeth, Inc., 37 A.3d 549, 558 (N.J. 2008). See also Cordray v. Planned Parenthood, 911 N.E.2d 871, 875 (Ohio 2009) [“Off-label use of drugs approved by the FDA does not violate federal law or FDA regulations, because the FDA regulates the marketing and distribution of drugs, not the practice of medicine.”]. Moreover, as the Nebraska Attorney General recently explained, “[p]rescribing medicines for off-label use – that is, for some purpose other than the use approved by the FDA – often falls within the standard of care. Indeed, “[o]ff-label use is

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legal, common and necessary,” . . . and “[c]ourts have repeatedly recognized the propriety of off-label use.” Neb. Op. Att’y Gen. No. 21017 (Oct. 14, 2021).

Furthermore, courts have expressed time and again a reluctance to interfere in the doctor-patient relationship or in the policies of a hospital. As one court has advised, “[t]he role of the courts is not to overrule the medical judgment of the treating physicians and the policies of the treating hospital.” Frey v. Trinity Health-Michigan, 2021 WL 5871744 (Mich. Ct. App. 2021) at * 6. In the hospital setting, our Court of Appeals has noted that “[p]atients whose treatment is under the control of a privately retained physician are in a categorically different relationship with the hospital, which is merely providing hospital care, as opposed to patients whose attending physician is provided by the hospital.” Strickland v. Madden, 323 S.C. 63, 71, n. 5, 448 S.E.2d 581, 585, n. 5 (Ct. App. 1994) (citing Brown v. Coastal Emerg. Services, Inc., 354 S.E.2d 632, 636-37 (Ga. 1987)). In the latter situation, the hospital typically takes action against a physician’s privileges if the hospital believes the physician has acted improperly. Bauman v. Mt. Sinai Hosp., *supra*.

In Simmons v. Tuomey Regional Medical Center, 341 S.C. 32, 49, 533 S.E.2d 312, 321 (2000), our Supreme Court emphasized the considerable deference, if not absolute binding nature, which must be given the medical judgment of the treating physician vis a vis the hospital. While the Court in Simmons found that Tuomey affected the “practice of medicine” through decisions related to funding, staffing etc., it did not practice medicine in the traditional sense and that medical decisions in the treatment of the patient must be left to the attending physician:

[W]e reject Tuomey Regional’s insistence that “hospitals may not practice medicine” – a point it has asserted throughout this litigation. It is true that a hospital may not decide that Patient X is to receive a dose of a particular medication twice a day; nor may a hospital order that Patient Y undergo specified tests at 2 p.m. on a particular day. Only licensed physicians may make such decisions. But the “practice of medicine” encompasses a much broader range of actions than those specific directives.

(emphasis added). In short, the Simmons Court strongly indicated that the doctor’s prescription served as a “directive,” to the hospital. See also Mills v. Angel, 995 S.W.2d 262, 274-75 (Tex. App. 1999) [“A hospital should not second guess the performance of physicians working in the hospital. . . . [M]edical decisions are to be made by attending physicians. . . . Most hospital administrators are lay persons who lack medical training.”].

Muse v. Charter Hosp. of Winston-Salem, Inc., 452 S.E.2d 589, 594 (N.C. Ct. App. 1995), *aff’d*, 464 S.E.2d 44 (1995), is particularly instructive here. In Muse, the North Carolina Court stated the following:

[o]ur Supreme Court has recognized that hospitals in this State owe a duty of care to their patients. *Id.* In Burns v. Forsyth County Hospital Authority, Inc., 81 N.C. App.

556, 563, 344 S.E.2d 839, 845 (1986), this Court held that a hospital has a duty to the patient to obey the instructions of a doctor, absent the instructions being obviously negligent or dangerous. Another recognized duty is the duty to make a reasonable effort to monitor and oversee the treatment prescribed and administered by doctors practicing at the hospital. Bost v. Riley, 44 N.C. App. 638, 647, 262 S.E.2d 391, 396, dis. review denied, 300 N.C. 194, 269 S.E.2d 621 (1980). In light of these holdings, it seems axiomatic that the hospital has the duty not to institute policies or practices which interfere with the doctor's medical judgment. We hold that pursuant to the reasonable person standard, Charter Hospital had a duty not to institute a policy or practice which required that patients be discharged when their insurance expired and which interfered with the medical judgment of Dr. Barnhill.

(emphasis added).

With respect to the liability of a hospital for a physician's negligence, the law in South Carolina has been summarized as follows:

[a] hospital may be held liable for a physician's negligence based on three theories. Under the doctrine of respondent superior, a hospital can be held liable for the torts of employees acting within the scope of employment. . . . Under the doctrine of ostensible agency or apparent authority, a hospital may be subject to suit for the acts of an independent physician. . . . In addition, pursuant to the doctrine of corporate negligence, a hospital owes a direct duty to the patient and will be liable for a breach of that duty. . . .

18 S.C. Jur. Hospitals § 14. Thus, as was stated in Muse, the "hospital has a duty to make a reasonable effort to monitor and oversee the treatment prescribed and administered by doctors practicing at the hospital."

The recent opinion of the Attorney General of Nebraska is especially instructive here. In that lengthy, well-reasoned, balanced and well-documented opinion, the Nebraska Attorney General concluded:

[i]n the end, as we explain below, we find that the available data does not justify filing disciplinary actions against physicians simply because they prescribe ivermectin or hydroxychloroquine to prevent or treat COVID-19. If, on the other hand, healthcare providers neglect to obtain informed consent, deceive their patients, prescribe excessively high doses, fail to check for contraindications, or engage in other misconduct, they might be subject to discipline. But based on the evidence that currently exists, the mere fact of prescribing ivermectin or hydroxychloroquine for COVID-19 will not result in our office filing disciplinary actions. While our terminology throughout this opinion focuses on physicians prescribing these medicines, what we conclude necessarily applies to other licensed healthcare professionals who prescribe, participate in, or otherwise assist with a treatment plan utilizing these medications.

We agree with this analysis and believe it to be consistent with the law. The Nebraska Attorney General appropriately went on to say that:

[W]e emphasize in closing that our office is not recommending any specific treatments for COVID-19. That is not our role. There are multiple treatment options outside the scope of this opinion – including treatments that have been officially approved by the FDA – that physicians and their patients should carefully consider. This opinion takes no position on them. Rather, we address only the off-label early treatment options discussed in this opinion and conclude that the available evidence suggests they might work for some people. Allowing physicians to consider these early treatments will free them to evaluate additional tools that could save lives, keep patients out of the hospital, and provide relief for our already strained healthcare system.

The analysis of the Nebraska Attorney General is well-founded, particularly the necessity of the physician obtaining the patient's informed consent. Our Supreme Court has recognized that:

South Carolina courts have specifically addressed issues involving informed consent in the context of medical care. In Hook v. Rothstein, the court of appeals explicitly held that lack of informed consent cases fall under the medical malpractice framework. 281 S.C. 541, 553, 316 S.E.2d 690, 698 (Ct. App. 1984) (holding a patient must show that, based on expert testimony of the standard of care, the physician provided insufficient information to enable the patient to make an intelligent and informed decision). Additionally, in Harvey v. Strickland, 350 S.C. 303, 312, 566 S.E.2d 529, 534 (2002), we held that South Carolina recognizes a medical malpractice claim stemming from lack of informed consent.

Linog v. Yampolsky, 376 S.C. 182, 186, 656 S.E.2d 355, 357 (2008).

Finally, we note that in 2021, the General Assembly approved a Joint Resolution providing limited immunity to physicians who prescribe off-label drugs for COVID-19. In Joint Resolution 39 (S. 147), the Legislature found that “providing businesses and healthcare providers with reasonable protections from the risk and expense of lawsuits related to actual, alleged, or feared exposure to or contraction of the coronavirus will help encourage them to reopen and remain open and will help to protect those who provided services or goods that were novel or altered in an effort to combat the coronavirus pandemic.” § 2. Among the protections granted was the “prescribing or dispensing of medicines for off-label use to attempt to combat the coronavirus.” § 3(b)(i). The immunity did not apply to “grossly negligent, reckless, willful, or intentional misconduct.” § 4(a). Section 9 of The Joint Resolution provided that:

[t]his joint resolution takes effect upon approval by the Governor and its provisions apply to all civil and administration causes of action that arise between March 13,

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2020, and June 30, 2021, or one hundred eighty days after the final state of emergency is lifted for COVID-19 in this State, whichever is later, and that are based upon facts that occurred during this time period.

Thus, the General Assembly has endorsed a physician's prescription of off-label usage of medications to combat COVID-19.

Conclusion

There are no easy answers to Covid, and thus the law should provide the broadest possible leeway to medical practitioners in treating this life-threatening disease. Therefore, even though a court is likely to conclude the "Right to Try" Act is inapplicable to the situation outlined in your letter, nonetheless, South Carolina law strongly supports the principle of no interference in a physician's prescription of medication to his or her patient, including for the treatment of COVID-19 through off-label drugs. Our earlier opinion in 1976 points out the exceedingly broad discretion given the physician in prescribing medication and concludes that a pharmacist cannot interfere in the doctor's decision. A doctor may – and often does – prescribe off-label, if in his or her judgment, such treatment is warranted. Off-label prescriptions are generally legal.

Moreover, our Supreme Court has stated that a hospital may not interfere in the medication prescribed by a physician. Indeed, the North Carolina courts have explained that "a hospital has a duty to the patient to obey the instructions of a doctor, absent the instructions being obviously negligent or dangerous." While we are unable to determine the facts in a given situation, or to determine whether off-label prescriptions of the type referenced in your letter are appropriate, we point out the general law that hospitals must generally abide by the physician's judgment in the treatment of the patient.

Furthermore, the Fourth Circuit has emphasized that the state may not violate the First Amendment rights of a doctor in his relationship with his patient. The Court has stated that "the state cannot commandeer the doctor-patient relationship to compel a physician to express its preference to the patient. . . . Transforming the physician into the mouthpiece of the state undermines the trust that is necessary for facilitating healthy doctor-patient relationships and, through them, successful outcomes. *Stuart v. Camnitz*, 774 F.3d 238, 253 (4th Cir. 2014). The constitutional right to treat a patient according to the physician's best medical judgment has been recognized.

We reference in this same regard a recent opinion of the Nebraska Attorney General. This opinion is well-researched, ably documented and we fully agree with it. The opinion of the Nebraska Attorney General is a model to be followed. There, the Attorney General of Nebraska concluded, with certain caveats, including the requirement of informed consent, that "based upon the evidence that currently exists, the mere fact of prescribing Ivermectin or Hydroxychloroquine for COVID-19" does not warrant filing disciplinary action against a

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physician. As the Nebraska Attorney General concluded, “[a]llowing physicians to consider these early treatments will free them to evaluate additional tools that could save lives, keep patients out of the hospital, and provide relief for our already strained health care system.” This conclusion is in accord with the foregoing authorities and provides sound advice.

Moreover, such a conclusion is consistent with the Legislature’s Joint Resolution in 2021 affording limited immunity for “prescribing or dispensing of medicines for off-label use to attempt to combat the coronavirus.” This is further proof that the law supports the conclusion that a hospital does not usually have the right “to interfere with the physician[’s] medical judgments in the diagnosis and care” of the patient. Kornstein v. Azla, 2016 WL 888373 at * (Conn. 2016). The doctor-patient relationship is one of the zones of privacy accorded constitutional protection. See Doe v. Bolton, 410 U.S. 179, 197-98 (1973) [The “right to receive medical care in accordance with” the licensed physician’s best judgment.].

Again, not to repeat ourselves, determination of the propriety of a prescription for Ivermectin or Hydroxychloroquine in this situation is beyond the authority or capacity of this Opinion, which is primarily a decision for the treating physician to make. We would emphasize that informed consent is a prerequisite. However, we cannot adjudge specific facts in a given situation, nor can we determine issues of federal law. Also, we note again that we do not address what action a hospital may take with respect to a physician’s privileges for off-label drug usage. But see, Bauman v. Mt. Sinai Hosp., *supra* [revocation of privileges]. Such review is more appropriately accomplished through legal analysis over a fact-specific contractual relationship between a doctor and an admitting hospital than it is under the general legal analysis provided for in this opinion. This Office is not equipped to address an infinite number of fact-specific scenarios. Nevertheless, we can point out, and fully support, the general law protecting the physician’s decision, particularly if informed consent is obtained.

Sincerely,



Alan Wilson
Attorney General