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NYSBA

Health Law Journal

A Peer Reviewed Law Journal

A publication of the Health Law Section of the New York State Bar Association

Meet the 2022 Summer NYSBA Diversity Health Law Fellows

Second Opinions Should Be Mandated in Clinical Trials When Treating Physicians Recommend Their Own Research as Treatment for a Patient's Life-Threatening Illness

Guidance on How the HIPAA Rules Permit Covered Health Care Providers and Health Plans To Use Remote Communication Technologies for Audio-Only Telehealth

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Publication and Editorial Policy

Persons interested in writing for this *Journal* are welcomed and encouraged to submit their articles for consideration. Your ideas and comments about the *Journal* are appreciated as are letters to the editor.

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Message From the Section Chair

By Jane Bello Burke

Hello, colleagues!

It is my pleasure, as the Chair of the NYSBA Health Law Section, to welcome you to this edition of the *Health Law Journal*. I am grateful to Anoush Koroghlian-Scott for her outstanding service as immediate past chair and her efforts to bring about a seamless transition. Thanks, too, to fellow officers Lisa Hayes (Chair-Elect), Mary Beth Morrissey (Vice Chair), Mark Ustin (Treasurer), and James Dering (Secretary), and our colleagues on the Executive Committee for their guidance and encouragement as we move forward into the 2022-23 term.

Last year, we had hoped 2021 would be the year we got back to business in-person. Although that was not to be, our Section carried on with online meetings, programs and events without missing a beat. Now, with signs that this will be the year we resume in-person events, we look forward to renewing old connections and creating new ones. We plan to place a priority on developing attorneys who are newer to the practice of health care law through training, networking, mentoring and other opportunities. Our priority dovetails with the goal of investing in the future of our profession, which NYSBA President Sherry Levin Wallach has set as the focus of her tenure.

We are fortunate to be able to build on the work of our prior chairs who established the Health Law Section more than 25 years ago as a forum for the exchange of ideas. Thanks to their efforts, our Section offers many options for learning, networking, practice development and mutual encouragement. Here are some of the highlights.

- **Section Committees**. The committees, it is said, are the lifeblood of the Sections. Our committees offer opportunities to meet and network with colleagues in a range of substantive areas. Go online at https://nysba.org/committees/health-law-section/ and check them out. Have you thought about serving as a chair or co-chair for a committee? Do you know someone who would be great in a leadership role? We want to hear from you!

- **Meetings and CLE Programming**. In our **Fall Meeting**, we will recognize Assemblyman Dick Gottfried, who holds the record as the longest-serving legislator in New York's history (52 years). In 1987, Assemblyman Gottfried became chair of the New York State Assembly Committee on Health. In that role, he amassed an extensive body of health care-related accomplishments. Come and learn about his legacy! For our **Annual Meeting**, NYSBA will be offering an in-person option at the New York Hilton Midtown, after two years of virtual-only attendance. Will 2023 be the year we get together again in person? Stay tuned for developments. More **CLE Programs** are in the works on current topics, including professional discipline and fraud and abuse developments. Let us know if you would like to organize or present a program in your area of interest.

- **Health Law Curriculum.** In 2021, we laid the groundwork for our Health Law Curriculum, which we envision as a comprehensive catalog of educational programs and resources on the practice of health law in New York. We are developing content and anticipate going live in the near future. Contact us if you would like to develop a program in your practice area.

- ***Health Law Journal***. We are fortunate to have the *Health Law Journal* available to us as a peer-reviewed resource to foster continuous learning. In this issue, there are articles on the No Surprises Act billing requirements; the lobbying laws applicable to not-for-profit corporations; the need for administrative action to review exposure to harmful pesticides; and the importance of second opinions when treating physicians recommend their own clinical research to treat life-threatening illnesses. For information on contributing an article for publication, please contact Cassandra DiNova.

- **Diversity Interns**. Over the past decade, the Health Law Section's diversity summer fellowship program has offered law students from diverse backgrounds an opportunity to experience health law practice. In 2022, we were pleased to place interns in positions at Westchester County Medical Center and Catholic Health Services of Long Island. We are grateful to our sponsors for partnering with us to make these positions available. If you would like to host a summer intern or know someone who would benefit from the experience, please let us know.

- **Mentorship.** In 2018, our Section implemented a mentoring initiative to pair newer health care attorneys

with more experienced practitioners who provide guidance on career development. If you are an experienced attorney, consider signing up to share your experience with someone new to our practice area. If you are a newer attorney, consider availing yourself of a mentorship opportunity. There is no substitute for professional relationships with experienced practitioners as we navigate our careers.

We hope you will get involved, stay involved and encourage others to get involved. The benefits of participation are many.

I look forward to working with you and to seeing you soon at an upcoming event!

Jane Bello Burke
Chair, Health Law Section

In the New York State Courts

By Dayna B. Tann and Marc A. Sittenreich

Southern District of New York Rejects Challenge to FDA Exemption Allowing Use of Anti-Static Chemical Compound in Dry Food Packaging

***Nat. Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 2022 WL 1094790 (S.D.N.Y. Apr. 12, 2022).** Plaintiffs are environmental, health, and consumer protection interest groups that brought an action against the U.S. Food and Drug Administration (FDA) and the FDA Commissioner in the United States District Court for the Southern District of New York, challenging a decision exempting sodium perchlorate monohydrate ("perchlorate") from certain restrictions under the Food Safety Act (FSA). Perchlorate is used as an additive in the plastic packaging of dry foods, such as cereal, flour and spices. While the purpose of this additive is to reduce the buildup of static charges in such foods that may cause a "dust explosion" during transport, perchlorate, once ingested, can disrupt the human endocrine system and affect the development of fetuses, infants, and children.

The FSA prohibits the introduction of food products into interstate commerce that are "adulterated," or contain unsafe food additives, unless there is a regulation prescribing how the additive may be used safely. However, the FDA may issue a Threshold of Regulation exemption ("TOR Exemption") excusing from the regulation requirement an additive that migrates from a "food-contact article"—e.g., food packaging or food-processing equipment—to food itself, if the additive migrates in sufficiently low concentrations.

The FDA issued a TOR Exemption for perchlorate, allowing for its use in certain concentrations in dry food packaging. Plaintiffs, along with other nonprofit organizations, submitted a citizen petition challenging the TOR Exemption and requesting that the FDA promulgate a rule banning the use of perchlorate in food-contact materials. The FDA denied the petition, as well as plaintiffs' subsequent objections to the denial.

Plaintiffs commenced this action contending that the FDA's denial of their citizen petition violated the FSA and the Administrative Procedure Act (APA) and seeking declaratory and injunctive relief. Plaintiffs then moved for summary judgment based on three grounds: (i) that the FDA violated the APA by ignoring the data and results from its Total Diet Study regarding the presence of perchlorate in the United States food supply, which it conducted in 2008 and then updated in 2016; (ii) that the FDA violated the FSA and the APA by failing to consider the cumulative effects of perchlorate in the diet; and (iii) that the FDA violated the APA by not taking into account that foods might contact multiple food-contact articles containing perchlorate. Defendants cross-moved for summary judgment, arguing that their decision did not violate the FSA and was not arbitrary and capricious in violation of the APA. By Opinion and Order dated April 12, 2022, the Southern District of New York ruled in favor of defendants, finding that their decision denying plaintiffs' citizen petition did not violate either statute.

The court first addressed plaintiffs' contention that the decision was arbitrary and capricious because the FDA failed to consider the results of the Total Diet Study. The court observed that plaintiffs did not submit the results as part of their petition, nor did they attempt to amend or supplement their petition with the results before the FDA issued the decision. Instead, they offered the results for the first time as part of their post-decision objections. As applicable regulations make clear, the administrative proceeding record closed on the date the FDA issued its decision, preventing documents from being added during the objection phase. The court noted that the plaintiffs also failed to submit a new petition to modify the FDA's decision, which is the only permissible way of introducing documents post-decision. The court further rejected plaintiffs' contention that the FDA should have considered the study results as "new information," since: (i) the addition of "new information" to the record must still comply with the established

procedures under applicable regulations; (ii) requiring agencies to consider all "new information" regardless of whether it was part of the submitted record would improperly flip the burden on the agency; and (iii) in any event, the regulations state only that an agency "may" consider new information post-decision (and is thus not required to do so). Finally, the court rejected plaintiffs' argument that the FDA needed to consider the study results because they related to "an important aspect of the problem" that the FDA has "entirely failed to consider." The court asserted that the study results did not address any aspect of the problem other than the food supply's exposure to perchlorate, which the FDA already considered at length in issuing its decision. Accordingly, the court found that plaintiffs missed their opportunity to submit the study results for consideration.

The court then turned to plaintiffs' second argument—that the FDA failed to evaluate the cumulative effects of perchlorate introduced through the TOR Exemption as well as through other sources. The court began by acknowledging that the FDA is required, under the FSA, to consider the cumulative effect of a food additive when evaluating whether it is "unsafe." This analysis is not applicable, however, when the FDA is deciding whether to issue a TOR Exemption for an additive that migrates from a food-contact article. Under those circumstances, the FDA need only determine whether the migration "is so negligible as to present no public health or safety concerns, even to assure a wide margin of safety." The court found that plaintiffs' proposed interpretation of the FSA "would eviscerate the TOR Exemption and make it meaningless."

Next, the court addressed plaintiffs' argument that the TOR Exemption violates the FSA's purpose of "protect[ing] the health and safety of the public at large" because cumulative exposure to perchlorate and other *de minimis* substances would collectively rise to harmful levels. The court rejected this argument on the basis that it was an "inherent challenge to the FDA's TOR Regulation itself," and thus plaintiffs should have raised this issue through a separate petition regarding the regulation specifically. The court also disposed of plaintiffs' contention that the TOR Regulation itself requires the FDA to consider cumulative exposure. The court noted that plaintiffs relied on a section of the regulation that merely allowed, but did not require, the FDA to reconsider TOR Exemptions under certain circumstances, and, in any event, the use of the phrase "dietary concentration" in that section did not refer to total dietary concentration under a plain reading of the regulation. Accordingly, the FDA was in no way required to consider cumulative exposure to perchlorate.

Lastly, the court addressed plaintiffs' final argument that the FDA failed to consider that food would come into contact with numerous perchlorate-containing plastics other than its final packaging. The court found that the FDA's analysis did, in fact, comply with the APA in this regard. Specifically, the FDA did not use a "consumption factor" (i.e., a variable accounting for the percentage of one's diet that consists of the perchlorate-exposed food) in assessing migration. In other words, the FDA effectively assumed that all foods an individual consumes would have touched material containing perchlorate, that all contact materials would contain perchlorate at the maximum allowed use level, and that only single-use packaging, which results in higher levels of migration, would be used. Deferring to the agency's expertise, the court found that the FDA reasonably concluded that its methodology was "significantly more conservative" and protective than that proposed by the plaintiffs and, therefore, did not violate the APA.

New York Court of Appeals Resolves MLMIC Demutualization Dispute in Favor of Employees

***Columbia Memorial Hosp. v. Hinds*, 2022 WL 1572408 (N.Y. May 19, 2022).** This case stems from the 2018 conversion of Medical Liability Mutual Insurance Company (MLMIC) from a mutual insurance company to a stock insurance company. MLMIC's demutualization generated more than $2.5 billion in cash consideration to be distributed among its members. In the ensuing years, courts throughout the state were called upon to decide who was entitled to that money: the physicians insured under MLMIC-issued professional liability policies, or the employers who paid for those policies. In *Hinds*, the Court of Appeals decided that "absent contrary terms in the contract of employment, insurance policy, or a separate agreement, the employee, who is the policyholder, is entitled to the proceeds."

By way of background, in mid-2018, National Indemnity Company (NICO) sought to purchase MLMIC for $2.502 billion. Shortly thereafter, MLMIC submitted a "plan of conversion" (the "plan") to the New York State Department of Financial Services (DFS), seeking approval to convert from a mutual insurance company—owned by its respective members—to a stock insurance company. Under the plan, the $2.502 billion in cash consideration would be distributed to eligible policyholders, defined as "each person who had a policy in effect during the three-year period preceding the MLMIC Board's adoption of the resolution" to convert. In September 2018, both DFS and two-thirds of MLMIC's policyholders approved the plan. On Oct. 1, 2018, MLMIC and NICO closed on both the demutualization and the acquisition.

Hinds brought eight separate cases before the Court of Appeals, each involving a dispute over entitlement to the MLMIC demutualization proceeds. In each case, the provider/employee was the sole named policyholder on a MLMIC professional liability policy provided by the practice/employer pursuant to their respective employment agreements. In most

cases, the employee designated the employer as the "policy administrator," and the employer handled all logistics associated with the policy—including receiving dividends and paying premiums. Despite the absence of any assignment agreement, the employers asserted they were entitled to the cash consideration by virtue of having paid all premiums for the policies. After mixed results at the trial court level, the employees prevailed in all cases before the Appellate Division. In the lead case, the Third Department held that "entitlement to the MLMIC funds is not contingent on who paid the premiums for the subject policy. Rather, the sole policyholder, here, [the employee], is entitled to receive said funds unless he or she executed an assignment of such rights to a third party."

On review, the Court of Appeals presented the issue as follows: "When an employer pays premiums to a mutual insurance company to obtain a policy for its employee, and the insurance company demutualizes, who is entitled to the proceeds from demutualization: the employer or the employee?" In answering this question, the court started and finished its analysis with the plain language of N.Y. Insurance Law § 7307(e)(3). Under that statute, a demutualization plan must include "the manner and basis of exchanging the equitable share of each eligible mutual policyholder for securities or other consideration." Further, the plan must provide that "each person who had a policy of insurance in effect" during the preceding three years "shall be entitled to receive in exchange for such equitable share . . . consideration payable in voting common shares of the insurer or other consideration, or both." The court interpreted this language to mean that "when an insurance company demutualizes, it must exchange the equitable share of 'each eligible mutual policyholder' for, as relevant here, consideration."

In each case before the court, it was "undisputed that each medical professional/employee was the sole named policyholder of a professional liability policy issued by MLMIC." Moreover, none of the eight cases involved an employment contract or other agreement purporting to "assign the employee/policyholder's rights in the demutualization consideration to anyone." As a result, the court concluded that "the medical professionals/employees are legally entitled to the cash consideration."

The court rejected the employers' claim that choosing the policies, performing administrative tasks, and paying premiums made them "de facto" policyholders. Specifically, the court noted that the "premiums paid for the cost of insurance coverage, not for an ownership interest in MLMIC. A policyholder's ownership in a mutual insurance company is an incident of the structure of mutual insurance policies, not something purchased through the payment of premiums." Further, the court found that the employers' status as policy administrator "does not convert the employer into a policyholder or member, it merely authorizes [them] to undertake various tasks on behalf of the employee policyholder." Likewise, the court rejected the employers' reliance on the formula set forth in Insurance Law § 7307(e)(3), which calculates a policyholder's "equitable share" based on "the net premiums . . . such policyholder properly and timely paid to the insurer." Citing this language, the employers contended that, because the employees did not pay any of the "net premiums," their equitable share is zero, and the proceeds belong to whomever actually paid the premiums. In response, the court ruled that this provision "merely addresses the method by which the amount of consideration is to be allocated among the members who own the mutual insurance company—the policyholders—not to whom it is payable." The court also noted that, because the employers paid the premiums on behalf of the employees, "such payments are ultimately attributable to the employee for purposes of Insurance Law § 7307."

Last, the court rejected the employers' unjust enrichment claims, thereby overruling the First Department's 2019 decision in *Schaffer, Scholholz & Drossman, LLP v. Title*, 171 A.D.3d 465. In doing so, the court remarked that "the employees should receive the cash consideration because they have lost something valuable as a direct result of the demutualization: their ownership interests as members of MLMIC." The court also found that the employees would not be receiving the cash consideration "at their employers' expense." That is, "the employers did not pay the insurance premiums gratuitously; they paid the premiums on the employees' behalf because they were contractually obligated to do so by the employment agreements that they negotiated, and the employers received the full benefit of those agreements since they received the services of the employees and the residual benefits of their staff being insured." Finally, the court saw "nothing inequitable" in awarding the proceeds to the employees, particularly since the employers "could have written agreements assigning the demutualization benefits to themselves."

Southern District of New York Dismisses Complaint Challenging Constitutionality of School Mask Mandate for Disabled Schoolchildren

***Donohue v. Hochul*, 2022 WL 673636 (S.D.N.Y. Mar. 7, 2022).** Plaintiffs, three parents of disabled children who attend school in New York City, filed a class action complaint against the governor of New York and several other state and city officials and entities (the "state defendants" and "city defendants," respectively), seeking a declaration that the statewide school face mask mandate then in effect was unlawful and an injunction preventing the state defendants and the city defendants from implementing the mask requirement for reasons related to their children's disabilities.

In their 187-page class action complaint, plaintiffs set forth three sets of claims. The first set asserted that the mask mandate violated the rights of disabled students under various federal statutes. Specifically, plaintiffs alleged that the mandate violated the Individuals with Disabilities Education Act (IDEA) and Section 504 of the Rehabilitation Act because it contravened the terms of their children's individual education plans (IEPs). Plaintiffs also alleged that defendants violated the "stay-put" provision of Section 1415(j) of the IDEA when they enforced the mask mandate during plaintiffs' administrative proceedings. Plaintiffs further alleged that the mandate violated Title II of the Americans with Disabilities Act (ADA) on the ground that a mask is an impermissible "restraint." Lastly, plaintiffs alleged that the mandate exceeded the terms of any emergency use authorization (EUA) from the U.S. Food and Drug Administration (FDA).

The second set of claims asserted that the mask mandate violated various federal constitutional rights. Among other things, plaintiffs alleged that the mask mandate violated the First Amendment Establishment Clause, the Fourth Amendment prohibition on unreasonable searches and seizures, the Eighth Amendment prohibition against cruel and unusual punishment, the Fourteenth Amendment Due Process Clause, and the Fourteenth Amendment Equal Protection Clause. Plaintiffs further asserted rights to family integrity, privacy, personal autonomy, and bodily integrity, along with a claim under 42 U.S.C. § 1983.

The third set of claims asserted causes of action under state law, including allegations that the mask mandate exceeded statutory authority. Plaintiffs also asserted that the mandate violated N.Y. Education Law § 313, which prohibits discrimination in school admissions, and Title XI of the New York State Constitution, which obligates New York to maintain public schools.

Plaintiffs moved for a preliminary injunction to enjoin the state defendants and the city defendants from further implementing a mask mandate for students enrolled in elementary and secondary schools in New York. Both the city defendants and the state defendants opposed the preliminary injunction motion. The city defendants also moved to dismiss the complaint. In a detailed decision, the Southern District of New York dismissed the complaint in its entirety and denied plaintiffs' request for a preliminary injunction.

The court began its analysis by addressing plaintiffs' federal statutory claims. The IDEA obligates states to "develop appropriate plans to provide a free and appropriate public education to children with disabilities." To satisfy that requirement, school districts must develop an IEP for each disabled student. States must also develop an administrative review process for parents who are dissatisfied with their child's education or IEP.

Plaintiffs alleged that defendants "denied their schoolchildren a free and appropriate education because defendants subjected them to 'mandatory masking, contrary to the terms of their IEPs.'" The court held that plaintiffs had not stated a failure-to-implement claim under the IDEA or the Rehabilitation Act because the complaint did not identify any provision in any of the students' IEPs that specified that the students would not wear a mask, and the IEPs themselves, which were attached to the complaint, did not appear to contain any such provisions. Moreover, the court found that plaintiffs' claim was subject to dismissal because they did not "demonstrate that the school board or other authorities failed to implement substantial or significant portions of the IEP" in enforcing the mask requirement.

The court next turned to plaintiffs' claims under the IDEA's "stay-put" provision. The statute generally provides that "during the pendency of any proceedings conducted pursuant to [the IDEA], unless the state or local educational agency and the parents otherwise agree, the child shall remain in [his or her] then-current educational placement." Plaintiffs alleged that they initiated proceedings under the IDEA and that the mask mandate altered the terms of their children's plans during those proceedings. The court held that plaintiffs failed to state a claim because they did not allege any change to the "educational placement" of their children during their alleged proceedings. The court again noted that the IEPs attached to the complaint did not address masks and thus did not direct the district not to impose a mask mandate. Furthermore, the court asserted that "educational placement," under the "stay-put" provision, "refers only to the general type of educational program in which the child is placed . . . such as 'the classes, individualized attention, and additional services a child will receive.'" Because plaintiffs did not allege that the mask mandate changed any student's educational program, classes, attention, or services, the court held that they did not allege any change in "educational placement."

The court then rejected plaintiffs' arguments that the mask mandate implemented a "mandatory restraint" in violation of the ADA, or that it exceeded the FDA's EUA for face masks. Plaintiffs were unable to identify any authority for the proposition that the ADA bars mandatory restraints, and the court found that proposition unreasonable because the ADA bars exclusion and discrimination. The court likewise disposed of plaintiffs' EUA claim because the Food, Drug, and Cosmetic Act, which authorizes the FDA to issue EUAs, contains no private right of action to challenge alleged violations.

Turning to plaintiffs' federal constitutional claims, the court similarly found no violation. The court rejected plaintiffs' First Amendment claim for multiple reasons, including that (1) statements by Governor Hochul on which plaintiffs relied were about vaccination, not masking, and therefore did not

raise any inference about the mask mandate; (2) in any event, the Second Circuit had already determined that Governor Hochul's statements "cannot reasonably be understood to imply an intent on the part of the state to target those with religious beliefs contrary to hers"; and (3) the complaint did not raise a plausible inference, as plaintiffs argued, that the mandate embraced beliefs related to humanism. With regard to plaintiffs' Fourth Amendment claims, the court held that there was no "seizure," as plaintiffs did not allege that "defendants ever "applied 'physical force to the body of a person with intent to restrain,' made a 'show of authority' that 'in some way restrained the liberty' of a person, or otherwise made a 'reasonable person' believe 'that he was not free to leave.'" The court also dismissed plaintiffs' Eighth Amendment claim because the clause prohibiting cruel and unusual punishment has no application when there has been no adjudication of guilt, such as a conviction for a crime. The court disposed of plaintiffs' procedural due process claims on the grounds that plaintiffs are not entitled to protections against government action that is legislative in nature, and plaintiffs failed to allege the loss of a protected interest. The court dismissed plaintiffs' substantive due process claims because the complaint did not raise an inference that the mask mandate undermined family integrity or revealed any private information, and because the Supreme Court and the Second Circuit have consistently stated that "the Constitution embodies no fundamental right that in and of itself would render vaccine requirements imposed in the public interest, in the face of a public health emergency, unconstitutional," including "medical freedom" and "bodily autonomy." The court found that plaintiffs had not stated an equal protection claim because they did not allege that the mask mandate discriminated against a protected class, nor did they argue that it was selectively enforced. Finally, the court dismissed plaintiffs' Ninth Amendment claim because that Amendment "is not an independent source of individual rights." Finally, finding no deprivation of substantive constitutional rights, the court dismissed plaintiffs' claim under 42 U.S.C. § 1983.

As all of plaintiffs' federal claims were dismissed with prejudice, the court denied plaintiffs' motion for a preliminary injunction. It also declined to exercise jurisdiction over plaintiffs' state claims, which were dismissed without prejudice to refile in state court.

Southern District of New York Dismisses Putative Class Action Contending That Oxford Improperly Charged Health Plan Members More for Covered Prescription Drugs Than It Paid Out to Pharmacies in Plan Benefits

***Mohr-Lercara v. Oxford Health Ins., Inc.*, 2022 WL 524059 (S.D.N.Y. Feb. 22, 2022).** Plaintiff, a former participant in an employer-sponsored health plan governed by the Employee Income Security Act (ERISA), brought a putative class action in the United States District Court for the Southern District of New York against the plan's underwriter, Oxford Health Insurance, Inc. ("Oxford"), Oxford affiliate Optum, Inc., and Oxford's pharmacy benefit manager, Optum Rx, Inc. (collectively, "defendants"). Plaintiff alleged that defendants violated both ERISA and the Racketeer Influenced and Corrupt Organizations Act (RICO) by overcharging her and other plan participants for prescription drugs. Specifically, plaintiff contended plan participants should not have had to pay any more than the "pharmacy rate"—i.e., the rate that Oxford agreed to reimburse the pharmacy—when purchasing covered prescription drugs from pharmacies participating in the plan's network. Defendants moved for summary judgment dismissal of plaintiff's claims, which the court granted in its entirety.

The court began its decision with an overview of the applicable plan terms at the time plaintiff was a member. From 2010 to 2013, prescription drug coverage was outlined in a rider to the plan's certificate of coverage, which set forth differing payment obligations for covered outpatient prescription drugs depending on where and how they were purchased. When purchasing covered prescription drugs from a "network pharmacy," plaintiff was responsible for paying the lower of the (i) applicable "out-of-pocket expense" or (ii) the "network pharmacy's usual and customary charge" for those drugs. When purchasing covered prescription drugs from Oxford's mail order supplier, however, plaintiff was responsible for paying the lower of (i) the applicable "out-of-pocket expense" or (ii) the pharmacy rate. In addition to that rider, from 2011 to 2013, Oxford circulated a "member handbook," which indicated that plan members seeking services from "network providers" would "not be responsible for any amount billed in excess of the contracted fee for the covered service." The certificate of coverage defined network providers to include physicians, certified nurse midwives, hospitals, skilled nursing facilities, and "any other duly licensed or certified institution or health professional under contract with [Oxford] to provide Covered Services to Members."

From 2014 to 2016, plaintiff's prescription drug coverage was outlined in her health plan's certificate of coverage, and not in a rider, but contained substantially the same payment obligations for members who purchased covered prescription drugs from a "Participating Pharmacy." A separate section of the certificate of coverage stated, however, that if the "allowed amount"—i.e., the rate negotiated between the plan and a "participating provider"—is less than the member's copayment, then the member is only responsible for the lesser amount.

Based on her interpretation of these terms and applicable law, plaintiff brought multiple claims under ERISA, seeking plan benefits and alleging that defendants caused a prohibited transaction and breached their various fiduciary duties. Plain-

tiff also asserted claims for violation of RICO and conspiracy to violate RICO. Defendants contended, on summary judgment, that both sets of claims should be dismissed because there was no dispute that they complied with the terms of the plan.

The court first addressed plaintiff's ERISA claims. The court noted that the purpose of ERISA is to "promote the interests of employees and their beneficiaries in employee benefit plans and to protect contractually defined benefits." The statute creates a private right of action for plan participants and beneficiaries to recover benefits or to enforce or clarify their rights under an employer-sponsored plan. It also imposes duties on plan fiduciaries and prohibits certain transactions believed to pose a "high risk of fiduciary self-dealing." The court recognized, however, that a plan fiduciary cannot be liable for breach of its duties simply by adhering to the negotiated terms of the plan, unless it involves the exercise of discretionary authority.

As the plan's certificate of coverage contained a clear choice-of-law provision, the court turned to the principles of contract interpretation under New York law. Among other things, the court described the "well settled rule" of *ejusdem generis*, which applies when "certain things are enumerated, and such enumeration is followed or coupled with a more general description." In such circumstances, the "general description is commonly understood to cover only things" that are "of the same kind or class" as "the particular things mentioned." The court also observed that "when a contract omits a term typically included in similar contracts, 'the inescapable conclusion is that the parties intended the omission.'" Furthermore, the court noted that "contracts should be interpreted to give each provision meaning and effect, and they should not be read such that any provision is rendered 'meaningless or without force or effect.'"

Applying these principles, the court held that plaintiff was not entitled to pay the pharmacy rate for covered prescription drugs purchased from network pharmacies from 2010 to 2013, and that defendants complied with the terms of the plan during that period. The court noted that the plain language of the rider made clear that plaintiff was to pay the lesser of two amounts for covered prescription drugs purchased from network pharmacies, neither of which was the pharmacy rate. The court noted that the same rider did permit members to pay the pharmacy rate when purchasing covered prescription drugs from Oxford's mail order supplier, indicating that the plan "deliberately chose not to do so for drugs purchased from Network Pharmacies."

The court then considered, and rejected, plaintiff's argument that the member handbook—which stated that plan members would not be responsible for more than the contracted fee when receiving "covered services" from "network providers"—entitled her and other plan participants to pay no more than the pharmacy rate. The court asserted that "network provider" and "network pharmacy" were "separately defined" in the plan and were thus "intended to mean different things." The court also noted that plaintiff's interpretation of "network provider" to encompass "network pharmacies" was contrary to the principle of *ejusdem generis*. It found that pharmacists and retail pharmacies are "not of the same type" as physicians, hospitals, skilled nursing facilities, and other providers expressly included in the definition of "network provider," which practice medicine and "provide emergency and long-term care to the ill and injured." The court also held that to construe the member handbook as plaintiff suggested would render the provision establishing the price of covered prescription drugs "essentially meaningless," and that even if there were an inconsistency between the member handbook and the rider, the more specific terms of the rider would control.

For similar reasons, the court held that defendants complied with the plain terms of the certificate of coverage from 2014 to 2016. Plaintiff contended that the plan's prescription drug coverage was modified by a different provision in the certificate of coverage stating that members would not be responsible for any copayment that exceeds the "allowed amount" for the service. According to plaintiff, that provision entitled it to pay no more than the pharmacy rate for covered prescription drugs purchased from a participating pharmacy. The court also found this argument unavailing for several reasons. First, the court found that it would render meaningless the participating pharmacies provision in the certificate of coverage. Second, the court recognized that since the plan entitled members to pay the pharmacy rate for prescription drugs purchased from Oxford's mail order supplier—as it did between 2010 and 2013—the plan again "deliberately chose" not to extend that payment term to prescription drugs purchased from participating pharmacies. Third, the court found that the plan separately defined participating providers and participating pharmacies—as it did with network providers and network pharmacies—and that including participating pharmacies in the definition of participating providers would likewise violate the rule of *ejusdem generis*.

Having determined that defendants fully complied with the terms of the plan, the court dismissed all of plaintiff's ERISA claims. The court then turned to plaintiff's RICO claims, which were all predicated on plaintiff's contention that defendants "intentionally overcharged her" for covered prescription drugs. Because the court found "no evidence of any underlying fraud" by defendants, it dismissed those claims as well.

First Department Orders Hospital To Disclose Identities of Sexual Assault Victims Over Claims of Quality Assurance Privilege, Doctor-Patient Privilege, and HIPAA Protection

***Newman v. Mount Sinai Med. Ctr.*, 205 A.D.3d 548 (2d Dep't 2022).** Defendant David Newman, M.D. pleaded guilty to sexually assaulting four female patients, including plaintiff, who were under his care in Mount Sinai Medical Center's emergency room between the fall of 2015 and January 2016. Plaintiff brought an action against Dr. Newman and the medical center, among others, in New York State Supreme Court, New York County. Plaintiff's claims against the medical center and related entities (collectively, the "medical center") sounded in negligent hiring, retention, and supervision of employees.

Plaintiff moved to compel the medical center to provide certain discovery, including incident reports, the identity of the three other patients who Dr. Newman pleaded guilty to assaulting, and the identity of the medical center employees who worked with Dr. Newman at the time of each assault. The medical center cross-moved for a protective order, contending that the discovery sought by plaintiff was privileged quality assurance materials under N.Y. Education Law § 6527(3) and N.Y. Public Health Law § 2805-j(1) and constituted protected health information barred from disclosure under the Health Information Portability and Accountability Act (HIPAA). The medical center also argued that it need only disclose the identity of witnesses to plaintiff's assault, and that because there were no witnesses, it was not obliged to disclose the names of employees working with Dr. Newman or the names of the three other patients who were assaulted. The Supreme Court denied plaintiff's motion to compel and granted the medical center's motion for a protective order. Plaintiff appealed.

The Appellate Division, First Department, first addressed the medical center's assertion of the quality assurance privilege to documents apart from the incident reports. The court asserted that documents generated in connection with a quality assurance review under Education Law § 6527(3) are shielded from disclosure, except as to party statements. In support of its application for a protective order, the medical center submitted an affidavit from its Chief Medical Officer (CMO) stating that she reviewed the quality assurance materials maintained in connection with the investigation into Dr. Newman, and, based on that review, there were no recorded party statements. The court took issue with the CMO's affidavit, finding that it failed to outline what specific documents were reviewed and determined to be quality assurance materials, whether the CMO considered materials related to the other three patients to be within the scope of her search, or whether the quality assurance materials contained statements attributed to anonymous sources, who may be parties. As such, the court directed the medical center, on remand, to produce any party statements that are contained in documents kept and prepared in the ordinary course of business—and not in connection with a quality assurance review—and to produce a privilege log identifying those materials covered by the quality assurance privilege. Likewise, the court directed the medical center to produce all incident reports concerning Dr. Newman generated in the ordinary course of business, and to prepare a privilege log setting forth the basis for any assertion of the quality assurance privilege.

Second, the court held that neither the doctor-patient privilege nor HIPAA could serve as a basis to withhold the identities of the three other patients who were assaulted. The court explained that the doctor-patient privilege protects information relevant to a patient's medical treatment, and not incidents of abuse separate from treatment. Moreover, the court stated that federal regulations provide an avenue for disclosure of HIPAA-protected documents if the party seeking the disclosure makes a showing of a good faith effort to secure a qualified protective order, which plaintiff did.

Finally, the court held that the names of Dr. Newman's coworkers at the time of each of the assaults were relevant, and thus must be disclosed.

New York State Supreme Court Finds That Telemetry Physician on City Emergency Response Team Was Engaged in a Governmental Function and Thus Immune From Malpractice Liability

***Artemiou v. City of New York*, 75 Misc. 3d 567 (Sup Ct., N.Y. County 2022).** Plaintiff, the administrator of the estate of decedent, brought suit against the City of New York (the "city"), New York and Presbyterian Hospital (NYPH) and several other entities and individuals in New York State Supreme Court, New York County, alleging, among other things, medical malpractice resulting in the wrongful death of decedent.

On Feb. 11, 2014, a 911 call was made requesting assistance for decedent who appeared to be having a seizure. In response, NYPH paramedics were dispatched to decedent's office. Shortly after their arrival, one of the paramedics contacted the NYC Telemetry Unit, stating that he was "fighting a patient right now." The call was transferred to a board-certified emergency physician for her authorization to give the decedent a sedative. The paramedic informed the physician of decedent's height and weight and explained that he needed to sedate him as decedent posed a threat to himself or others. The physician asked the paramedic if "anyone knew anything about [decedent] medically" and if he "could get close to [decedent]." The paramedic indicated that he could not even get

close enough to obtain a finger-stick, after which he repeated three times that decedent was "6'2" tall, 350 pounds and very, very violent." The physician authorized the use of 10 milligrams of Versed intramuscularly, directed the paramedic to read back the order, and wished him luck.

Decedent became unresponsive 10 to 15 seconds after the injection. The paramedics commenced efforts to resuscitate decedent, which took approximately 20 minutes. EKG testing confirmed that decedent had experienced an ST-Elevated Myocardial Infarction, or a cardiac arrest. Decedent was transported to NYPH, but was unable to recover consciousness or the ability to breathe outside of mechanical support during his 29-day stay. Decedent died on March 10, 2014.

The city moved for dismissal of the complaint, arguing, among other things, that the telemetry physician's conduct was immune from liability because, as a member of the city's emergency response team, she performed a governmental function. The city further argued that plaintiff failed to plead or allege the existence of a special duty between the doctor and the decedent in the Notice of Claim, Verified Complaint, or Bill of Particulars sufficient to expose the city to liability.

As a matter of first impression, the court considered whether the telemetry physician was engaged in a governmental or a proprietary function on the morning of Feb. 11, 2014, which, it noted, is the first issue to decide in a negligence claim against a municipality. Where a municipality is deemed to be engaged in a proprietary function, it is subject to suit under the ordinary rules of negligence applicable to nongovernmental parties. Typically, a governmental entity performs a purely proprietary role when its activities essentially substitute for or supplement traditional private enterprises. Conversely, a municipality is considered to be engaged in a governmental function, and thus shielded from liability, when its acts are undertaken for the protection and safety of the public pursuant to its general police powers. This immunity is not available, however, if a plaintiff is able to establish that a special duty was owed to the injured party. A special duty may arise in three situations: (1) where the plaintiff belongs to a class for whose benefit a statute was enacted; (2) where the government entity voluntarily assumes a duty to the plaintiff beyond what is owed to the public generally; or (3) where the municipality takes positive control of a known and dangerous safety condition.

Here, the court determined that the physician was acting in a governmental capacity at the time plaintiff's claim arose. It based that determination on the "specific facts of this case," including that the physician was "a member of the city's emergency response team" and that her job "was to answer telephone calls at a remote office, in a pre-hospital setting, and to respond to questions posed by paramedics 'whose range of approved emergency services is limited by law.'"

The court next addressed whether the physician voluntarily assumed a special relationship with decedent beyond the general duty that is owed to the public sufficient to create an exception to the immunity. Applying the four elements set forth in *Cuffy v. City of New York*, 69 N.Y.2d 260 (1987)—(1) "whether the municipality, through promises or actions, assumed an affirmative duty to act on behalf of the injured party"; (2) "knowledge on the part of the municipality's agents that inaction could lead to harm"; (3) "some form of direct contact between the municipality's agents and the injured party"; and (4) "the party's justifiable reliance on the municipality's affirmative undertaking"—the court concluded that she did not. The court noted that the telemetry physician was miles away from the office building at which decedent was located and completely reliant upon the representations of the on-site paramedics. Importantly, the physician made no assurances that might lead decedent or plaintiff to justifiably rely on her conduct, which is critical in establishing the existence of a special relationship.

Separately, NYPH moved for summary judgment dismissal of the complaint against it, contending that "its paramedics did not depart from accepted standards of care and that any alleged acts or omissions on their part were not a proximate cause of the decedent's injuries and death." The court granted the motion in part, because plaintiff did not address certain arguments raised therein, but found that there was sufficient evidence to submit to a jury to decide whether the defendant's conduct was the proximate cause of decedent's alleged injuries and wrongful death.

Northern District of New York Enjoins Correctional Facility Ban on Methadone for Detainees Suffering From Opioid Use Disorder

***M.C. v. Jefferson County, New York*, 2022 WL 1541462 (N.D.N.Y. May 16, 2022).** Plaintiffs, two individuals detained at Jefferson Correctional Facility (the "facility"), brought a putative class action against Jefferson County, its sheriff and undersheriff, and the administrator of the facility (collectively, "defendants") in the United States District Court for the Northern District of New York. Plaintiff claimed that defendants' implementation of a policy that banned opiate use disorder medicine (e.g., Methadone) for all non-pregnant individuals detained at the facility violated Title II of the Americans with Disabilities Act (ADA), the Eighth and Fourteenth Amendments, and related state law. On the same day that the complaint was filed, plaintiffs also moved for class certification and sought a preliminary injunction barring the enforcement of the policy pending the outcome of the lawsuit.

The court first addressed plaintiffs' motion for class certification and found that they had adequately satisfied all of the requirements under Rule 23(a) of the Federal Rules of Civil Pro-

cedure. The court held that plaintiffs established numerosity by identifying approximately 12 individuals who were impacted by the facility's ban in the month of February alone, noting that the ban would continue to apply to future detainees. As for commonality and typicality, the court held that plaintiffs carried their burden on both of these elements because the putative class shares claims based on the common application of the challenged policy of denying opioid use disorder medication. Lastly, the court held that the proposed class representatives met their burden to establish that "they will fairly and adequately protect the interests of the class" because they would be subject "to the same common course of treatment, by the same officials, on the basis of the same practices." The court certified the class, holding that this was a "prime example of a Rule 23(b)(2) class action because plaintiffs are challenging a systemic policy or practice by which all class members face denial of prescribed [opioid use disorder medication] in violation of their constitutional and statutory rights."

The court then turned to plaintiffs' motion for a preliminary injunction. The court held that plaintiffs were likely to succeed on the merits of their claim under the ADA. In so holding, the court determined that plaintiffs were qualified individuals with disabilities within the meaning of the ADA; that they were eligible for treatment while detained at the facility, which is an entity subject to Title II; and that the ban on methadone and other opiate use disorder medicines effectively deprives plaintiffs of "meaningful access" to the facility's health care services. The court also found that plaintiffs were "substantially likely to succeed on the merits of their constitutional claims," as they provided evidence that opioid use disorder is a "chronic brain disease," that "opioid withdrawal has been recognized as an 'objectively' serious medical condition by other courts" in the Second Circuit, and that "forcibly withdrawing them from medically necessary treatment . . . will expose them to the serious harms of withdrawal and the danger of relapse." The court found this same evidence to "strongly establish[]" irreparable harm and a public interest in granting the preliminary injunction.

Finally, the court noted that its decision coincides with new legislation, effective Oct. 7, 2022, which requires New York State prisons to provide "medication assisted treatment" to incarcerated individuals determined to have, and undergoing treatment for, a substance use disorder.

Third Department Denies Neurosurgical Group's Petition To Annul DOH Volume-Based Requirement for Certified Stroke Centers

***Neurological Surgery, P.C. v. New York State Dep't of Health*, 203 A.D.3d 1252 (3rd Dep't 2022).** In 2019, the New York State Department of Health (DOH) promulgated 10 N.Y.C.R.R. § 405.34, which establishes a voluntary program whereby facilities could apply to be a designated stroke center with one of three levels of specialty care—primary, thrombectomy capable, and comprehensive. The certification program was intended to provide the highest quality of care to each stroke patient by creating a "tiered system" where each facility is "independently certified as meeting the latest evidence-based standards." In connection with the regulation, the DOH issued a guidance document setting forth the prerequisites for thrombectomy capable certification. The guidance directed that certified thrombectomy capable hospitals have the ability to perform mechanical thrombectomies on a 24-hours basis, seven days a week and must have at least 15 patients for the preceding 12-months or 30-patients over a 24-month term. Lastly, the document requires that all primary neurointerventionists who perform such procedures at the facilities must have performed, as the primary operator, an average of 15 mechanical thrombectomies over the past 12-months, or 30 procedures over the last 24-months.

Petitioner, a neurosurgical group, commenced a CPLR Article 78 proceeding seeking to annul the volume requirement as arbitrary and capricious. Petitioner contended that the volume rule would "result in compromised patient care due to the lack of" certified facilities "and the increased transport time for patients to reach one of the few select hospitals." Petitioner further stated that the rule would "limit the supply of physicians qualified to perform thrombectomies" and subject the few physicians who are qualified to a "rigorous on-call schedule" that they would not be able to tolerate, thus exacerbating the problem. The New York State Supreme Court, Albany County, denied the petition, finding that the DOH had rationally determined that the volume requirement would elevate the standard of medical care given to stroke patients, thereby improving patient outcomes. Petitioner appealed.

The Appellate Division, Third Department, affirmed. The court first observed that it is required to afford a "high-degree of judicial deference" to an administrative agency, "especially when the agency acts in the area of its particular expertise," and that the petitioner challenging an agency determination bears a "heavy burden of showing that the regulation is unreasonable and unsupported by any evidence." The court also found that the record reveals that the regulation has a rational basis and is supported by medical and factual evidence. Among other things, the DOH relied upon a number of medical and stroke advisory experts, consulted numerous medical publications and studies, performed its own analysis using data from the Statewide Planning and Research Cooperative System to determine which hospitals performed mechanical thrombectomies and how many each hospital performed, and assessed whether the current number of endovascular procedures performed supported the state's needs. Consequently, the court held that the volume-based requirement has a rational basis and is therefore not arbitrary and capricious.

Finally, the court noted that petitioner's contentions were "not baseless" and that it "shares these concerns." However, the court was constrained to uphold the DOH's determination, as it "has a rational basis and is not arbitrary and capricious," even if the court "may have reached a different result."

Northern District of New York Dismisses Health Care Workers' Constitutional and Title VII Claims Against Hospital for Terminating Their Employment Pursuant to State COVID-19 Vaccine Mandate

***Doe v. Hochul*, 2022 WL 446332 (N.D.N.Y. Feb. 14, 2022).** On Aug. 26, 2021, the New York State Department of Health adopted an emergency regulation requiring most health care workers to be vaccinated against COVID-19 (the "vaccine mandate"). Among other things, the vaccine mandate eliminated a religious exemption that had been included in the first iteration of the state's vaccination requirement. Plaintiffs are four medical professionals employed by Our Lady of Lourdes Memorial Hospital (the "hospital") who claimed to have a sincere religious objection to the existing COVID-19 vaccines. Each plaintiff requested a religious exemption to the vaccination requirement from the hospital. Three of the plaintiffs alleged that they received a form letter from the hospital indicating that their refusal to comply with the vaccine mandate would be deemed a voluntary resignation. The fourth plaintiff alleged that she was similarly denied a religious exemption, but was granted a medical exemption to the vaccine mandate.

On Oct. 1, 2021, plaintiffs filed an action pursuant to 42 U.S.C. § 1983 in the United States District Court for the Northern District of New York against the hospital, New York State Governor Kathy Hochul, and New York State Health Commissioner Howard A. Zucker, alleging, *inter alia*, that their employment was improperly suspended or terminated for refusing to comply with the vaccination requirement. On Nov. 23, 2021, plaintiffs filed an amended complaint seeking relief on behalf of themselves and a putative class of similarly situated health care workers. In their five-count complaint, plaintiffs allege that the hospital, Governor Hochul, and Commissioner Zucker violated their rights under the U.S. Constitution, Title VII of the Civil Rights Act of 1964, and related state law. The hospital moved to dismiss the complaint against it for failure to state a cause of action.

The court first dismissed plaintiffs' constitutional claims against the hospital and its parent organization—which were undisputedly private entities—holding that plaintiffs' allegations were "nowhere near enough to plausibly allege state action." The court held that "the fundamental question" is "whether the private entity's challenged actions are 'fairly attributable' to the state.'" The court asserted that the fact that the hospital is licensed and regulated by the state is "not sufficient to trigger 'state action.'" Likewise, the court rejected plaintiffs' reliance on the hospital's "ideological alignment" with public statements made by Governor Hochul regarding the religious exemption, holding that plaintiffs failed to "allege facts demonstrating that the [hospital] acted *in concert with*" the state. At most, the court found, plaintiffs alleged "a course of *independent* conduct" by the hospital. The court held that a "private entity's decision to comply with a state regulation does not transform into 'state action' merely because public and private viewpoints happen to align."

The court then dismissed plaintiffs' Title VII claims because they had not properly exhausted their administrative remedies with the Equal Employment Opportunity Commission (EEOC). Under the statutory scheme, the EEOC has 180 days to review a charge, and must issue a "right-to-sue" notice at the end of that period. This "180-day window provides a critical opportunity for the aggrieved parties to conciliate and is an integral component of the Title VII scheme." The court noted that the exhaustion requirement is "not a *jurisdictional* requirement" and thus subject to equitable defenses. Nevertheless, the court found plaintiffs' argument—that the EEOC was "too busy to provide adequate relief" and that "a right-to-sue letter is just a 'formality'"—to be "insufficient to warrant equitable relief."

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In the Legislature

By Michael A. Paulsen

The New York State Legislature concluded its 2022 Legislative Session in early June. The legislative agenda was largely influenced by current external events, including the leaked draft U.S. Supreme Court decision that would overturn *Roe v. Wade*, the mass shootings that occurred both in New York and nationally, and the New York State Court of Appeals decision requiring new district lines for Congress and the state Senate to be drawn and delaying the primary for these races by nearly two months. Ultimately, the Legislature enacted a package of 10 bills related to gun violence and six bills establishing protections for those seeking or providing reproductive health care services.

The package of gun violence bills contained a significant modification to New York's "Red Flag Law," which authorizes certain individuals (i.e., law enforcement) to file an extreme risk protection order to prevent an individual who show signs of being a threat to themselves or others from purchasing or possessing any kind of firearm. S9113A (Skoufis)/A10502 (Cahill) expands this law to authorize health care providers, including physicians, registered nurses, nurse practitioners and other licensed health care professionals, to file for an extreme risk protection order against any individual they treated in the six months preceding the filing of the petition. This bill was signed by the governor immediately after session concluded.[1]

With respect to reproductive health rights, the Legislature adopted a portfolio reproductive health protection related bills designed to protect out of state patients traveling to New York for reproductive health services and New York practitioners providing services to out of patients. Enacted protections include:

- Creating a statutory exception for the extradition of abortion providers and prohibits New York State courts from cooperating with out-of-state civil and criminal cases that stem from abortions performed legally in New York;[2]
- Establishes a cause of action for unlawful interference with protected rights to protect individuals who travel to New York for reproductive health services;[3]
- Prohibit professional misconduct charges against health care practitioners in New York who provide legal reproductive health services to patients who reside in states where such services are illegal;[4]
- Allow reproductive health care services providers, employees, volunteers, patients, and immediate family members of reproductive health care services providers to enroll in the Address Confidentiality Program;[5] and
- Study and issue a report examining the unmet health and resource needs facing pregnant women in New York and the impact of limited services pregnancy centers.[6]

Despite the wide support for this legislation, lawmakers failed to come to an agreement on a constitutional amendment to secure certain reproductive rights in New York's Constitution.

For those that follow health policy in the Legislature, the impending retirement of Assemblymember Richard Gottfried, the long-serving chair of the Assembly Health Committee, marks the end of an era. Gottfried has had a significant impact on the development of health policy and evolution of the state's health care system over his 52-year tenure in the Legislature. Gottfried has authored much of the legislation that impact the everyday practice of the readers of this *Journal*, making his retirement significant to a much broader audience. Many articles have been published since he first announced his retirement that highlight his accomplishments and impact on health policy. One issue that Gottfried has long sponsored and championed was the New York Health Act, which would establish a single-payer system to provide for universal health care in New York. Single-payer advocates made a strong push for this legislation to be passed in 2022; however, it was not passed by either house. While a successor for his chairmanship has not been made, it is recognized that Gottfried's deep knowledge and understanding of health policy will be missed and present to be a difficult act to follow.

While the primary focus at the end of session with respect to health policy was reproductive health protections, the Legislature, as usual, acted on a wide range of health-related legislation. The following list reflects most of the bills passed by both houses in the health and human services arena, organized into somewhat arbitrary categories. As of this writing, the governor has not acted on many of these bills—some of which may be vetoed, although the conventional wisdom is that the governor is expected to continue the cooperative

posture with the Legislature and will be inclined to minimize the use of the veto pen. Those that have already been signed into law are noted by a reference to their chapter number**.** To check on whether a bill has been enacted, you can access the status of any legislation by clicking the home tab at the Legislative Bill Drafting Commission site at: http://public.leginfo.state.ny.us/navigate.cgi?NVMUO.

Hospitals

Restrictions on Mandatory Overtime for Nurses: A trio of bills made significant modifications to the existing law that prohibits mandatory overtime for nurses except under certain circumstances:

- A286A (Gunther)/S1997A (Jackson) establishes a mechanism for civil penalties to be imposed and overtime to be collected for a violation of current labor law restrictions on consecutive hours of work for nurses. Currently, Article 28 operators are prohibited by law from requiring a nurse to work more than that nurse's regularly scheduled work hours except in cases of a federal, state or county declaration of emergency, a health care disaster, an ongoing medical or surgical procedure, or other emergencies.
- S4885A (Savino)/A181A (Gunther) expands this law to include Article 36 providers within the definition of employer.
- S8063A (Ramos)/A8874B (Joyner) modifies the existing statutory exceptions to the restrictions on nurse work hours. For the exception related to a health care disaster, the limitation on mandatory overtime shall not exceed three consecutive days. For the exception related to a declared emergency, the bill provides that the limitations on mandatory overtime shall be reinstated at the end of the declared emergency or after 30 consecutive days, whichever is shorter. The bill also expressly provides that a staffing emergency does not include routine nurse staffing needs that arise from typical staffing patterns, levels of absenteeism, and time off approved for vacations, sick leave, and personal leave.

Medical Debt Collection (S6522A Rivera/A7363A Gottfried): This bill prohibits hospitals and health care providers from placing a lien on an individual's primary residence or securing wage garnishments to satisfy a judgment in a medical debt action against an individual.

Facility Fee Notification (S2521-C Rivera/A3470-C Gottfried): This bill requires notice to patients by hospitals or professional practices prior to being charged a facility fee as to what that fee will be and whether their insurer will cover that fee. Notice would have to be provided prior to delivering medical services, except where advance notice is infeasible because a visit was secured less than seven days in advance of the service being provided.

Policy to Prevent Exposure to Surgical Smoke (A9974 Gottfried/S8869 Rivera): This bill requires general hospitals and ambulatory surgery centers (ASCs) to adopt and implement policies to prevent exposure to surgical smoke with an airborne contaminant evacuation system. The system is required to remove surgical smoke at the site of origin and before surgical smoke makes ocular contact or contact with the respiratory tract of any individual, including patients.

Information on Chest Wall Reconstruction Surgery (A8537 Pheffer Amato/S7881 Stavisky): This bill requires general hospitals that provide mastectomy surgery, lymph node dissection or a lumpectomy to include information to the patient on both breast and chest wall reconstructive surgery and a description of aesthetic flat closure, as defined by the National Cancer Institute.

Wrongful Death Actions (S74A Hoylman/A6770 Weinstein): This bill adds grief and anguish to the types of damages that family members may recover in a wrongful death proceeding; it also expands the classes of persons who may recover those claims. Further, the legislation extends the statute of limitations for a wrongful death claim from two years to three and a half years.

Enhanced Whistleblower Allowable Amounts in *Qui Tam* Actions (A1431 Dinowitz/S1120 Kaminsky): This bill allows courts to increase the percentage of proceeds to a person commencing a *qui tam* action by up to 5% more than the current allowable amounts if the action is based on the disclosure of specific information on the use of government funds during a declaration of a state of emergency. The legislation is designed to encourage whistleblowers to come forward with fraudulent activity regarding the use of government funds during federal- and state-declared states of emergency.

Long-Term Care

Notice of Infection of Residents or Staff (A6052 Lunsford/S1785A Skoufis): This bill requires nursing homes to provide residents, their families and community supports with notice of detecting an infection among residents or staff. It also requires that nursing homes have a plan or procedure for designated separated cohort areas during an infectious disease outbreak for the separation of residents who are suspected of being infectious. The notice must be provided within 12 hours of the detection of an infection. The type of infection that would require notice to be provided is not limited to COVID-19 and presumably would include all types of detectable infections.

Hospice Services for Assisted Living Program (ALP) Residents (A8006 Gottfried/S7626 Rivera): This bill clari-

fies that residents of Adult Care Facilities (ACFs) may receive both hospice services and ALP services without having to disenroll from either benefit, and directs that a work group be established to make recommendations as to the coordination and division of services, responsibilities and reimbursement of ALPs and hospice programs. Current DOH policy has required ALP-enrolled residents who choose hospice care to disenroll from ALP.

Closure Plan Requirements for Assisted Living Residences (ALRs) (A2211 Simon/S3932 Savino): This bill establishes specific closure plan requirements for ALRs, which include a minimum of 120 days' notice prior to the anticipated date of closure. The bill prohibits an operator from admitting new residents or increasing any rent, fees, or other surcharges once the closure plan is submitted and prior to the approval of the plan.

LTC Ombudsman Annual Report (S8617A May/A10045A Clark): This bill expands the Long Term Care (LTC) Ombudsman Annual Report to include patterns of complaints in LTC facilities, identify all complaints received by the office listed by type of complaint and facility name, and identify the number of visits by the office to LTC facilities as well as identify any facilities that did not receive any visits.

Prohibition on For-Profit Hospices (A8472 Gottfried/S9387 Krueger): This bill prohibits the approval of applications for establishment, construction, or increased capacity by for-profit hospices. This will result in the prohibition of new hospices being established by for-profit entities, and for those hospices that are already operated by a for-profit entity, it will prohibit such hospices from expanding their current capacity.

Nursing Home Patient Private Right of Action (A159 Gottfried/S995 Hoylman): This bill authorizes a patient's legal representative or the patient's estate to bring any action against a nursing home that may be brought by a nursing home patient. The bill clarifies that the right of a nursing home patient to bring an action against a nursing home under PHL § 2801-d extends to the nursing home patient's representative or estate.

Public Health

Primary Care Reform Commission (A7230B Gottfried/S6534C Rivera): This bill establishes the Primary Care Reform Commission that will be tasked to define, measure and report on current primary care spending in New York and identify the means to increase the proportion of the health care dollar that goes to primary care services across all payers. It will require Medicaid managed care plans and health insurers to provide data on primary care spending, total health care spending and the total cost of care for the past five years.

New York Living Donor Support Act (S1594 Rivera/A146A Gottfried): This bill establishes a program for living donors who are New York residents to pay for certain expenses that arise due to the act of living donation. Expenses eligible for reimbursement include lost wages, the economic value of sick or vacation days expended, travel and lodging, childcare, and the costs of medication and care associated with living donation surgery.

Expanded Authority to Administer Rescue Inhalers (A2440 Reyes/S4935 Rivera): This bill includes provisions to allow parties who currently have access to epinephrine auto-injectors through non-patient-specific prescriptions to benefit from similar liability protections and access to asthma rescue inhalers.

Myalgic Encephalomyelitis Education (A7712B Gottfried/S6928B Rivera): This bill adds myalgic encephalomyelitis/chronic fatigue syndrome to the list of conditions covered under DOH's education and outreach program. The syndrome is also associated with the conditions commonly referred to as "long COVID."

Women's Health Services Provider Representation on Public Health and Health Planning Council (PHHPC) (Ch. 179): This bill adds a representative of women's health services providers to the state's PHHPC and expands the council by one member to 25 members.

Falsification of COVID-19 Vaccination Records (Ch. 24): This bill clarifies that a person may be guilty of computer tampering in the third degree when he or she enters that a person did or did not receive a COVID-19 vaccine, in addition to altering or destroying such computer material.

Elevated Lead-Level Screenings in Children (S5024D Rivera/A7325C Peoples-Stokes): This bill expands on blood lead-level screening programs to require primary care providers to give additional information to parents and guardians of children under six years of age on lead poisoning, primary care providers to conduct a risk assessment at well-child visits at least annually until six years of age, expanded in-school screening options and school integration for continuity of care in children's medical records.

Expansion of State Disaster Preparedness Plan (A1905 Dinowitz/S1086 Gaughran): This bill requires the state to contemplate within its disaster preparedness plan the delivery of medical supplies and medication to pharmacies and hospitals within the area experiencing the disaster.

Sickle Cell Disease Detection and Education (A6430B Hyndman/S5605B Sanders): This bill creates the sickle cell disease detection and education program within DOH to promote screening and detection of sickle cell disease, as well as to provide counseling and referral services, with a particular

focus on underserved populations. The bill directs the commissioner of health to issue grants to support screening, detection, and counseling services.

Office of Hospice and Palliative Care Access (A8881A Wallace/S8206A Hinchey): This bill establishes an Office of Hospice and Palliative Care Access and Quality within DOH. The office would be granted several responsibilities, including the opportunity to provide expertise and input on hospice and palliative care policy development and regulation. The office would help facilitate communication between DOH and hospice and palliative care providers.

Fentanyl Abuse and Overdose Prevention Task Force (A9348 Cusick/S8516 Savino): This bill establishes the Fentanyl Abuse and Overdose Prevention Task Force to conduct a comprehensive study on fentanyl abuse and overdose prevention, promote access and availability of treatment for substance use disorders and identify options for expanding awareness of the severity of using fentanyl illegally.

Nightlife Opioid Antagonist Program (S8633A Comrie/A9697A Griffin): This bill directs DOH to establish a Nightlife Opioid Antagonist program to allow nightlife establishments, such as bars, clubs and restaurants, to apply to receive an opioid antagonist, free of charge, to be administered to patrons, staff or individuals on the premises.

Reimbursement for Early Intervention (EI) (S5676 Rivera/A6579 Gottfried): This bill requires DOH to conduct a rate adequacy review of reimbursement rates in the EI program and submit a report to the legislature on its findings. The report must include an assessment of the existing reimbursement methodology and levels, recommendations for maintaining or changing the methodologies, and the projected number of children who will need EI services over the next five years.

Office of Health Equity (A9764 De Los Santos/S9185 Rivera): This bill renames the New York State Office of Minority Health to the Office of Health Equity. It requires the office to conduct health promotion and educational outreach and to develop interventions intended to achieve health equity.

Medicaid, Medicaid Managed Care, Managed Long-Term Care and Child Health Plus

Synchronization of Prescriptions (A187 Gottfried/S431A Hoylman): This bill requires DOH to establish a program to allow the synchronization of prescription medications for Medicaid enrollees who are receiving multiple prescriptions as a part of their care. The provisions cover both fee-for-service and Medicaid managed care and would require changes to benefit coverage to allow for partial prescription fills and allow for pharmacy override of denials for prescriptions filled in advance of their anticipated refill.

Portable Diagnostics Program (A9298A McDonald/S8290A May): This bill directs DOH to establish a portable diagnostics program that demonstrates the cost-effectiveness of Medicaid coverage of portable diagnostic services, including X-rays, electrocardiograms, and ultrasounds. The bill directs DOH to reimburse portable diagnostics at the Medicare fee schedule and for such rates to apply to Medicaid recipients enrolled in Medicaid managed care and MLTC.

Applied Behavior Analysis (ABA) Coverage (A299B Gottfried/S1578B Rivera): This bill includes ABA under standard coverage for Medicaid beneficiaries, making access to ABA services comparable to access currently provided for under commercial insurance coverage.

Office of Medicaid Inspector General (OMIG) Reform Measures (A7889A Gottfried/S4486B Harckham): This bill makes reforms to OMIG audit and recovery procedures to require OMIG and DOH annual reporting on the impacts of civil and administrative enforcement actions on quality and accessibility of medical care and services. It also restricts repeat reviews and audits without new information or good cause, requires that OMIG abide by laws and regulations in place at the time the claim or conduct in question occurred, and prohibits OMIG from making recoveries from providers based purely on administrative defects without 30 days' notice to correct.

Physician's Assistants (PA) as Primary Care Practitioners in Medicaid (S5956A Rivera/A6056 Gottfried): This bill authorizes PAs to serve as primary care providers for the purposes of providing primary care, care management and health care services to Medicaid enrollees in New York. The proposal requires managed care providers to provide the same access to and enrollment of PAs as other previously approved primary care providers.

Notice for Changes to Model Contract (A9442A Gottfried/S9207 Rivera): This bill requires that public notice be provided detailing any changes to the terms, conditions or timing requirements for providers under the Medicaid managed care model contract and that similar notice be provided for any requests for proposals targeting managed care providers to participate in the managed care program.

Programs of All-Inclusive Care for the Elderly (PACE) (A9542 Gottfried/S8903 May): This bill establishes a new section under the Public Health Law (PHL) for the establishment and oversight of PACE. It directs DOH to establish a uniform authorization process for existing and prospective PACE programs, encompassing all program requirements into a singular licensure.

Changes to Public Assistance and Medicaid Overpayment Recovery (S4540A Rivera/A5613A Gottfried): This

bill changes to the state's process for recovery from individuals receiving public benefits and/or Medicaid services that are deemed as overpayments. Changes include prohibiting recovery under certain circumstances, providing debt relief for those impacted by COVID-19, and reducing the interest on judgments.

Health Insurance

HEAL Act (S7199A Gounardes/A8169A Cruz): This bill prohibits contracts between health insurers and health care providers that contain a most-favored-nation provision or restrict the ability of a health plan to disclose actual claims costs or price information required to be disclosed under federal law, including the allowed amount, negotiated rates or discounts, or any other claim-related financial information.

Qualifications of Clinical Peer Reviewers (A879 Gottfried/S8113 Cleare): This bill requires that all clinical peer reviewers, whether physicians or other health care professionals, be licensed or certified in New York State. It also requires that when the clinical peer reviewer is a physician, he or she be board-certified or board-eligible in the same or similar specialty as the physician who typically recommends the treatment or manages the condition under review.

Co-Payment Prohibition for Opioid Treatment Program (OTP) Services (A372 Rosenthal/5690 Harckham): This bill prohibits commercial health insurance policies from imposing a co-payment during treatment at an OTP. This will prohibit multiple co-payments for OTP services for the duration of the treatment received.

Coverage for Colorectal Cancer Screening (A2085A Dinowitz/S906B Sanders): This bill requires health insurers to cover preventive colorectal cancer screening for all examinations and laboratory tests in accordance with the American Cancer Society Guidelines for colorectal cancer screening of average-risk individuals.

Prohibits Step Therapy for Mental Health Treatment (A3276 Gunther/S5909 Kaminsky): This bill prohibits the application of any fail-first or step therapy protocol by health insurers to mental health benefits, including drug coverage.

Coverage for HIV Prevention Medication (A807 O'Donnell/S688 Hoylman): This bill requires health insurance policies to include coverage for the cost of pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) for the prevention of HIV infection.

Prescription Drug Benefits

Patient Prescription Information and Choice Act (S4620C Breslin/A5411D McDonald): This bill requires health plans to provide cost, benefit and coverage data to covered individuals (or their provider or third party by request) with current information no less than one day old regarding the costs to the individual of patient-specific prescription costs and cost sharing.

Pharmacy Benefit Cost-Sharing Calculation (S5299 Rivera/A1741 Gottfried): This bill requires any third-party payments, financial assistance, discount, voucher or other price reduction instrument for out-of-pocket expenses made on behalf of an insured individual for the cost of prescription drugs to be applied to the insured's deductible, co-payment, co-insurance, out-of-pocket maximum or any other cost-sharing requirement when calculating such insured individual's overall contribution to any out-of-pocket maximum or any cost-sharing requirement.

Pharmacy

Neuromusculoskeletal Non-Opioid Treatments (A273 Gottfried/S4640 Rivera): This bill requires practitioners treating patients for neuromusculoskeletal conditions causing pain disorders to discuss with their patients and, where appropriate to the course of treatment, to refer or prescribe non-opioid treatments prior to treating the condition with an opioid pharmaceutical. Exceptions are made for medical emergencies, immediate post-surgical care, end-of-life and hospice care, and cancer treatment programs.

Prohibits Unconscionable Pricing in Drug Shortages (S3081B Salazar/A5860B Reyes): This bill prohibits manufacturers, suppliers, wholesalers, distributors, or retail sellers of any drug subject to a shortage from charging an unconscionably excessive price during that shortage. Violations of pricing are a question of law delegated to the courts. Violations of the statute create a cause of action for the Attorney General to pursue on behalf of the state, and penalties may be awarded in amounts not to exceed $25,000 per violation or three times the gross receipts for the relevant drug, whichever is greater, as well as restitution to aggrieved parties.

Pharmacists to Administer Substance Abuse and Mental Health Injectable Medications (S4870B Breslin/A3040D McDonald): This bill allows administration of injectable long-acting antipsychotics by pharmacists following an initial administration and evaluation by a prescribing provider.

Public Health Emergency Exception for Nonresident Pharmacies (S9448 Brouk/A5413A Dinowitz): This bill authorizes pharmacies to receive prescription drugs from other pharmacies outside the state of New York that are not registered with the SED, with the intent to provide improved patient access to medications in the course of a public health emergency.

Mental Health

Maternal Mental Health Work Group (S7752 Brouk/A9085 Clark): This bill establishes a Maternal Mental Health Work Group within the OMH to study and issue recommendations on maternal mental health disorders. The work group will identify underrepresented and vulnerable populations, risk factors, and successful screening and treatment methods, and make recommendations on policy initiatives, funding models and evidence-based practices for health care providers.

Comprehensive Review of Postpartum Depression Screening (S7753 Brouk/A9102 Gonzalez-Rojas): This bill requires the New York State Office of Mental Health (OMH), in conjunction with DOH and maternal health experts, to conduct a comprehensive study of postpartum depression screening measures and the differential impacts on Black women, brown women and birthing people.

Expansion of the Community Health Access to Addiction and Mental Health Project (A9344A Steck/S8057A Harckham): This bill requires the New York State Office of Addiction Services and Supports (OASAS) and OMH to coordinate with several specific state agencies to increase awareness among targeted populations about the successful independent substance use disorder and mental health ombudsman program.

Runaways and Homeless Youth Authority to Consent (S8937 Brisport/A9604 Gottfried): This bill provides runaways and homeless youth with the legal authority to consent to medical, dental, health and hospital services for themselves.

New Facilities Providing Chemical Dependence Services (A8386A McDonald/S7349A Harckham): This bill requires that privacy be a key factor in the design of newly constructed facilities that provide chemical dependence services and receive funding from the office of addiction services and supports. Patient privacy must be taken into consideration when designing spaces to support bathing, sleeping and counseling services.

Substance Use Disorder Ombudsman Annual Reporting (A9730 Gunther/S8219A Harckham): This bill requires the office of the independent substance use disorder and mental health ombudsman to present an annual report, due Oct. 31, to the governor and to the legislature, summarizing the program's work of the previous year as well as recommendations for the future.

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Health Professions

Pathway to Licensure for ABA Professionals (S9402 Stavisky/A10454 Glick): This bill makes technical amendments to the requirements and procedures for the professional licensure of behavior analysts and certified behavior analyst assistants.

Licensure of Physical Therapist Assistants (A6727A Zebrowski/S8746 Stavisky): This bill addresses the shift in the treatment of physical therapist assistants from certified professionals to licensed professionals under New York law and makes conforming changes to Education Law to comply with that new status.

Permitting Occupational Therapy Treatment Without Referral (A3202C McDonald/S5663A Kennedy): This bill would permit treatment by an occupational therapist (OT) for up to either 10 visits or 30 days, whichever occurs first, without referral from a physician or nurse practitioner. The practicing OT would be required to have three years of full-time practice, and the patient would need to be notified that without a referral, their health plan may not cover the services.

Clinical Lab Technician Practice (A10162A/S7020B): To address consistent workforce shortages and pressures in the profession, this bill creates the histotechnician profession in lieu of the histological technician role, aligning the state with national standards. It provides a pathway for histological technicians meeting national standards to become licensed in New York, which includes recognizing professional experience as qualifying education for licensure.

Endnotes

1. Chapter 208 of the Laws of 2022.
2. Chapter 219 of the Laws of 2022.
3. Chapter 218 of the Laws of 2022.
4. Chapter 220 of the Laws of 2022.
5. Chapter 222 of the Laws of 2022.
6. Chapter 217 of the Laws of 2022.

In the New York State Agencies

By Caroline B. Brancatella

COVID-19 Masking Program

Notice of Emergency Rule Making. The Office of Mental Health added Part 556 to Title 14 N.Y.C.R.R. to implement COVID-19 Mask Program. Filing Date: Feb. 14, 2022. Effective Date: Feb. 14, 2022. *See* N.Y. Register Mar. 02, 2022.

Telehealth Expansion

Notice of Emergency Rule Making. The Office of Mental Health amended Part 596 of Title 14 N.Y.C.R.R. to establish regulations regarding the expansion of telehealth. Filing Date: Feb. 11, 2022. Effective Date: Feb. 11, 2022. *See* N.Y. Register Mar. 02, 2022.

Tobacco Use in Adult Services

Notice of Adoption. The Office of Alcoholism and substance Abuse Services amended Part 856 of Title 14 N.Y.C.R.R. to allow for OASAS programs to become "tobacco-limited" rather than "tobacco-free" if they choose to. Filing Date: Feb. 22, 2022. Effective Date: Mar. 01, 2022. *See* N.Y. Register Mar. 09, 2022.

Face Coverings for COVID-19 Prevention

Notice of Emergency Rule Making. The Department of Health amended § 2.60 and repealed Subpart 66-3 of Title 10 N.Y.C.R.R. to control and promote the control of communicable diseases to reduce their spread. Filing Date: Feb. 22, 2022. Effective Date: Feb. 22, 2022. *See* N.Y. Register Mar. 09, 2022.

Article 28 Nursing Homes; Establishment; Notice and Character and Competence Requirements

Notice of Adoption. The Department of Health amended §§ 600.1 and 600.2 of Title 10 N.Y.C.R.R. to strengthen the establishment application review process for all Article 28 facilities. Filing Date: Feb. 17, 2022. Effective Date: Mar. 09, 2022. *See* N.Y. Register Mar. 09, 2022.

Updated Retention Standards for Adult Care Facilities

Notice of Proposed Rule Making. The Department of Health amended §§ 487.4, 488.4, 490.4 of Title 18 N.Y.C.R.R. to ensure admission and retention standards for adult care facilities are consistent with the American with Disabilities Act. *See* N.Y. Register Mar. 09, 2022.

Establishes Crisis Stabilization Centers

Notice of Revised Proposed Rule Making. The Office of Mental Health added Part 600 to Title 14 N.Y.C.R.R. to establish standards for a Crisis Stabilization Center which provides full range of psychiatric and substance use services. *See* N.Y. Register Mar. 09, 2022.

Patient Rights in OASAS Programs

Notice of Proposed Rule Making. The Office of Alcoholism and Substance Abuse Services amended Part 815 of Title 14 N.Y.C.R.R. to establish patient rights and provider obligations regarding rights in OASAS programs. *See* N.Y. Register Mar. 16, 2022.

Substance Use Disorder Residential Services

Notice of Proposed Rule Making. The Office of Alcoholism and Substance Abuse Services amended Part 819 of Title 14 N.Y.C.R.R. to include requirements for substance use disorder residential services. *See* N.Y. Register Mar. 16, 2022.

Substance Use Disorder Withdrawal and Stabilization Services

Notice of Proposed Rule Making. The Office of Alcoholism and Substance Abuse Services amended Part 816 of Title 14 N.Y.C.R.R. to include requirements for providers of substance use disorder withdrawal and stabilization services. *See* N.Y. Register Mar. 16, 2022.

Residential Services

Notice of Proposed Rule Making. The Office of Alcoholism and Substance Abuse Services amended Part 820 of Title 14 N.Y.C.R.R. to include requirements for the delivery of residential services. *See* N.Y. Register Mar. 16, 2022.

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General Provisions Applicable to All Programs Certified, Funded or Otherwise Authorized by OASAS

Notice of Proposed Rule Making. The Office of Alcoholism and Substance Abuse Services amended Part 800 of Title 14 N.Y.C.R.R. to include general provisions applicable to all programs certified, funded, or otherwise authorized under OASAS. *See* N.Y. Register Mar. 16, 2022.

Substance Use Disorder Residential Rehabilitation Services for Youth

Notice of Proposed Rule Making. The Office of Alcoholism and Substance Abuse Services amended Part 817 of Title 14 N.Y.C.R.R. to establish standards for substance use disorder residential rehabilitation services for youth. *See* N.Y. Register Mar. 16, 2022.

Substance Use Disorder Inpatient Rehabilitation

Notice of Proposed Rule Making. The Office of Alcoholism and Substance Abuse Services amended Part 818 of Title 14 N.Y.C.R.R. to include requirements for substance use disorder inpatient rehabilitation services. *See* N.Y. Register Mar. 16, 2022.

General Service Standards for Substance Use Disorder Outpatient Programs

Notice of Proposed Rule Making. The Office of Alcoholism and Substance Abuse Services amended Part 822 of Title 14 N.Y.C.R.R. to give general service standards for substance use disorder outpatient programs. *See* N.Y. Register Mar. 16, 2022.

Incident Reporting in Oasas Certified, Licensed, Funded, or Operated Services

Notice of Proposed Rule Making. The Office of Alcoholism and Substance Abuse Services amended Part 836 of Title 14 N.Y.C.R.R. to include incident reporting in OASAS Certified, Licensed, Funded, or Operated Services. *See* N.Y. Register Mar. 16, 2022.

Designated Services

Notice of Proposed Rule Making. The Office of Alcoholism and Substance Abuse Services amended Part 830 of Title 14 N.Y.C.R.R. to add a new Adolescent Program Endorsement and new Ancillary Withdrawal Designation. *See* N.Y. Register Mar. 23, 2022.

Managed Care Organizations (MCOs)

Notice of Adoption. The Department of Health amended § 98-1.11(e) of Title 10 N.Y.C.R.R. to maintain the contingent reserve requirement at 7.25% through 2022 applied to Medicaid Managed Care, HIV, SNP, and HARP programs. Filing Date: Mar. 03, 2022. Effective Date: Mar. 23, 2022. *See* N.Y. Register Mar. 23, 2022.

Clinical Laboratories and Blood Banks

Notice of Proposed Rule Making. The Department of Health amended Subpart 58-1 of Title 10 N.Y.C.R.R. to allow for remote supervision and updates to provide concordance with NYSED law for qualifications of technical personnel. *See* N.Y. Register Mar. 23, 2022.

Reporting of Acute HIV Infection

Notice of Proposed Rule Making. The Department of Health amended §§ 63.2 and 63.4 of Title 10 N.Y.C.R.R. to require clinicians to report any case of acute HIV within 24 hours of diagnoses. *See* N.Y. Register Mar. 23, 2022.

Telehealth Services

Notice of Proposed Rule Making. The Department of Health amended §§ 505.17 and 533.6 and added Part 538 to Title 18 N.Y.C.R.R. to ensure continuity of care of telehealth services provided to Medicaid enrollees. *See* N.Y. Register Mar. 23, 2022.

Notice of Expiration

The following notice has expired and cannot be reconsidered unless the Office of Mental Health publishes a new notice of proposed rulemaking.

(i) Redesigning Residential Treatment Facilities (RTF): I.D. No. OMH-09-21-00001-EP. Proposed on Mar. 03, 2021. Expired on Mar. 03, 2022. *See* N.Y. Register Mar. 23, 2022.

Masking Requirements in All OASAS Certified/ Funded/ Otherwise Authorized Settings

Notice of Emergency Rulemaking. The Office of Alcoholism and Substance Abuse Services added Part 808 to Title 14 N.Y.C.R.R. to prevent the ongoing threat to public health of the spread of COVID-19 in OASAS settings. Filing Date: Mar. 10, 2022. Effective Date: Mar. 10, 2022. *See* N.Y. Register Mar. 30, 2022.

Establishment of Youth Assertive Community Treatment (ACT)

Notice of Adoption. The Office of Mental Health amended Part 508 of Title 14 N.Y.C.R.R. to include children in the populations eligible to receive ACT and other conforming changes. Filing Date: Mar. 15, 2022. Effective Date: Mar. 30, 2022. *See* N.Y. Register Mar. 30, 2022.

Community Transition Services

Notice of Adoption. The Office for People with Developmental Disabilities added § 635-10.5 to Title 14 N.Y.C.R.R. to match Federal limitations and use gender neutral terminology. Filing Date: Mar. 09, 2022. Effective Date: Mar. 30, 2022. *See* N.Y. Register Mar. 30, 2022.

Minimum Standards for Form, Content, and Sale of Health Insurance, Including Standards of Full and Fair Disclosure

Notice of Emergency Rule Making. The Department of Financial Services added § 52.76(b) to Title 11 N.Y.C.R.R. to require immediate coverage, without cost-sharing, for COVID-19 immunizations and the administration thereof. Filing Date: Mar. 16, 2022. Effective Date: Mar. 16, 2022. *See* N.Y. Register Apr. 06, 2022.

Prevention of COVID-19 Transmission by Covered Entities

Notice of Emergency Rule Making. The Department of Health added § 2.61; amended §§ 405.3, 415.19, 751.6, 763.13, 766.11, 794.3 and 1001.11 of Title 10 N.Y.C.R.R.; and amended of §§ 487.9, 488.9 and 490.9 of Title 18 N.Y.C.R.R.. Filing Date: Mar. 22, 2022. Effective Date: Mar. 22, 2022. *See* N.Y. Register Apr. 06, 2022.

Telehealth Services

Notice of Emergency Rule Making. The Department of Health added Part 538 to Title 18 N.Y.C.R.R. to _____. Filing Date: Mar. 22, 2022. Effective Date: Mar. 22, 2022. *See* N.Y. Register Apr. 06, 2022.

Hospice Residence Rates

Notice of Adoption. The Department of Health amended § 86-6.2 of Title 10 N.Y.C.R.R. to authorize Medicaid rate of payment to increase the Hospice Residence reimbursement rates by 10%. Filing Date: Mar. 22, 2022. Effective Date: Apr. 06, 2022. *See* N.Y. Register Apr. 06, 2022.

Charges for Professional Health Services

Notice of Emergency Rule Making. The Department of Financial Services amended Part 68 (Regulation 83) of Title 11 N.Y.C.R.R. to establish schedules of maximum permissible charges for professional health services payable as no-fault insurance benefits. Filing Date: Apr. 04, 2022. Effective Date: Apr. 04, 2022. *See* N.Y. Register Apr. 20, 2022.

Reportable Incidents

Notice of Adoption. The Office for People with Developmental Disabilities amended § 86-6.2 of Title 10 N.Y.C.R.R. to authorize Medicaid rate of payment to increase the Hospice Residence reimbursement rates by 10%. Filing Date: Mar. 22, 2022. Effective Date: Apr. 06, 2022. *See* N.Y. Register Apr. 06, 2022.

Procedures for the Control of COVID-19

Notice of Emergency Rule Making. The Office for People with Developmental Disabilities added § 680.14 to Title 14 N.Y.C.R.R. for the preservation of public health, public safety and general welfare. Filing Date: Apr. 08, 2022. Effective Date: Apr. 08, 2022. *See* N.Y. Register Apr. 27, 2022.

Mandatory Face Coverings in OPWDD Settings

Notice of Emergency Rule Making. The Office for People with Developmental Disabilities added § 633.26 to protect public health. Filing Date: Apr. 15, 2022. Effective Date: Apr. 15, 2022. *See* N.Y. Register May 04, 2022.

Face Coverings for COVID-19 Prevention

Notice of Emergency Rule Making. The Department of Health repealed § 2.60, Subpart 66-3 and added new § 2.60 to Title 10 N.Y.C.R.R. to control and promote the control of communicable diseases to reduce their spread. Filing Date: Apr. 22, 2022. Effective Date: Apr. 22, 2022. *See* N.Y. Register May 11, 2022.

Investigation of Communicable Disease; Isolation and Quarantine

Notice of Emergency Rule Making. The Department of Health amended Part 2, § 405.3; and added of § 58-1.14 to Title 10 N.Y.C.R.R. for the control of communicable disease. Filing Date: Apr. 22, 2022. Effective Date: Apr. 22, 2022. *See* N.Y. Register May 11, 2022.

Surge and Flex Health Coordination System

Notice of Emergency Rule Making. The Department of Health added §§ 1.2, 700.5, Part 360; amended §§ 400.1, 405.24 and 1001.6 of Title 10 N.Y.C.R.R.; and amended §§ 487.3, 488.3 and 490.3 of Title 18 N.Y.C.R.R. to provide authority to the commissioner to direct certain actions and waive certain regulations in an emergency. Filing Date: Apr. 25, 2022. Effective Date: Apr. 25, 2022. *See* N.Y. Register May 11, 2022.

COVID-19 Vaccinations of Nursing Home and Adult Care Facility Residents and Personnel

Notice of Emergency Rulemaking. The Department of Health added Subpart 66-4 to Title 10 N.Y.C.R.R. to require nursing homes and adult care facilities to conduct ongoing COVID-19 vaccinations of their residents and personnel. Filing Date: Apr. 25, 2022. Effective Date: Apr. 25, 2022. *See* N.Y. Register May 11, 2022.

Telehealth Expansion

Notice of Emergency Rule Making. The Office of Mental Health amended Part 596 of Title 14 N.Y.C.R.R. to establish regulations regarding the expansion of telehealth. Filing Date: Apr. 25, 2022. Effective Date: Apr. 25, 2022. *See* N.Y. Register May 11, 2022.

Certification of the Facility Class Known as Individualized Residential Alternative

Notice of Emergency Rule Making. The Office for People With Developmental Disabilities amended § 686.16 of Title 14 N.Y.C.R.R. to increase IRA capacity in cases of emergent circumstances. Filing Date: Apr. 25, 2022. Effective Date: Apr. 25, 2022. *See* N.Y. Register May 11, 2022.

General Purpose

Notice of Emergency Rulemaking. The Office for People With Developmental Disabilities amended § 686.3 of Title 14 N.Y.C.R.R. to increase IRA capacity in cases of emergent circumstances. Filing Date: Apr. 25, 2022. Effective Date: Apr. 25, 2022. *See* N.Y. Register May 11, 2022.

Ingredient Disclosures for Vapor Products and E-Cigarettes

Notice of Adoption. The Department of Health added Subpart 66-4 to Title 10 N.Y.C.R.R. to authorize Medicaid rate of payment to increase the Hospice Residence reimbursement rates by 10%. Filing Date: Mar. 22, 2022. Effective Date: Apr. 06, 2022. *See* N.Y. Register Apr. 06, 2022.

COVID-19 Vaccination Program

Notice of Emergency Rule Making. The Office of Mental Health amended Part 557 of Title 14 N.Y.C.R.R. to implement a COVID-19 vaccination program in OMH Operated or Licensed Hospitals. Filing Date: May 03, 2022. Effective Date: May 03, 2022. *See* N.Y. Register May 18, 2022.

Masking Requirements in All OASAS Certified/ Funded/Otherwise Authorized Settings

Notice of Emergency Rule Making. The Office of Alcoholism and Substance Abuse Services amended Part 808 to Title 14 N.Y.C.R.R. to prevent the ongoing threat to public health of the spread of COVID-19 in OASAS settings. Filing Date: May 06, 2022. Effective Date: May 06, 2022. *See* N.Y. Register May 25, 2022.

Training Flexibilities

Notice of Emergency Rule Making. The Office for People with Developmental Disabilities added § 633.27 to Title 14 N.Y.C.R.R. to provide flexibilities in training requirements. Filing Date: May 16, 2022. Effective Date: May 16, 2022. *See* N.Y. Register Jun. 01, 2022.

Administrative Compensation

Notice of Adoption. The Office for People with Developmental Disabilities repealed Part 645 of Title 14 N.Y.C.R.R. to repeal Part 645. Filing Date: May 11, 2022. Effective Date: Jun. 01, 2022. *See* N.Y. Register Jun. 01, 2022.

Pharmacy Benefits Bureau

Notice of Proposed Rule Making. The Department of Financial Services amended Part 450 (Regulation 219) of Title 11 N.Y.C.R.R. to establish the Pharmacy Benefits Bureau and revise the rules for the Drug Accountability Board. *See* N.Y. Register Jun. 08, 2022.

Registration of Pharmacy Benefit Managers

Notice of Proposed Rule Making. The Department of Financial Services added Part 451 (Regulation 221) to Title 11 NYCR to establish regulations for the registration and first annual report of pharmacy benefit manager. *See* N.Y. Register Jun. 08, 2022.

Prescription Refills

Notice of Adoption. The Department of Health amended § 505.3(d)(2) of Title 18 N.Y.C.R.R. to limit Medicaid FFS prescriptions to a maximum of 12 fills within one year from the date the prescriber initiates a prescription. Filing Date: May 24, 2022. Effective Date: Jun. 08, 2022. *See* N.Y. Register Jun. 08, 2022.

Hospital and Nursing Home Personal Protective Equipment (PPE) Requirements

Notice of Proposed Rule Making. The Department of Health amended §§ 405.11 and 415.19 of Title 10 N.Y.C.R.R. to ensure that all general hospitals and nursing homes maintain a 60-day supply of PPE during the COVID-19 emergency. *See* N.Y. Register Jun. 08, 2022.

COVID-19 Vaccinations of Nursing Home and Adult Care Facility Residents and Personnel

Notice of Proposed Rule Making. The Department of Health added Subpart 66-4 to Title 10 N.Y.C.R.R. to require nursing homes and adult care facilities to conduct ongoing COVID-19 vaccinations of their residents and personnel. *See* N.Y. Register Jun. 08, 2022.

Relating to the Certification, Operation and Reimbursement of Clinic Treatment Programs Serving Adults and Children

Notice of Proposed Rule Making. The Office of Mental Health amended Part 599 of Title 14 N.Y.C.R.R. to align such program with the State Plan Amendment. *See* N.Y. Register Jun. 08, 2022.

Registration of Pharmacy Benefit Managers

Notice of Emergency Rule Making. The Department of Financial Services added Part 451 (Regulation 221) to Title 11 N.Y.C.R.R. to establish the registration and first annual reporting requirements for pharmacy benefit managers. Filing Date: May 25, 2022. Effective Date: May 25, 2022. *See* N.Y. Register Jun. 15, 2022.

Minimum Standards for the Form, Content and Sale of Health Insurance, Including Standards of Full and Fair Disclosure

Notice of Adoption. The Department of Health amended Part 52 of Title 11 N.Y.C.R.R. to provide additional minimum standards for the content of health insurance identification cards in accordance with federal law. Filing Date: May 31, 2022. Effective Date: Jul. 15, 2022. *See* N.Y. Register Jun. 15, 2022.

COVID-19 Reporting and Testing

Notice of Emergency Rule Making. The Department of Health added §§ 2.9 and 2.62 to Title 10 N.Y.C.R.R. to require COVID-19 reporting in schools and to permit the commissioner to issue testing determinations in certain settings. Filing Date: May 27, 2022. Effective Date: May 27, 2022. *See* N.Y. Register Jun. 15, 2022.

New York State Fraud, Abuse and Compliance Developments

Edited by Melissa M. Zambri

New York State Department of Health Medicaid Decisions[1]

Compiled by Dena M. DeFazio

Sprain Brook Manor Rehab, LLC (Decision After Hearing, Apr. 5, 2022, Natalie J. Bordeaux, ALJ)

Appellant was a residential health care facility (RHCF) licensed under Article 28 of the Public Health Law, and located in Westchester, New York. At issue in this audit was the capital portion of appellant's RHCF cost reports (RHCF-4) submitted for the 2011–2014 calendar years. These cost reports were used to determine the capital portion of appellant's daily Medicaid program rate for the period of January 1, 2013 through December 31, 2016.

On June 26, 2019, the New York State Office of the Medicaid Inspector General (OMIG) issued a draft audit report identifying seven categories of disallowances for claimed property expenses and proposing to recover an estimated overpayment of $260,741. A final audit report, issued on Oct. 2, 2019, included a reduced overpayment amount of $241,174. Of the seven findings contained in the final audit report, three were at issue at hearing: (1) Property Expense Disallowance 1a: insurance premiums for business income insurance; (2) Property Expense Disallowance 3b: laundry and linen service expenses; and (3) Property Expense Disallowance 4: state sales tax on utilities in excess of the allowable residential rate.

Property Expense Disallowance 1a—insurance premiums for business income insurance—related to appellant including the cost of premiums for business income (or business interruption) insurance in its reported costs for property insurance premiums in its 2011–2014 calendar year cost reports. OMIG disagreed with this cost reporting, and determined that the premiums may only be considered in the facility rate's operating component, as the insurance was unrelated to the loss or damage of physical property. At hearing, appellant argued that these insurance premiums should be considered a property expense, because the coverage stems from damage to property. Administrative Law Judge (ALJ) Bordeaux rejected appellant's argument that the Centers for Medicare and Medicare Services' (CMS) Provider Reimbursement Manual (PRM-1) establishes that business income insurance is reimbursable as a capitalized expenditure, concluding that appellants' contention "significantly distort[ed] PRM-1 § 2806.2(d)" and "relie[d] on an unwarranted presumption, without any supporting documentation, that pay-outs from [appellant's] policy would be used to pay capital-related costs in the event of business interruption." Decision at 6. Considering that appellant's insurance coverage stated that reimbursement was only for actual loss of business income, ALJ Bordeaux concluded that the business income insurance did not provide for reimbursement of capital-related costs. Although business interruption or other similar insurance may be reimbursable in the operating component of a rate, the expenses may not be reimbursed as capital-related costs, and as such, OMIG's determination to disallow the premiums as a property cost was affirmed.

Property Expense Disallowance 3b—laundry and linen services—stemmed from appellant reporting laundry and linen expenses in the laundry and services cost center as operating expenses for calendar years 2011–2014, and also reporting linen rentals as property expenses in the same cost reports. OMIG disallowed the reported costs on the grounds that they were operating expenses, not property expenses. At hearing,

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appellant asserted that the costs were properly included in the property component as rented moveable equipment subject to capitalization due to the large volume utilized that exceeded a value of $500, and that the capitalization of these expenses was not explicitly prohibited by applicable regulation. *See* 10 N.Y.C.R.R. § 455.9. ALJ Bordeaux rejected these arguments, noting that the applicable regulation does not authorize appellant to elect to classify the expenditures as capital costs, and that the RHCF-4 manual characterizes linens as being inappropriate for capitalization. Additionally, the reimbursement guidelines set out in PRM-1 provide that agreements for the purchase of services are not capital-related costs. *See* PRM-1 §§ 2806.1, 2806.2. Pointing to invoices from the applicable vendors, ALJ Bordeaux concluded that the business interactions between the vendors and appellant were primarily service-oriented, as evidenced by the word "services" in the vendor's names. Additionally, the ALJ noted that the processing charges that appellant paid were based on the number of pieces of laundry and that the costs were incurred for processing or laundering and replacing linens.

Appellant's argument that the capitalization of the linens received was supported by generally accepted accounting principles (GAAP) was also rejected by the ALJ, who concluded that the distinction between operating and capital leases for purposes of GAAP was not relevant to whether lease costs could be include in capital-related costs. *See* PRM-1 § 2806.1(C). Finally, appellant argued that the expenses were based on the rental of the linens, rather than laundry services. *See* PRM-1 § 2806.3(B). This argument was rejected by ALJ Bordeaux, as the record did not show that the agreements and reported expenses at issue were based mainly on linen rentals, rather than laundering. Moreover, even if this argument were accepted, the charges for the use of the linen and laundry services were not allocated in the Linen Services Agreement, rendering appellant's classification of the expenditures improper. Noting that no applicable regulation, the RHCF-4 form, or any portion of the PRM-1 justified capitalizing rented linens obtained and used incidental to a laundry services agreement, ALJ Bordeaux upheld OMIG's determination to disallow the reported costs as a capital expense.

Finally, Property Expense Disallowance 4 pertained to the state sales tax on utilities reported in appellant's 2013 and 2014 cost reports. Specifically, OMIG disallowed the portion of the reported sales tax expenses for utilities in the amount that exceeded the local sales tax, which resulted in a decrease in allowable utilities sales tax from 6.35% to 3%. Although taxes paid by RHCFs are allowable costs to the extent they are actually incurred and related to beneficiary care, taxes that have exemptions available are not allowable costs, and RHCFs are exempt from paying New York State sales tax on utilities. *See* PRM-1 § 2122.1; *see also* N.Y. Tax Law § 1105-A; N.Y. St. Dep't of Taxation and Finance, Taxpayer Servs. Div., Technical Servs. Bureau, Advisory Opinion TSB-A-90(60)S. At hearing, appellant asserted that it was unaware of the exemption and that the costs should be allowed since the state utility sales tax was paid. ALJ Bordeaux rejected this argument and upheld the disallowance, finding that appellant was responsible for availing itself of any available exemptions and that the costs were not allowable.

Therefore, OMIG's overpayment findings were affirmed as each of the three disallowances at issue at hearing were found to be correct and were upheld.

Granville Center for Rehabilitation and Nursing (Decision, Mar. 16, 2022, John Harris Terepka, ALJ)

This decision without a hearing considered whether appellant's request for a hearing was timely. OMIG requested a determination that the hearing request was untimely, as the final audit report was mailed to appellant on April 28, 2021, and was received by appellant on April 30, 2021, but appellant did not request a hearing until July 21, 2021.

In reaching a decision, ALJ Terepka noted that it was undisputed that appellant did not request a hearing until after recoupment of the overpayment began, which was more than 60 days after the receipt of the final audit report. Appellant's assertion that its late hearing request should be excused due to "extenuating circumstances[,]" including appellant's failure to forward the final audit report to its business office or accountants for response, was rejected by the ALJ. *See* Decision at 3. In concluding that the hearing request was untimely, ALJ Terepka noted that appellant failed to dispute OMIG's evidence that appellant responded to the draft audit report, even though it was also sent to the facility administrator, and appellant did not present any evidence showing that it authorized or requested that OMIG send the final audit report or a copy to any other address.

As appellant failed to provide a reasonable excuse for the late request for a hearing, the request was denied.

Pro Med Ambulette Service, Inc. (Decision, Jan. 19, 2022, Jean T. Carney, ALJ)

Appellant was an ambulette and transportation service operating in New York. OMIG conducted a desk audit of ambulette services paid by the Medicaid Program for the period of March 1, 2012 through December 31, 2015 by comparing driver's license numbers with data kept by the Department of Motor Vehicles to verify the drivers' qualifications on the claim dates of service. Through its review, OMIG identified $44,694.93 in overpayments, stemming from 397 transportation claims for ambulette services that were provided by alleged unqualified/disqualified drivers.

The issue at hearing was whether OMIG was correct in its determination to recover overpayments from transporta-

tion claims for ambulette services with alleged unqualified/disqualified driver's license numbers for the dates of service. Appellant did not present any evidence at hearing, but alleged, in its closing statement, that it was unable to respond to OMIG's draft audit report because the report was sent to an incorrect address. The draft audit report was sent to the correct address, but the wrong zip code was listed. ALJ Carney rejected this argument, recognizing that the evidence presented at the hearing confirmed that the draft audit report was, in fact, received, and appellant did not deny that both the draft and final audit reports were received. Additionally, appellant contacted OMIG with questions about the draft audit report, but failed to actually respond until after the final audit report was received.

Appellant's remaining arguments—that health issues impacted its representative's ability to exercise adequate oversight and that the repayment plan was a hardship on the business—were rejected without discussion. ALJ Carney concluded that appellant did not present evidence at the hearing that contradicted OMIG's determination to deny the claims, and found that the audit findings were uncontroverted. As such, OMIG's determination to recover the overpayments was affirmed.

New York State Attorney General Press Releases

Compiled by Samuel Chubb, Jamie Dughi Hogenkamp, and Bridget Steele[2]

Attorney General James Leads Multi-State Coalition in Continued Fight to Protect Family Planning Funding—Mar. 31, 2022—Co-leading a coalition of 23 attorneys general, Attorney General (AG) James filed an amicus brief in the U.S. Court of Appeals for the Sixth Circuit, in support of the Biden-Harris administration's efforts to reverse a Trump era rule. The new Title X rule, issued in 2021 by the U.S. Department of Health and Human Services (HHS), removes the Trump administration's restrictions on family planning funding and ensures the distribution of Title X funds to a greater number of family planning and health services providers. The amicus brief was filed in the case *Ohio v. Becerra*, and opposed the plaintiff states' continued efforts to halt the implementation of the new HHS rule through an appeal of a December 2021 decision from the U.S. District Court for the Southern District of Ohio, which rejected their request for a preliminary injunction to prevent the new rule's continued application. In contrast to the 2019 rule, which imposed burdensome requirements regarding physical separation of abortion and non-abortion services at any clinic, the new rule, once again, allows Title X funds to go to clinics that financially separate abortion and non-abortion services, even if they do not separate the services physically. The amicus brief filed by the coalition argues that the Sixth Circuit should reject the plaintiff states' request to reverse the district court order and issue a preliminary injunction halting the continued application of HHS' 2021 rule.

https://ag.ny.gov/press-release/2022/attorney-general-james-leads-multi-state-coalition-continued-fight-protect-family

Attorney General James Secures Nearly $7 Million From Home Health Agencies for Cheating Workers and Medicaid Fraud—Mar. 25, 2022—AG James announced agreements with two home health agencies for cheating employees out of wages and submitting false Medicaid claims. The two home health agencies—All American Home Care Agency, Inc. and Crown of Life Care, LLC—have admitted their wrongful conduct and entered into settlement agreements with the U.S. Attorney's Office for the Eastern District of New York (EDNY) to resolve their Medicaid fraud liability. The investigation of the agencies resulted in more than $5 million being repaid to the Medicaid Program and more than $1 million distributed to underpaid workers.

https://ag.ny.gov/press-release/2022/attorney-general-james-secures-nearly-7-million-home-health-agencies-cheating

Attorney General James Announces Sentencing of Bronx Clinic Owner for Stealing More Than $4 Million—Mar. 24, 2022—The owner of Healthy Living Community Center and LCM Livery P/U, Inc., Leslie Montgomery, was sentenced in Bronx County Supreme Court to three to nine years in state prison and ordered to pay back $4 million in restitution to New York State. The sentence stemmed from allegations that the owner exploited low-income workers and defrauded the Medicaid Program by submitting false Medicaid claims. The scheme included advertising a fake housing assistance program in order to lure low-income individuals into providing their personal information, and after their personal information was acquired, false claims were submitted to Medicaid-funded managed care organizations for custom-molded back braces that were not needed and never ordered by patients. A civil complaint has also been filed by the Office of the Attorney General (OAG) against the owner and her companies seeking to recover the Medicaid program funds obtained by the defendants.

https://ag.ny.gov/press-release/2022/attorney-general-james-announces-sentencing-bronx-clinic-owner-stealing-more-4

Attorney General James Provides $2.4 Million to Brooklyn Substance Abuse Treatment Programs—Mar. 24, 2022—AG James provided more than $2.4 million to the Brooklyn Community Foundation (BCF) to fund substance use disorder treatment programs throughout Brooklyn. The funds were derived from the charitable assets remaining after the OAG dissolved a not-for-profit provider due to the organization's involvement in a Medicaid fraud scheme. The provider and its owners had previously pled guilty to grand larceny in the first degree, and the New York County Supreme Court

issued an order for the OAG to dissolve the organization and distribute its assets for use by other substance use disorder treatment programs. According to New York's Not-for-Profit Corporation Law, assets that remain after the dissolution of a non-profit organization must be distributed to another non-profit organization engaged in similar activities to those of the dissolving non-profit. Using the funds, the BCF will award grants over three successive years (beginning in 2021) to Brooklyn not-for-profit substance use treatment providers.

https://ag.ny.gov/press-release/2021/attorney-general-james-provides-24-million-brooklyn-substance-abuse-treatment

Attorney General James, 1199SEIU Call for Stronger Protections for Nursing Home Workers—Mar. 21, 2022— AG James and 1199 SEIU President George Gresham called for stronger protections for nursing home workers who have been on the front lines of the pandemic for more than two years. A January 2021 report released by the OAG found that many nursing homes were neither adequately equipped nor prepared to deal with the crisis of the COVID-19 pandemic due to poor staffing levels and a lack of compliance with infection control protocols, which endangered residents and workers alike. AG James and the 1199 SEIU President called for nursing homes to be required to implement appropriate staff-to-resident ratios and to invest sufficiently in employee wages and facility operations.

https://ag.ny.gov/press-release/2022/attorney-general-james-1199seiu-call-stronger-protections-nursing-home-workers

Attorney General James Announces Guilty Plea of Former Not-for-Profit Executive for Stealing Hundreds of Thousands From Medicaid—Mar. 18, 2022—AG James announced the guilty plea of a former not-for-profit executive who embezzled more than $650,000 from its Medicaid-funded organization which provided outpatient, community-based services to children and adults who are developmentally disabled. The executive admitted to stealing funds from January of 2014 to September of 2018 in the plea, and has agreed to repay the stolen amount in restitution to the OAG's Medicaid Fraud Control Unit (MFCU). In addition to MFCU's criminal prosecution, the OAG's Charities Bureau filed a civil lawsuit seeking recovery of the funds that the executive admitted to stealing and a permanent bar prohibiting the executive from holding any fiduciary role in a charitable or non-profit organization operating in New York.

https://ag.ny.gov/press-release/2022/attorney-general-james-announces-guilty-plea-former-not-profit-executive-stealing

Attorney General James Urges U.S. Department of Justice to Investigate Texas Anti-Transgender Order for Civil Rights Violations—Mar. 9, 2022—Leading a coalition of 30 national, state, and local advocacy groups, AG James called on the U.S. Department of Justice (DOJ) to launch a federal investigation into Texas Governor Gregg Abbott's recent directive to treat gender-affirming care for transgender children as child abuse. On February 22, 2022, Governor Abbott ordered the Texas Department of Family and Protective Services to investigate the use of gender-affirming procedures on children and called for investigations into parents and doctors who provide transgender children with gender-affirming care. The letter from AG James and the coalition to DOJ's Civil Rights division argued that Governor Abbott's order is discriminatory, potentially unlawful, and does untold harm to transgender youth in Texas. Additionally, the coalition asserted that the investigation, and potential separation, of transgender youth and their parents for seeking out doctor-recommended medical treatment may violate the Equal Protection Clause of the 14th Amendment.

https://ag.ny.gov/press-release/2022/attorney-general-james-urges-us-department-justice-investigate-texas-anti

Attorney General James Sues to Block UnitedHealth Group's Proposed Acquisition of Change Healthcare—Feb. 24, 2022—AG James joined with the DOJ and the State of Minnesota to sue UnitedHealth Group (United), after an investigation found that a proposed merger with Change Healthcare would increase health care costs. The antitrust lawsuit was filed in the U.S. District Court for the District of Columbia to stop the proposed acquisition of Change Healthcare by United. It alleges that the acquisition of Change Healthcare would give United a substantially unfair competitive advantage, and would allow it to use the data acquired from Change Healthcare to raise costs for its competitors, hinder their ability to compete, and deny them access to innovations. The lawsuit also alleges that the acquisition would reduce competition among health insurers, which would likely lead to increased health care costs and decreased quality of services for New Yorkers.

https://ag.ny.gov/press-release/2022/attorney-general-james-sues-block-unitedhealth-groups-proposed-acquisition-change

Attorney General James Delivers Over $640,000 to New York Breast Cancer Organizations—Feb. 23, 2022—The OAG has recovered funds from organizations and individuals who defrauded New Yorkers into making donations that went into the pockets of telemarketers. These funds were recovered from Breast Cancer Survivors Foundation, Inc. and Garrett Morgan, a telemarketer, who misled donors into contributing to a sham breast cancer organization on Long Island. Five non-profit organizations were selected by the OAG Charities Bureau to receive the restitution funds, including the American Cancer Society, Living Beyond Breast Cancer, West Islip Breast Cancer Coalition, Babylon Breast Cancer Coalition, and Manhasset Women's Coalition Against Breast Cancer.

https://ag.ny.gov/press-release/2022/attorney-general-james-delivers-over-640000-new-york-breast-cancer-organizations

Attorney General James Sues Couple for Embezzling $1 Million in Charity Funds—Feb. 18, 2022—The OAG filed a civil complaint against the former executive director and board chair of a New York not-for-profit corporation alleging that the former executive director improperly diverted or misused nearly $1 million in the organization's charitable assets for personal gain. The OAG's investigation into the suspected financial improprieties found that over the course of six years, the former executive director falsified loans to clients, manipulated expense reimbursements, and took salary overpayments. It is also alleged that the former board chair was aware of and helped conceal the conduct.

https://ag.ny.gov/press-release/2022/attorney-general-james-sues-couple-embezzling-1-million-charity-funds

Attorney General James Recovers Over $400,000 for Consumers Unfairly Charged for Expedited COVID-19 Tests—Feb. 14, 2022—The OAG has recovered more than $182,000 from ClearMD Health and more than $230,000 from Sameday Health for New Yorkers who paid for expedited COVID-19 tests, but received their results later than the promised timeframe. The companies also corrected their advertising and instructed employees to provide accurate information concerning turnaround times. The OAG first launched an investigation in December 2021 and issued eight warning letters to labs and testing companies to stop misrepresenting turnaround times for results. The OAG will continue to take action against COVID-19 testing sites and labs that are misleading New Yorkers.

https://ag.ny.gov/press-release/2022/attorney-general-james-recovers-over-400000-consumers-unfairly-charged-expedited

Attorney General James Secures Reimbursements for Consumers Charged for COVID-19 Vaccine Administration Fees—Feb. 7, 2022—The OAG announced that it has secured refunds for New Yorkers who were wrongfully charged administration fees by two pharmacies for receipt of the COVID-19 vaccine. The pharmacies were found to have improperly charged hundreds of COVID-19 vaccine recipients a fee. The OAG's investigation found that the pharmacies engaged in deceptive acts and practices by imposing a vaccine administration fee on consumers. The two pharmacies have reimbursed those improperly charged and will implement stronger training programs for staff.

https://ag.ny.gov/press-release/2022/attorney-general-james-secures-reimbursements-consumers-charged-covid-19-vaccine

Attorney General James Reminds New Yorkers About Increased Protections From Surprise Medical Bills—Feb. 2, 2022—In a released statement, AG James reminded New Yorkers of new safeguards against surprise bills. After becoming effective on January 1, 2022, the federal No Surprises Act builds upon existing New York law to shield New Yorkers from many unexpected medical bills. Under the new law, hospitals and health care providers are prohibited from billing patients for more than their in-network co-payment or deductible on many unexpected out-of-network bills. These surprise bills include bills for emergency services, non-emergency services provided at in-network facilities, and air ambulance services. The No Surprises Act has additional provisions that protect consumers from getting entangled in billing disputes. For instance, the Act requires the disclosure of all surprise billing protections directly to all patients and on the health care provider's website. Providers must also submit surprise out-of-network bills directly to patients' health plans, so that the health plan can send a payment to the provider and send the patient an Explanation of Benefits (EOB) indicating the amount the patient owes the out-of-network provider. Furthermore, patients have the right to appeal if a health plan applies out-of-network coverage to a surprise bill. New York passed its "surprise bill" law in 2014. It was the first legislation in the nation to protect consumers from surprise medical bills.

https://ag.ny.gov/press-release/2022/attorney-general-james-reminds-new-yorkers-about-increased-protections-surprise

Attorney General James' Statement on Appellate Court's Decision To Continue the Stay Preserving New York's Mask Mandate—Jan. 31, 2022—AG James issued a statement after the Appellate Division, Second Department granted the OAG's motion to keep the statewide mask mandate in effect for the duration of a pending appeal.

https://ag.ny.gov/press-release/2022/attorney-general-james-statement-appellate-courts-decision-continue-stay

Attorney General James Issues Statement on Anniversary of Nursing Homes Report—Jan. 28, 2022—AG James issued a statement on the first anniversary of the OAG's report on nursing homes' response to COVID-19. Her statement recounts that the OAG released a comprehensive report demonstrating that the previous administration undercounted deaths in nursing homes due to COVID-19 by as much as 50% and how its policy decisions may have contributed to the deaths of those residents. The report resulted in nursing home legislation being passed in New York State.

https://ag.ny.gov/press-release/2022/attorney-general-james-issues-statement-anniversary-nursing-homes-report

Attorney General James Announces Conviction of Western New York Optician for Medicaid Fraud—Jan. 27, 2022—An optician was arrested and charged with Grand Larceny for allegedly defrauding the Medicaid Program by submitting false Medicaid Program claims. An investigation by MFCU found that the Medicaid Program claims submitted by the optician for nursing home residents were for services that were never provided, as, in some cases, the residents were actually deceased and in others, the optician never actually visited

the nursing homes on the dates of service claimed. According to the charges, it is alleged that the optician fraudulently received approximately $74,000 in Medicaid payments between 2016 and 2019. After pleading guilty to grand larceny in the fourth degree, a class E Felony, the optician was sentenced to 90 days in prison, followed by five years of probation. The optician was also ordered to pay $74,000 in restitution.

https://ag.ny.gov/press-release/2022/attorney-general-james-announces-conviction-western-new-york-optician-medicaid

Attorney General James Issues Warning Letter to Testing Lab To Stop Misrepresenting Turnaround Times for COVID-19 Test Results—Jan. 27, 2022—The OAG has issued a warning letter to PacGenomics, following numerous complaints from customers regarding false and misleading claims. Specifically, customers have alleged waiting more than 10 days for test results after the lab stated they could deliver results in 24-hours. These wait times have disrupted work, school, and travel for many consumers.

https://ag.ny.gov/press-release/2022/attorney-general-james-issues-warning-letter-covid-19-testing-lab-pacgenomics

Attorney General James Announces Progress on $26 Billion Opioid Agreement—Jan. 27, 2022—New York has secured full subdivision participation in the opioid agreement between the nation's major pharmaceutical distributors—Cardinal Health Inc., McKesson Corporation, Amerisource Bergen Drug Corporation—and Johnson & Johnson over the companies' roles in the nation's opioid crisis. The full subdivision participation will ensure that New York receives the maximum amount of $230 million available under the settlement agreement. Pursuant to the new law establishing the opioid settlement fund, all funds collected by the state from opioid settlements or litigation victories will be allocated specifically for abatement efforts in communities impacted by the opioid crisis and will not go towards the general fund.

https://ag.ny.gov/press-release/2022/attorney-general-james-announces-major-progress-26-billion-opioid-agreement

Attorney General James' Statement on Judge's Decision To Temporarily Allow Enforcement of New York's Mask Mandate—Jan. 25, 2022—AG James released a statement after the OAG's motion to stay a decision striking down the state's mask mandate was granted. Under the order, the mask mandate will stay in effect until further action on the pending appeal is taken by the appellate court.

https://ag.ny.gov/press-release/2022/attorney-general-james-statement-judges-decision-temporarily-allow-enforcement

Attorney General James Announces $600,000 Agreement With EyeMed After 2020 Data Breach—Jan. 24, 2022—A settlement agreement was reached with EyeMed following a data breach in 2020 that compromised the personal information of approximately 2.1 million people nationwide, including 98,632 New Yorkers. In June of 2020, an attacker gained access to an EyeMed email account, which was used by EyeMed clients to provide sensitive consumer data in connection with vision benefits and enrollment coverage. The intrusion was made possible, in part, by EyeMed's failure to implement a multifactor authentication system for the breached email accounts. The settlement agreement requires EyeMed to pay $600,000 in penalties and to enact a series of measures to protect consumers' personal information from cyberattacks in the future.

https://ag.ny.gov/press-release/2022/attorney-general-james-announces-600000-agreement-eyemed-after-2020-data-breach

Attorney General James Emerges Victorious in Suit Against "Pharma Bro" Martin Shkreli—Jan. 14, 2022—A federal court has ruled in favor of New York State, the Federal Trade Commission (FTC), and six other states, finding that Martin Shkreli engaged in illegal and monopolistic behavior while serving as the chief executive officer of Vyera Pharmaceuticals (Vyera). The illegal scheme perpetrated by Vyera, Shkreli, and his business partner involved restrictive distribution and supply agreements, as well as data secrecy, with the intent and effect of delaying entry by lower cost generic competitors. In addition to finding that Shkreli's conduct was illegal, the federal court has banned him from the pharmaceutical industry for life and will require him to pay nearly $65 million.

https://ag.ny.gov/press-release/2022/attorney-general-james-announces-600000-agreement-eyemed-after-2020-data-breach

New York State Office of the Medicaid Inspector General Update

Compiled by Dena M. DeFazio

UPDATE: NYC Pharmacy Owners Pleads Guilty in $6.8 Million Health Care Fraud and Kickback Scheme—Apr. 29, 2022.

https://omig.ny.gov/news/2022/update-nyc-pharmacy-owner-pleads-guilty-68-million-health-care-fraud-and-kickback-scheme

Governor Hochul Announces Major Transparency Improvements to State Government—Oct. 28, 2021.

https://omig.ny.gov/news/2021/governor-hochul-announces-major-transparency-improvements-state-government

Endnotes

1. Please note that these decisions are summarized after they are posted on the Department of Health's website, which is often many months after the date of the decision.
2. The editor wishes to thank Jessie Gregorio, Barclay Damon LLP summer associate Samuel Levin, and Barclay Damon LLP law clerk Rex McKeon, who each assisted in the summaries of these press releases.

In the Law Journals

By Jeff Ehrhardt

A Global Pandemic Treaty Must Address Antimicrobial Resistance, Lindsay A. Wilson *et al.*, 49 J. of L., Med. & Ethics, 688-691 (2021).

A Reliability Check on Expert Witness Testimony in Medical Malpractice Litigation: Mandatory Medical Simulation, Julie L. Campbell, 31 Health Matrix 1 (2021).

A Truly Modern Prometheus: Law and Policy at the Brink of A Genetic Revolution, Howard A. Zucker, M.D. J.D. & Richard Thomas, Esq., 31 Alb. L. J. Sci. & Tech. 1 (2021).

AI, Predictive Models and Medical Records: A Dangerous Decision for Healthcare Privacy and Restoring the Sacred Trust of Patient Confidentiality, Riyad A. Omar, 24 Quinnipiac Health L. J. 459 (2021).

Attorneys as Healthcare Advocates: The Argument for Attorney-Prepared Advance Healthcare Directives, Grace W. Orsatti, 50 J. of L., Med. & Ethics, 157-168 (2022).

Big Data, Surveillance Capitalism, and Precision Medicine: Challenges for Privacy, Mark A. Rothstein, 49 J. of L., Med. & Ethics, 666-676 (2021).

Cannabis Considerations for Health Care Entities, Vanessa K. Burrows, 24 J. Health Care L. & Pol'y 89 (2021).

Choosing Death, Shaping Death: Assumptions About Disabilities, Race, and Death, Janet L. Dolgin, 25 Quinnipiac Health L. J. 61 (2022).

Compassionate Release in the Context of COVID-19 and Future Pandemics, Drew Lewis, 21 Hous. J. Health L. & Pol'y 371 (2022).

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For Your Information

By Claudia O. Torrey

Due to the unexpected hospitalization of the columnist, it is hoped that the "FYI" column will return for the next issue of the *Health Law Journal*. Thank you very much in advance for your understanding!

Brendan Parent, Benjamin Sundholm and Robert Swidler

By Cassandra DiNova

"We must find time to stop and thank those the people who make a difference in our lives."

– John F. Kennedy

As a growing professional, there are some people in one's life that make a lasting impact. For me, both former Editors-in-Chief Robert Swidler and Brendan Parent, have been such people. Both have served as wonderful professional mentors to me and I would not be where I am today without their fantastic guidance. I also which to thank Benjamin Sundholm for many years as an editor. The NYSBA *Health Law Journal* (the "*Journal*") is forever in Robert, Brendan and Benjamin's debt for their years of work.

Brendan Parent is an assistant professor, Department of Population Health and assistant professor, Department of Surgery at NYU Langone Health. His primary research focuses are organ donation, procurement, and transplantation ethics and policy. Brendan worked as an editor for the *Journal* for approximately five years. The Winter 2017 issue was his first as an editor. Brendan is an active member of the NYSBA Health Law Section and was the chair of the Ethical Issues in the Provision of Health Care. He started the peer review process in the *Journal*, which improved the already great caliber of the *Journal*. He also created special issues based on the Health Law Section committees, such as the Public Health and the Young Lawyers committees.

I first worked with Brendan on one of these Young Lawyer Committee special issues, specifically the 2021 Vol. 26 No. 1. The special issue was an opportunity for young health law attorneys to get their work published. The *Journal* has done two special issues for young heath law attorneys. I was the co-chair of the Young Lawyers Committee at the time, which meant I assisted with the editing of that special issue. Through his mentorship, I learned the editing process along with what it meant to be "an editor."

Benjamin Sundholm is currently a fellow in medical ethics at Weill Cornell Medicine. He previously worked as an associate at Debevoise & Plimpton. He worked as an editor for approximately two years, first joining the *Journal* for the Summer 2020 issue. He worked with the columnists and was second to none in terms of efficiency with managing the *Journal*'s publication deadlines.

Robert Swidler is vice president of legal services at St. Peter's Health Partners. My first introduction to the *Journal* was through Robert Swidler, while I was still a law student. One of my law professors had encouraged me to submit my Note article for publication and Robert Swidler, the editor at the time, had encouraged me to do the same. It was an amazing opportunity as a law student. An opportunity the *Journal* still continues to offer. A few years later, Robert assisted in transitioning the "In the Journals" column to me and has since encouraged me to stay involved in the *Journal*. His career and accomplishments are truly admirable, not only for being a great practicing attorney but also a great mentor.

Because of their legacy, this *Journal* holds a special place in my heart and I am beyond honored to be continuing its legacy. Thank you Robert, Brendan and Benjamin for all your years of hard work. You will be missed!

A Troubling Trend: Human Exposure to Harmful Pesticides and the Absence of Administrative Action

By Audrey A. Hollick

I. Introduction

It is nearly impossible to separate the image of America from the country's robust and plentiful agricultural industry. The U.S. has long been recognized and imagined as a land of "amber waves of grain" and "fruited plains."[1] However, in recent decades, the reality of the dangers inherent in commercial agricultural practices has come to the attention of farmers and citizens across the globe. The U.S. began the practice of using synthetic pesticides and herbicides to increase farm yields in the 1930s.[2] Since this time, the use of such chemicals has increased in quantity and sophistication.[3] Despite an increase in knowledge about the risks and benefits of pesticides and herbicides, the U.S. has largely failed to mitigate the potential harm caused by them.[4] While many countries have made strides in reducing the risks inherent in commercial farming, the U.S. has fallen behind many other developed countries in limiting the use of harmful chemicals for farming.[5]

II. Pesticide Use in the U.S.

About one billion pounds of conventional pesticides are used each year in the United States.[6] In 2017, the U.S. used approximately 400 different pesticides for agricultural purposes.[7] Shockingly, of the pesticides used, about 150 of them were deemed "hazardous" by the World Health Organization (WHO).[8] Data showed that of these 150 chemicals, approximately 70 of them were banned in at least one other country.[9] An analysis of data from the U.S. Geological Survey and Pesticide Action Network International showed that at that time, the United States still used 25 pesticides banned in over 30 other countries.[10] An example of this is the insecticide "phorate."[11] Phorate was marked by the WHO as "extremely hazardous."[12] Despite this warning—and the fact that 38 other countries had banned the insecticide—the U.S. still used over 500,000 pounds of phorate in 2017.[13]

These numbers demonstrate a stark contrast in pesticide regulation between the U.S. and other developed nations.[14] Some may wonder why the U.S. has not fallen in line with other countries and the WHO to better monitor and regulate its pesticide use. The U.S. Department of Agriculture claims that more pesticides are used in the U.S. because they "contribute to higher yields and improved product quality by controlling weeds, insects, nematodes, and plant pathogens."[15] This argument fails, however, as China—having the largest agricultural industry in the world—has banned many of the pesticides that the U.S. keeps in use.[16] Furthermore, other massive agricultural economies, including those of the European Union (EU) and Brazil, recognized the dangers of many pesticides used in the U.S. and implemented their own bans and regulations.[17]

III. Pesticide Regulation, Generally

Supervision and regulation of pesticide use in the U.S. is done by the Environmental Protection Agency (EPA).[18] The EPA "regulates and enforces pesticide actions under the Federal Food, Drug, and Cosmetic Act (FFDCA)."[19] Specifically, the FFDCA allows the EPA to establish tolerances, or the "maximum legally permissible levels" of pesticides in our food.[20] In other words, under the FFDCA, the EPA is responsible for determining the allowable amount of pesticides on food grown in the U.S.[21]

The standard applied by the EPA in determining whether the presence of a pesticide on a food item is "safe" is whether there is a "*reasonable certainty of no harm*."[22] In the past, the EPA has relied upon findings from toxicity studies done on laboratory animals to determine the degree of harm likely to come from a pesticide.[23] It was only in 2010, when the EPA first included human data in their findings, and not until December 2016, that the EPA developed a "formal framework for incorporating human epidemiological data."[24] For the EPA, determining that there will be no harm to a reasonable degree of certainty is not always an easy task, and—as will be demonstrated throughout the course of this article—the EPA has made mistakes in their determinations in the past, and in all likelihood, the present as well.[25]

In addition to the powers and responsibilities entrusted to the EPA under the FFDCA, the EPA has the power to authorize companies to register pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).[26] Specifically, FIFRA enforcement focuses on "the sale, distribution, and use (which can include disposal) of pesticides."[27] Registration of a pesticide with the EPA is required prior to the sale or use of the chemical in U.S. markets.[28] In order to have a pesticide registered, an applicant must demonstrate to the EPA that the pesticide "will not generally cause unreasonable adverse effects on the environment."[29] Generally, it is required that the pesticide not result in

> [a]ny unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide[; or a]ny human dietary risk from residues that result from use of a pesticide in or on any food inconsistent with the standard under . . . the [FFDCA].[30]

As one may imagine, the regulation of pesticides in the U.S. is an enormous task. "[T]here are approximately 1,250 active ingredients being used in nearly 17,000 registered products."[31] Unsurprisingly, registration errors have occurred despite the EPA's review of pesticides under FIFRA.[32] Consequently, a number of chemicals detrimental both to human health and the environment have slipped through the cracks of EPA regulation under the FFDCA and FIFRA.[33] The result of this administrative failure is that the U.S. has fallen behind many other developed nations in the area of pesticide regulation.[34]

IV. EPA Ban of Chlorpyrifos

A. Organophosphates

A commonly used pesticide in U.S. farming and agriculture is organophosphate.[35] Organophosphates (OP or OPs) were created in the 1930s–40s and originally developed as human nerve gas agents.[36] They have been adapted in lower doses to serve as insecticides.[37] In the U.S., many OPs "were licensed for insecticidal use before requirements to evaluate human toxicity or ecologic effects were established."[38] This has left the EPA in the precarious position of determining the danger to human health that is posed by the OPs after they are already in use.[39]

Since their development, OPs have been an "attractive alternative" to other pesticides, as they have a greater acute toxicity, making them stronger and more effective.[40] The drawback of OPs' acute toxicity is that it causes a greater risk to those who come in contact with them.[41] Thus, although the use of many chemical pesticides, including OPs, has substantial benefits in the U.S. agricultural economy, many have been found to have considerable negative effects on human health.[42] In fact, studies have shown that "OPs are one of the most common causes of poisoning worldwide occurring as a result of agricultural use, suicide or accidental exposure."[43]

B. *League of United Latin American Citizens v. Regan*

In August 2021, the EPA issued a final rule which revoked all tolerances for chlorpyrifos.[44] This action was a response to a Ninth Circuit order "directing EPA to issue a final rule in response to the 2007 petition filed by Pesticide Action Network North America (PANNA) and Natural Resources Defense Council (NRDC)."[45] "The petition requested that EPA revoke all chlorpyrifos tolerances, or the maximum allowed residue levels in food, because those tolerances were not safe, in part due to the potential for neurodevelopmental effects in children."[46] Prior to this regulation, chlorpyrifos was the most commonly used pesticide in the U.S.[47]

The chlorpyrifos ban was a long time coming.[48] In 2007, PANNA and NRDC filed their petition under § 408(d) of the FFDCA, requesting that the EPA revoke all chlorpyrifos tolerances due to their alleged harm to human health.[49] However, no action was taken on this petition until the Ninth Circuit's order in April 2021.[50] What is troubling about the EPA's failure to act is not only the sheer length of time it took for the 2021 regulation to be enacted, but the fact that the

EPA *knew* of the dangers posed by chlorpyrifos and continued to allow its use for farming.[51]

In December 2014, a risk assessment was released by the EPA which determined that there was water contaminated by chlorpyrifos that was unsafe for human consumption.[52] As a result of these findings, the EPA proposed a ban of chlorpyrifos from food in 2015.[53] However, the proposed ban was blocked by the Trump administration and never went into effect.[54] In 2016, the EPA further concluded that chlorpyrifos exposure from food or drinking water alone could result in "unacceptably high population exposures" and that "some reproductive-aged women, infants, and children consumed levels of chlorpyrifos *substantially above* the acceptable level for th[ose] vulnerable life stages."[55] These findings revised the 2014 risk assessment by confirming that chlorpyrifos exposure from food, drinking water, and pesticide drift is unsafe.[56] The toddlers examined in that study were found to have been exposed to chlorpyrifos at 40 times more than the predetermined "safe" level."[57]

The case of *League of United Latin American Citizens v. Regan* led to the EPA's ban of chlorpyrifos by court order.[58] In the opinion of the Ninth Circuit, Judge Rakoff noted that for over a decade the EPA and its Scientific Advisory Panels (SAPs) failed to comply with the FFDCA requirement that there be a "reasonable certainty of no harm" from the pesticide.[59] The court further noted that the 2012 SAP was aware that existing evidence suggested that chlorpyrifos "can affect neurodevelopment,"[60] and that the 2014 Revised Human Health Risk Assessment stated that "chlorpyrifos likely played a role in the neurodevelopmental outcomes observed in the[ir] epidemiology studies."[61] Furthermore, in 2015, the EPA was unable to assert that "exposure to residues of chlorpyrifos, including all anticipated dietary exposures and all other non-occupational exposures . . . are safe."[62] Despite these findings, the EPA failed to institute a ban on the pesticide until after the Ninth Circuit's order, although it did amend the Human Health Risk Assessment in 2016 and noted evidence of "adverse health outcomes" as a result of even low chlorpyrifos exposure.[63]

The Court also cited a Columbia Study, which—along with other supporting studies—determined that there was "sufficient evidence that there are neurodevelopmental effects occurring at chlorpyrifos exposure levels."[64] This finding was unsurprising, as a study done in 2013 demonstrated that OPs including chlorpyrifos "have neurotoxic effects on developing organisms, even from low levels of exposure, causing various diseases of [the] nervous and immune system."[65] Based on the sum of this evidence, as well as other evidence presented to the court, the Ninth Circuit reasoned that the EPA could not conclude that there was a reasonable certainty of no harm, as required by the FFDCA, and therefore held that the present tolerances for chlorpyrifos were not safe.[66] The majority also recognized that "the EPA has sought to evade, through one delaying tactic after another, its plain statutory duties."[67] Even the dissent noted that the EPA "dithered far too long before ruling on the petition."[68]

These findings shed light on a fatal flaw of pesticide regulation by the EPA—the involvement of partisan politics in what ought to be an objective determination of safety in regulating pesticide use. In 2015, under the Obama administration, it was announced that chlorpyrifos would be banned following EPA studies indicating that the pesticide was linked to possible damage to brain development in children.[69] Unfortunately, the ban had not yet taken effect in 2017, when Scott Pruitt was appointed as administrator of the EPA and rejected the petition to ban the pesticide.[70] The rejection occurred less than a month after he was confirmed as the EPA's administrator.[71] This reversal was made despite the fact that it was clear from the EPA's 2016 Revised Human Health Risk Assessment that chlorpyrifos in food, drinking water, and pesticide drift posed a risk to humans—particularly children.[72]

Three years later, in 2020, the EPA had still failed to adequately address the harm being done by the use of chlorpyrifos, despite its *own scientists* recommending that it be taken off the market.[73] This continued refusal triggered a wave of lawsuits by environmental and farm worker activist groups demanding that the pesticide be banned in the U.S.[74] These challenges coalesced in the Ninth Circuit, where the EPA was ordered to either demonstrate that chlorpyrifos is not harmful to children or end the use of the pesticide on food crops.[75] Being unable to demonstrate that chlorpyrifos was not harmful, the Ninth Circuit ultimately ordered the EPA to revoke all chlorpyrifos tolerances.[76]

Essentially, this case demonstrates systemic failures by the EPA to regulate pesticides that are detrimental to human health and the environment. The chlorpyrifos ban is merely one example of the judiciary stepping in to ensure that the EPA complies with its own mission to "protect human health and the environment."[77]

V. Glyphosate

Despite the victory of advocacy groups in *League v. Regan*, countless pesticide suits remain to be litigated in the U.S.[78] At the forefront of these suits are cases against the Bayer-Monsanto corporation (Bayer).[79] During the past few years, numerous claims have been brought by plaintiffs alleging that they developed non-Hodgkin's lymphoma (NHL) as a result of exposure to glyphosate.[80] More specifically, plaintiffs claim to have been exposed to the common pesticide "Roundup,®" which is used in both agricultural and non-agricultural settings.[81]

Glyphosate presents a more controversial issue than chlorpyrifos. While the use of chlorpyrifos was widely condemned by many members of the international community prior to the Ninth Circuit's decision, a large number of countries still use glyphosate-based herbicides as a method of weed prevention in farming industries.[82] In fact, the European Union—typically a leader in banning potentially harmful pesticides—has yet to ban the use of glyphosate.[83] This does not mean that all countries accept the use of the herbicide, as many nations have already prohibited the use of glyphosate, or have pledged to replace glyphosate-based herbicides in the near future.[84] Despite the uptick in glyphosate litigation and growing evidence of the link between glyphosate and NHL, many governments worldwide have yet to take action to prevent the widespread use of glyphosate.[85]

A. Scale of Glyphosate Use

Glyphosate is the world's most widely-used weedkiller.[86] It is a chemical herbicide that has been registered for use with the EPA since 1974.[87] The herbicide is heavily used in the agriculture industry for commercial farming, but is also used for residential purposes.[88] Commonly, households use glyphosate—primarily in the form of Roundup® weed killer—to prevent weeds from sprouting in their driveways, sidewalks, and gardens.[89] Glyphosate is the most widely used agricultural chemical in history, and it is projected that farmers will continue to use glyphosate and glyphosate pesticides such as Roundup® as "a growing population increases the demand for food."[90] The EPA estimated that from 2012–2016 "[a]bout 280 million pounds of glyphosate [was] applied to an average of 298 million acres of crop land annually."[91] In addition to this figure, the EPA has noted that "millions of pounds of glyphosate are applied to non-crop sites every year."[92] In 2014, an estimated 1.8 billion pounds of glyphosate was used worldwide.[93] The staggering presence of glyphosate in American agriculture and residential properties make one thing apparent—exposure to glyphosate is unavoidable.[94]

Despite the already massive amounts of glyphosate being used throughout the U.S., the amount of glyphosate used—particularly for agriculture—continues to rise.[95] When the herbicide was first available for use in 1974, U.S. farmers applied only an estimated 0.8 million pounds of glyphosate annually.[96] This number rose steadily (though not dramatically) through 1995, with 28 million pounds being applied in that year.[97] In 1996, however, the numbers began to increase more rapidly.[98] By the year 2000, 79 million pounds of glyphosate was being applied to U.S. crops each year.[99] In 2000, glyphosate-based herbicides accounted for 80% of total herbicides used in the U.S.[100] By 2010, glyphosate accounted for 90% of herbicides used in the U.S.[101] "Glyphosate use in the agricultural sector rose 300-fold from 1974 to 2014."[102] Between 1974 and 2014, three billion pounds of glyphosate was applied for agricultural purposes in the U.S.[103] These numbers continue to rise[104] and the benefits of glyphosate-based herbicides have been further magnified by the development of genetically modified organisms (GMOs).[105]

GMOs are living organisms that have their naturally-occurring genetic code altered in some way.[106] Typically, genes from two different sources are mixed to produce a more desirable product.[107] In 1996, to further amplify the benefits gained from glyphosate, Monsanto developed the first "Roundup Ready®" seeds.[108] These seeds were designed to be resistant to the glyphosate in Roundup,® so that the herbicide would not kill crops along with the surrounding weeds.[109] Because of their glyphosate-resistance, the herbicide may be applied to farmland not only before and after planting and harvesting, but also while plants are growing.[110] Thus, the sale of Roundup Ready® seeds resulted in a larger amassing and application of glyphosate-based herbicides (including Roundup®), and corresponds with the substantial increase in glyphosate use we have seen between 1996 and the present day.[111] Today, 94% of soybeans and approximately 90% of corn and cotton crops nationwide are resistant to glyphosate, allowing it to kill weeds but not the crops.[112]

B. The Global Stance on Glyphosate

According to the EPA, glyphosate has been reviewed and assessed to determine its safety, and is undergoing registration review, a program designed for re-evaluating pesticides on a fifteen year cycle.[113] In January 2020, in response to public health concerns regarding potential harm caused by glyphosate exposure, the EPA released an interim decision for their registration review of glyphosate.[114] This decision made two key determinations: first, the EPA found no risk to human health "when glyphosate is used in accordance with its current label";[115] second, the EPA found that "glyphosate is unlikely to be a human carcinogen."[116] Though the EPA's findings align with some other global authorities, there have been numerous independent studies that indicate a substantial link between glyphosate exposure and NHL.[117] In 2015, the WHO reported a link between glyphosate and cancer, finding that glyphosate is "*probably carcinogenic to humans*."[118] The WHO's stance is also supported by independent and institutional studies done on glyphosate.[119]

C. A Chilling Correlation: Non-Hodgkin's Lymphoma

The greatest concern among those that have studied the effects of glyphosate on human health is the emerging evidence of a correlation between exposure to glyphosate and the development of NHL. As mentioned *supra*, glyphosate was first sold and used in 1974.[120] Between the years 1975 and 2006, the incidence of NHL in the U.S. nearly doubled.[121] Glyphosate-based herbicides were implicated in studies on the uptick of NHL, as the populations experienc-

ing the increased risk were largely those exposed to glyphosate occupationally, or those living in a residence treated with the herbicide.[122] Though studies have not yet revealed a concrete *causal* link between glyphosate exposure and NHL, the subject has also not been rigorously studied with reference to human populations.[123]

Of the studies that have been done, findings have revealed a myriad of other health issues related to glyphosate exposure.[124] For example, multiple studies have revealed "effects indicative of endocrine disruption."[125] These studies noted that "the developing fetus, infants, and children are most at risk."[126] Though the effects of endocrine disruption are not always apparent early in life, they typically manifest later in life or during adulthood in the form of "acute diseases [or] chronic health problems."[127] Additionally, in Argentina and Paraguay, there was an increase in the incidence of severe birth defects where Roundup Ready® crops were widely grown.[128] These studies concluded that the increased incidence of severe birth defects may be linked to the ability of glyphosate-based herbicides to "increase retinoic acid activity during fetal development" which can lead to fetal and birth defects.[129]

Further studies conducted on animals have revealed other pressing concerns.[130] Developmental studies of rats "undertaken at relatively high levels of exposure" suggest possible glyphosate-induced neurotoxicity "*through multiple mechanisms*."[131] Additionally, "[g]lyphosate-contaminated soybean feeds used in the pork industry have also been associated with elevated rates of gastrointestinal-health problems and birth defects in young pigs."[132] Similar effects have been reported in studies done on poultry.[133] Furthermore, some studies have concluded that glyphosate "may interfere with normal sexual development and reproduction in vertebrates."[134] "Experiments with zebrafish with dosing of [glyphosate] in the upper range of environmentally-relevant contamination levels, show morphological damage to ovaries."[135]

Studies of microorganisms exposed to glyphosate have also raised concerns.[136] One report demonstrated that "environmentally relevant concentrations of commercially available [glyphosate-based herbicides] alter the susceptibility of bacteria to six classes of antibiotics."[137] Thus, there is a correlation between the application of glyphosate and increased bacterial resistance to antibiotics.[138]

Despite countless studies indicating that glyphosate likely poses a substantial risk to human health, the federal government—and particularly the EPA—has failed to conduct substantial studies on human populations to determine the safety of glyphosate.[139] Thus, they have failed to follow their own standard of certifying pesticides for use only if there is a "reasonable certainty of no harm."[140]

D. Glyphosate Litigation

The uptick in NHL diagnoses has resulted in a landslide of litigation against Bayer, the largest producer of glyphosate.[141] Many of these suits are brought by plaintiffs alleged to have developed NHL by working with Bayer's Roundup® weed-killer.[142] In several of these suits, juries have determined that exposure to Roundup® caused or contributed to the plaintiffs' development of NHL.[143] Some verdicts have resulted in unprecedentedly large damages.[144] For example, in 2019, Alva and Alberta Pilliod—both of whom had been diagnosed with NHL—were awarded over $2.055 *billion* in damages.[145] The jury came to this figure of approximately $2.055 billion after determining that Roundup® was a "substantial factor" in the Pilliods' development of NHL.[146] The Pilliods owned four properties and had been using Roundup® to combat weeds on the properties for over 30 years.[147] The jury award was reduced to $87 million by the trial judge, who determined that the jury's initial calculation of damages exceeded the constitutional limits on damages set by the Supreme Court.[148]

On appeal, the appellate court affirmed the jury's verdict and the trial judge's reduction of damages,[149] noting that "Monsanto's conduct evidenced reckless disregard of the health and safety of the multitude of unsuspecting consumers it kept in the dark."[150] The California Court of Appeals stated that the Pilliods' exposure "was not an isolated incident," noting that "Monsanto's conduct involved repeated actions over a period of many years motivated by the desire for sales and profit[, and t]he harm Monsanto caused was the result of malice."[151]

The Pilliods are neither the first nor the last to recover damages in a suit against Bayer, as claims continue to be brought against the chemical corporation.[152] In fact, there are approximately 125,000 lawsuits from plaintiffs claiming that glyphosate-based weed killers caused or contributed to their NHL diagnosis.[153] "The company resolved about 75% of the cases with a nearly $10 billion settlement last year, but it still faces about 30,000 cases and possibly additional ones in the future."[154] A majority of these claims stem from residential use of the herbicide.[155]

In response to the mass of litigation that the corporation is faced with, Bayer announced in July of 2019 that they will cease selling glyphosate-based products for residential use in the U.S. beginning in 2023.[156] However, the company does not intend to cease sales of Roundup® residentially; rather, they are reformulating the herbicide to avoid the use of glyphosate in its chemical makeup.[157] Bayer's CEO, Werner Baumann stressed that "[g]lyphosate-based herbicides will still be available for professional and agricultural uses."[158] Baumann further stated that the ban "is exclusively geared at managing litigation risk and not because of any safety concerns."[159] Though it is encouraging that Bayer will no longer sell glyphosate

based-products for residential use, two critical questions arise following their announcement: (1) what herbicide will replace glyphosate in Roundup's® chemical makeup? and (2) what is being done to protect farmworkers and consumers impacted by glyphosate-based products used in the agricultural industry?

At the present time, there is no answer to the former question. Bayer is still in the process of reformulating Roundup®, so it is unclear what will replace glyphosate in the product. As for the second query, the short answer would be very little. Though some governments in the U.S. have taken action on the county-level to ban the herbicide, the federal government has yet to take action to protect farm workers and consumers.[160]

E. Glyphosate Used in Agriculture Reaches the Greater Population

Though it is encouraging that Bayer will be pulling residential glyphosate-based herbicides from retail shelves, there is still cause for concern regarding the use of glyphosate in the agricultural industry.[161] Undoubtedly, farm workers experience the highest risk of glyphosate exposure and potential health issues that may stem from that exposure.[162] Studies of farm workers have demonstrated that "the average urinary glyphosate level in occupationally exposed individuals is [] *disconcertingly high*."[163] Though the prevalence of glyphosate in these tests has actually decreased in recent years, scientists believe that the decrease is caused by the use of more effective personal protective equipment rather than a decrease in actual exposure.[164]

Though far less testing has been done than is reasonably necessary,[165] the testing that has been done has revealed that it is not only the farm workers who are exposed to glyphosate.[166] A 2017 study demonstrated that glyphosate levels have been increasing over time for non-farmer U.S. and European adults.[167] Glyphosate has been detected in testing done on urban, as well as rural populations.[168] Though glyphosate levels among the greater population vary from location to location—the general finding remains the same: plants are not the only organism ingesting glyphosate.

Glyphosate reaches the greater population primarily because it does not fully dissolve when sprayed on crops.[169] The effect of this is that glyphosate may be found in the public's water[170] and food.[171] Because glyphosate residue can linger on food long after application, the EPA has set "limits on glyphosate residue that may permissibly remain on crops after they have been harvested."[172] Accordingly, the FDA is tasked with "ensur[ing] that food products do not contain glyphosate residue in excess of the EPA limits."[173]

Despite FDA supervision, glyphosate residues have been found in food.[174] A study focusing on soybeans found that "of the 300 samples tested, 90.3% contained glyphosate at a mean level of 1.9 ppm, while 95.7% contained AMPA—a microbial degradation product of glyphosate—at 2.3 ppm."[175] To contrast with other herbicide residues, "the next highest residue reported by USDA in soybeans was malathion, present at 0.026 ppm in just 3.7% of samples . . . [therefore,] the mean levels of glyphosate and AMPA in soybeans were 73-fold and 83-fold higher than malathion, respectively."[176] On soybeans known to be grown from Roundup Ready® seeds, glyphosate and AMPA residues were found in nearly all mature soybeans.[177] Moreover, soybeans are not the only crops containing glyphosate residues, as research has found that other crops including wheat, barley, oilseeds, vegetables, and others contain glyphosate residue.[178] Additionally, crops are being sprayed with glyphosate-based herbicides late in the season to "accelerate crop death, drying, and harvest options . . . average residue levels on . . . some harvested grains, oilseeds, and certain other crops are substantially higher than they were a decade ago."[179] As a result of this additional herbicide treatment and subsequent increase in glyphosate residue, "human dietary exposures are rising."[180]

Pesticides can also infiltrate water sources through rain runoff, streams, and by being absorbed into the soil and penetrating the groundwater below.[181] "Once [glyphosate] fumigation is performed, the residues are deposited in the soil and, through infiltration processes, the compounds are leached out of the soil by the rain until they reach bodies of water, with the consequent transfer to aquatic organisms, or they can eventually reach phreatic (groundwater) levels, where they can be extracted through wells for human use."[182] Thus, humans are exposed to glyphosate as it can infiltrate water used for washing, bathing, and drinking.[183]

In fact, the WHO has taken notice of pesticide exposure in the general population.[184] The organization has noted that although the general population is less at risk than those directly exposed to pesticides, some people are experiencing pesticide exposure at a higher rate than is considered safe.[185] The WHO has noted that even those "who are not in the area where pesticides are used" are exposed to pesticide residues through food and drinking water.[186]

F. Incidental Exposure to the Greater Population Poses a Risk to Public Health

Though some may view glyphosate exposure to human populations as minimal, it raises substantial health concerns. A study revealed that there is "evidence of heightened cancer risk in human populations at levels of exposure *actually experienced in human populations*."[187] As a result of this finding, Myers et al. concluded that "existing toxicological data and risk assessments are not sufficient to infer that GBHs [(glyphosate-based herbicides)], as currently used, are safe."[188]

VI. Solutions

A. Science and Stability Within the EPA

Under FIFRA, pesticides shall not be registered nor used where they cause

> [a]ny unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide[; or a]ny human dietary risk from residues that result from use of a pesticide in or on any food inconsistent with the standard under . . . the [FFDCA].

This standard has proven to be too flexible.

The facts of *League v. Regan* demonstrate that the EPA is given far too much discretion in discerning how much harm to human health is "reasonable."[189] As noted above, EPA officials refused to revoke chlorpyrifos tolerances for years despite being aware of the harm that the pesticide caused to human health.[190] The same pattern is emerging with glyphosate-based herbicides. Although the EPA has been made aware of the potential risks of glyphosate exposure through independent studies, mounting lawsuits, and an announcement by the WHO, it has largely failed to act to research or mitigate these risks.

The starting point for this prevention is simple. First, the EPA must conduct large-scale, comprehensive testing to determine how much the greater population is exposed to pesticides, and whether a correlation can be found between certain pesticide exposures and detrimental health conditions. The current state of testing for glyphosate exposure alone is shockingly low.[191] In fact, "[l]arge-scale and sophisticated biomonitoring studies of the levels of glyphosate, its metabolites, and other components of GBH mixtures in people have not been conducted anywhere in the world."[192] Considering that glyphosate is the most widely-used herbicide in the country, the EPA ought to conduct comprehensive testing to determine its effect on the human population.

Fortunately, such procedural and structural change within the EPA seems attainable at this time. In February of 2022, the EPA announced that it was implementing a new Science Advisory Board process known as "Science Supporting EPA Decisions."[193] This new process is intended to strengthen the role that science plays in EPA decision making.[194] EPA Administrator Michael Regan stated that

> [e]verything we do as an agency must adhere to the highest standards of scientific integrity, and today's action is a major step towards stronger, independently reviewed science . . . Science Supporting EPA Decisions, will allow EPA to effectively engage the Science Advisory Board while ensuring the important independent advisory status of the Board is maintained.[195]

While there is no specific mention of FIFRA or pesticide regulation in the Science Supporting EPA Decisions memo, this new process may indicate that the EPA is taking a step toward proactive management of potential risks to human health.[196] The announcement itself brings attention to the Biden-Harris administration's commitment to restoring science-backed processes to promote and protect public health.[197] As promising as this is in the short-term, it brings to light a fatal flaw in EPA regulation—the involvement of partisan politics.[198]

Because the current administration has demonstrated a commitment to reintroducing strong scientific influences into EPA decision-making, the EPA will demonstrate a commitment to strong scientific influences in decision-making. The president appoints the EPA administrator, who is then confirmed by the Senate.[199] Undoubtedly, some presidents have appointed administrators who will carry out their own partisan agenda, rather than the EPA's proposed mission of promoting human health and the environment.[200] In a 2019 article, Madeline Krass described these appointed administrators as "presidentially appointed environmental agency saboteurs."[201] Krass noted that "[p]residential politicization of the federal bureaucracy plagues a wide swath of federal agencies . . . [and] becomes extreme when a president inserts an agency saboteur for the very purpose of diminishing agency performance."[202] Both parties have participated in the polarization of federal agencies.[203]

A recent example of an environmental agency saboteur was Scott Pruitt.[204] Pruitt was appointed by President Trump in 2017.[205] From the time of Pruitt's confirmation, he "sought to undermine the agency by imposing drastic budget and staff cuts, bringing in pro-[oil] industry allies, and exiling career employees."[206] During Pruitt's first four months as administrator, he "moved to undo, delay or otherwise block more than 30 environmental rules, a regulatory rollback larger in scope than any other over so short a time in the agency's 47-year history."[207] These actions received strong support from President Trump.[208] As noted above, Pruitt's actions directly impacted pesticide regulation, as the EPA reneged on its decision to revoke chlorpyrifos tolerances in 2017, after the change in administration.[209]

Though it is promising that the current administration has made an effort to rebuild the EPA's regulatory fluency,[210] the harsh reality is that it is only a matter of time before a new administration with a different agenda comes into office. The current system of presidentially appointed administrators leads to political flip-flopping which degrades both the efficiency and the effectiveness of the EPA. This imbalance leads

to adverse outcomes—intentional or not—such as the failure to revoke chlorpyrifos tolerances and the lack of substantial testing on glyphosate-based herbicides.

Though there is no one clear solution to this problem, the nexus of the issue appears to be the presidential appointment of administrators. The current policy undermines the EPA's integrity in regulation and decision-making. As politics become more polarized, it has become impossible for some executives to serve both their constituents as well as human health and the environment. As a result, it may be time to appoint administrators based on merit rather than affiliation in order to reduce polarization within the EPA.

B. Curbing Pesticide Use

The lingering question is what ought to be done now to prevent or deter the use of pesticides that may be harmful to human health. Some urge that the best course of action is to eliminate the use of pesticides altogether. However, despite the risks presented by chemical pesticides, there are undoubted benefits to pesticide use in commercial farming.[211] With a national population of over 330 million people, and a global population rapidly approaching eight billion, it is necessary to ensure that enough food is being produced.[212] Though pesticides pose a risk to human health, it is unlikely that the risk outweighs the threat of starvation that many would experience if the world were faced with a food shortage.[213] However, this does not mean that we should maintain the status quo and continue the use of pesticides known to be harmful or at least known to pose a potential threat. More ought to be done to prevent the flow of pesticides from crops to the human body.

Steps can be taken to reduce human exposure to pesticides by simply reducing the amount of pesticides used in American farming.[214] One way that the government may accomplish this is by subsidizing organic agriculture. "The USDA defines organic agriculture as 'a production system that is managed to respond to site-specific conditions by integrating cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity.'"[215] More specifically, organic farming principles emphasize the "[r]eduction of external and off-farm inputs and elimination of synthetic pesticides and fertilizers and other materials."[216]

Studies have demonstrated that an organic diet can reduce the amount of pesticides entering the human body.[217]A 2015 study tested the urine of children while they were fed a "conventional" diet containing food that had been grown with pesticides, and then an organic diet not containing pesticides.[218] The researchers found that when the children were eating the organic diet, exposure to organophosphates was lower than when they were eating a conventional diet.[219] These findings were supported by another study which determined that " in a group of 23 children ranging in age between three and 11 years, the concentrations of organophosphates, malathion, and chlorpyrifos in urine diminished when a conventional diet was changed to a feeding regimen with organic products."[220]

As awareness of the benefits of organic agriculture has grown, so has the market for organic food.[221] As a result, the number of organic farms in the U.S. has also increased.[222] In fact, between 2016 and 2019, there was a "17% increase in the number of certified farms in the U.S."[223] The shift of many farms toward organic practices demonstrates the feasibility of a comprehensive national shift toward organic agriculture subsidized by the government and regulated by the EPA.

VII. Conclusion

The current system of pesticide use and regulation in the U.S. does not adequately protect human health. Chlorpyrifos and glyphosate are simply two examples of widely used pesticides which have been systemically under-tested and under-regulated. Though the Ninth Circuit stepped in to order the revocation of chlorpyrifos tolerances, no such order exists for glyphosate. The pesticide remains both registered with the EPA and widely used throughout the nation despite a blatant lack of comprehensive testing, as well as ongoing litigation regarding the pesticide's alleged link to cancer. While the current administration's commitment to relying upon science in their regulatory processes is promising, it does not foreclose the possibility of another regression in the future. It is crucial that the EPA be separated from the influence of partisan politics to ensure that the agency is fulfilling its mission to protect human health. It is equally critical that our regulatory industries make a shift toward healthy farming practices that substantially reduce the risk of exposure to harmful chemicals, because every human should have the right to pesticide-free food, water, and air.

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Endnotes

1. *See The Power Behind 'America the Beautiful'*, NPR (Nov. 4, 2008), https://www.npr.org/2008/11/04/92198269/the-power-behind-america-the-beautiful.
2. *Bacillus Thuringiensis,* University of California San Diego, http://www.bt.ucsd.edu/synthetic_pesticide.html (last visited Nov. 8, 2021).
3. *Id.*
4. Pramod Acharya, *The United States Still Uses Many Pesticides Banned in Other Countries*, The Counter (Oct. 20, 2020, 12:36 PM), https://thecounter.org/the-us-still-uses-many-pesticides-banned-in-other-countries/ [hereinafter "The Counter"]. 2017 is the last year that data was available for this topic; *see also* Pramod Acharya, *The U.S. Still Uses Dozens of Pesticides Banned in Other Countries*, In These Times (Oct. 18, 2020), https://inthesetimes.com/article/banned-pesticides-herbicides-agricultural-chemicals-industrial-farming [hereinafter "In These Times"].
5. *Id.*
6. Nancy Baker & Megan Shoda, *Pesticides*, USGS: Ohio-Kentucky-Indiana Water Science Center, https://www.usgs.gov/centers/oki-water/science/pesticides?qt-science_center_objects=0#qt-science_center_objects, (last visited Nov. 9, 2021).
7. The Counter, *supra* note 4.
8. *Id.*
9. *Id.*
10. *Id.*
11. *Id.*
12. *Id.*
13. *Id.*
14. *Id.*
15. In These Times, *supra* note 4.
16. As of 2017, China had banned or was in the process of a complete phase-out of pesticides "approved for outdoor application" that were still in use in the U.S. Concurrently, of the pesticides used by the U.S. in 2016, 40 million pounds of them were pesticides banned in China. Nathan Donley, *The USA Lags Behind Other Agricultural Nations in Banning Harmful Pesticides*, 18:44 BMC J. Envtl Health, 3 (2019).
17. As of 2017, the EU had banned or was in the process of banning 72 pesticides approved for outdoor use by the U.S., and in 2016 the U.S. used 322 million pounds of pesticides banned in the EU for agriculture. In comparison, there were 17 pesticides banned or in the process of being phased-out by Brazil in 2017 still in use in the U.S., and in 2016 the U.S. consumed 26 million pounds of pesticides banned in Brazil. Donley, *supra* note 16, at 3.
18. Donley, *supra* note 16, at 2; *see also Regulatory and Guidance Information by Topic: Pesticides*, U.S. Envtl Protection Agency, https://www.epa.gov/regulatory-information-topic/regulatory-and-guidance-information-topic-pesticides, (last updated May 11, 2021).
19. Donley, *supra* note 16, at 2.
20. *Regulatory and Guidance Information*, *supra* note 18.
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22. *Id.* (emphasis added).
23. *Id.*
24. *Id.*
25. *Id.*
26. Donley, *supra* note 16, at 7.
27. *Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Federal Facilities*, U.S. Envtl Protection Agency, https://www.epa.gov/enforcement/federal-insecticide-fungicide-and-rodenticide-act-fifra-and-federal-facilities, (last updated Feb. 16, 2021).
28. *Id.*
29. *Id.*
30. *Id.*
31. Terence J. Centner, *Pesticide Registration Fails to Protect Human Health: Damages from Exposure to Glyphosate-Based Herbicides*, 36 J. Envtl L. & Litig. 69, 73 (2021).
32. *Id.*
33. *See id.*
34. *See generally* Donley, *supra* note 16.
35. *See* Irva Hertz-Picciotto et al., *Organophosphate Exposures During Pregnancy and Child Neurodevelopment: Recommendations for Essential Policy Reforms*, PLOS Medicine: Policy Forum, Oct. 24, 2018, at 2, https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002671.
36. *Id.*
37. *Id.*
38. These OPs include: malathion, dichlorvos, azinphos-methyl, and chlorpyrifos. *See id.* at 2.
39. *See id.*
40. Mirjana B. Čolović et al., *Acetylcholinesterase Inhibitors: Pharmacology and Toxicology*, 11 Current Neuropharmacology, 315, 324 (2013).
41. OP toxicity is not limited to the acute phase, but that injury and illness has been reported as a result of chronic exposure. In fact, "repeated or prolonged exposure to OPs may result in the same effects as acute exposure including the delayed symptoms." *Id.* at 324.
42. *Id.*
43. *Id.*
44. Tolerances establish the "amount of a pesticide that is allowed on food." The result of the EPA's final rule is that no amount of chlorpyrifos may be present on food in the U.S. *See* EPA Press Office, *EPA Takes Next Step to Keep Chlorpyrifos Out of Food, Protecting Farmworkers and Children's Health*, U.S. Envtl.Protection Agency (Feb. 25, 2022), https://www.epa.gov/newsreleases/epa-takes-next-step-keep-chlorpyrifos-out-food-protecting-farmworkers-and-childrens.
45. *EPA Takes Action to Address Risk from Chlorpyrifos and Protect Children's Health*, U.S. Envtl Protection Agency: News Releases from Headquarters: Chem. Safety and Pollution Prevention (OCSPP) (Aug. 18, 2021), https://www.epa.gov/newsreleases/epa-takes-action-address-risk-chlorpyrifos-and-protect-childrens-health.
46. *Id.*
47. *See* Hertz-Picciotto et al., *supra* note 35, at 7.
48. *Id.*
49. *Summary of the Federal Food, Drug, and Cosmetic Act*, U.S. Envtl. Protection Agency, https://www.epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act#:~:text=Section%20408%20

of%20the%20Federal,to%20seizure%20by%20the%20government (last visited Apr. 20, 2022).

> Section 408 of the [FFDCA] authorizes EPA to set tolerances, or maximum residue limits, for pesticide residues on foods. In the absence of a tolerance for a pesticide residue, a food containing such a residue is subject to seizure by the government. Once a tolerance is established, the residue level in the tolerance is the trigger for enforcement actions. That is, if residues are found above that level, the commodity will be subject to seizure.

50. *Id.*
51. Erin Fitzgerald, *EPA Ignores Evidence Chlorpyrifos Causes Damage to Children's Brains*, Earthjustice (Sept. 22, 2020), https://earthjustice.org/news/press/2020/epa-ignores-evidence-chlorpyrifos-causes-permanent-damage-to-childrens-brains.
52. *Id.*
53. *Id.*
54. *Id.*
55. Hertz-Picciotto et al., *supra* note 35, at 7–8 (emphasis added).
56. Fitzgerald, *supra* note 51.
57. *Id.*
58. *See generally League of United Latin American Citizens v. Regan*, 996 F.3d 673 (9th Cir. 2021).
59. *League v. Regan*, 996 F.3d at 701.
60. *Id.*
61. *Id.* at 702.
62. *Id.* at 702 (quoting Chlorpyrifos; Tolerance Revocations, 80 Fed. Reg. 69,080, 69,081 (Nov. 6, 2015)).
63. *Id.* at 702.
64. *See id.* at 702 & n. 160. Generally, these neurological effects occur because organophosphates are irreversible acetylcholinesterase (AChE) inhibitors. For a further explanation of AChE inhibition, *see* Čolović, *supra* note 40 (explaining the process of AChE inhibition and the role that organophosphates play in neurological and other defects).
65. Čolović et al., *supra* note 40, at 324.
66. *League v. Regan*, 996 F.3d at 702.
67. *Id.* at 678.
68. *Id.* at 704 (Bybee, J. Dissenting).
69. Lisa Friedman, *E.P.A. Won't Ban Chlorpyrifos, Pesticide Tied to Children's Health Problems*, N.Y. Times (July 18, 2019), https://www.nytimes.com/2019/07/18/climate/epa-chlorpyrifos-pesticide-ban.html.
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71. Eric Lipton, *Court Orders E.P.A. to Ban Chlorpyrifos, Pesticide Tied to Children's Health Problems*, N.Y. Times (Aug. 9, 2018), https://www.nytimes.com/2018/08/09/us/politics/chlorpyrifos-pesticide-ban-epa-court.html.
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73. Coral Davenport, *E.P.A. to Block Pesticide Tied to Neurological Harm in Children*, N.Y. Times (Aug. 18, 2021), https://www.nytimes.com/2021/08/18/climate/pesticides-epa-chlorpyrifos.html.
74. *Id.*
75. *Id.*
76. *EPA Takes Action to Address Risk from Chlorpyrifos*, *supra* note 45.
77. *Our Mission and What We Do*, EPA, https://www.epa.gov/aboutepa/our-mission-and-what-we-do, (last updated July 2, 2021).
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79. *Id.*; In 2018, Bayer merged with the U.S. corporation Monsanto, making Bayer the sole owner of the Monsanto corporation. *See Bayer Closes Monsanto Acquisition*, Bayer (June 7, 2018), https://media.bayer.com/baynews/baynews.nsf/id/Bayer-closes-Monsanto-acquisition.
80. *See* Legal Examiner, *supra* note 78.
81. *Glyphosate*, U.S. Envtl Protection Agency (Nov. 16, 2021), https://www.epa.gov/ingredients-used-pesticide-products/glyphosate; Roundup® was originally manufactured and sold by the Monsanto Corporation. For this reason, suits brought prior to June 2018 were against the Monsanto Corporation. Because of the 2018 merger, Bayer has borne liability from Roundup® suits that have arisen post-merger.
82. *Where Is Glyphosate Banned?*, Baum Hedlund Aristei Goldman PC, https://usrtk.org/monsanto-roundup-trial-tracker/white-house-has-monsantos-back-on-pesticides-newly-revealed-document-says/ (last updated Aug. 2021).
83. *Id.*
84. *Id.*
85. Legal Examiner, *supra*, note 78; *see generally* John Myers et al., *Concerns Over Use of Glyphosate-Based Herbicides and Risks Associated with Exposures: A Consensus Statement*, 15 BMC Env. Health J. (2016), https://ehjournal.biomedcentral.com/articles/10.1186/s12940-016-0117-0.
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87. *Glyphosate*, *supra* note 81.
88. Glyphosate—Response to Comments Usage and Benefits—Final (Apr. 18, 2019), https://www.epa.gov/sites/default/files/2019-04/documents/glyphosate-response-comments-usage-benefits-final.pdf.
89. *Id.*
90. Cohen, *supra* note 86.
91. Glyphosate—Response to Comments Usage and Benefits, *supra* note 88, at 2.
92. *Id.*
93. Rachel Shaffer, *What's the Risk?*, rachel talks tox: Toxicology and Environmental Health [Commentary] Blog (Feb. 20, 2019), https://racheltalkstox.wordpress.com/2019/02/20/whats-the-risk/.
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95. Residential use has risen, but at a substantially slower rate than agricultural use. This can be attributed to the limited available uses of glyphosate in a residential setting. *See* Charles M. Benbrook,

Trends in Glyphosate Herbicide Use in the United States and Globally, 28 Env. Sci. Eur. Feb. 2, 2016, at 1, 5.

96. *Id.* at 5.
97. *Id.*
98. *Id.*
99. *Id.*
100. *Id.*
101. *Id.*
102. *Id.*
103. *Id.*
104. *See id.*
105. Jordan Wilkerson & Brian Chow, *Why Roundup Ready Crops Have Lost Their Allure*, Harv. Univ., Signal to Noise Special Edition: GMOs and Our Food (Aug. 10, 2015), https://sitn.hms.harvard.edu/flash/2015/roundup-ready-crops/.
106. *What are GMOs?*, Purdue Univ. Coll. of Agric., https://ag.purdue.edu/GMOs/Pages/WhatareGMOs.aspx (last visited May 10, 2022).
107. *Id.*
108. Wilkerson, *supra* note 105.
109. *Id.*
110. Benbrook, *supra* note 95, at 10.
111. *See id.* at 5.
112. Cohen, *supra* note 86.
113. *Glyphosate*, *supra* note 81.
114. *Id.*
115. *Id.*
116. *Id.*
117. *See generally* Some Organophosphate Insecticides and Herbicides (IARC Monographs on the Eval. of Carcinogenic Risks to Hums., Vol. 112, 2015).
118. *See id.* at 398 (emphasis in original).
119. *See* Myers et al., *supra* note 85.
120. Benbrook, *supra* note 95, at 5.
121. Myers et al., *supra* note 85, at 6.
122. *Id.* at 6.
123. *Id.* at 7. This article also noted that "proving links between chronic disease and exposures to GBHs [(glyphosate-based herbicides)] is made more difficult by the fact that people are routinely exposed to complex mixtures of glyphosate and other toxic chemicals."
124. *Id.* at 6–7.
125. *Id.* at 7.
126. *Id.*
127. *Id.*
128. *Id.*
129. *Id.* at 11.
130. *Id.* at 7.
131. *Id.* (emphasis added).
132. *Id.*
133. *Id.*
134. *Id.*
135. *Id.*
136. *See id.*
137. *Id.*
138. *Id.* Glyphosate-based herbicides can "induce multiple antibiotic-resistance phenotypes in potential human pathogens (E. coli and Salmonella enterica serovar typhimurium)."
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140. Hu & Horin, *supra* note 21.
141. Britt E. Erikson, *Bayer to End Glyphosate Sales to US Consumers*, Am. Chem. Soc'y: Chem. & Eng'g News (July 30, 2021), https://cen.acs.org/environment/pesticides/Bayer-end-glyphosate-sales-US/99/web/2021/07.
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143. *Id.*
144. *Id.*
145. *Id; Pilliod v. Monsanto Co.*, 67 Cal. App. 5th 591, 601 (Cal. Ct. App. Aug. 9, 2021) ("After a six-week trial, the jury found for plaintiffs, awarded the wife over $37 million in compensatory damages, awarded the husband over $18 million in compensatory damages, and awarded each $1 billion in punitive damages.").
146. *Id.* at 607, 612.
147. *Id.* at 604,

> For years, the Pilliods had used Roundup to kill weeds on four residential properties. They started spraying Roundup at their primary residence in 1982. Alberta estimated that they sprayed about a gallon of Roundup on that property each week, nine months per year, until 2011. They also sprayed Roundup at three other properties throughout the years. Alberta estimated that at one of the three, they used two gallons each week, nine months per year, for two years; at another they used one gallon per month, nine months per year, for 10 years; and at a third, which they owned for two years, they used a total of about nine gallons.

148. *Pilliod*, 67 Cal. App. 5th at 600.
149. *Id.* at 601.
150. *Id.* at 647.
151. *Id.*
152. *See Monsanto Roundup Lawsuit*, Baum Hedlund Aristei Goldman PC, https://www.baumhedlundlaw.com/toxic-tort-law/monsanto-roundup-lawsuit/ (last visited April 20, 2022); *see also* Legal Examiner, *supra* note 78.
153. Erickson, *supra* note 141.
154. *Id.*
155. *Id.*
156. *Id.*
157. *Id.*
158. *Id.*
159. *Id.*

160. *See generally Glyphosate*, U.S. Envtl.Protection Agency, https://www.epa.gov/ingredients-used-pesticide-products/glyphosate (last visited Apr. 20, 2022).
161. *See* Erikson, *supra* note 141.
162. *See* Gillezeau et al., *supra* note 139.
163. *Id.* at 7 (emphasis added).
164. *Id.* at 7.
165. *Id.*; *see also* Myers et al., *supra* note 85.
166. *See generally* Myers et al., *supra* note 85.
167. Gillezeau, *supra* note 139, at 7.
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170. *See* Sierra-Diaz et al., *supra*, note 168, at 6.
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173. *Id.*
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176. *Id.*
177. *Id.*
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180. *Id.*
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Parole Conditions for Child Sex Offenders: An Analysis on the Constitutionality of Chemical Castration Mandates

By Michael Pitcher

Sexual abuse against children is a significant problem.[1] Moreover, effective treatment of child sexual abusers can often be elusive,[2] and the conventional assumption is that "sexual recidivism"[3] rates remain troublingly high.[4] To deal with the problem of recidivism, multiple states have begun implementing chemical castration requirements for sex offenders.[5] Although the history of castration is gruesome at times, the modern equivalent does not involve surgery, but rather hormonotherapy to achieve similar results through chemical means.[6] The courts have yet to rule on the issue of whether mandating chemical castration as a condition of parole runs afoul of the First and Eighth Amendments.[7]

This article will demonstrate why it is not a violation of the constitution to mandate that child sex offenders undergo chemical castration treatment as a condition for receiving parole. In understanding the both the legal and bioethical implications of such laws, courts are likely to find that the condition does not run afoul of the First or Eighth Amendments because parolees are subject to reasonable limitations on constitutional rights and precedent indicates a willingness to uphold physical castration, a punishment of an arguably more cruel and unusual nature than the modern pharmacological equivalent. Similarly, ethicists should find the condition acceptable if medically and statutorily qualifying parolees give informed consent to undergo the treatment.

Part I will provide a brief examination of the use of castration throughout history, followed by the current child sexual abuse crime rates and legislation that attempts to repurpose castration for the 21st century. Part II will address the various bioethical issues that are raised by mandating chemical castration as a condition of parole and will discuss the legal arguments regarding whether this condition of parole should survive a court challenge. Part III will examine some potential solutions to the issues raised and their shortcomings, as well

as other unresolved issues and suggestions for current statutes that should be addressed.

I. The Implementation of Castration in the Criminal Justice System

History and Use of Physical Castration

Physical castration[8] dates back centuries to ancient history and lore, appearing in both the Bible[9] and Greek mythology.[10] Castrated men, "eunuchs," were used to guard women's quarters in some ancient cultures.[11] Castration has also appeared in warfare as a way to torture and demoralize an enemy.[12] In the 18th century, young male Sistine Choir members were castrated to maintain a high singing voice despite the onset of puberty.[13] In the late 19th century, Indiana began castrating some sex offenders to lower recidivism rates.[14] In the 20th century, when marriage restrictions were deemed insufficient, the United States experienced a wave of eugenics in the form of castration and sterilization[15] of criminals and the mentally challenged in a misguided effort to preserve the integrity of society by drying up undesirable gene pools.[16]

Around 1914, some laws mandating castration or sterilization of certain criminals were struck down in federal courts for violating the Eighth Amendment, holding that these procedures are cruel and unusual when performed as a punishment.[17] In 1927, the Supreme Court issued its own opinion on sterilization in *Buck v. Bell*.[18] By an 8-1 decision the Court upheld a law requiring involuntary sterilization of institutionalized persons with heritable mental defects, which encompassed criminals and those with mental disabilities or illness.[19] In 1942, the Supreme Court reversed course slightly in the case of *Skinner v. Oklahoma* by unanimously striking down a law that mandated sterilization of habitual criminals.[20] This was not a full repeal of the Court's decision in *Buck* as it only addressed sterilization as a punishment for criminals but left sterilization of the mentally disabled and mentally ill intact.[21] The Court refused to address whether sterilization of an incarcerated person was a violation of the Eighth Amendment.[22] The question of castration as a condition of parole was not at issue in either case.

Modern Advancement to Chemical Castration

Chemical castration, also referred to as hormonal castration, is a biological or pharmacological process through which female sex hormones are used to inhibit testosterone production.[23] This acts to limit the brain's exposure to testosterone, thereby depriving a male of his ability to experience sexual fantasies, urges, and desires—essentially putting the man in a prepubescent state of erotic apathy.[24] First experimented with in 1944,[25] this modern approach to castration has some support in the medical community because it achieves similar results to physical castration without requiring surgery.[26]

Chemical castration involves the injection of an antiandrogen drug, typically Depo Provera, on a weekly basis by a health care professional.[27] Some proponents in the criminal justice community claim that chemically castrating sexual offenders will help a patient gain more capacity for self-control, relieve intrusive erotic obsessions, and avoid the need to quarantine the offender from the community.[28] Moreover, a pharmacological regimen is much more palatable to society than mandated surgery.[29]

Unlike physical castration, the effects of chemical castration are largely reversible once the antiandrogen treatment ceases.[30] However, potentially severe side effects of chemical castration include testicular atrophy, muscle weakness, nightmares, weight gain, cold sweats, hot flashes, loss of bone mass, and insomnia.[31] Moreover, this treatment has only been shown to reduce sexual desire in men suffering from pedophilic disorder,[32] not in preventing opportunistic or violent men from committing sexual offenses against children for non-sexual reasons.[33]

The Growing Problem of Child Sexual Abuse

In 2020, the United States Department of Health and Human Services (HHS) found strong evidence to indicate that, in that year alone, 57,963 children were victims of sexual abuse.[34] One out of every four girls and one out of every 13 boys are sexually abused at some point in their childhood.[35] As far back as 2001, one in five children reported being sexually solicited online before reaching the age of 18.[36] It is difficult to determine the prevalence of child sexual abuse because this crime is often unreported, but there are likely far more incidents than appear in statistics.[37]

Experiencing sexual abuse as a child has been linked to adverse physical and psychological consequences both in the short term and throughout the victim's lifetime.[38] Potential physical consequences can include sexually transmitted infections, physical injuries, and chronic conditions like heart disease, obesity and cancer.[39] Psychological consequences have been found to include depression, posttraumatic stress disorder symptoms, substance abuse and an increased risk of suicide.[40] Further, victims of child sexual abuse are at an increased risk of re-victimization throughout their life,[41] while simultaneously posing an increased risk of committing sex offenses against children.[42]

Chemical Castration Laws as a Solution to Child Sexual Abuse

Perpetrators of child sexual abuse often have multiple victims.[43] Punishment for these offenses, including incarceration and treatment, are not consistently effective in preventing repeat offenses after release.[44] As a result of high recidivism rates, many states began implementing chemical castration mandates for certain parolees as a way to treat those who

commit sexual offenses.[45] California passed the first chemical castration statute in 1996.[46] Under that statute, certain sex offenders are required to receive medroxyprogesterone acetate (MPA) treatment to reduce testosterone to pre-puberty levels.[47] Several states followed California's lead, with six currently having castration laws which permit either chemical castration as a punishment for committing certain sexual offenses or as a condition of parole after incarceration for such an offense.[48]

II. Potential Medical and Legal Issues Related to Chemical Castration Laws

A. Bioethical Issues

Some scholars argue that stripping individuals of their personal autonomy through the deprivation of their sexual freedom runs counter to bioethical principles.[49] However, *prisoners*—as opposed to *parolees*—suffer even greater deprivation by being incarcerated.[50] If child sex offenders can be rehabilitated and safely released from prison with the use of a less intrusive deprivation of autonomy, this is arguably a better and more ethical solution than imprisonment. Because traditional rehabilitation methods have proven largely unsuccessful for child sex offenders,[51] chemical castration would allow these prisoners to be released on parole by preventing them from feeling the urge to commit abuse.[52] However, chemical castration touches all four principles of medical ethics, each of which should be evaluated and weighed to determine if the benefits of this parole condition outweigh these ethical concerns.

Beneficence: Benefiting the Patient

Paraphilic disorder is a "recurrent and intense sexual arousal over a period of at least [six] months with nonconsenting victims through voyeurism, exhibitionism, frotteurism, sexual sadism, and pedophilia" and is estimated to affect 12% of males.[53] Chemical castration has been shown to be highly effective in treating those with paraphilic disorder by offering freedom from painful and undesirable sexual urges.[54] Treatment for this disorder also allows patients to be free from prison and offers a greater ability to stay within the bounds of the law after release.[55] However, felonious child sex offenders face many difficulties upon release, particularly a lack of available housing and employment options, leaving many homeless and in arguably worse conditions than those offered in a prison.[56] Some prisoners may also have no desire to limit their ability to form sexual thoughts.[57] If a patient suffering from paraphilic disorder provides informed consent to undergo antiandrogen treatment, a physician has an obligation to provide help to that patient. However, if informed consent is not received and the physician proceeds with the treatment, the physician will be in conflict with nonmaleficence.

Nonmaleficence: Do No Harm

The American Medical Association (AMA) has expressed opposition to physician participation in any medical treatment undertaken solely for criminal punishment.[58] Statutes mandating chemical castration do not currently distinguish between sex offenders who have been shown to benefit from this treatment and those who have not.[59] Therefore, physicians must do more than follow orders to provide medication and observe behaviors, they must weigh the risks and benefits of a treatment.[60] However, denying a qualified inmate the benefits of this treatment would force the inmate to remain in prison longer rather than allowing them to live freely in society. Additionally, denial of treatment might cause inmates with paraphilic disorder to continue to suffer painful thoughts.[61]

Autonomy: Patient Self-Determination

Determining whether parolees are freely consenting to chemical castration as a condition of parole is critical in balancing respect for the autonomy of parolees who are capable of making informed decisions and protecting those who are agreeing to a mind and body altering treatment because of undue influence.[62] Because the prisoner's freedom hinges on their acceptance of this parole condition, it is arguable that consent to this potentially disabling treatment can never be truly voluntary.[63] Further, the medical community would arguably be required to strip parolees of their autonomy in sexual thought.[64] However, many patients suffering from pedophilic and paraphilic disorders, including inmates, have willingly chosen to undergo chemical castration.[65] By permitting inmates to undergo chemical castration, physicians are freeing these prisoners from the greater deprivation of autonomy they face in prison.

Justice: Equitable Treatment

Payment for ongoing treatment raises concerns about fairness because many parolees do not have the means to cover the continuing costs.[66] Alabama requires parolees undergoing chemical castration to pay for their own treatment, meaning parolees who are unable to pay may be required to stay behind bars.[67] As already discussed, offenders face immense difficulties in securing steady employment, likely resulting in insufficient income to maintain their freedom after being released on parole.[68] Nonetheless, this treatment option is available to all who qualify under statute.

Bioethical Conclusion

Perhaps because inmates suffer a near total deprivation of personal autonomy, allowing them to be released on parole while requiring that they be deprived of personal autonomy only in relation to sexual thoughts and desires appears to be a more ethical alternative. Thus, if physicians denied in-

mates the ability to undergo chemical castration in exchange for parole, physicians would, in effect, be forcing a lengthier imprisonment than necessary on inmates. Further, the high rates of sexual recidivism among sex offenders[69] suggest that there may be substantial harm caused to the community if offenders were not treated. It is, therefore, ethically prudent for physicians to administer the treatment of chemical castration when informed consent is given by a qualified inmate.

B. Constitutional Issues

The Eighth Amendment and Modernized Chemical Torture

The Eighth Amendment prohibits the government from inflicting cruel and unusual punishments on criminals.[70] Some have argued that an Eighth Amendment analysis can be avoided by classifying chemical castration as a treatment rather than a punishment.[71] But the Supreme Court does not care about labels and will instead look to the underlying purpose of the statute.[72] Treatment is the purpose of chemical castration when a physician diagnoses a patient with pedophilic disorder and determines that he will benefit from the regimen, but it cannot be ignored that the same regimen is being imposed by the government on potentially non-medically indicated populations and will act to deprive those parolees of the fundamental right of mentation and procreation.[73] Therefore, a court could find that treatment is, at least in part, acting as a punishment.

The Supreme Court determines whether a punishment is cruel and unusual using a three-part test: (1) whether the punishment is inherently cruel; (2) the proportionality of the punishment to the crime; and (3) whether the punishment is in excess of what is needed to achieve the government's goal.[74]

First, a court will assess contemporary values of society to determine whether the punishment is inherently cruel.[75] Chemical castration comes with the potential for multiple side effects, some undoubtedly severe.[76] Yet, modern society has little sympathy for those who commit sexual offenses against children,[77] and it is hard to argue that the public would view the reversible treatment of chemical castration as cruel and unusual. While government-mandated physical castration may raise cause for concern, a pharmacological regimen is much more palatable to society.[78] Further, chemical castration is offered as a condition of parole, but there is no requirement that the inmate choose to be released on parole; the option of remaining in prison is available. Because the treatment is not performed unless voluntarily consented to by the inmate, any view of inherent cruelty under this factor is negated.[79]

Second, the proportionality of the punishment appears to be in line with what the Supreme Court has previously suggested is permissible.[80] The Court's majority opinion in *Coker v. Georgia* held that the death penalty was disproportionate to the crime of rape, while also noting that statutes limiting the death penalty to only those who commit rape against a child may be proportional.[81] Additionally, in finding that physical castration violated Due Process under the Fourteenth Amendment, the Court gave weight to the procedure's irreversibility but refused to comment on its Eighth Amendment implications.[82] Chemical castration carries with it the potential for a number of serious side effects and the treatment may need to persist through the remainder of the offender's life to continue its effectiveness.[83] However, as a condition of parole, some states permit the treatment to be discontinued when the term of parole ends.[84]

Because chemical castration is reversible and arguably less severe than both the death penalty and physical castration, with any potential side effects largely ceasing together with treatment at the end of the parole term, a court is likely to find that chemical castration does not appear disproportionately harsh when weighed against the lifelong physical and mental harms suffered by victims.

Third, the punishment does not appear to be excessive compared to what is needed for the government to achieve its interest in protecting children. Despite nationwide laws placing restrictions on sex offenders such as limitations on where they may reside and requiring registration with the state, sexual recidivism rates of sex offenders have remained high.[85] Because preventing sexual recidivism is part of the government's underlying goal in imposing chemical castration and other restrictions placed on child sex offenders have proven unsuccessful, a court would likely find that the treatment is not in excess of that which is needed to reach the government's goal of protecting children from becoming victims of a sexual offense.[86]

Utilizing these factors to reach a definitive answer on an Eighth Amendment analysis is difficult given the lack of guidance offered by the Supreme Court in evaluating non-capital punishments.[87] This factual scenario also gives rise to undeniable tension between the evaluation of the second prong's

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proportionality and third prong's excessiveness. While some states cease chemical castration when parole ends[88]—thereby placing offenders at risk of recidivism and children in danger of being victimized—requiring treatment to continue indefinitely may run counter to the suggestion of its reversibility in the second prong. However, because effective treatment may require a more scientific and indeterminate time frame,[89] the third prong may be strengthened by showing that current statutes are far from excessive in what is required for the government to achieve its goal, rather, they potentially fall far short of keeping children safe over the long term.

Nonetheless, chemical castration is arguably less severe than its surgical alternative; it is reversible and is one of many pharmacological treatments that achieves the desirable result of permitting the parolee to reintegrate into society.[90] Further, the Supreme Court gives significant deference to state legislatures and trial courts in determining the appropriate punishment for an offender.[91] This further suggests that courts are likely to find imposing chemical castration as a condition of parole does not violate the Eighth Amendment.

The First Amendment and Pedophilic Fantasies

The First Amendment's protection of freedom of speech has been held to encompass freedom of thought.[92] Therefore, it is arguable that government-mandated chemical castration is infringing on the rights of parolees to experience sexual thoughts.[93] However, the Supreme Court has continuously held that not all speech receives full First Amendment protections,[94] and prisoners and parolees are not afforded the same equal protection guarantees as non-offending citizens.[95] Although the Supreme Court has continuously found that an ordinary citizen's mentation is beyond the reach of the government,[96] it would seem that not all limitations placed on mentation are unconstitutional—particularly when the mentation has previously led to prohibited acts.[97] Because parolees are subject to limitations that are not placed on the non-convicted population, parole conditions may permissibly encroach on the right to mentation.[98] However, even parole conditions must not violate fundamental constitutional rights[99] without being held in check by some form of scrutiny.[100]

Many courts use the "reasonable relationship" test in determining whether parole conditions are valid.[101] To pass this test, the condition typically must: (1) serve to rehabilitate the parolee; and (2) advance public safety.[102] The first prong is likely satisfied if the condition relates to the crime or serves to prevent future criminal conduct.[103] Because chemical castration reduces male sex drive,[104] and the underlying crime involves a sexual offense against a child, the first prong appears satisfied, as this would help to prevent the parolee from committing future sexual offenses. The second prong is likely satisfied under similar reasoning. Because felony child sex offenders will have their sex drives reduced through chemical castration, the public—particularly children—will benefit from the diminished threat of being targeted by these parolees as a victim of a sexual offense.[105]

However, it can also be argued that chemical castration is only effective in rehabilitating those suffering from pedophilic disorder, but will do nothing to prevent violent or opportunistic offenders from committing sexual offenses against children, consequently lulling the public into a false sense of security when these offenders are released on parole.[106] This concern seems much less relevant when considering that pedophilic offenders generally begin offending at an earlier age, have a larger number of victims,[107] and are strongly indicated for sexual recidivism compared to nonpedophilic offenders.[108] Therefore, chemical castration would successfully achieve the government's compelling interest of protecting the public, particularly would-be child victims. States should be cautious to narrowly tailor chemical castration laws to prevent the treatment of non-pedophilic offenders, but chemical castration will nonetheless successfully protect many children.

III. Proposed Solution and Additional Considerations

The Supreme Court has acknowledged the centrality of the First Amendment's protection of mentation, noting that "[o]ur whole constitutional heritage rebels at the thought of giving government the power to control men's minds."[109] However, First Amendment protections are not unlimited.[110] We are all free to have whatever thoughts we would like, but when those thoughts turn into illegal acts the government is permitted to impose an appropriate punishment.[111] When the illegal act is particularly atrocious, such as the sexual abuse of a child, the offender has arguably forfeited their First Amendment right to form the thoughts upon which the illegal act was predicated.[112] Limited intrusions into personal freedoms have been found to be acceptable conditions for parole,[113] even when those intrusions may have mind-altering effects.[114] Therefore, if a parolee willfully agrees to undergo chemical castration, there has likely been no First Amendment violation despite the potentially unusual nature of the parole condition.

Permitting the government to control the thoughts of citizens in the name of public safety arguably invokes images of a dystopian future,[115] using a modern approach to what has historically been used as torture.[116] However, sexual offenses committed against children are of such a heinous nature that the prevention of repeated offenses is a compelling governmental interest thereby permitting the government to impose treatments that may appear cruel and unusual in other contexts. Courts are likely to find that imposing chemical castration as a condition of parole for child sex offenders does not violate the Eighth Amendment because the punishment is

proportional to the crime, is not inherently cruel, and is permissible for the government to achieve its compelling interest of protecting children.

Lastly, it should be noted that most statutes do not conform with current medical knowledge surrounding chemical castration. Treatment may need to continue through the remainder of an offender's life to maintain its effectiveness.[117] Yet, only three states permit chemical castration to continue until shown to be unnecessary, whereas other states rely on arbitrary timelines.[118] Likewise, statutes should safeguard against parolees undergoing chemical castration when the treatment is not medically indicated for them.[119] Chemical castration has been shown to be effective only for those with pedophilic interests but may not prevent recidivism in those who committed a sexual offense due to an antisocial personality disorder.[120] States must narrowly construe chemical castration statutes to target only those parolees who will benefit from the treatment, evaluate inmates to verify qualifications, tailor appropriate parole conditions based on the parolee's underlying condition—that is, paraphilic disorder, anti-social deviant behavior, etc.—and permit treatment to continue indefinitely at the discretion and guidance of medical professionals rather than an arbitrarily drawn parole end date. Therefore, the use of chemical castration may serve to protect children while also giving parolees the best chance of a successful recovery, appearing both ethically prudent and thoroughly constitutional.

Endnotes

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3. "Sexual recidivism" is the engagement in a new sex offense after reentering the community. United States Sentencing Commission, Federal Child Pornography Offenses, 293 (2012).
4. *See, e.g.*, H.R. Rep. No. 2966 (2003) (Conf. Rep.) ("Recidivism is a huge problem in sexual exploitation cases.").
5. *See* Cal. Penal Code § 645; Fla. Stat. Ann. § 794.0235; La. Rev. Stat. § 15:538 (permits chemical castration to be performed prior to the offender's release but not as a condition of parole); Mont. Code § 45-5-512; Wis. Stat. Ann. § 304.06(1q); Ala. Code § 15-22-27.4; Tex. Gov't Code § 501.061 (permits physical castration); 9 Guam Code Ann. §§ 80.101–106. Georgia and Oregon enacted and subsequently repealed their chemical castration laws in 2006 and 2011, respectively.
6. John F. Stinneford, *Incapacitation Through Maiming: Chemical Castration, the Eighth Amendment, and the Denial of Human Dignity*, 3 U. St. Thomas L.J. 559, 565 (2006).
7. *E.g., id.* at 562.
8. Sometimes referred to as surgical castration, achieved by performing an "orchiectomy" to remove the testes unilaterally (removing one testicle) or bilaterally (removing both testicles). Asian J Androl, *How do we define "castration" in men on androgen deprivation therapy?*, 5 Asian J. Andrology 441 (2020). Not to be confused with "demasculinization," which refers to castration and the removal of the penis and scrotum. Georg K. Strup, *Castration: The Total Treatment, in* Sexual Behaviors: Social, Clinical, and Legal Aspects 361, 361 (H.L.P. Resnik & M.E. Wolfgang eds., 1972).
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11. Edward S. Tauber, *Effects of Castration upon the Sexuality of the Adult Male*, 2 Psychosomatic Med. 74, 75 (1940).
12. David Eichert, *"Homosexualization" Revisited: An Audience-Focused Theorization of Wartime Male Sexual Violence*, 21 Int'l Feminist J. Pol. 409 (2019).
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14. Angela Gugliotta, *Dr. Sharp with His Little Knife: Therapeutic and Punitive Origins of Eugenic Vasectomy—Indiana, 1892–1921*, 53 J. Hist. Med. & Allied Scis. 371 (1998).
15. Sterilization is performed to render the subject infertile thereby ending their ability to reproduce, commonly by performing a vasectomy on males. *See* Julius Paul, *State Eugenic Sterilization History: A Brief Overview in* Eugenic Sterilization 25 (Jonas Robitscher ed., 1973). Vasectomy does not require the removal of the testes, and was therefore argued to be a more humane option than castration. *See* Stephen Michael Smith, Thesis, *Eugenic Sterilization in the 20th Century Georgia: From Progressive Utilitarianism to Individual Rights*, 594 Electronic Theses & Dissertations Ga. S.U. 32 (2010), https://digitalcommons.georgiasouthern.edu/etd/594.
16. Kris W. Druhm, Comment, *A Welcome Return to Draconia: California Penal Law 645, the Castration of Sex Offenders and the Constitution*, 61 Alb. L. Rev. 285, 343 (1997); *see* Smith *supra* note 15, at 32–33.
17. *See generally Davis v. Berry*, 216 F. 413, 416–17 (S.D. Iowa 1914) (stating "[castration] belongs to the Dark Ages"); *Mickle v. Henrichs*, 262 F. 687, 688–91 (D. Nev. 1918) (explaining that a Nevada law providing for vasectomies of those convicted of specific crimes was unconstitutional under the Eighth Amendment, and while castration by vasectomy is not cruel in itself, it becomes cruel when imposed as punishment).
18. 274 U.S. 200 (1927).
19. *Id.*
20. 316 U.S. 535 (1942) (noting that forced sterilization was a violation of equal protection under the Fourteenth Amendment).
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22. Heinz R. Hink, *The Application of Constitutional Standards of Protection to Probation*, 29 U. Chi. L. Rev. 483, 490 (1962).
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25. Robert D. Miller, *Forced administration of sex-drive reducing medications to sex offenders: treatment or punishment?*, 4 Psych. Pub. Pol'y L. 175 (1998).

26. Druhm, *supra* note 16, at 311.

27. Avital Stadler, Comment, *California Injects New Life Into an old Idea: Taking a Shot at Recidivism, Chemical Castration, and the Constitution*, 46 Emory L. J. 1285, 1286 (1997); Kathryn M. Curtis et al., *Update to U.S. Selected Practice Recommendations for Contraceptive Use: Self-Administration of Subcutaneous Depot Medroxyprogesterone Acetate*, 70 Morbidity Mortality Wkly. Rep. 739, 742 (2021).

28. *See* J. T. Melella et al., *Legal and Ethical Issues in the Use of Antiandrogens in Treating Sex Offenders*, 17 Bull. Am. Acad. Psych. & L. 223, 229 (1989); *cf* John M. W. Bradford, *Organic Treatment for the Male Sexual Offender*, 528 Annals N.Y. Acad. Sci. 193, 197 (1988) (noting that recidivism occurred if pharmacological treatment with antiandrogens was stopped). When treating pedophilia and offenders who have committed a sexual offense against a child, pharmacological treatment should be used in conjunction with psychotherapy. *See* A. Kenneth Fuller, *Child Molestation and Pedophilia: An Overview for the Physician*, 261(4) JAMA 602, 604 (1989) (reviewing various treatments available for paraphilic syndromes such as pedophilia).

29. *See* Fred S. Berlin, *The Case for Castration, Part 2*, Wash. Monthly, May 1994, at 28, 29.

30. *See* Pamela K. Hicks, *Castration of Sexual Offenders*, 14 J. L. Med. 641, 646 (1993) (discussing the permanent nature of surgical castration as compared to chemical castration).

31. *See* William Green, *Depo-Provera, Castration, and the Probation of Rape Offenders: Statutory and Constitutional Issues*, 12 U. Dayton L. Rev. 1, 6 (1986); Kimberly A. Peters, *Chemical Castration: An Alternative to Incarceration*, 31 Duq. L. Rev. 307, 311 (1993) (both discussing the side effects of Depo-Provera). Loss of bone mass being unique in that it is potentially irreversible upon treatment cessation. *See* Mohamed Shareldeen et al., *Effect on Bone Mineral Density in Surgical Versus Medical Castration for Metastic Prostate Cancer*, Turk. J. Urology 120 (2021).

32. Pedophilic disorder, a class of paraphilia—the persistence of sexual urges—is "a persistent sexual interest in sexually immature children," which can manifest in sexual thoughts, urges, behaviors, or arousal, causing distress and dysfunction and recurs over a period of at least six months. Thanh Ly et al., *Characteristics and Treatment of Internet Child Pornography Offenders*, 36 Behav. Sci. L. 216, 223–24 (2018); U.S. Sent'g Comm'n, Federal Child Pornography Offenses, app. A at 7 (2012).

33. *See* Druhm, *supra* note 16, at 303–05; Peters, *see also* Peters, *supra* note 31, at 312 (explaining that some child sex offenders have no attraction to children and blame their offenses on drugs or alcohol, or may be motivated by anger or power).

34. Child Maltreatment, *supra* note 1, at 45. "Each state has its own definitions of child abuse and neglect that are based on standards set by federal law. Federal legislation provides a foundation for states by identifying a set of acts or behaviors that define child abuse and neglect." *Id.*

35. Centers for Disease Control and Prevention, Child Sexual Abuse, (last accessed April 5, 2022), https://www.cdc.gov/violenceprevention/childsexualabuse/fastfact.html.

36. ABC News, Study: One in Five Kids Solicited Online (2006), https://abcnews.go.com/Health/story?id=117379.

37. National Center for Victims of Crime, Child Sexual Abuse Statistics, https://victimsofcrime.org/child-sexual-abuse-statistics (last accessed April 5, 2022).

38. *Id.*

39. *Id.*

40. *Id.*

41. *Id.* (noting that child sexual abuse victims are twice as likely to experience non-sexual intimate partner violence, and female victims are up to 13 times as likely to suffer sexual victimization in adulthood).

42. *See* William Winslade et al., *Castrating Pedophiles Convicted of Sex Offenses Against Children: New Treatment or Old Punishment?*, 51 SMU L. Rev. 349, Part II.A.2.b.

43. *Id.* at Part II.A.2.a

44. *See generally* Gordon C. Nagayama Hall, *Sexual Offender Recidivism Revisited: A Meta-Analysis of Recent Treatment Studies*, J. Consulting & Clinical Pathology 802, 805–07 (1995) (reviewing 12 published studies between 1988 and 1992, and finding through a meta-analysis of the studies that 19% of the study participants committed additional sexual offenses following completion of treatment).

45. *See supra* note 5 for a list of state laws regarding chemical or physical castration of sexual offenders.

46. *See* Act of Sep. 17, 1996, ch. 596, 2, 1996 Cal. Legis. Serv. 2711 (West) (codified as amended at Cal. Penal Code 645 (West Supp. 1997)).

47. Sandra Norman-Eady, Castration of Sex Offenders, OLR Research Report (2006), https://www.cga.ct.gov/2006/rpt/2006-r-0183.htm.

48. *See supra* note 5.

49. Jukka Varelius, *The Value of Autonomy in Medical Ethics*, 9 Med. Health Care & Phil. 377 (2006).

50. *See* Darlene C. Goring, *Fourth Amendment—Prison Cells: Is There a Right to Privacy*, 75 J. Crim. L. & Criminology 609, 615–16 (1984).

51. *See* Billhartz, *supra* note 2, at 527–38.

52. Charles L. Scott & Trent Holmberg, *Castration of Sex Offenders: Prisoners' Rights Versus Public Safety*, 31 J. Am Acad. Psych. L. 502 (2003).

53. Alyssa Greenwood Francis et al., AMA Study of Chemical Castration in Incarceration, 1:13–16 (2021).

54. Georg K. Strup, *Treatment of Sexual Offenders in Herstedvester Denmark*, 204 Acta Psychiatrica Scandinavica 1, 19 (1968) ("Many of our castrates have started new careers and built up big businesses, and several of them have complained that we did not press them enough to be castrated, so that they could have lived the way of life they now live much earlier."); Janelle Nanos, *Taming the Beast Within*, Bos. Mag., Mar. 2014, https://www.bostonmagazine.com/news/2014/02/25/chemical-castration ("There are side effects, however . . . [offenders] tell [the psychiatrist] this is better than feeling unwanted urges.").

55. Seymour L. Halleck, *The Ethics of Anti-Androgen Therapy*, 138 Am. J. Psych., 642 (May 1981).

56. Catherine Wagner, Note, *The Good Left Undone: How to stop Sex Offender Laws From Causing Unnecessary Harm at the Expense of Effectiveness*, 38 Am. J. Crim. L. 263 (2011).

57. *See* Hunting Warhead, *Becoming Warhead*, Canadian Broadcasting Corporation, (Mar. 20, 2022), https://www.cbc.ca/listen/cbc-podcasts/387-hunting-warhead/episode/15747095-episode-5-becoming-warhead (interviewing a convicted child sexual abuser who expresses no remorse for his actions and states he would not have changed anything about his life).

58. *See, e.g.,* Am. Med. Assn. H. of Delegates Policy H-140.955, Court-Ordered Castration ("The AMA opposes physician participation in castration and other surgical or medical treatments initiated solely for criminal punishment.") (1998).

59. *See supra* note 5 and accompanying statutes.

60. Halleck, *supra* note 55.

61. Melella et al., *supra* note 28, at 230–31.

62. *See* Paul S. Appelbaum, *Assessment of Patients' Competence to Consent to Treatment*, 357 N. Eng. J. Med. 1834, 1834 (2007).

63. Halleck, *supra* note 55.

64. *See* discussion *infra* Section I.B.

65. Druhm, *supra* note 16, at 289–92; *e.g.*, *E.g.*, *State v. Brown*, 284 S.C. 407, 326 S.E.2d 410 (1985).

66. *See* discussion *infra* Section II.A.1.

67. Stinneford, *supra* note 6, at 580.

68. *See* discussion *infra* Section II.A.1.

69. Roger Przybylski, *Recidivism of Adult Sexual Offenders*, U.S. Dep't of Justice, 4–5 (2015).

70. U.S. Const. amend. VIII. The Fourteenth Amendment extends these protections to acts by state governments. *See Timbs v. Indiana*, 139 S. Ct. 682 (2018).

71. *See, e.g.*, Stadler, *supra* note 27, at 1321; Druhm, *supra* note 16, at 309–10.

72. *Trop v. Dulles*, 356, U.S. 86, 94–95 (1958) ("How simple would be the tasks of constitutional adjudication and of law generally if specific problems could be solved by inspection of the labels pasted on them!"). Regardless of the semantics, chemical castration laws have been allowed to stand for over 20 years, and physical castration laws for almost 100. *See Buck v. Bell*, 274 U.S. 200 (1927) (upholding a law permitting involuntary sterilization of "feebleminded" individuals housed in state facilities, in order to prevent the propagation of "feebleminded offspring").

73. *Skinner v. Oklahoma*, 316, U.S. 535, 541 (1942); *see* discussion *infra* Section I.B.2.

74. Stadler, *supra* note 27, at 1322–24 (citation omitted).

75. *Id.* (citing *Gregg v. Georgia*, 428 U.S. 153, 173 (1976)).

76. *See* discussion *infra* Section I.B.

77. Vaillancourt, *supra* note 24, at 68.

78. *See* Berlin, *supra* note 29, at 28, 29.

79. Druhm, *supra* note 16, at 315.

80. *Id.* at 315–16.

81. Druhm, *supra* note 16, at 315–16.

82. *See Skinner v. Oklahoma*, 316 U.S. 535, 538 (1942).

83. Peters, *supra* note 31, at 314.

84. *But cf.* Cal. Penal Code § 645(d); Mont. Code § 45-5-512(4); Ala. Code § 15-22-27.4(c) (all three requiring chemical castration to continue until the treatment is determined no longer necessary).

85. *See generally*, Steven, J. Wernick, Note, *In Accordance With a Public Outcry: Zoning Out Sex Offenders Through Residence Restrictions in Florida*, 58 Fla. L. Rev. 1147 (2016) (discussing the lack of impact these restrictions have had on recidivism rates); Centers for Disease Control and Prevention, Child Sexual Abuse, (last accessed April 5, 2022) (explaining that rates of *general* recidivism among sex offenders is lower than that of offenders who committed non-sex offenses, but that recidivism for a *sexual* offense remains comparatively higher). Although a discussion for another paper, the argument could be made that chemical castration may even negate the need for these restrictions. If a parolee were to undergo this treatment and subsequently have no sexual desire, the parolee would no longer pose the same threat to children.

86. *E.g.*, Scott & Holmberg, *supra* note 52, at 508.

87. The Supreme Court has not found that a non-capital punishment violated the Eighth Amendment for over 60 years. After the case of *Trop v. Dulles* in 1958, it was not until 2009 that the Court determined sentencing a juvenile to life without parole qualified as cruel and unusual punishment. William W. Berry, *Cruel and Unusual Non-Capital Punishments*, 58 Am. Crim. L. Rev. 1627, 1655 (2021).

88. *See La. Rev. Stat. § 15:538(C)(3)(d); Wis. Stat. Ann. § 304.06(1q); 9 Guam Code Ann. §§ 80.102(c).*

89. Peters, *supra* note 31, at 314.

90. *Closs v. Weber*, 238 F.3d 1018 (8th Cir. 2001) (upholding a condition of parole in which the parolee voluntarily agreed to, inter alia, comply with a pharmacological regimen to treat his schizophrenia); Ctr. for Substance Abuse Treatment, U.S. Dep't of HHS, Substance Abuse Treatment For Adults in the Criminal Justice System, 214 (2005), https://www.ncbi.nlm.nih.gov/sites/books/NBK572948 ("Parolees . . . must meet certain conditions in order to avoid incarceration or reincarceration. Often, treatment for drug or alcohol dependence is one of those conditions.").

91. *See Solem v. Helm*, 463 U.S. 277, 290 (1983) ("Reviewing courts, of course, should grant substantial deference to the broad authority that legislatures necessarily possess in determining the types and limits of punishments for crimes, as well as to the discretion that trial courts possess in sentencing convicted criminals."); Berry, *supra* note 87, at 1632–34.

92. *Stanley v. Georgia*, 394 U.S. 557, 564 (1969).

93. *E.g.,* Stelzer, *supra* note 10; Scott & Holmberg, *supra* note 52.

94. *E.g., Konigsberg v. State Bar of California*, 366 U.S. 36, 49 (1960) ("we reject the view that freedom of speech . . . [is] 'absolute[]'"); *Orient Ins. Co. v. Daggs*, 172 U.S. 557, 566 (1899) ("no right is absolute").

95. *E.g., Morrissey v. Brewer*, 408 U.S. 471, 478 (1972) (discussing substantial restrictions placed on parolees, including requirements that they seek permission before engaging in certain activities or to produce written reports of their activities).

96. *See, e.g., Abood v. Detroit Bd. of Educ.*, 431 U.S. 209, 235 (1977) ("In a free society one's beliefs should be shaped by his mind and his conscience rather than coerced by the State."); *Paris Adult Theatre I v. Slaton*, 413 U.S. 49, 67 (1973) ("The fantasies of a drug addict are his own and beyond the reach of government"); *Stanley v. Georgia*, 394 U.S. 557, 565 (1969) ("Our whole constitutional heritage rebels at the thought of giving government the power to control men's minds."); *West Virginia Bd. of Educ. v. Barnette*, 319 U.S. 624,

641 (1943) (stating that the Bill of Rights safeguards the "freedom to be intellectually and spiritually diverse or even contrary").

97. Stelzer, *supra* note 10, at 1696; Druhm, *supra* note 16, at 332–36.

98. *See United States v. Consuelo-Gonzalez*, 521 F.2d 259, 265 (9th Cir. 1975) (citation omitted); *see also Abrams v. United States*, 250 U.S. 616, 627 (1919) (Holmes, J., dissenting) ("I do not doubt for a moment that by the same reasoning that would justify punishing persuasion to murder, the United States constitutionally may punish speech that produces or is intended to produce a clear and imminent danger that it will bring about forthwith certain substantive evils that the United States constitutionally may seek to prevent."); *Closs v. Weber*, 238 F.3d 1018 (8th Cir. 2001) (permitting the use consensual use of psychotropic prescriptions as a condition of parole)

99. W. Kent Davis, *Answering Justice Ginsburg's Charge That the Constitution is "Skimpy" in Comparison to Our International Neighbors: A Comparison of Fundamental Rights in American and Foreign Law*, 39 S. Tex. L. Rev. 951, 958–68 (1998) (discussing ways in which a right is found to be fundamental). Of relevance to this paper, rights incorporated within the Bill of Rights are considered fundamental. *See e.g.*, *Stanley v. Georgia*, 394 U.S. 557, 564 (1969) ("[the] right to receive information and ideas, regardless of their social worth, is fundamental to our free society . . . also fundamental is the right to be free, except in very limited circumstances, from unwanted governmental intrusions into one's privacy.").

100. Stelzer, *supra* note 10, at 1702–03.

101. *Id.* at 1703.

102. *United States v. Consuelo-Gonzalez*, 521 F.2d 259, 265 (9th Cir. 1975) (citation omitted). A third prong was laid out by the court, however, it will not be evaluated here because subsequent court decisions have relied almost exclusively on the test as structured here. *See* Stadler, *supra* note 28, at 1318.

103. Stelzer, *supra* note 10, at 1692.

104. Stinneford, *supra* note 6, at 573.

105. Przybylski, *supra* note 69, at 4–5. This study notes that sex offenders have lower rates of general recidivism but higher rates of sexual recidivism compared to offenders who committed non-sex crimes. The highest rate of sexual recidivism occurs in men who offend against young boys.

106. *See, e.g.*, Stadler, *supra* note 27, at 315–18; *see also* Bradford, *supra* note 30, at 197; David Van Biema, *A Cheap Shot at Pedophilia?*, Time, Sept. 9, 1996, at 60 (quoting Dr. Berlin as saying, "there are many sex offenders for whom [Depo-Provera] is not going to be appropriate or useful . . . in effect, the legislators are practicing medicine without a license").

107. Gene G. Abel et al., *Sex Offenders: Results of Assessment and Recommendations for Treatment*, *in* Clinical Criminology: The Assessment and Treatment of Criminal Behavior, 207, 209–12 (1985) (noting that about half of adult sex offenders began their sexually deviant behavior in adolescence); J. V. Becker et al., *Adolescent Sexual Offenders: Demographics, Criminal Sexual Histories, and Recommendations for Reducing Future Offenses*, 1 J. Interpers. Violence, 431 (1986) (finding that adolescent sex offenders within the study had an average of seven victims, with some disclosing 30 or more victims).

108. Adult Sex Offender Typologies, U.S. Dep't of Justice, Office of Justice Programs, Office of Sex Offender Sentencing, 1 (2015).

109. *Stanley v. Georgia*, 394 U.S. 557, 565 (1969).

110. *See* discussion *infra* Section II.B.2.

111. *Id.*

112. *See* Scott & Holmberg, *supra* note 52.

113. *See Samson v. California*, 547 U.S. 843, 857 (2006) (holding that a police officer's suspicionless search of a parolee does not violate the Fourth Amendment); *Legal Issues in Drug Testing Probation and Parole Clients and Employees*, U.S. Dep't of Justice, Nat'l Institute of Corrections (1989).

114. *Closs v. Weber*, 238 F.3d 1018 (8th Cir. 2001) (permitting the use consensual use of psychotropic prescriptions as a condition of parole).

115. *See* Anthony Burgess, A Clockwork Orange (W.W. Norton & Co., Inc. 1987).

116. Eichert *supra* note 12, at 409–33.

117. Peters, *supra* note 31, at 314.

118. *Compare* Cal. Penal Code § 645(d), La. Rev. Stat. § 15:538(C)(3)(d), Mont. Code § 45-5-512(4), and Ala. Code § 15-22-27.4(c); with Fla. Stat. Ann. § 794.0235(2)(a)(1), Wis. Stat. Ann. § 304.06(1q), and 9 Guam Code Ann. §§ 80.102(c).

119. *See* discussion *infra* Section II.B.1.

120. *See id.*; *supra* note 33 and accompanying text.

Meet the 2022 Summer NYSBA Diversity Health Law Fellows

Jacinda Themidor


Jacinda Thermidor

My name is Jacinda Thermidor. I am a rising 2L at St. John's University School of Law. I am a first-generation Haitian-American who received a bachelor's degree in global history at John Jay College of Criminal Justice. Growing up, I volunteered at a nursing home under the recreation department. Although that experience sparked my interest in health care, I knew I did not want to become a medical worker. Instead, I wanted to pursue law. After witnessing all that occurred during the COVID-19 pandemic, I decided to merge these two interests and planned to specialize in health law, specifically medical malpractice and nursing home abuse. I joined the Health Law Society at St. John's University School of Law, became a 1L representative, and am currently the director of diversity and inclusion for the 2022–23 term.

Through my fellowship with the New York State Bar Association, I have been placed at Catholic Health Services Long Island as a legal intern. I am excited about the skills and experience I will receive after completing this fellowship and the significant impact it will have on my career as a health lawyer.

Gabriella Gomes Pereira


Gabriella Gomes Pereira

Gabriella Gomes Pereira is an alumnus from Manhattanville College where she earned a Bachelor of Arts in both legal studies and philosophy. She also minored in social justice. During her time at Manhattanville College, Gabriella served multiple roles in the Student Government Association. Additionally, she was the president of the Campus Activities Board, vice-president of the Pre-Law Society, a member of the Commuter Council, and a student in Manhattanville College's Castle Scholars Honors Program. Gabriella completed her undergraduate education a semester early and was able to successfully complete the process for admission into law school.

Currently, Gabriella is a rising second year student at Elisabeth Haub School of Law at Pace University. Since beginning her juris doctor, Gabriella has developed a passion for corporate, employment and health law. She is the president of the Women's Association of Law Students, the vice-president of the Health Law Society, and a member of the Corporate Law Society on campus.

Upon being selected by the New York State Bar Association Health Law Section for the Summer Diversity Fellowship, Gabriella was placed at Westchester Medical Center. At this time, she is working alongside the general counsel and labor relations specialist in the Legal Affairs department.

About the Fellowship

The Diversity Summer Fellowship in Health Law was developed in 2011 by the Health Law Section as part of the New York State Bar Association's Diversity Challenge to develop and execute initiatives to increase the diversity of its membership, leadership and programs and to evaluate the results. The primary goal of the Diversity Summer Fellowship in Health Law is to increase representation of lawyers and students from a diverse range of backgrounds in health law.

The Fellowship will provide students from a diverse range of backgrounds an opportunity to experience health law practice. The ultimate goal of the diversity effort of the Health Law Section is to create a network and forge relationships which will foster greater diversity among health law attorneys throughout the state.

The Fellowship seeks to promote diversity in the legal community, particularly in health law. Since 2012, the Health Law Fellowship Program has placed law students at NYU Langone Medical Center, Montefiore Medical Center, Mount Sinai Health System and Catholic Health Services of Long Island. NYU Langone Medical Center has been a special partner of this program, sponsoring the very first Fellow in 2013 and continuing to sponsor students year after year. The Diversity Committee has also sponsored panel discussions to promote interest in health law. In 2014, the first panel discussion was held at Proskauer and in 2016, the second panel discussion was held at Brooklyn Law School. The Fellowship is operated in partnership with and administered by the New York State Bar Foundation. Under the direction of Lisa D. Hayes, the Diversity Committee of the Health Law Section was awarded a Section Diversity Champion Award in 2013 for its efforts. Special thanks to Diversity Committee members Kathleen Lyons, Beverly Jones, Dionne Schuler (2013 Fellow), and Edwina Martin, member, Bar Foundation.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office for Civil Rights

Guidance to Nation's Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Access to Comprehensive Reproductive Health Care Services

Pharmacies—and the pharmacists they employ—play a critical role in the American health care system. This has never been more apparent than the efforts taken to administer vaccines during the COVID-19 pandemic, for which your continued partnership has been crucial.[1] As our nation faces another significant health care crisis, this guidance is to remind the roughly 60,000 retail pharmacies in the United States[2] of the unique role pharmacies play in ensuring access to comprehensive reproductive health care services. This guidance covers the nondiscrimination obligations of pharmacies under federal civil rights laws.

Under Section 1557 of the Affordable Care Act (Section 1557), 42 U.S.C. § 18116, and its implementing regulation, 45 C.F.R. part 92, recipients of federal financial assistance are prohibited from excluding an individual from participation in, denying them the benefits of, or otherwise subjecting them to discrimination on the basis of sex and disability, among other bases, in their health programs and activities.[3] Under Section 504 of the Rehabilitation Act of 1973 (Section 504), 29 U.S.C. 794, recipients of federal financial assistance are prohibited from discriminating in all programs and activities, on the basis of disability. Pharmacies, therefore, may not discriminate against pharmacy customers on the bases prohibited by Section 1557and Section 504—including with regard to supplying medications; making determinations regarding the suitability of a prescribed medication for a patient; or advising patients about medications and how to take them.

The United States has the highest maternal mortality rate among developed nations; though most maternal deaths in the United States are preventable, they have been rising over the last two decades.[4] Maternal deaths are especially high among Black women and Native American

[1] *See, e.g.*, *The Federal Retail Pharmacy Program for COVID-19 Vaccination*, U.S. Dep't of Health & Human Servs., Ctrs. for Disease Control & Prevention (last updated June 24, 2022), https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/index.html.

[2] IQVIA, *U.S. National Pharmacy Market Summary 2021: Market Insights Report* (2021), https://www.onekeydata.com/downloads/reports/2021_US_Pharmacy_Market_Report.pdf.

[3] Covered entities should also note that Title IX of the Education Amendments of 1972 (Title IX), 20 U.S.C. § 1681 *et seq*., prohibits discrimination on the basis of sex in education programs and activities of recipients of federal financial assistance. Pharmacies that are affiliated with a covered education program or activity are also subject to Title IX nondiscrimination requirements. *See also* 45 C.F.R. part 86 (HHS Title IX implementing regulations).

[4] Roosa Tikkanen et al., *Issue Brief: Maternal Mortality and Maternity Care in the United States Compared to 10 Other Developed Countries*, Commonwealth Fund (Nov. 18, 2020),

women—regardless of their income or education levels. [5] The Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, No. 19-1392, 2022 WL 2276808 (U.S. June 24, 2022), will exacerbate these inequities and disparities for women across the country. Further, the early loss of pregnancy (before 13 completed weeks) is extremely common, experienced by about 10 percent of those who know they are pregnant.[6] The Department is committed to improving maternal health—including for individuals who experience miscarriages—and vigorous enforcement of our civil rights laws is one way in which we plan to do so.

Pharmacies are often the most accessible health care provider for millions of Americans, with most Americans living within five miles of a pharmacy.[7] It is estimated that more than 131 million people (66 percent of adults) in the United States use prescription medication,[8] and therefore come into contact with pharmacies. Of the 7.6 billion retail prescription drugs filled by pharmacies in 2019, 44 percent were paid for either by Medicare or Medicaid health coverage.[9] As recipients of federal financial assistance, including Medicare and Medicaid payments, pharmacies are prohibited from discriminating on the basis of race, color, national origin, sex, age, and disability in their programs and activities under a range of federal civil rights laws.

Among its civil rights enforcement responsibilities, the Department of Health and Human Services' (HHS or Department) Office for Civil Rights (OCR) is responsible for protecting the rights of women and pregnant people in their ability to access care that is free from discrimination. This includes their ability to access reproductive health care, including prescription medication from their pharmacy, free from discrimination. A recent study by the Centers for Disease Control and Prevention showed that nearly 25 percent of women aged 15–49 in the United States who use contraception use some form of prescribed method (e.g., oral contraception pill, contraceptive ring).[10]

Furthermore, discrimination against pregnant people on the basis of their pregnancy or related conditions (examples below) is a form of sex discrimination. Such discrimination can have significant health consequences from denial of medication or treatment which can have negative health impacts on a patient. Under federal civil rights law, pregnancy discrimination

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https://www.commonwealthfund.org/publications/issue-briefs/2020/nov/maternal-mortality-maternity-care-us-compared-10-countries.

[5] Emily Petersen et al., *Racial/Ethnic Disparities in Pregnancy-Related Deaths — United States, 2007–2016*, 68 Morbidity & Mortality Wkly. Rep. 762 (2019), https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6835a3-H.pdf.

[6] *FAQs: Early Pregnancy Loss*, Am. Coll. of Obstetricians & Gynecologists (last updated Jan. 2022), https://www.acog.org/womens-health/faqs/early-pregnancy-loss.

[7] *Federal Retail Pharmacy Program*, U.S. Dep't of Health & Human Servs., Ctrs. for Disease Control & Prevention (last updated June 24, 2022), https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/index.html.

[8] *Prescription Drugs,* Georgetown Univ., Health Pol'y Inst., https://hpi.georgetown.edu/rxdrugs (last visited June 29, 2022).

[9] *Number of Retail Prescription Drugs Filled at Pharmacies by Payer*, Kaiser Fam. Found., https://www.kff.org/health-costs/state-indicator/total-retail-rx-drugs/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (last visited June 29, 2022).

[10] Kimberly Daniels & Joyce C. Abma, U.S. Dep't of Health & Human Servs., Ctrs. for Disease Control & Prevention, Nat'l Ctr. for Health Stats., *Data Brief: Current Contraceptive Status Among Women Aged 15-49: United States, 2015-2017* (2018), https://www.cdc.gov/nchs/data/databriefs/db327-h.pdf.

includes discrimination based on current pregnancy, past pregnancy, potential or intended pregnancy, and medical conditions related to pregnancy or childbirth.[11]

Examples:

- An individual experiences an early pregnancy loss (first-trimester miscarriage) and their health care provider prescribes pretreatment with mifepristone followed by treatment with misoprostol to assist with the passing of the miscarriage.[12] If a pharmacy refuses to fill the individual's prescription—including medications needed to manage a miscarriage or complications from pregnancy loss, because these medications can also be used to terminate a pregnancy—the pharmacy may be discriminating on the basis of sex.

- An individual experiences severe and chronic stomach ulcers, such that their condition meets the definition of a disability under civil rights laws. Their gastroenterologist prescribes misoprostol to decrease risk of serious complications associated with ulcers. If the pharmacy refuses to fill the individual's prescription or does not stock misoprostol because of its alternate uses, it may be discriminating on the basis of disability.

- An individual presents to a hospital emergency department with chills, fever, and vaginal bleeding. The treating physician diagnoses a miscarriage complicated by a uterine infection (known medically as a septic abortion) and orders an antibiotic. If the hospital pharmacy refuses to provide the antibiotic required for treatment because of concern that subsequent care may include uterine evacuation (via medical or surgical abortion), the pharmacy may be discriminating on the basis of sex.

- An individual who has been undergoing fertility treatments receives a positive pregnancy test. After the individual expresses concern with symptoms associated with an ectopic pregnancy,[13] their medical provider performs an ultrasound to determine where the pregnancy is developing. The ultrasound indicates the fertilized egg is growing in a fallopian tube. The medical provider orders methotrexate to halt the pregnancy. If a pharmacy refuses to fill the prescription because it will halt the growing of cells and end the pregnancy, it may be discriminating on the basis of sex.

- An individual with rheumatoid arthritis, such that their condition meets the definition of a disability under civil rights laws, is prescribed methotrexate by their physician's assistant as a standard immunosuppressive treatment. If the pharmacy refuses to fill the individual's prescription or does not stock methotrexate because of its alternate uses, it may be discriminating on the basis of disability.

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[11] Covered entities should also note that, while pregnancy itself is not a disability, medical issues resulting from pregnancy can qualify as a disability under Section 504 of the Rehabilitation Act of 1973 (Section 504), 29 U.S.C. § 794, which prohibits discrimination on the basis of disability in programs and activities of recipients of federal financial assistance. *Webster v. U.S. Dep't of Energy*, 267 F. Supp. 3d 246, 267 (D.D.C. 2017).

[12] Am. Coll. of Obstetricians and Gynecologists, *Practice Bulletin: Pregnancy Loss* (2018), https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2018/11/early-pregnancy-loss.

[13] An ectopic pregnancy is a pregnancy that occurs when fertilized egg grows outside of the uterus. *FAQs: Ectopic Pregnancy,* Am. Coll. of Obstetricians and Gynecologists (last updated Feb. 2018), https://www.acog.org/womens-health/faqs/ectopic-pregnancy.

- An individual presents a prescription for an emergency contraceptive at their local pharmacy after a sexual assault to prevent pregnancy. If the pharmacy otherwise provides contraceptives (e.g., external and internal condoms) but refuses to fill the emergency contraceptive prescription because it can prevent ovulation or block fertilization, the pharmacy may be discriminating of the basis of sex.

- An individual's health care provider sends the individual's prescription for hormonal contraception (e.g., oral contraceptive pill, emergency contraception, a patch placed on the skin, a contraceptive ring, or any other FDA-approved contraceptive product) to a pharmacy. If the pharmacy otherwise provides contraceptives (e.g., external and internal condoms) but refuses to fill a certain type of contraceptive because it may prevent a pregnancy, the pharmacy may be discriminating on the basis of sex.

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Second Opinions Should Be Mandated in Clinical Trials When Treating Physicians Recommend Their Own Research as Treatment for a Patient's Life-Threatening Illness

By Evan Bernstein

I. Introduction

Physicians who administer therapeutic care to patients can also serve as research investigators for an experimental treatment when their patients are also research subjects; this is called the dual physician-investigator role.[1] Although a dual physician-investigator may hold both a therapeutic and investigative relationship with a patient-subject, the duty owed to a patient in therapeutic care is not the same duty owed to a subject in research.[2] However, patients do not always recognize this distinction.[3] Often patients with life-threatening illnesses agree to participate in their treating physician's study under the assumption that their physician is pursuing their best interests.[4] Moreover, while it can appear that a patient has provided adequate informed consent before participating in research, often the informed consent procedures do not account for the societal and subconscious influences that impacted the patient's decision.[5] Furthermore, patients with life-threatening illnesses are often desperate for any cure for their disease, making them likely to trust the physician to look after their health and not understand the physician's conflicted role when acting as an investigator.[6] Therefore, there is a need for further measures to protect the autonomy of a patient with a life-threatening illness.[7] This article proposes that patients receive a second opinion from an independent physician before choosing to participate in a treating physician's research and that the patient also be represented by a patient advocate to protect the patient's autonomy.

II. Background

According to the National Institutes of Health, a clinical trial is "a research study in which one or more human subjects are prospectively assigned to one or more intervention or control (placebo or comparative therapeutic) groups to evaluate the effects of a particular intervention on health-related biomedical or behavioral outcomes."[8] Randomized controlled trials (RCT) measure the effectiveness of a new intervention or treatment.[9] In a RCT, recruited participants are randomly assigned to either the group that receives the experimental treatment or the control group (a comparative treatment such as another drug or a placebo).[10] Ideally, RCTs are conducted so that both the subjects and the investigators are unaware of which subjects received the experimental treatment and

which were in the control group until the trial has finished (this is also known as a "double-masked trial" or "double-blind trial").[11]

The goals of medical treatment and medical research are not the same.[12] Treatment is health care provided to a particular individual designed explicitly for that individual.[13] Health care services that qualify as treatment include individualized "[p]reventive, diagnostic, therapeutic, rehabilitative, maintenance, and palliative care."[14] On the other hand, research is "a systematic investigation, including research development, testing, and evaluation, [that is] designed to develop or contribute to generalizable knowledge."[15] Generalizable knowledge is health data that can be extrapolated to the larger group with the medical condition being studied.[16] For example, researchers plan to study a treatment for leukemia in a clinical trial with 300 participants with the potential to help 100,000 leukemia patients. Sometimes, physicians do not widely accept a research treatment as effective and believe it may be worse than the current "gold standard" therapy.[17]

The primary factor in determining the benefit of clinical research is whether it will result in an immediate therapeutic benefit to the individual or society.[18] According to the Belmont Report, clinical research is therapeutic when subjects in at least one group benefit from the treatment, no subjects are worse off than if treated by conventional means, and the study is organized to generate externally and internally valid data.[19] The external validity of a research study refers to how well the study results can be generalized to the public.[20] Internal validity refers to how closely the study results represent the truth about the patients in the study.[21] The tension between the subjects' benefit and society's benefit is judged by weighing the harms to the subjects versus the therapeutic benefits to society.[22] The Belmont Report declares that research that has therapeutic benefits justifies the use of human subjects when the study has scientific merit, the benefits to society exceed the risks to the individual subject, the subject understands the risks and benefits of their participation, and the subject has provided informed consent before participation.[23]

The entity that supervises biomedical research is usually the Institutional Review Board (IRB).[24] In addition, the Office for Human Research Protections (OHRP) is a federal office that is a part of the Department of Health and Human Services and administers the IRBs.[25] IRBs review almost every research project which involves human subjects and is federally funded.[26] In addition, based on the procedures outlined in the research institution, the IRB may review research projects that are not federally funded.[27]

The IRB includes five or more members with varying expertise responsible for reviewing and approving the subject research and taking appropriate steps to protect the rights and welfare of the participating subjects.[28] The IRB reviews the protocols of a project, determines the adequacy of the informed consent procedures (does the patient understand what he or she is getting into), does a risk and benefit analysis, determines whether the methods to be employed adhere to proper standards, reviews the privacy and confidentiality protections, and ensures compliance with the reporting requirements.[29] The research reporting requirements include internal and external adverse events that are not expected and are potentially related to the experimental treatment, and put the subject at more significant risk of economic, social, psychological, or physical harm than was anticipated.[30] An IRB also reviews the potential safety and health hazards of the proposed research, especially on vulnerable subjects, such as children, financially or educationally disadvantaged persons, or prisoners.[31] The ultimate authority to disapprove human-subject research at the institutions rests with the IRB.[32] An institutional official cannot override IRB rejection, but institutions may choose not to allow research that the IRB accepted.[33]

The patient advocate (also known as a patient navigator) is a trained professional who helps guide patients through the health care system.[34] Patient advocates' duties include guiding patients through the different stages of health care, such as diagnostic testing, diagnoses, treatments and follow-up.[35] Some groups of patient advocates, such as registered nurses, social workers, and health plan administrators, have professional experience in the medical field.[36] Patient advocates can be employed and available at medical organizations, nonprofit volunteers, or professionals in private practice.[37] Patient advocates work with patients and their doctors to ensure that patients have the background they need to understand the risks and benefits of their treatment and make decisions that align with their health care goals.[38]

This article first introduces the bioethical conflict between beneficence and autonomy in clinical research, including the "therapeutic misconception" that originates from the social normative mistaken belief that a physician in medical research makes clinical decisions in their patient's best interests.[39] Second, this article discusses the different legal mechanisms that have failed to address the problem of therapeutic misconception, including the doctrine of informed consent and the negligence standard.[40] Finally, this article proposes using a patient advocate as a liaison between the physician and patient and mandating a second opinion from an independent specialist when the clinical research is for a life-threatening illness to mitigate the negative impact on patient autonomy from the therapeutic misconception.

III. Bioethical Issues in Experimental Treatment

Clinical research creates bioethical issues related to both autonomy (the obligation to obtain informed consent based upon adequate information) and beneficence (the obligation

to benefit patients).[41] It should also be kept in mind that informed consent is itself a legal issue that creates an overlap between the bioethics and legal issues discussed.

A. The Therapeutic Misconception and Problems With Autonomy

The bioethical issue regarding autonomy in research derives from the subject's failure to recognize the lack of a physician-patient relationship between the clinical researcher and the subject.[42] The absence of a physician-patient relationship in research originates, in part, from the non-existence of human experimentation in the Hippocratic Oath.[43] For reference, the traditional Hippocratic Oath includes a three-way pact between the teacher, student and patient, involving the tenet of the sacredness of life and the supreme importance of the patient, and the physician's role as a healer.[44] However, a potential subject may lack autonomy when providing informed consent to an experimental treatment because they commonly decide to participate under the false assumption that the investigator structures the study to treat the individual's illness.[45] Moreover, potential subjects often fail to recognize that the investigator is executing a research protocol in which s/he has an interest in the outcome.[46]

The subject's misunderstanding that the investigator makes treatment decisions according to the subject's best interests instead of the research protocol guidelines was coined the "therapeutic misconception" in 1982.[47] Although knowledge of the therapeutic misconception has existed since 1982, today, laypersons interested in receiving an experimental treatment still often believes that they are under the care of the investigating physician who is making medical decisions to treat that person's illness.[48] However, the aim of experimental treatment is to produce valid data that will improve the treatment outcomes of future patients, not necessarily the outcome of the individual research subject.[49] This gives rise to an autonomy issue because the patient conflates the physician's role as an investigator with the physician's role as a health care provider.[50] A patient miscomprehending the investigator's duty may put blind faith in the investigator's administration of the experimental treatment and, therefore, also misconceive the risks and benefits of participating.[51] Without an adequate understanding of the risks and uncertainties of the experimental treatment, the patient's informed consent is also inadequate because they agree to a treatment that may not provide the personal benefit they desire.[52] Indeed, studies measuring the occurrence and effects of therapeutic misconception on subjects indicate that many subjects underappreciate the treatment's risks, overestimate the treatment's benefit, do not recognize that the primary goal of treatment is to advance science, and often conflate experimental treatment with therapeutic care.[53]

The reasons behind the subject's conflation of the research obligations of a clinical investigator with the therapeutic obligations of a physician are readily discernible.[54] The potential subject lives in a world that propagates the ideology that physicians are solely dedicated to improving one's health.[55] The subjects see the investigators as physicians because they are typically dressed in white coats, wearing a stethoscope, and working in hospitals.[56] The investigator appears as a prototypical physician, making it more difficult for the subject to understand that the experimental treatment is not designed for their well-being.[57] In addition, this perceived conflation of roles often happens when subjects suffer from such life-threatening ailments as cancer, AIDS, or other conditions where experimental treatments have become common.[58] Indeed, these patients are often referred to experimental treatment to receive cutting-edge therapy.[59] As these subjects become more desperate for any cure for their disease or treatment that ameliorates its effects, they may become blind to the investigator's role and continue to believe the experimental treatment is for their individualized care.[60] Thus, these subjects lack autonomy as they agree to participate in the research under the false premise that it is therapeutic.[61]

The difference in care between therapy and research is significant.[62] A physician whose primary purpose is to provide health care has the liberty of tailoring the treatment to the individual patient's needs, while a clinical researcher has to provide standardized care to each subject.[63] As an example, the physician may learn that their patient's antidepressants are causing them to have issues sleeping and either adjust the dosage of the medication, stop administration of the drug, or start administering a new medication.[64] However, an investigator would not provide a subject undergoing experimental treatment with a dosage adjustment or alternative medication options unless severe side effects exist.[65]

Some subjects also fail to understand that research clinicians are often evaluated based on the quality and quantity of their research as a metric of success.[66] On the one hand, it is in everyone's interest to improve the patient's condition in therapeutic care.[67] On the other hand, whether the physician provided the best possible care to each subject is not a factor in the success of their research.[68] For an experimental treatment to be successful or have high efficacy, there needs to be a statistically significant difference in the results from one arm of the study compared to another.[69] If all arms of the study have similar results, the experimental therapy will have low efficacy.[70] Thus, the physician may have a subconscious bias shifting focus away from the improvement of those patients who are not part of the experimental arm of the study toward those patients who are.

B. Altering the Physician's Duty is Not a Feasible Solution to the Therapeutic Misconception

Some commentators in medicine and bioethics have suggested that investigators should owe their subjects the same duty of care that treating physicians owe their patients.[71] In other words, they should act under the principle of beneficence or the professional obligation to promote the individual patient's-subject's well-being.[72] If this duty were initiated, investigators who administer experimental treatments would be required to cater to the best interests of each subject rather than maintaining the integrity of the research.[73] The obvious problem with imposing this obligation on investigators is that the methodological demands of experimental treatments generate inescapable conflicts with the best interests of individual subjects.[74] For example, to show a statistically significant difference in outcomes, an investigator must allow some subjects to face the consequences of their illness with what the investigator believes is a less effective treatment.[75] The logical conclusion is that if the equivalent duty of a treating physician were imposed on investigators, experimental research could not exist.[76] Furthermore, instating this duty would ignore the possibility that subjects might knowingly choose to relinquish the physician-patient relationship in exchange for the potential benefits of experimental treatment.[77]

Conversely, since experimental treatments are not the same as therapeutic treatments, other commentators argue that investigators have no obligation to promote each subject's well-being.[78] This argument relies heavily upon the goal of investigators to produce statistically significant information that can be used to help society at large and dismisses the therapeutic obligations that a physician owes a patient in a therapeutic setting.[79] Following this approach would allow investigators to take actions inconsistent with the promotion of the well-being of each subject, such as by assigning a terminally ill patient to the placebo arm of a study.[80] This approach heavily relies upon subjects voluntarily giving informed consent and understanding that they should not rely on the investigator to look out for their well-being.[81] The issue with following this approach is that it fails to recognize the negative impacts on patient autonomy.[82] The investigator's duty to benefit society at large may conflict with patient autonomy because the patient may not fully understand the danger of manipulation or the therapeutic misconception.[83]

IV. Legal Doctrines That Fail To Resolve the Therapeutic Misconception

A. Informed Consent

To obtain informed consent to an experimental treatment, the physician is obligated to provide (a) a reasonable explanation to the potential subject of the procedures to be observed and their significance, including identifying the experimental procedures; (b) a description of any associated discomforts and risks reasonably to be expected; (c) a description of any benefits reasonably to be expected; (d) a disclosure of any suitable alternative procedures that might be helpful for the potential subject; (e) an offer to answer any inquiries by the individual concerning the procedures; and (f) an instruction that the potential subject is allowed to withdraw their consent and to cease involvement in the human research at any stage without backlash.[84] If the physician-investigator obtains proper informed consent, the medical professional may be released from liability for malpractice by a patient who suffered from disclosed risks due to participating in a risky experimental treatment that might, or might not, generally be accepted as therapeutic.[85]

However, the informed consent process does not always account for the physician-patient relationship's influence on the patient.[86] A patient may be misled into participating in research because investigators often recruit subjects from their own therapeutic patients.[87] This practice creates a problematic situation where the physician-investigator must account for both the well-being of the patient-subject and the requirements of experimental trials to produce generalizable knowledge.[88] A patient who is a subject recruited by their physician is especially likely not to discern that they are involved in research instead of therapy.[89] The patient in this situation is expected to have already formed a relationship with the treating physician and is very likely to believe the physician will be looking out for their well-being.[90] There should be firmer rules requiring the physician to explain the dual investigator-physician role before informed consent is considered effective in these cases.[91] For example, the IRB at the University of California, Los Angeles (UCLA) requires that the conflict of interest be disclosed using the following wording:

> Your health care provider may be an investigator of this research protocol, and as an investigator, is interested both in your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another doctor who is in no way associated with this project. You are not under any obligation to participate in any research project offered by your doctor.[92]

In addition, the IRB at UCLA sometimes discourages physicians from directly approaching their patients to participate in experimental studies, recognizing that this disclosure may not be enough to counteract the therapeutic misconception.[93] In these instances, the IRB suggests that the physician place information about the trial in the waiting room and wait for the patient to approach them.[94] However, UCLA's

permissive requirement that a patient seek a second opinion will often not be enough. Patients who trust their physicians' views will often see a second opinion as unnecessary and thus choose to participate under the influence of the therapeutic misconception.[95]

An additional consideration in evaluating the adequacy of obtained informed consent is whether the patient who is consenting to participate in an experimental treatment and has a life-threatening illness is particularly vulnerable to manipulation.[96] Usually, patients volunteer for experimental research with the hope of finding a better therapy after their former treatments proved ineffective or their current treatment will not continue to be effective in the case of chemotherapy.[97] Patients with life-threatening illnesses can be particularly susceptible to manipulation based on the tacit promises and prospects offered by the experimental treatment.[98] This susceptibility is due to the fact that patients on the verge of death, who have exhausted most treatment options, are desperate for any solution that gives them a chance at a better quality of life.[99] These patients should still be allowed to seek experimental treatment because it may provide them with a chance at a better life and also benefit future patients.[100] Furthermore, some patients find it important to have their disease help others, making them feel their impending death is not without purpose.[101]

However, because patients with life-threatening illnesses are susceptible to manipulation, physicians-investigators need to be careful not to manipulate patients subconsciously.[102] Some researchers may be overly eager to enroll as many subjects as possible to make their research a success or because they genuinely have faith in the experimental treatment.[103] Although incentivized to discount enrollment risks, the physician-investigator may adequately disclose all experimental treatment risks via an IRB-approved informed consent protocol.[104] However, the information may be conveyed in a way that affects the patient's-subject's autonomy.[105] In clinical trial research, informational manipulation occurs when the investigator changes the subject's understanding of the risks and benefits of the treatment by portraying them positively.[106] Manipulation of the patient's perception and reaction to the risks and benefits of the treatment can also occur when investigators use a "tone of voice [or] forceful gesture."[107] This type of manipulation may significantly impact the patient's decision to participate, negatively affecting the patient's autonomy.[108] Since patients with life-threatening illnesses are particularly susceptible to manipulation, doctors should be extra cautious in framing the risks and benefits of the treatment to ensure they are not overly optimistic.[109]

The informed consent process often does not protect the patient from the influence of therapeutic misconception on their decision to participate. The informed consent process fails to account for the impact of the physician-patient relationship, the vulnerability of patients with life-threatening illnesses, and how treating physicians can subconsciously influence the patient. Recognizing the inadequacy of the informed consent process, some commentators have argued that the negligence standard holds physicians accountable for protecting the patient's autonomy.

B. Negligence

The negligence standard is also not an adequate solution to therapeutic misconception. Negligence fails to resolve therapeutic misconception because of the differing standards between therapeutic treatment and research, the physician's insulation from liability based upon obtaining the patient's informed consent, and because the patient has often impliedly assumed the risk of participation.

Some researchers argue that investigators should not be allowed to obtain informed consent to experimental treatments that would be considered negligence if provided for standard medical treatment.[110] They contend that patients cannot waive the duty of physicians to adhere to minimum standards.[111] Not allowing patients to waive negligence claims aligns with public policy because of the unequal bargaining power between investigators and subjects.[112] However, this argument fails to consider that negligence in experimental treatments differs from that of standard treatment.[113] According to the Restatement of Torts 2d, negligence is conduct that falls below the standard of care established for the protection of others.[114] Thus, the context of the activity is taken into account when determining whether the defendant failed to conform to a particular standard of care.[115] In a clinical setting, physicians have a duty to benefit the patient.[116] Conversely, in research, the potential to benefit the subjects is incidental to the primary purpose of obtaining generalizable knowledge.[117] Therefore, unlike medical treatment, an investigator has not breached the duty of due care when an IRB has approved the experimental treatment as pursuing a sufficiently important scientific goal, even if the investigator has not benefited the patient during the experiment.[118] It should also be noted that the subject's informed consent is a factor justifying the experimental risks because informed consent allows the investigator to depart from the subject's medical interests.[119] If proper informed consent were not obtained, an investigator could be negligent in failing to pursue treatment that benefits the subject.[120]

C. Primary Implied Assumption of the Risk

Another consideration in determining whether negligence has occurred is the torts principle of primary implied assumption of the risk, which establishes that risks that may be considered unacceptably dangerous can be acceptable if implied consent is given.[121] According to the Restatement of Torts

2d, primary implied assumption of the risk will defeat a negligence claim when (1) the risks were an inherent part of the activity in which those exposed were voluntarily participating and (2) it was reasonable for the person imposing the risks to assume that those participating in the activity knowingly accepted the dangers involved.[122] For example, in a treatment setting, primary implied assumption of the risk could be found when a physician prescribes medication and explains to the patient that stomach pain is a risk.[123] If the patient takes the drug and suffers stomach pain, the patient could be said to have impliedly assumed the risk of taking the medication, and the patient could not recover from a negligence claim.[124] By obtaining the patient's informed consent, the physician has insulated herself from liability.[125]

In the context of experimental treatment, a subject can similarly have impliedly assumed the risks even absent providing adequate informed consent when (1) the risks are necessary components of the experimental treatment and (2) the subject knowingly agreed to participate in the experimental trial.[126] The first requirement is usually met because it is virtually impossible for the investigator to always pursue the patient's best interests during a randomized controlled trial.[127] As for the second requirement, informed consent obtained with the subject's signature evidences the subject's awareness of the fact that the treatment received is part of an experimental trial.[128] However, this does not mean that the subjects genuinely understood or accepted all risks.[129] Thus, courts will consider circumstances external to the patient's informed consent that indicates the subject has impliedly assumed the risks of participation.[130]

In some situations, the risks associated with an experimental treatment are insignificant.[131] The subject may not care if they are in the placebo arm of the study if, for example, the subject is in a study comparing an experimental treatment for a minor condition such as mild seasonal allergies compared to nontreatment.[132] The subject may be willing to experience mild adverse symptoms.[133] In other situations, subjects may be willing to risk receiving a placebo because participating in an experimental treatment is the only way they can access a promising new drug or therapy.[134] The patients generally do not know whether they will be receiving the placebo or the actual drug, but they are often willing to risk receiving the placebo with the hope that they will receive the actual experimental treatment.[135] Further, some subjects believe that participating in a randomized control trial can improve their condition even if placed in the placebo arm of the study (also known as the "inclusion benefit").[136]

Furthermore, some participants forgo the standard therapeutic relationship for altruistic reasons.[137] Although the experimental treatment may not benefit them personally, they may enroll in a study to benefit their family (e.g., with a genetic condition), future and current patients who suffer from the same rare disease, or a group of people to whom they feel an affinity (i.e., men who have testicular cancer).[138] Another reason why subjects may be willing to forego the therapeutic relationship is that they don't have the financial means to access a therapeutic treatment.[139] In the U.S., some patients cannot access treatment because there is no universal health care or the treatment is so new and experimental that it is not yet covered by insurance, and participating in a subsidized experimental treatment may be their only affordable option.[140] While the prospect that a subject enrolls in an experimental treatment due to lack of another option is disturbing, the patient may still impliedly assume the risk of participation.[141]

Thus, an investigator may be able to deviate from pursuing the subject's best interests without liability.[142] For research studies to be effective, the physician-patient relationship must be suspended, and the patient protected by adequate informed consent.[143] However, informed consent still has the problem of therapeutic misconception, which needs to be resolved.[144]

V. How a Patient Advocate Consultation and a Second Physician's Opinion Can Resolved the Influence of the Therapeutic Misconception

The use of patient advocates in the experimental treatment setting and the requirement that patients receive a second opinion from an independent physician before choosing to participate in a treating physician's research could help protect the patients' autonomy.[145] The patient advocates could help effectively communicate the potential risks and benefits of the experimental treatment to prospective volunteers.[146] A second opinion from an independent physician before choosing to participate in a treating physician's research could help patients to discover a treatment, sometimes outside of the study, that matches the patient's risk tolerance and desired benefits.

A. Patient Advocates

One current active area for patient advocates is representing healthy children who plan to donate bone marrow to ailing siblings.[147] Patient advocates are essential in this context due to potential parental conflicts of interest.[148] For example, one group using patient advocates assigned a child advocate from their local public defender's office to all potential children bone marrow donors.[149] The appointed advocate investigated the facts, closely analyzed the informed consent, and made a recommendation to the administrative judge of the family court, who either ratified or declined the recommendation.[150] Another active area for patient advocates is assisting live organ donors.[151] Patient advocates help ensure that family members are not pressuring the patient into donating their organs against the patient's wishes.[152]

A similar process could be effective with experimental treatments. A patient advocate would be assigned to patients with life-threatening conditions because they are often desperate for any cure for their disease and likely to become blind to the investigator's role and continue to believe the experimental treatment is for their individualized care.[153] Conversely, a patient advocate should not be mandatory for experimental treatments where the patient suffers from a minor condition. Patients in this category of experimental treatments are more likely to fully exercise their autonomy in selecting whether to participate because they have more options, including nontreatment.[154] Furthermore, the risks in these studies are less significant, so even if the patient does not fully comprehend the risks and benefits, their loss is minimal.[155] Likewise, scarce resources such as patient advocates are better conserved for patients who face significant risks, such as life-threatening illnesses.[156] In addition, nonprofit organizations such as the patient advocate foundation can mitigate costs for patients by providing those facing a chronic, life-threatening, or debilitating disease with free patient advocate services.[157]

There are several considerations that should be taken into account in determining whether a patient advocate can effectively represent a patient's best interests. First, the patient advocate needs to be carefully selected. The patient advocate should not be affiliated with the institution conducting the experimental treatment protocol or have conflicts of interest that would inhibit an unbiased review.[158] Second, the patient advocate needs to protect the patient's autonomy. The advocate should be responsible for reviewing the informed consent disclosure to ensure it is in understandable language, it includes what the patient would want to know, that the patient had sufficient opportunity to discuss and consider the information, and any danger of manipulation has been minimized.[159] Third, the advocate should make a recommendation to the IRB in charge of the experimental treatment, and then the IRB would consider that recommendation in performing its evaluation procedure.[160] If it is a recommendation, then the IRB can choose whether to follow it.[161] Also, the advocate should explain the experiment's protocols to the patient and the physician's role when overseeing a study to counter the therapeutic misconception.

B. Independent Physician's Second Opinion

In addition to consulting a patient advocate, a patient must obtain a second opinion from an independent physician before choosing to participate in their treating physician's research. A patient may choose to not participate in an experimental treatment recommended by their physician if the patient knows better treatment options, including other experimental treatments, are available. Physicians-investigators who need to increase enrollment in an experimental study they are conducting may overlook factors that would make recommending a different treatment option better for the patient.[162] At the same time, while circumstances exist that make an experimental treatment in the patient's best interests, many physicians would use research as a last resort because of the risks involved.[163] Furthermore, despite an experimental treatment having positive therapeutic potential, sometimes the patient can access the treatment outside of the study, which would allow them to maintain a doctor-patient relationship.[164]

In most circumstances, a patient advocate alone would not be enough to protect the patient's autonomy from the therapeutic misconception. An independent physician can assess the efficacy of a particular treatment more accurately than a patient advocate. Patient advocates generally do not have the medical training necessary to give a second opinion.[165] Physicians are better able to choose between several treatment options and inform the patients of the risks and benefits of each option by analyzing the technical medical literature, referencing personal experiences, and speaking with colleagues.[166] Furthermore, the independent physician should be a physician who has medical training in the area of the desired experimental treatment so as to mitigate the chances that the physician will rely on the patient's treating physician's opinion. Thus, a dispassionate physician with subject area medical proficiency who is not affiliated with the institution and does not have other conflicts of interest that inhibit an unbiased assessment could best provide the patient with a second opinion regarding which treatment option best matches their desired level of risk and benefit, including those outside the study.

VI. Conclusion

The requirement that a patient consults with a patient advocate and obtain a second opinion from an independent physician before participating in their treating physician's research may help ameliorate the concerns of those who believe physicians should be prohibited from exercising the dual role of treating physician-investigator. These commentators fear that the patient's trust in the physician to look after their health will interfere with their understanding of the physician's conflicted role when acting as an investigator.[167] A patient advocate could serve as an intermediary by explaining the physician's differing role in the research setting and informing the patient that they must receive a second opinion from another doctor who is not associated with the institution or research.[168] The independent physician who has medical knowledge of the patient's condition will provide the patient with an unbiased assessment of their fitness for the experimental treatment at issue, the opportunity to choose between several treatment options, and inform the patient of the risks and benefits of each option.

Implementing these reforms is necessary to overcome many subjects' beliefs that participating in experimental treatments is part of their therapeutic care. Furthermore, although somewhat burdensome, subjects who suffer from such ailments as cancer, AIDS, or other life-threatening conditions where patients are particularly susceptible to manipulation by researchers should be required to consult with a patient advocate and receive a second opinion. On the other hand, no such provision is needed where patients suffer from a minor illness. With these reforms in place, beneficial research can continue with limited infringement on patient autonomy.

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63. *Id.* at 398.
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66. *Id.* at 401.
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98. *Id.*
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100. *See* Coleman, *supra* note 5, at 412.
101. *See id.*
102. *See* Lenrow, *supra* note 1, at 40.
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127. *Id.* at 410–11.
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130. *See id.*
131. *Id.* at 411.
132. *See id.*
133. *Id.*
134. *Id.*
135. *See id.* at 411–12.
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138. *See id.*
139. *Id.* at 412-13.
140. *Id.*
141. *Id.*
142. *Id.* at 413.
143. *Id.* at 418.
144. *See id.* at 421.
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150. *Id.*
151. *Understanding the Process: Donor Advocate and Informed Consent*, Weil Cornell Medicine, https://weillcornell.org/services/kidney-and-pancreas-transplantation/living-donor-kidney-center/our-services/understanding-the-process-donor-advocate-and-informed-consent (last visited Apr. 28, 2022).
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154. *See* Coleman, *supra* note 5, at 410.
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159. *See* Umesh Chandra Gupta, *Informed consent in clinical research: Revisiting few concepts and areas*, Perspect Clin Res. 2013 Jan–Mar; 4(1): 26–32.
160. *See* Rubinstein, *supra* note 147, at 290.
161. *See id.* at 290–91.
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164. *Id.*
165. Patient Advocate Foundation, *supra* note 156.
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167. Lenrow, *supra* note 1, at 47.
168. *See* Ronai, *supra* note 92.

Guidance on How the HIPAA Rules Permit Covered Health Care Providers and Health Plans To Use Remote Communication Technologies for Audio-Only Telehealth

U.S. Department of Health and Human Services[1]

Covered health care providers and health plans (covered entities)[2] can use remote communication technologies[3] to provide audio-only telehealth[4] services when such communications are conducted in a manner that is consistent with the applicable requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy, Security, and Breach Notification Rules (HIPAA Rules).[5] The U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) developed this guidance to help covered entities understand how they can use remote communication technologies for audio-only telehealth[6] in compliance with the HIPAA Rules, including when OCR's Notification of Enforcement Discretion for Telehealth Remote Communications (Telehealth Notification)[7] is no longer in effect.[8]

HHS is issuing this guidance on audio-only telehealth in direct response to the Executive Order on Transforming Federal Customer Experience and Service Delivery to Rebuild Trust in Government (E.O. 14058).[9] This guidance will help ensure that individuals can continue to benefit from audio-only telehealth by clarifying how covered entities can provide telehealth services and improving public confidence that covered entities are protecting the privacy and security of their health information.

In addition, while telehealth can significantly expand access to health care, certain populations may have difficulty accessing or be unable to access technologies used for audio-video telehealth because of various factors, including financial resources, limited English proficiency, disability, internet access, availability of sufficient broadband, and cell coverage in the geographic area. Audio-only telehealth, especially using technologies that do not require broadband availability, can help address the needs of some of these individuals.[10] To support access to such telehealth services, this guidance addresses questions that HHS has received about whether, and in what circumstances, audio-only telehealth is permissible under the HIPAA Rules.[11]

OCR's Telehealth Notification and FAQs

In March 2020, in response to the COVID-19 public health emergency (PHE), OCR issued the Telehealth Notification to assist the health care industry's response to the PHE and to quickly expand the use of remote health care services. OCR also published a set of FAQs to support and clarify the Telehealth Notification.[12]

The Telehealth Notification provides that OCR will exercise its enforcement discretion and will not impose penalties on covered health care providers[13] for noncompliance with the requirements of the HIPAA Rules in connection with the good faith provision of telehealth using non-public facing[14] audio or video remote communication technologies during the COVID-19 PHE.[15] As such, under the Telehealth Notification, covered health care providers can use any available non-public facing remote communication technologies for telehealth, even where those technologies, and the manner in which they are used, may not fully comply with the HIPAA Rules. The Telehealth Notification will remain in effect until the Secretary of HHS declares that the COVID-19 PHE no longer exists, or upon the expiration date of the declared PHE, whichever occurs first.

The following FAQs provide guidance to assist covered entities in complying with the HIPAA Rules when OCR's Telehealth Notification is no longer in effect.

1. Does the HIPAA Privacy Rule permit covered health care providers and health plans to use remote communication technologies to provide audio-only telehealth services?

Yes. HIPAA covered entities can use remote communication technologies to provide telehealth services, including audio-only services, in compliance with the HIPAA Privacy Rule.

The HIPAA Privacy Rule requires that covered entities apply reasonable safeguards to protect the privacy of protected health information (PHI) from impermissible uses or disclosures, including when providing telehealth services.[16] For example, OCR expects covered health care providers to provide telehealth services in private settings to the extent feasible. If telehealth services cannot be provided in a private setting (e.g., where a provider shares an office with a colleague or a family member), covered health care providers still must implement reasonable safeguards, such as using lowered voices and not using speakerphone, to limit incidental uses or disclosures of PHI.[17]

In addition, if the individual is not known to the covered entity, the entity must verify the identity of the individual either orally or in writing (which may include using electronic methods).[18] The HIPAA Rules do not mandate a specific way to verify identity. However, covered entities should be mindful that civil rights laws generally require communications with an individual with a disability to be as effective as communications with others, including by providing appropriate auxiliary aids and services where necessary.[19] This requirement extends to all communications with an individual with a disability, including communications related to verifying an individual's identity. In addition, when necessary, covered entities must verify the individual's identity by using language assistance services to provide meaningful access for individuals with limited English proficiency.[20]

2. Do covered health care providers and health plans have to meet the requirements of the HIPAA Security Rule in order to use remote communication technologies to provide audio-only telehealth services?

Yes, in certain circumstances. The HIPAA Security Rule applies to electronic protected health information (ePHI), which is PHI transmitted by, or maintained in, electronic media.[21,22]

The HIPAA Security Rule does not apply to audio-only telehealth services provided by a covered entity that is using a standard telephone line, often described as a traditional landline,[23] because the information transmitted is not electronic. Accordingly, a covered entity does not need to apply the Security Rule safeguards to telehealth services that they provide using such traditional landlines (regardless of the type of telephone technology the individual uses).

However, traditional landlines are rapidly being replaced with electronic communication technologies such as Voice over Internet Protocol (VoIP)[24] and mobile technologies that use electronic media, such as the Internet, intra- and extranets, cellular, and Wi-Fi.[25] The HIPAA Security Rule applies when a covered entity uses such electronic communication technologies. Covered entities using telephone systems that transmit ePHI need to apply the HIPAA Security Rule safeguards to those technologies. Note that an individual receiving telehealth services may use any telephone system they choose and is not bound by the HIPAA Rules when doing so. In addition, a covered entity is not responsible for the privacy or security of individuals' health information once it has been received by the individual's phone or other device.

For example, some current electronic technologies that covered entities use for remote communications that require compliance with the Security Rule, may include:

- Communication applications (apps) on a smartphone or another computing device.

- VoIP technologies.
- Technologies that electronically record or transcribe a telehealth session.
- Messaging services that electronically store audio messages.

Potential risks and vulnerabilities to the confidentiality, integrity, and availability of ePHI when using such technologies need to be identified, assessed, and addressed as part of a covered entity's risk analysis and risk management processes, as required by the HIPAA Security Rule.[26] A covered entity's risk analysis and risk management should include considerations of whether:

- There is a risk the transmission could be intercepted by an unauthorized third party.
- The remote communication technology (e.g., mobile device, app) supports encrypted transmissions.
- There is a risk ePHI created or stored as a result of a telehealth session (e.g., session recordings or transcripts) could be accessed by an unauthorized third party, and whether encryption is available to secure recordings or transcripts of created or stored telehealth sessions.[27]
- Authentication is required to access the device or app where telehealth session ePHI may be stored.
- The device or app automatically terminates the session or locks after a period of inactivity.

As communication technologies (e.g., networks, devices, apps) continue to evolve at a rapid pace, a robust inventory and asset management process can help covered entities identify such technologies and the information systems that use them, to help ensure an accurate and thorough risk analysis.[28] For information about implementing the HIPAA Security Rule requirements, see OCR's Security Rule guidance webpage.[29]

3. Do the HIPAA Rules permit a covered health care provider or a health plan to conduct audio-only telehealth using remote communication technologies without a business associate agreement in place with the vendor?

Yes, in some circumstances. The HIPAA Rules require a covered entity to enter into a business associate agreement (BAA)[30] with a telecommunication service provider (TSP)[31] only when the vendor is acting as a business associate.[32] As explained in previous guidance, a covered entity using a telephone to communicate with patients is not required to enter into a BAA with a TSP that has *only transient access to the PHI it transmits*,[33] because the vendor is acting merely as a conduit for the PHI.[34] If the TSP is not also creating, receiving, or maintaining PHI on behalf of the covered entity, and the TSP does not require access on a routine basis to the PHI it transmits in the call,[35] no business associate relationship has been created. Therefore, a BAA is not needed.

- For example, a covered health care provider may conduct an audio-only telehealth session with a patient using a smartphone without a BAA between the covered health care provider and the TSP, where the TSP does not create, receive, or maintain any PHI from the session *and* is only connecting the call.

However, a covered entity must enter into a BAA with a vendor that is more than a mere conduit for PHI.

- For example, a covered health care provider may want to conduct audio-only telehealth sessions with patients using a smartphone app offered by a health care provider that stores PHI (e.g., recordings, transcripts) in the app developer's cloud infrastructure for the provider's later use. In this case, the app would not be providing mere data transmission services and would instead also be creating, receiving, and maintaining PHI. Because it is not merely a conduit for transmission of the PHI, the provider would need to enter into a BAA with the app developer before it can use the app with patients.
- Similarly, a covered health care provider would need a BAA with the developer of a smartphone app that the provider uses to translate oral communications to another language to provide meaningful access to individuals with limited English proficiency,[36] because the app is creating and receiving PHI, and therefore the developer is a business associate of the provider.[37]

4. Do the HIPAA Rules allow covered health care providers to use remote communication technologies to provide audio-only telehealth if an individual's health plan does not provide coverage or payment for those services?

Yes. Covered health care providers may offer audio-only telehealth services using remote communication technologies consistent with the requirements of the HIPAA Rules, regardless of whether any health plan covers or pays for those services. Health plan coverage and payment policies for health care services delivered via telehealth are separate from questions about compliance with the HIPAA Rules and are not addressed in this document.

RESOURCES

OCR Resources

- OCR Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID–19 Nationwide Public Health Emergency - PDF
- FAQs on Telehealth and HIPAA during the COVID-19 nationwide public health emergency - PDF
- Guidance on the HIPAA Security Rule
- Guidance on HIPAA and Cloud Computing
- Guidance on HIPAA Business Associate Agreements
- FAQ: Use of Telecommunications Relay Service (TRS) does not require a business associate agreement with the TRS
- HHS Security Risk Assessment Tool (jointly developed by OCR and the Office of the National Coordinator for Health Information Technology (ONC))
- Filing a complaint with OCR if you believe that a HIPAA covered entity or business associate violated your (or someone else's) health information privacy rights or committed another violation of the HIPAA Rules

HHS Resources

- Telehealth resources are available at https://telehealth.hhs.gov/ and https://www.hhs.gov/coronavirus/telehealth/index.html
- HHS information about Medicare and Medicaid coverage and billing for telehealth services is available at https://telehealth.hhs.gov/providers/billing-and-reimbursement/
- CMS Telehealth Resources about Medicare and Medicaid coverage
    - https://www.cms.gov/About-CMS/Agency-Information/OMH/equity-initiatives/c2c/consumer-resources/telehealth-resources
    - https://www.medicaid.gov/medicaid/benefits/telemedicine/index.html
    - https://www.cms.gov/Medicare/Medicare-general-information/telehealth
- SAMHSA Guidance regarding telehealth and Confidentiality of Substance Use Disorder Treatment Records regulations (42 CFR Part 2)
    - https://www.samhsa.gov/sites/default/files/covid-19-42-cfr-part-2-guidance-03192020.pdf – PDF
    - https://www.samhsa.gov/resource/ebp/telehealth-treatment-serious-mental-illness-substance-use-disorders
    - https://www.samhsa.gov/section-223/care-coordination/telehealth-telemedicine

Endnotes

1. Document available at https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hipaa-audio-telehealth/index.html.
2. A HIPAA covered entity is a health plan, health care clearinghouse, or "a health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter." Where this guidance refers to a covered entity, the language also applies to a business associate acting on behalf of, or providing certain services to or for, a covered entity to conduct the activity. *See* 45 CFR 160.103 (definitions of "Covered entity" and "Business associate").
3. *See* OCR "FAQs on Telehealth and HIPAA during the COVID-19 nationwide public health emergency" for more information on what are public and non-public facing remote communication products at https://www.hhs.gov/sites/default/files/telehealth-faqs-508.pdf.
4. The HHS Health Resources and Services Administration (HRSA) defines telehealth as the use of electronic information and telecommunications technologies to support and promote long-distance clinical health care, patient and professional health-related education, and public health and health administration. *See* https://www.hrsa.gov/rural-health/topics/telehealth/what-is-telehealth.
5. *See* 45 CFR Subchapter C, parts 160 and 164.
6. Except where an FAQ response addresses a specific audio-only technology, the information in this guidance is generally applicable to the provision of all telehealth services, and not just audio-only telehealth.
7. *See* 85 FR 22024-25 (April 21, 2020), https://www.govinfo.gov/content/pkg/FR-2020-04-21/pdf/2020-08416.pdf – PDF.
8. The Notification will remain in effect until the Secretary of HHS declares that the public health emergency no longer exists, or upon the expiration date of the declared public health emergency, including any extensions, whichever occurs first. *See* 85 FR 22024. OCR will issue a notice to the public when it is no longer exercising its enforcement discretion based upon the latest facts and circumstances.
9. *See* E.O. 14058, 86 FR 71357 (Dec. 16, 2021).
10. A person with limited English proficiency may need a qualified interpreter whose services are easier to coordinate over the phone. Audio-only telehealth may serve remote patients with limited access to computers or high-speed internet. While audio-only telehealth may be preferred by some individuals with disabilities, covered entities should be mindful that audio-only telehealth may

not provide effective communication for other individuals with disabilities, such as individuals who are deaf.

11. This guidance does not provide information about coverage or payment for health care services delivered via of telehealth. Certain health plans may have specific policies about, or limitations on, coverage and payment for health care services provided via telehealth, and these policies and limitations are not addressed in this document. *See Resources* below for more information. *See also* 45 CFR 160.103 (definition of "Health plan").

12. *See* https://www.hhs.gov/sites/default/files/telehealth-faqs-508.pdf – PDF.

13. The Telehealth Notification does not apply to health plans that provide telehealth.

14. A "non-public facing" remote communication product is one that, as a default, allows only the intended parties to participate in the communication. *See* OCR's HIPAA FAQ #3024 at https://www.hhs.gov/hipaa/for-professionals/faq/3024/what-is-a-non-public-facing-remote-communication-product/index.html

15. *See* original determination of a public health emergency related to COVID-19 https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx, and April 12, 2022 Renewal https://aspr.hhs.gov/legal/PHE/Pages/COVID19-12Apr2022.aspx.

16. *See* 45 CFR 164.530(c). *See also* OCR's HIPAA FAQ #482 at https://www.hhs.gov/hipaa/for-professionals/faq/482/does-hipaa-permit-a-doctor-to-share-patient-information-for-treatment-over-the-phone/index.html.

17. *See* 45 CFR 164.502(a)(1)(iii); *see also* OCR's HIPAA FAQ #3021 at https://www.hhs.gov/hipaa/for-professionals/faq/3021/where-can-health-care-providers-conduct-telehealth/index.html.

18. *See* 45 CFR 164.514(h). *See also* OCR's HIPAA FAQ #569 at https://www.hhs.gov/hipaa/for-professionals/faq/569/how-may-hipaas-requirements-for-verification-of-identity-be-met-electronically/index.html.

19. *See, e.g.*, 45 CFR 92.102; 45 CFR 84.52(c); 45 CFR 84.52(d); 28 CFR 35.160; 28 CFR 36.303(c).

20. *See* 45 CFR 80 and 45 CFR 92.201.

21. *See* 45 CFR 160.103 (definitions of "Electronic protected health information" and "Electronic media").

22. *See* the HIPAA Security Rule at 45 CFR Parts 160 and 164, Subpart C. The Security Rule also applies to a business associate, such as a technology vendor with routine access to ePHI.

23. Such traditional telephones use circuit-switched voice communication service technologies through the Public Switched Telephone Network (PSTN).

24. VoIP technologies convert audio into a digital signal that is then transmitted over the internet. *See* https://www.fcc.gov/general/voice-over-internet-protocol-voip.

25. A recent report by the Federal Communications Commission (FCC) stated that the "number of fixed retail switched-access lines declined over the past three years at a compound annual rate of 13%, while interconnected VoIP subscriptions increased at a compound annual growth rate of 3%." See Federal Communications Commission. *2020 Communications Marketplace Report*, p 102. https://docs.fcc.gov/public/attachments/FCC-20-188A1.pdf – PDF.

26. *See* 45 CFR 164.308(a)(1)(ii)(A)-(B), Risk analysis and Risk management.

27. For more information about encryption, *see* OCR Cybersecurity Newsletter Summer 2021 at https://www.hhs.gov/hipaa/for-professionals/security/guidance/cybersecurity-newsletter-summer-2021/index.html.

28. *See* OCR Cybersecurity Newsletter Summer 2020 at https://www.hhs.gov/hipaa/for-professionals/security/guidance/cybersecurity-newsletter-summer-2020/index.html.

29. *See* https://www.hhs.gov/hipaa/for-professionals/security/guidance/index.html?language=es.

30. *See* 45 CFR 164.308(b) and 45 CFR 164.502(e).Information about business associate agreements is available at https://www.hhs.gov/hipaa/for-professionals/covered-entities/sample-business-associate-agreement-provisions/index.html.

31. Telecommunication service provider means companies that provide voice and/or data transmission services, such as Internet Service Providers (ISPs), telecommunication carriers, and wireless carriers.

32. *See* 45 CFR 160.103 (definition of "Business associate").

33. Transient access occurs when a service provider *only* transmits PHI (whether in electronic or paper form) and does not maintain it except on a temporary basis incident to such transmission. More information about transient versus persistent access to PHI is available at https://www.hhs.gov/hipaa/for-professionals/special-topics/health-information-technology/cloud-computing/.

34. *See* OCR's HIPAA FAQ #245 at https://www.hhs.gov/hipaa/for-professionals/faq/245/are-entities-business-associates/index.html.

35. "A conduit transports information but does not access it other than on a random or infrequent basis as necessary for the performance of the transportation service or as required by law. Since no disclosure is intended by the covered entity, and the probability of exposure of any particular protected health information to a conduit is very small, a conduit is not a business associate of the covered entity." *See* OCR's HIPAA FAQ #245 at https://www.hhs.gov/hipaa/for-professionals/faq/245/are-entities-business-associates/index.html and HIPAA FAQ #2077 at https://www.hhs.gov/hipaa/for-professionals/faq/2077/can-a-csp-be-considered-to-be-a-conduit-like-the-postal-service-and-therefore-not-a-business%20associate-that-must-comply-with-the-hipaa-rules/index.html.

36. OCR encourages covered entities to ensure the accuracy and quality of any language assistance service provided, whether via smartphone app or live interpretation or translation. For further guidance on the use of automatic or machine translation, including digital services and websites, visit LEP.gov.

37. A covered entity would need to enter into a BAA with any language interpretation service it engages because the service is creating, receiving, maintaining, or transmitting PHI for or on behalf of the covered entity. In contrast, OCR has described when a covered entity can contact an individual using a Telecommunications Relay Service (TRS) communication assistant without having a business associate agreement in place with the TRS provider because the TRS provider is not acting for or on behalf of the covered entity. *See* OCR guidance at https://www.hhs.gov/hipaa/for-professionals/faq/500/is-a-relay-service-a-business-associate-of-a-doctor/index.html. Also *see* 86 FR 6446, 6496-6487 (Jan. 21, 2021) for discussion of HHS's proposals to modify the Privacy Rule to expressly permit disclosures to TRS communications assistants and to modify the definition of business associate to expressly exclude TRS providers.

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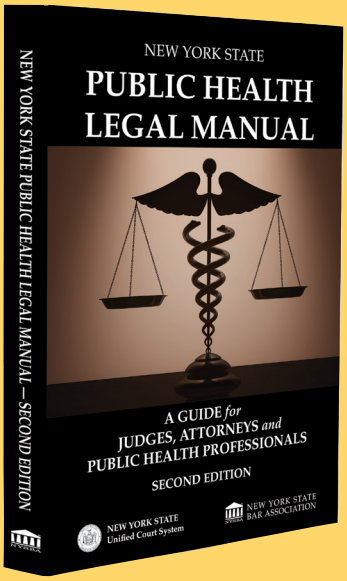

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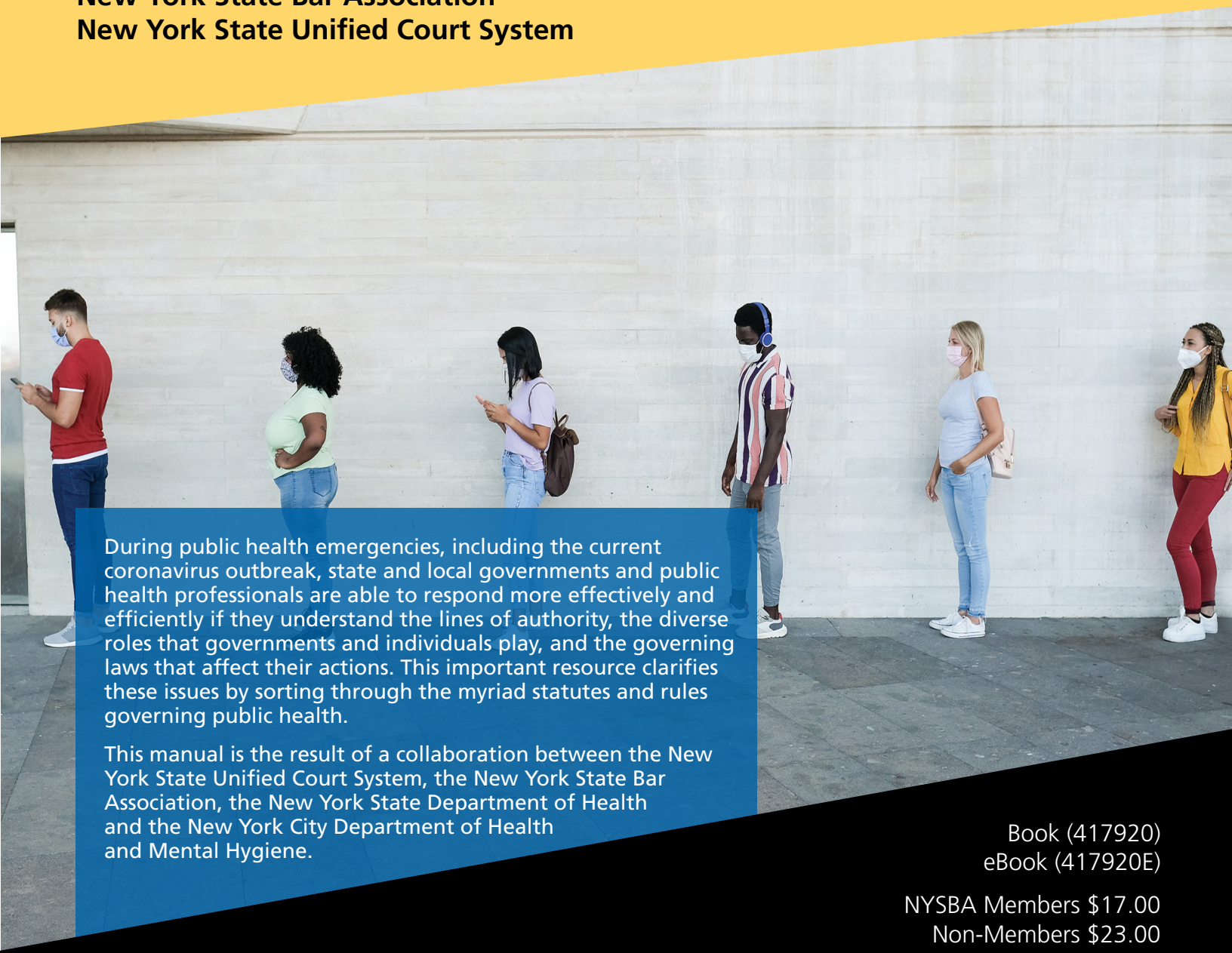

During public health emergencies, including the current coronavirus outbreak, state and local governments and public health professionals are able to respond more effectively and efficiently if they understand the lines of authority, the diverse roles that governments and individuals play, and the governing laws that affect their actions. This important resource clarifies these issues by sorting through the myriad statutes and rules governing public health.

This manual is the result of a collaboration between the New York State Unified Court System, the New York State Bar Association, the New York State Department of Health and the New York City Department of Health and Mental Hygiene.

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