

THE RACE FOR A COVID-19 VACCINE

Planning for the Employer Response

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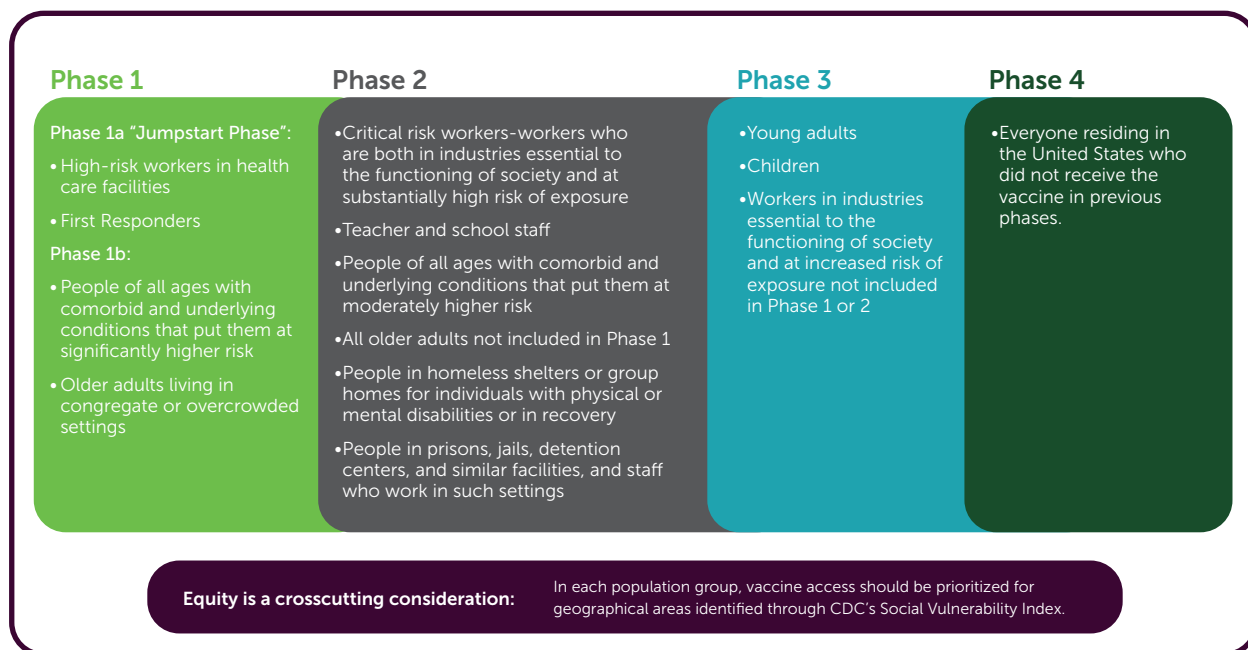
Introduction

Many employers are hopeful that a vaccine for COVID-19 will be the silver bullet that will enable employers to return to some semblance of a pre-COVID workplace. Assuming a vaccine is developed, can an employer mandate that employees be vaccinated before coming back to work? What happens when an employee cannot or will not take this vaccine, either for religious, medical, or other personal reasons? Can a union or group of workers successfully challenge employer-mandated vaccines? Aside from these potential challenges, are mandatory vaccinations the most appropriate response in fighting COVID-19?

This Report reviews the legal landscape as it pertains to employer-mandated vaccines, and as important, whether options other than mandated vaccines need to be considered by the employer community. As discussed below, the case developments to date primarily have involved vaccination programs to minimize flu-related risks, particularly by employers in the health care field. These case developments, however, can serve as a critical guidepost in helping employers take appropriate action as vaccinations are developed for COVID-19.

It clearly is not too early for employers to be carefully evaluating their options. Based on recent reports from the Centers for Disease Control and Prevention (CDC), preparations are underway for two coronavirus vaccines referred to as “Vaccine A” and “Vaccine B,” and the CDC recently advised public health agencies that limited doses of a vaccine may be available in late October or November 2020.¹ The first doses of another vaccine, being developed by the University of Oxford in tandem with a major pharmaceutical company, also may be available in the United States by the end of 2020.²

Despite the sense of urgency in developing and receiving approval for a COVID-19 vaccine, the employer community needs to be aware that there will be some significant delays until a vaccine is available for the general public. According to the CDC, a priority list has been developed for those who will eligible to receive the vaccine, which will be a four-phase process:³



Source: National Academy of Sciences, *Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine*, <http://nap.edu/25914>.

All of these factors need to be taken into consideration in developing a plan of action in dealing with a vaccine. As important, even after a vaccine is developed, many unanswered questions may remain. Are certain vaccines more effective than others? Will the effectiveness of a particular vaccine vary depending on an individual’s health status and/or age? For how long will a vaccine be

1 See Sheila Kaplan, Katherine J. Wu and Katie Thomas, *C.D.C. Tells States How to Prepare for Covid-19 Vaccine by Early November*, N.Y. Times, Sept. 2, 2020.

2 *Id.*

3 See National Academies of Sciences, Engineering, and Medicine 2020. *Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine*. Washington, DC: The National Academies Press.

effective? Are there any side effects that may pose greater risks to certain individuals? In short, there may be a multitude of issues that will need to be addressed as employers weigh their options.

From an employment perspective, employers need to take into account a broad range of issues, including but not limited to equal employment opportunity compliance, labor relations, workers' compensation, employee safety and other evolving issues, including the anti-vaccine movement.

Equal Employment Opportunity Compliance

The EEOC first issued guidance on *Pandemic Preparedness in the Workplace and the Americans with Disabilities Act* in October 2009 after President Obama declared a National Emergency in response to the H1N1 influenza pandemic.⁴ Based on the 2009 guidance, less drastic steps were approved, but as a precursor for future events, the EEOC explained that the guidance may be modified depending on the severity and pervasiveness of a pandemic, and that one might become so severe that employers' interests in protecting themselves and their businesses from the spread of disease could outweigh employees' rights under the ADA and other discrimination laws.⁵

On March 11, 2020, the coronavirus disease (COVID-19) was declared a pandemic. One week later, on March 19, 2020, the EEOC "re-issued" and updated the previously issued 2009 guidance. The EEOC declared that the World Health Organization (WHO), U.S. Department of Health and Human Services (HHS), and the CDC are the "definitive sources" of information about pandemics.⁶ The EEOC underscored that the 2020 guidance focuses on "implementing strategies in a manner that is consistent with the ADA and with current CDC and state/local guidance for keeping workplaces safe during the COVID-19 pandemic," and acknowledges that the guidance may change "as the COVID-19 situation evolves."

As many employers are aware, based on the current "pandemic" finding, the EEOC clearly has permitted employers far more leeway than ever before in developing infection control strategies without violating federal discrimination laws.⁷ No one knows as yet how and when the pandemic will end, but the EEOC views the new rules as a temporary measure.

At the time of issuance of the 2009 EEOC guidance, the EEOC expressly addressed vaccinations in a Q and A format, similar to other issues discussed in the guidance, and stated as follows:⁸

13. May an employer covered by the ADA and Title VII of the Civil Rights Act of 1964 compel all of its employees to take the influenza vaccine regardless of their medical conditions or their religious beliefs during a pandemic?

No. An employee may be entitled to an exemption from a mandatory vaccination requirement based on an ADA disability that prevents him from taking the influenza vaccine. This would be a reasonable accommodation barring undue hardship (significant difficulty or expense). Similarly, under Title VII of the Civil Rights Act of 1964, once an employer receives notice that an employee's sincerely held religious belief, practice, or observance prevents him from taking the influenza vaccine, the employer must provide a reasonable accommodation unless it would pose an undue hardship as defined by Title VII ("more than *de minimis* cost" to the operation of the employer's business, which is a lower standard than under the ADA).⁹

⁴ See Terri M. Soloman and Ronit M. Gurtman, [Planning for a Pandemic: The EEOC Issues Guidance](#), Littler Insight (Oct. 27, 2009).

⁵ See EEOC, [Pandemic Preparedness in the Workplace and the Americans with Disabilities Act](#), (herein "Pandemic Preparedness Guidance"), last updated March 21, 2020 at Section I.B. and Section II.B.

⁶ *Id.* at Section I. B.

⁷ See Barry Hartstein and Therese Waymel, [The Next Normal: A Littler Insight on Returning to Work – EEO Compliance](#), Littler Insight (May 11, 2020).

⁸ See *Pandemic Preparedness Guidance*, Section III.B. Question #13.

⁹ *Id.* and Footnote 36 in *EEOC Pandemic Preparedness Guidance*, including citation to the [EEOC Compliance Manual](#) Section 12: Religious Discrimination 56-65 (2008).

Generally, ADA-covered employers should consider simply encouraging employees to get the influenza vaccine rather than requiring them to take it.

To date, the 2009 guidance has remained unchanged in addressing employer vaccinations, except that the EEOC's updated guidance, issued on March 21, 2020, expressly provides: "As of the date this document is being issued, there is no vaccine available for COVID-19."

While it is anticipated that the EEOC will issue further guidance on employer-required vaccinations, employers already have a general "roadmap" regarding EEO issues that need to be addressed based on prior employer vaccination programs that have been challenged in the courts. Not surprisingly, consistent with the above-referenced EEOC guidance, the primary EEO challenges have involved individual failure-to-accommodate claims based on alleged religious discrimination under Title VII of the 1964 Civil Rights Act (Title VII) and disability discrimination claims under the Americans with Disabilities Act (ADA). (See Appendix A – *EEO Challenges to Mandated Employer Vaccination Programs*, for a detailed summary of EEO litigation involving mandatory employer vaccination programs.) A detailed discussion of select EEO decisions is discussed below.

Title VII – Religious Discrimination

As referenced above, the primary concern under Title VII involves the alleged failure to accommodate based on an individual's religious beliefs. With respect to religion, employers must reasonably accommodate an employee's "sincerely held religious beliefs, observances, and practices when requested, unless accommodation would impose an undue hardship on business operations."¹⁰ Undue hardship under Title VII is a "more than *de minimis* cost" to the employer, which is much a lower burden for the employer to meet than the undue hardship standard under the ADA ("significant difficulty or expense").¹¹

In the event a viable vaccine is developed, an employee may claim that they cannot comply with an employer-mandated vaccination requirement because taking a vaccine conflicts with their religious or other personal beliefs. When faced with an employee request for an exemption from a mandatory vaccination requirement on the basis of religion or personal belief, employers must assess three questions: (1) is the belief religious? (2) is the belief sincerely held? and (3) would providing a reasonable accommodation impose an undue hardship on the employer?

Is The Belief Religious?

The EEOC "defines 'religion' to include moral or ethical beliefs as to right and wrong that are sincerely held with the strength of traditional religious views."¹² The EEOC also clarifies, however, that "beliefs are not protected merely because they are strongly held," but rather religious beliefs generally concern "ultimate ideas" about "life, purpose, and death," as opposed to "[s]ocial, political, or economic philosophies, as well as mere personal preferences" which are not protected as a religious belief under Title VII.¹³

Beliefs do not need to be widely practiced to be religious. A belief can be religious even if no one else practices it. In a recent case involving religious objections to an employer-mandated vaccination requirement, a court denied the employer's motion for summary judgment and held that three employees with unconventional beliefs had "*bona fide*" religious reasons for requesting exemptions.¹⁴ One employee believed that "our bodies are a temple and that God gave us dominion over our bodies" and that "injecting the flu vaccine into her body is morally wrong."¹⁵ Another believed that "followers of her religion are 'healed by plants, fruits, and grains.'"¹⁶ The third believed that "injecting chemicals and diseases into her veins is not something God intends and that it is wrong."¹⁷

10 EEOC, [Section 12 Religious Discrimination](#), EEOC-CVG-2008-1 (July 22, 2008).

11 *Id.*

12 EEOC, [Section 2 Threshold Issues](#), EEOC-CVG-2000-2 (May 12, 2000).

13 *Id.*

14 *EEOC v. Mission Hosp., Inc.*, No. 1:16-cv-00118-MOC-DLH, 2017 U.S. Dist. LEXIS 124183, at *5 (W.D.N.C. Aug. 7, 2017).

15 *Id.*

16 *Id.*

17 *Id.*

However, if the employer has an “objective basis for questioning either the religious nature or the sincerity of a particular belief or practice, the employer would be justified in seeking additional supporting information.”¹⁸ When in “doubt about whether a particular set of beliefs constitutes a religion,” courts will “err on the side of” finding the beliefs to be religious.¹⁹

In two recent cases, courts have stated that medical objections to mandatory vaccination requirements were not religious in nature, and thus not protected by Title VII. In *Fallon v. Mercy Catholic Medical Center*, a medical center employee’s job was terminated because he refused a flu vaccination on the basis of his belief that “one should not harm their [sic] own body and [his strong belief] that the flu vaccine may do more harm than good.”²⁰ The court held that the employee’s objection to the vaccination was “a medical belief, not a religious one,” and thus Title VII did not apply. Earlier this year the U.S. Court of Appeals for the Third Circuit similarly held in a non-COVID-related case that an employee’s “concern that the flu vaccine may do more harm than good” and claims that a vaccine was unnecessary because she had “proven to remain healthy due to [her] African Holistic Health lifestyle” constituted a medical, rather than religious, belief.²¹

Though some courts have distinguished medical beliefs from religious ones, courts have not yet definitively decided the issue of whether a general moral opposition to vaccination is sufficient to trigger Title VII protections.²² In a recent case, the court allowed a suit to survive summary judgment in order to afford the employee the opportunity to prove that veganism constituted a religious belief, because the court found it “plausible that Plaintiff could subscribe to veganism with a sincerity equating that of traditional religious views.”²³ This case settled out of court and was not ultimately decided on the merits, but it illustrates the fine line between sincere personal beliefs and religious beliefs.

Because the issue of whether a belief is religious is such a nebulous one, employers need to exercise caution in determining too quickly that a specific belief falls outside the scope of a “religious belief.”

Is It Sincerely Held?

The EEOC lists four factors to consider in determining whether a belief is sincerely held:

- (a) Whether the employee has behaved in a manner markedly inconsistent with the professed belief;
- (b) Whether the accommodation sought is a particularly desirable benefit that is likely to be sought for secular reasons;
- (c) Whether the timing of the request renders it suspect (e.g., it follows an earlier request by the employee for the same benefit for secular reasons);
- (d) Whether the employer otherwise has reason to believe the accommodation is not sought for religious reasons.²⁴

18 [Section 2 Threshold Issues](#), *supra* note 12.

19 *United States v. Meyers*, 906 F. Supp. 1494, 1499 (D. Wyo. 1995), *aff’d*, 95 F.3d 1475, 1482-83 (10th Cir. 1996); *see also Employment Div., Dep’t of Human Res. of Oregon v. Smith*, 494 U.S. 872, 887 (1990).

20 877 F.3d 487, 492 (3d Cir. 2017).

21 *Brown v. Children’s Hosp. of Phila.*, 794 F. App’x 226 (3d Cir. 2020).

22 The Supreme Court has, however, taken such an expansive view of religion in the context of conscientious-objector provisions to the selective service law. *See United States v. Seeger*, 380 U.S. 163 (1965); *Welsh v. United States*, 398 U.S. 333 (1970) (If “an individual deeply and sincerely holds beliefs that are purely ethical or moral in source and content but that nevertheless impose upon him a duty of conscience to refrain from participating in any war at any time,” these beliefs qualify as religious beliefs that would entitle him to an exemption from the draft.).

23 *Chenzira v. Cincinnati Children’s Hosp. Med. Ctr.*, No. 1:11-CV-00917, 2012 U.S. Dist. LEXIS 182139 (S.D. Ohio Dec. 27, 2012).

24 [Section 12 Religious Discrimination](#), *supra* note 10.

Employers must consider all of these factors, as none is dispositive. This is a heavily fact-specific analysis and employers should be very cautious in evaluating the sincerity of the employee's belief as courts have recognized that an individual's beliefs can change over time.²⁵

Undue Hardship Standard

EEOC guidance states that some factors that are relevant to determining whether undue hardship exists include: "the type of workplace, the nature of the employee's duties, the identifiable cost of the accommodation in relation to the size and operating costs of the employer, and the number of employees who will in fact need a particular accommodation."²⁶ Undue hardship can exist "where the accommodation diminishes efficiency in other jobs, infringes on other employees' job rights or benefits, impairs workplace safety, or causes co-workers to carry the accommodated employee's share of potentially hazardous or burdensome work."²⁷ Courts have also found that undue hardship can exist if the proposed accommodation would "either cause or increase safety risks or the risk of legal liability for the employer."²⁸

Courts have recently addressed the issue of reasonable accommodation in the specific context of religious discrimination claims and employer-mandated vaccines. In *Robinson v. Children's Hospital*, a court granted summary judgment for the employer hospital, finding that the hospital offered a reasonable accommodation and that exempting the employee from the vaccination would constitute an undue hardship.²⁹ In this case, after the hospital announced a requirement of influenza vaccinations in patient-care areas, the employee requested an exemption on religious grounds because some vaccines contain pork byproducts. She subsequently objected to any vaccines after learning that her religion had a moratorium on all vaccinations. Although she previously had received a tetanus vaccine, she also alleged that she had an allergic reaction to that vaccine and had additional medical concerns regarding any vaccine.

As an accommodation, the hospital worked with the employee "several times" to try and address her concerns regarding the vaccine, including by encouraging "her to seek a medical exemption and granted her a temporary medical exemption while it reviewed her medical records" on the basis of her claimed allergy to the injection, and by assisting the employee in finding another position in an area of the hospital with no patient interaction, but there were no available positions for which she was qualified. The hospital ultimately deemed her termination a voluntary resignation, which gave her the ability to re-apply for other possible positions in the future. The court also found that simply exempting the employee from the vaccination requirement would have posed an undue hardship because "it would have increased the risk of transmitting influenza to its already vulnerable patient population."

25 See, e.g., *EEOC v. Union Independiente De La Autoridad De Acueductos*, 279 F.3d 49, 56-57 & n.8 (1st Cir. 2002) (evidence that Seventh-day Adventist employee had acted in ways inconsistent with the tenets of his religion, for example that he worked five days a week rather than the required six, had lied on an employment application, and took an oath before a notary upon becoming a public employee, can be relevant to the evaluation of sincerity but is not dispositive; the fact that the alleged conflict between plaintiff's beliefs and union membership kept changing might call into question the sincerity of the beliefs or "might simply reflect an evolution in plaintiff's religious views toward a more steadfast opposition to union membership"); *Hansard v. Johns-Manville Prods. Corp.*, 1973 WL 129 (E.D. Tex. Feb. 16, 1973) (employee's contention that he objected to Sunday work for religious reasons was undermined by his very recent history of Sunday work); *EEOC v. Ilona of Hungary, Inc.*, 108 F.3d 1569 (7th Cir. 1997) (en banc) (Jewish employee proved her request for leave to observe Yom Kippur was based on a sincerely held religious belief even though she had never in her prior eight-year tenure sought leave from work for a religious observance, and conceded that she generally was not a very religious person; the evidence showed that certain events in her life, including the birth of her son and the death of her father, had strengthened her religious beliefs over the years); *Cooper v. Oak Rubber Co.*, 15 F.3d 1375 (6th Cir. 1994) (that employee had worked the Friday night shift at plant for approximately seven months after her baptism did not establish that she did not hold sincere religious belief against working on Saturdays, considering that 17 months intervened before employee was next required to work on Saturday, and employee's undisputed testimony was that her faith and commitment to her religion grew during this time); *EEOC v. IBP, Inc.*, 824 F. Supp. 147 (C.D. Ill. 1993) (Seventh-day Adventist employee's previous absence of faith and subsequent loss of faith did not prove that his religious beliefs were insincere at the time that he refused to work on the Sabbath).

26 EEOC, [Questions and Answers: Religious Discrimination in the Workplace](#), EEOC-NVTA-2008-2 (July 22, 2008).

27 *Id.*

28 *EEOC v. Oak-Rite Mfg. Corp.*, No. 99-cv-1962-DFH, 2001 U.S. Dist. LEXIS 15621, 2001 WL 1168156, at *10 (S.D. Ind. Aug. 27, 2001). See also *Kalsi v. N.Y.C. Transit Auth.*, 62 F. Supp. 2d 745 (E.D.N.Y. 1998); *Bhatia v. Chevron U.S.A., Inc.*, 734 F.2d 1382 (9th Cir. 1984).

29 Civil Action No. 14-10263-DJC, 2016 U.S. Dist. LEXIS 46024 (D. Mass. Apr. 5, 2016).

A similar favorable employer outcome arose earlier this year in another non-COVID case. In *Horvath v. City of Leander*³⁰, the Fifth Circuit affirmed summary judgment in favor of the employer. In this case, a firefighter who also was an ordained minister, objected to vaccination as a tenet of his religion. The exemption was approved by the Fire Department and the employee was given the option of taking various protective steps, including wearing personal protective equipment to prevent spreading the flu to himself, co-workers, or patients with whom he may come into contact as a first responder. He also was offered an alternative job. The employee rejected both options, and his employment was ultimately terminated based on the view that his conduct constituted willful disobedience of a directive from a supervisor. In ruling in favor of the employer, the court held that the Fire Department reasonably accommodated the driver/pump operator who refused a TDAP (*i.e.*, Tetanus, Diphtheria, Pertussis) vaccine on religious grounds by offering two accommodation options: (1) reassignment to a different position, “which offered the same pay and benefits and did not require a vaccine,” and (2) remaining in the same position if the employee “agreed to wear personal protective equipment, including a respirator, at all times while on duty, submit to testing for possible diseases when his health condition justified, and keep a log of his temperature.”³¹

ADA and Reasonable Accommodations

General Requirements

Under the ADA, employees with an ADA-covered disability may be entitled to an exemption from a mandatory vaccination requirement if their disability prevents them from safely taking the vaccine. The ADA governs what medical information employers can seek from employees, prevents employers from excluding employees with disabilities from the workplace unless they present a “direct threat,” and requires employers to reasonably accommodate employees with disabilities.³²

Under the ADA, a “direct threat” exists if there is “a significant risk of substantial harm to the health or safety of the individual or others that cannot be eliminated or reduced by reasonable accommodation.” This risk determination must be based on “objective, factual information, ‘not on subjective perceptions . . . [or] irrational fears’ about a specific disability or disabilities.” The EEOC lists four factors for employers to consider when assessing the possible existence of a “direct threat”: “(1) the duration of the risk; (2) the nature and severity of the potential harm; (3) the likelihood that potential harm will occur; and (4) the imminence of the potential harm.”³³

The ADA and COVID-19

Based on the EEOC’s current view, it is “unclear whether COVID-19 is or could be a disability under the ADA.”³⁴ Regardless, in relying on the findings of the CDC and others public health authorities, the EEOC has determined that “an employer may bar an employee with the disease from entering the workplace” because the COVID-19 pandemic meets the “direct threat” standard under the ADA.³⁵ This determination has resulted in permitting employers significant leeway in developing infection control strategies without violating the ADA that would not be permitted in the absence of a pandemic. Thus, an effective vaccine to immunize individuals from the coronavirus appears to be a strategy worth serious consideration.

In dealing with the ADA and the pandemic, two issues come into play based on the potential use of vaccinations: (1) the standards to be applied in requiring a vaccination, whether it involves applicants or employees; and (2) reasonable accommodations that may be required under the ADA during a pandemic.

³⁰ 946 F. 3d 787 (5th Cir. 2020).

³¹ *Horvath v. City of Leander*, 946 F.3d 787 (5th Cir. 2020).

³² *Pandemic Preparedness Guidance*, *supra* note 5, Section II.B.

³³ *Id.*

³⁴ See EEOC, [Transcript of March 27, 2020 Outreach Webinar](#) (herein “EEOC Webinar”).

³⁵ *Id.* See also *Pandemic Preparedness Guidance* at Section II.B.

Applicable Standard for Requiring Vaccinations

In discussing the applicable legal standard for requiring a vaccination, the courts have treated a vaccination as a “medical examination” under the ADA.³⁶ While the EEOC’s *Pandemic Preparedness Guidance* does not expressly discuss the applicable legal standard for vaccinations, “medical examinations” are permitted for applicants and employees as follows: (1) The ADA permits “medical examinations” (e.g., vaccinations) after a conditional offer if all entering employees in the same job category are subject to the same examinations; and (2) the ADA prohibits medical examinations during employment “unless they are job related and consistent with business necessity.”³⁷

The issue of requiring vaccinations was discussed in *Hustvet v. Allina Health System*³⁸, a 2018 court decision that obviously preceded COVID-19. In that case, the plaintiff worked for a rehabilitation clinic that was acquired by a hospital chain. The hospital offered employment to all clinic employees subject to meeting certain conditions, including a pre-placement assessment screen that included taking one dose of a vaccine for Measles, Mumps, Rubella (MMR vaccine), which the hospital determined was needed because the patients were treated as if they had “compromised” or “fragile” immune systems. After the plaintiff refused to take the vaccine, which was viewed as one of the immunity requirements, her employment was terminated.

In affirming summary judgment in favor of the employer in the *Hustvet* decision, the Eighth Circuit discussed the requirement of vaccinations, relying on the above-referenced “medical examination” legal standards, and treated the entire health screen procedure as an “entrance examination” that was applied *after* the offer of continued employment and before the plaintiff began working for the hospital chain. In the alternative, even assuming the legal standard applicable to employees was applied, the appeals court concluded that the hospital’s “decision to force a class of employees (those employees with client contact who merged into the company) to undergo a health screen was job related and consistent with business necessity” and “no more intrusive than necessary.” The screening procedures focused on patient safety, and immunization was viewed as eliminating risks that could be posed to the vulnerable patient population in the absence of evidence of immunity.

Based on development of a vaccination for COVID-19, any requirement by an employer mandating employee vaccinations would need to withstand legal scrutiny. Based on the continued risks posed by COVID-19, an employer most likely would be able to demonstrate the legal justification for required vaccinations based on the “direct threat” standard and the health risks posed by COVID-19. Notwithstanding, any vaccine would need to pass muster under the ADA. As an example, in dealing with COVID-19 testing, which the EEOC has determined constitutes a medical examination, the EEOC has drawn a distinction between viral tests (a test to determine if someone has an active case of COVID-19) and antibody tests (a test to determine if an individual had a past infection with the virus that causes COVID-19), finding that only viral tests constitute “safe and accurate testing.” In dealing with such testing, the EEOC followed the recommendations by the CDC and information from the U.S. Food and Drug Administration.³⁹ It is anticipated that the EEOC would follow the same approach dealing with any vaccinations required by an employer. In short, the EEOC would defer to the CDC and U.S. Food and Drug Administration in determining whether the proposed vaccine is safe and reliable. (See Appendix B – *Ensuring the Safety of Vaccines in the United States*, as published by the U.S. Food and Drug Administration, for a summary of the vaccination approval process.)

Reasonable Accommodation

The issue of reasonable accommodation under the ADA clearly would come into play in the event that a vaccine receives approval from the CDC and/or other authorities relied on by the EEOC, and an individual thereafter requested to be excused from a mandatory vaccine required by their employer. The EEOC already has stated that “(a)n employee may be entitled to an exemption

³⁶ See *Hustvet v. Allina Health System*, 910 F.3d 399 (8th Cir. 2018). As discussed herein, *Hustvet* dealt with requiring vaccination by a health care workers, and the court treated vaccinations as a “medical examination” and discussed the different standard to be applied to applicants versus employees.

³⁷ See *Pandemic Preparedness Guidance* at Section II.A.

³⁸ See *Hustvet*, 910 F.3d 399.

³⁹ See EEOC, [What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Law](#), Sections A.6 and A.7, updated Sept. 8, 2020 (hereafter “EEOC Q&As”).

from a mandatory vaccination requirement based on an ADA disability that prevents him from taking the influenza vaccine,⁴⁰ and there is no reason to believe that the EEOC would stray from that view when dealing with a vaccine for COVID-19.

In the EEOC's view, two fundamental principles appear to be in play when dealing with reasonable accommodation in a COVID-19 environment:

- Employers are encouraged to be flexible in terms of requesting medical documentation and/or and engaging in the interactive process. This could include providing accommodations on a temporary basis, and even placing an "end date" on the accommodation.⁴¹ With respect to medical documentation, the EEOC has underscored, "for employers seeking documentation from a health care provider to support the employee's request, they should remember that because of the health crisis many doctors may have difficulty responding quickly. There may be other ways to verify the existence of a disability. For example, a health insurance record or a prescription may document the existence of the disability."⁴²
- In making reasonable accommodations, the EEOC also has taken a more realistic view of "undue hardship" based on today's economic climate, explaining that "an accommodation that would not have posed an undue hardship prior to the pandemic may pose one now,"⁴³ and "the sudden loss of some or all of an employer's income stream because of this pandemic is a relevant consideration."⁴⁴ The EEOC's technical guidance underscores that an employer can look to "current circumstances" in determining whether there may be "significant difficulty" in acquiring or providing certain accommodations, particularly for employees who may be teleworking. If a particular accommodation creates an undue hardship, employers and employees are encouraged to work together to determine whether an alternative "could be provided that does not pose such problems."⁴⁵

The EEOC's guidance on reasonable accommodation was updated on May 5, 2020, and supplemented on May 7, 2020, to specifically address concerns involving individuals with "higher risk of severe illness." The EEOC has made a distinction in its approach depending on whether an employee is making a request for an accommodation based on being part of this higher-risk pool, as contrasted with an employer deciding to exclude such employees from the workforce.⁴⁶

In providing guidance on this topic, the EEOC again has looked to the CDC for guidance regarding those who are expressly identified as having underlying medical conditions creating "higher risk for severe illness."⁴⁷

Assuming an employee in the higher-risk group makes an accommodation request, the general rules discussed above would apply. On the other hand, in the event an employer is considering keeping an employee out of the workplace because the employee is part of the higher-risk group, the rules are far stricter. In short, the EEOC requires: (1) application of the "direct threat" standard; and (2) there must be an "individualized assessment based on a reasonable medical judgment about this employee's disability – not the disability in general – using the most current medical knowledge and/or the best available objective evidence."⁴⁸

Even assuming that an employee's disability "poses a direct threat to his own health," the EEOC expects employers to explore potential reasonable accommodations absent an undue hardship. The first goal is to find a way, through the interactive process, to return an employee to work while still performing the position's essential functions. When those options are not available, an employer needs to consider other types of accommodations, such as telework, leave or reassignment.⁴⁹ Barring an employee from

40 See *Pandemic Preparedness Guidance*, Section III.B. Question #13.

41 See EEOC Q&As (Questions D.6 and D.7); see also EEOC Webinar, *supra* note 34.

42 See EEOC Webinar (Question #17 and response).

43 See EEOC Q&As (Question D.9).

44 *Id.* (Question D.11).

45 *Id.* (Question D.10).

46 See EEOC Q&As (Questions: G.3, G.4 and G. 5).

47 See CDC, [People Who Are at Higher Risk for Severe Illness](#), (last reviewed Apr. 15, 2020). In relevant part, the higher risk group includes individuals age 65 or older and individuals, regardless of age, with underlying conditions, such as those suffering from: (1) chronic lung conditions or moderate or severe asthma; (2) serious heart conditions; (3) those with a condition causing a person to be immunocompromised (e.g., cancer treatment, smoking, bone marrow or organ transplantation, immune deficiencies, poorly controlled HIV or AIDS, and prolonged use of corticosteroids and other immune-weakening medications; (4) severe obesity; (5) diabetes; (6) chronic kidney disease undergoing dialysis; and (7) liver disease.

48 EEOC Q&As (Question G.4).

49 *Id.*

the workplace must be viewed as a last resort, only when “the facts support the conclusion that the employee poses a significant risk of harm to himself that cannot be reduced or eliminated by reasonable accommodation.”⁵⁰

The EEOC has provided examples of potential accommodation to eliminate a potential “direct threat” to the affected employee in the higher-risk group, which may include protective gowns, gloves and other protective gear, erecting barriers that provide separation, elimination or substitution of particular marginal functions, modification of work schedules or moving the location where the employee performs work.⁵¹

The above guidelines were developed based on the EEOC guidance issued to date regarding reasonable accommodation under the ADA in a COVID-19 work environment. Employers need to closely monitor EEOC developments to determine whether any of the above employer obligations may be modified based on any mandatory vaccinations imposed by employers.

Other Relevant Statutory Schemes

Pregnancy Discrimination Act

Employers should also consider their obligations under other statutory schemes. For example, the Pregnancy Discrimination Act (PDA) offers similar protections as the ADA to employees with temporary disabilities related to their pregnancy or childbirth. Accordingly, a pregnant employee may have a qualifying disability that prevents them from taking a potential COVID-19 vaccine. As with an ADA-qualified employee, employers should consider all possible reasonable accommodations it can feasibly offer to an employee covered by the PDA, including a leave or an exemption from the vaccination requirement for the duration of the pregnancy-related disability.

Workers’ Compensation Risks

In considering whether to mandate vaccination, employers may be faced with a seeming catch-22 between the potential dangers faced by employees in either requiring or not requiring vaccination. At this point it is unclear whether a potential vaccine may cause side effects or adverse reactions in certain segments of the population, which also may create risks for employers. As an example, in dealing with other types of vaccinations, the California Supreme Court has held:

... the presence of an industrial injury is not always a prerequisite for compensability where injury results from the medical care which was required by the employer. The rule is well settled that where an employee submits to an inoculation or a vaccination at the direction of the employer and for the employer’s benefit, any injury resulting from an adverse reaction is compensable under the Workers’ Compensation Act.⁵²

Thus, mandatory vaccinations may lead to potential workers’ compensation claims from employees who suffer an adverse reaction to a potential vaccine.

Occupational Safety and Health Act

At the same time, employers may face liability under the federal Occupational Safety and Health (OSH) Act or a state equivalent for failure to provide a safe workplace. The OSH Act requires employers to furnish to each worker “employment and a place of employment, which are free from recognized hazards that are causing or are likely to cause death or serious physical harm.”⁵³ Thus, an employer that does not adopt measures to prevent the spread of the coronavirus at work adequately may face liability for failure to comply with its duty to provide a safe workplace. However, it is likely that robust workplace safety policies, even in the absence of an employer vaccination mandate, can meet the employer’s obligation under the OSH Act’s General Duty Clause, particularly based on the anticipated level of uncertainty regarding the effectiveness and/or potential side effects of a vaccine.

⁵⁰ *Id.*

⁵¹ *Id.* (Question G.5).

⁵² See *Maher v. Workers’ Compensation Appeals Board*, 33 Cal. 3d 729, 661 P.2d 1058, 190 Cal. Rptr. 904 (Cal. 1983).

⁵³ OSHA, [Covid-19 Standards](#), last visited Sept. 10, 2020.

National Labor Relations Act, Bargaining Obligations, and Free Speech Considerations

There is a strong likelihood that employers may face challenges if an employer mandates vaccinations in a union-represented work environment. As NLRB General Counsel Peter Robb recently noted in a memorandum outlining bargaining obligations in emergency situations:

[t]he Coronavirus pandemic has prompted many questions regarding the rights and obligations of both employers and labor organizations, particularly in light of responsive measures taken to contain the virus ... [s]ometimes these measures have been taken of prudence; other times they have been required by state, local or federal orders.⁵⁴

Even prior to a vaccine being developed for COVID-19, employers already have faced challenges in a unionized work environment, as best illustrated by a recent unfair labor practice claim filed after an employer announced its plan to require employees to record COVID-19-related symptoms on an app.⁵⁵ Screening apps are among the tools employers are using to take preventive steps to curb the spread of the coronavirus. After the employer announced plans to adopt use of the app, a union employee raised concerns that the app would “diminish their data privacy” and the employer “gave no clear alternatives to downloading it on their personal devices.” Employees also raised concerns regarding whether the app would do more harm than good “by creating a false sense of security.”⁵⁶ An unfair labor practice was filed with the NLRB on August 26, 2020, and is currently still pending.⁵⁷

In evaluating the potential risks in mandating a vaccine in a unionized environment, the most frequent focus in recent years has been with the health care institutions requiring vaccines of health care workers based on concerns of flu-related risks and obvious concerns in a health care setting.⁵⁸ In implementing such mandatory programs, aside from discrimination claims, employers have been faced with other challenges, particularly by unionized health care workers, claiming that implementing such policies is not permissible without first bargaining over implementation of a mandatory vaccination program. While there has not been an extensive amount of litigation or related challenges, the discussion below about one particular long-litigated NLRB and arbitration matter, highlights some of the bargaining and contract coverage issues that unionized employers need to consider when evaluating mandatory vaccination and/or testing policies.

In *Virginia Mason Hospital*, 357 NLRB 564 (2011), a Seattle-based hospital announced that it was amending its “Fitness for Duty” policy to require its entire workforce to be immunized against the flu. The union grieved the policy and submitted the matter to arbitration. Subsequently, an arbitrator issued an award in favor of the union. In conformity with the award, the hospital did not require the nurses to be immunized.⁵⁹ The hospital, however, implemented a new policy that required non-immunized nurses either to wear a protective facemask or to take antiviral medication. The union responded with an unfair labor practice charge claiming that the hospital violated Section 8(a)(5) of the Act by failing to bargain in good faith through the unilateral issuance of the policy. The hospital advanced several defenses to the 8(a)(5) unilateral-change allegation during the ALJ trial. It contended that it had no duty to bargain before implementing its flu-prevention policy because (a) the policy went to the hospital’s “core purpose” and was exempt from mandatory bargaining under *Peerless Publications*, 283 NLRB 334 (1987); (b) the decision to implement the policy

54 Memorandum GC 20-04 (Mar. 27, 2020).

55 See Julia Jacobs, N.Y. Times (Aug. 26, 2020) at <https://www.nytimes.com/2020/08/26/arts/design/natural-history-museum-coronavirus-app.html>.

56 *Id.*

57 NLRB Case No. 02-CA-265257 (Filed: 8/25/20).

58 Annual vaccination of health care workers against influenza has been recommended by the CDC since 1984. See Centers for Disease Control and Prevention. Prevention and control of influenza. MMWR Morb Mortal Wkly Rep 1984; 33:253–60, 265–6, as cited in Mandatory Flu Vaccine for Healthcare Workers: Not Worthwhile, by Michael B. Edmond (Apr. 17, 2019) at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6468124/#CIT0001>. See also CDC guidance, [Influenza Vaccination Information for Health Care Workers](https://www.cdc.gov/flu/vaccination-information-for-health-care-workers). It should be noted that there are various required vaccinations based on applicable state law for various conditions. As an example, currently 18 states establish flu vaccination requirements for hospital healthcare workers (e.g., California, Colorado, Georgia, Illinois, Maine, Maryland, Massachusetts, Nebraska, Nevada, New Hampshire, New York, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, Tennessee, and Utah.) These laws establish requirements based on the hospital type and the type of vaccination requirements. In addition, some state laws allow for vaccination exemptions. See Menu of State Hospital Influenza Vaccination Laws, at <https://www.cdc.gov/php/docs/menu-shfluvacclaws.pdf>.

59 *Washington State Nurses Assn. v. Virginia Mason Hospital*, FMCS 05-53154 (Aug. 8, 2005) (Escamilla, Arb.). The arbitrator’s decision was upheld by both the federal district court and the Ninth Circuit. See *Virginia Mason Hospital v. Washington State Nurses Assn.*, No. C05- 1434MJP, 2006 WL 27203 (W.D. Wash. 2006), *aff’d*, 511 F.3d 908 (9th Cir. 2007).

was subject to the balancing test the Supreme Court set forth in *First National Maintenance Corp. v. NLRB*, 452 U.S. 666 (1981), and applying that test, the balance tipped in favor of exempting the decision from mandatory bargaining; (c) federal and state law required the hospital to implement effective policies to control infection and communicable diseases; and (d) the union waived bargaining when it agreed to the management-rights and zipper clauses of the parties' collective-bargaining agreement.

Without analyzing the hospital's other defenses, the ALJ held that the employer was excused from its bargaining obligation based on the test set forth in *Peerless Publications*, 283 NLRB 334 (1987), as: (1) the policy went directly to the employer's core purpose: to protect patient's health; (2) the policy was narrowly tailored to prevent the spread of influenza; and (3) the employer limited the requirement to nurses who refused to be immunized. The Board, however, reversed and held that the hospital violated Section 8(a)(5) by unilaterally implementing the flu-prevention policy without affording the union notice and opportunity to bargain. The Board remanded the case back to ALJ to consider other defenses raised by the hospital, including whether the union waived its right to bargain through adoption of the current collective bargaining agreement.

Subsequently, the ALJ issued a supplemental decision finding that the union waived its right to bargain over the flu-prevention policy when it agreed to, among other things, the management-rights provision in the parties' collective bargaining agreement.⁶⁰ The management-rights provision endowed the hospital with an enumerated set of explicit rights. Under that clause, the union:

recognizes the right of the Hospital to operate and manage the Hospital, including but not limited to the right to require standards of performance and . . . to direct the nurses . . . to determine the materials and equipment to be used; to implement improved operational methods and procedures . . . to discipline, demote or discharge nurses for just cause . . . and to promulgate rules, regulations and personnel policies.

While the management-rights clause at issue did not specifically mention the wearing of facemasks, it specifically allowed the Hospital to unilaterally "direct the nurses" and "to determine the materials and equipment to be used; [and] to implement improved operational methods and procedures." Applying the "clear and unmistakable" waiver standard in place at the time, the ALJ concluded that the union waived its right to bargain based on: (1) language in the management-rights clause; (2) internal hospital policies; and (3) testimony that the hospital was required to have injection control policies in place, that it never bargained with the union over those policies, and that the union never objected to them. The Board affirmed the ALJ's decision.⁶¹

There are several practical takeaways from grievance and unfair labor practice litigation involving *Virginia Mason Hospital*. For starters, employers with union-represented employees need to carefully review existing collective bargaining agreements to determine whether there is sufficient management rights language that would permit an employer to mandate vaccinations as a condition of employment.⁶² While the hospital ultimately prevailed in the implementation of its revised flu-prevention policy consisting of a choice between masks or antiviral medication, it was unable to establish to the arbitrator that the collective

60 *Virginia Mason Hospital*, 358 NLRB 531 (2012). Notably, the ALJ determined that the hospital was unable to identify "a single Federal or State law or regulation mandating that registered nurses who are not immunized against influenza or not take antiviral medication be required to wear facemasks at all times when exposed to patients or members of the public."

61 *Id.*

62 While NLRB law has changed from time-to-time, to establish waiver of a statutory right to bargain over mandatory subjects, there generally must be a clear and unmistakable relinquishment of that right. Waivers can occur in any of three ways: (1) by express contract language, (2) by the parties' conduct (including past practice, bargaining history, and action or inaction), or (3) by a combination of the two. The legal principles governing waiver by inaction are well established: before implementing a change involving a mandatory bargaining subject, an employer is required to give timely notice to the union and a meaningful opportunity to bargain. It is then incumbent upon the union to act with due diligence in requesting bargaining.

bargaining agreement allowed it to impose mandatory vaccinations.⁶³ Furthermore, to the extent an employer seeks to avoid a bargaining obligation by claiming that a mandatory vaccination is consistent with a local, state, or federal law/regulation, it will need to show that it is actually mandated by the government to require such vaccination. Virginia Mason Hospital made that argument concerning its flu-prevention policy but could not show a nondiscretionary government mandate. NLRB law is well established that an employer has no duty to bargain over a nondiscretionary change in terms and conditions of employment mandated by federal, state, or local law.⁶⁴ However, “when an employer has discretion over how to implement certain changes in employee wages, hours, or other terms and conditions of employment mandated or imposed on it by statute or regulation, it has a duty to notify and bargain with the employees’ representatives over how such changes should be implemented before making any such changes.”⁶⁵ For example, even if a government order requires employees to be vaccinated, employers with union-represented employees may have to consider, and even negotiate, some of the following “effects” of the order before implementation:

- Classes of employees subject to vaccination (unless specified by the order)
- Frequency and timing of the vaccination
- Consequences of an employee’s refusal to submit to vaccination
- Staff/contractors who will perform the vaccination
- Where the vaccination will be performed
- Compensation for time spent in vaccination procedure

Dealing with Challenges Based on the Anti-Vaccination Movement and Other “Protected Concerted Activity”

Even in a non-union environment, employers need to brace themselves for those already part of the “anti-vaccine movement,” or who may have concerns regarding the safety of a vaccine for the coronavirus. As an example, one group’s website “attacks Anthony Fauci, director of the U.S., National Institute of Allergy and Infectious Diseases for ‘risky and uncertain coronavirus vaccines’ into development as part of a ‘sweetheart deal’ for drug companies.”⁶⁶

To the extent that an employee or group of employees mobilize co-workers to challenge mandatory vaccines being imposed by an employer, this could be viewed as “protected concerted activity” under Section 7 of the National Labor Relations Act (NLRA) even in the absence of a union and result in potential unfair labor practices being filed against the employer.⁶⁷ Section 7 of the NLRA provides that employees have the right to engage in “concerted activities for the purpose of collective bargaining or other mutual aid or protection.”⁶⁸ The “mutual aid or protection” clause focuses on the goal of concerted activity and “whether there is

63 Following a union grievance over the mandatory vaccination program by Virginia Mason Hospital, the arbitrator sustained the grievance and ordered rescission of the required vaccination protocol from the “fitness for duty” policy. The arbitrator concluded that the management rights clause only covered operational decisions, not policies that directly affected terms and conditions of employment. As significantly, the arbitrator rejected application of a so-called “zipper clause” (*i.e.*, reserving to management all matters not specifically discussed during negotiations or included in the collective bargaining agreement, taking the view that filing a grievance over the policy was “sufficient negotiation or discussion of the issue such that it was not waived”). After Virginia Mason filed an application in federal court, seeking to vacate the arbitration award, the district court: (1) rejected the argument that the arbitrator had exceeded his authority; (2) concluded that the arbitrator’s view of the collective bargaining agreement was plausible; and (3) the employer did not show that “any explicit, well-defined, and dominant public policy that was contravened by the arbitrator’s decision.” On appeal, the Ninth Circuit rejected the employer’s arguments based on the union contract, including the management rights clause and zipper clause, thus finding that the arbitrator’s decision “was not procedurally unsound because of any failure to apply relevant provisions of the CBA.” *Virginia Mason Hospital v Washington State Nurses Association*, 2005 WL 6288744 (W.D. Wash, Aug. 19, 2005), *aff’d* 511 F. 3d 908, 912-14 (9th Cir. 2007).

64 *Long Island Day Care Services*, 303 NLRB 112, 117 (1991); *Lifeway Foods, Inc.*, 2016 NLRB LEXIS 806, *33 (2016); see also July 13, 2017 letter from NLRB Office of Appeals in *Save Mart Supermarkets*, Case 20-CA-170581 (denying union’s appeal because employer had no discretion to depart from California’s mandatory 24-hour paid sick leave statute and had no obligation to negotiate with the union over its decision to implement the state-mandated leave).

65 *Pacific Maritime Association*, 2019 NLRB LEXIS 263, *101 fn. 28 (2019); *Long Island*, 303 NLRB at 117; *Wexford Health Sources, Inc.*, 2014 NLRB LEXIS 684, *48-49 (2014).

66 See Liz Szabo, [How Anti-Vaccine Activists are Using COVID-19 to Boost Their Movement](#), Spectrum, Kaiser Health News (Apr. 28, 2020).

67 29 U.S.C. 157 (“Employees shall have the right to self-organization, to form, join, or assist labor organizations, to bargain collectively through representatives of their own choosing, and to engage in other concerted activities for the purpose of collective bargaining or other mutual aid or protection . . .”)

68 *Id.*

a link between activity and matter concerning the workplace or employees' interests as employees.⁶⁹ Further, this clause covers employee efforts to "improve their lot as employees through channels outside the immediate employee-employer relationship" as well as activities "in support of employees of employers other than their own."⁷⁰ This means that an employer generally may not prohibit conversations or conduct related to working conditions, even if those actions are couched in terms of political or current events. Thus, employees may engage in protected political activity under the NLRA so long as it relates to labor or working conditions, and such advocacy can include contacting legislators, testifying before government agencies, or joining protests and demonstrations.⁷¹

Employee speech related to mandated vaccinations may be viewed by the NLRB as having a direct nexus to employees' interest as the vaccinations would be considered a term or condition of employment. Indeed, there have been recent activities by labor organizations to capitalize on safety-related concerns posed by COVID-19, as illustrated by recent efforts by the Communications Workers of America, with their website: "COVID-19: FAQ for Engaging in Protected Concerted Activity to Stay Safe from COVID-19 at Work." This website includes "COVID-19 Information for Non-Union Workers."⁷²

The scope of protection based on state legislation involving protected "political activities" also may be relied on by groups of workers in selected jurisdictions. Several states have laws that prohibit employers from taking adverse action against employees because of their off-duty lawful political activities. In California, employers may not coerce employees, discriminate or retaliate against them, or take any adverse action because they have engaged in political activity.⁷³ Similar prohibitions exist in other states, including Colorado, Louisiana, New York, South Carolina, and Utah. Connecticut actually extends First Amendment protection of free speech to the employees of private employers.⁷⁴ Some of these laws provide exceptions for public or religious employers or for off-duty employee conduct that creates a material conflict with respect to the employer's business interests. Under such laws, and absent some exception, adverse employment actions because of lawful, off-the-clock political activity would be illegal. Employers, however, should be mindful of free speech-type claims when taking action against employees for off-duty conduct and social media postings.

Privacy and Public Policy Concerns

Finally, employers should be aware of potential privacy and public policy concerns. In a recent action, although in a non-union environment, a healthcare employee filed a putative class action on behalf of himself and others against a health care facility, and a network of hospitals and healthcare facilities in South Carolina, claiming that mandatory flu vaccination requirements constituted an unreasonable invasion of privacy under that state's constitution and common law.⁷⁵ The employer's "Influenza Immunization Protocol" provided that "unless an approved exemption is made," the flu vaccination will be "a condition of initial and continued employment" for all employees. The Protocol permitted employees to request an exemption from the immunization requirement, but only for conditions listed in the guidelines from the CDC, which included: severe egg allergy, severe allergy to any component of the vaccine, a past severe reaction to the influenza vaccine, or a history of Guillain-Barre syndrome. The Protocol required employees who were unvaccinated because of an exemption to wear surgical masks while on duty if they had direct patient contact, or, if they did not have direct patient contact, when they were within six feet of another individual. Employees without an

69 *Fresh & Easy Neighborhood Market*, 361 NLRB No. 12, slip. op. at 3 (Aug. 11, 2014).

70 *Eastex, Inc. v. NLRB*, 437 U.S. 556, 559-60, 565 (1978) (upholding Section 7 protection for distribution of literature that, inter alia, urged employees to vote for candidates supporting a federal minimum wage increase and to lobby legislators against incorporation of right-to-work statute into state constitution).

71 See NLRB Advice Memorandum, Case 07-CA-193475 (Aug. 30, 2017) (finding employees to be engaged in protected activity where employees walked off the job in support of "Day without Immigrants" demonstration).

72 See Communication Workers of America, [COVID-19: FAQ for Engaging in Protected Concerted Activity To Stay Safe From COVID-19 at Work](#).

73 Cal. Lab. Code §§ 98.6(a), 1102.

74 Conn. Gen. Stat. § 31-51q. The statute applies broadly to any content that "addresses as a matter of public concern." *Daconto v. Trumbull Housing Authority*, No. CV-03-4007847-S, 2008 Conn. Super. LEXIS 251, at *43 (J.D. Ansonia-Milford, Jan. 31, 2008) (protected speech includes discussing health and safety of other employees).

75 See *Bertha Hunter v Ahmed Health*, Case No. 2010 CP 0403433 (S.C. Court of Common Pleas, Filed 9/24/10), as discussed in George E. O'Brien Jr., [Healthcare Workers Again Challenge Mandatory Flu Vaccinations](#), Littler ASAP (Oct. 13, 2010).

approved exemption who were not immunized or who violated any of the protocol requirements had the choice of resigning or having their jobs terminated.

The South Carolina lawsuit sought to enjoin the health care entity from implementing or enforcing its Influenza Immunization Protocol, alleging that the Protocol violated South Carolina's public policy and Article 1, §10 of the state constitution, which prohibits "unreasonable invasions of privacy." The employer issued a statement noting that thousands of Americans die as a result of the flu and flu-related illnesses, and that the immunization policy was issued in an effort to "reduce the risk of infection and in turn help save the lives of those we care for and those we care about." Three months later, the suit was dismissed for "failure to prosecute."

Although this case did not move forward, it is conceivable that similar suits based on privacy rights or public policy grounds may arise. The potential outcome may depend on the applicable facts and state law at issue.

Conclusion

While everyone is hopeful that a vaccine for COVID-19 will be approved and available for the employer community in a matter of months, various factors suggest otherwise, including that any rollout most likely will occur in phases, with health care workers and older adults as well as those with underlying conditions that put them at higher risk, being the initial group offered the vaccine.

The above discussion clearly demonstrates that, when available, employers may be permitted to require mandatory vaccinations to help minimize the risk of COVID-19 being spread in the workplace. Employers in certain sectors, particularly health care, may conclude that immediate adoption of mandatory vaccinations are in the best interests of both employees and patients. Accommodations may be required for certain workers.

On the other hand, many employers may be better served by considering other options based on the numerous potential challenges posed by implementing mandatory vaccination policies. Employers may need to accommodate those seeking an exemption on religious grounds or based on a disability or pregnancy that may pose a medical risk based on receiving the vaccine. This could be compounded by groups of employees challenging the vaccine on political grounds as part of the anti-vaccination movement, those with concerns of potential short-term and/or long-term medical risks caused by the vaccine or even a labor organization in a unionized setting based on unilaterally implementing the policy. In addition, in the event of any potential adverse effects caused by vaccine, an employer could be faced with workers' compensation or other potential claims.

Based on all these considerations, employers may want to consider initially encouraging vaccinations on a voluntary basis as more is learned over the coming year.

We hope this Report serves as a useful resource as employers evaluate their various options over the coming months while we await the availability of a vaccine for COVID-19.

APPENDIX A

EEO CHALLENGES TO EMPLOYER-MANDATED VACCINATION PROGRAMS

Applicable Case	Date Filed	Nature of Claim and Outcome
<p><i>Brown v. Children's Hosp. of Philadelphia</i> Case No. 18-2363 (E.D. Pa., Nov. 9, 2018)</p> <p><u>Related decisions:</u></p> <p>2018 U.S. Dist. LEXIS 191968, 2018 WL 5884545 (E.D. Pa., Nov. 9, 2018), granting the employer's Motion to Dismiss, <i>aff'd</i>, 794 F.App'x 226 (3d Cir. 2020) (reh'g en banc denied)</p>	12/13/18	<p><u>Religious Discrimination (Favorable Employer Outcome)</u></p> <p>The hospital employer requires all employees to receive a flu shot. Plaintiff objected to the shot as she "could no longer go against [her] beliefs and obtain the flu shot." Plaintiff further stated that "she did not have a pastor to validate her beliefs" and that she had "proven to remain healthy due to [her] African Holistic Health lifestyle." Her employment was terminated for failure to comply with the employer's flu shot mandate.</p> <p>The district court dismissed the employee's claim for failure to allege sufficient facts to support the requisite elements of a Title VII religious discrimination claim. The district court held that the employee failed to identify a sincerely held religious belief that conflicted with the employer's flu shot policy.</p> <p>The Third Circuit affirmed the district court's order dismissing Plaintiff's complaint, holding that the employee's "concern that the flu vaccine may do more harm than good" and claims that a vaccine was unnecessary because she had "proven to remain healthy due to [her] African Holistic Health lifestyle" constituted a medical, rather than religious, belief.</p>

Applicable Case	Date Filed	Nature of Claim and Outcome
<p><i>Horvath v. City of Leander</i></p> <p>Case No. 1:17-CV-256-RP (W.D. Tex. Oct. 10, 2018)</p> <p><u>Related decisions:</u></p> <p>2018 U.S. Dist. LEXIS 236718, 2018 WL 10771965 (W.D. Tex. Oct. 10, 2018), granting summary judgment in favor of the employer, <i>aff'd</i>, 946 F. 3d. 787 (5th Cir. 2020).</p>	<p>11/29/18</p>	<p><u>Religious Discrimination (Favorable Employer Outcome)</u></p> <p>A driver /pump operator for a fire department refused a TDAP vaccine on religious grounds. As an accommodation, the employer offered the employee a different position with no public contact or requiring the employee to wear PPE, including an N95 mask, at all times while on duty. The employee refused to be moved to a different position and objected to wearing the N95 respirator at all times. The employee instead proposed to wear the respirator “when encountering patients who are coughing or who have a history of communicable illness.” The employer reiterated its proposed accommodations, and the employee refused again. The employee’s job was terminated.</p> <p>The district court ruled in favor of the employer granting summary judgment because the employer offered two reasonable accommodations and there was no evidence of discriminatory animus on the employer’s part.</p> <p>In affirming summary judgment for the employer, the Fifth Circuit held that the employer reasonably accommodated the employee by offering two accommodation options: (1) reassignment to a different position, “which offered the same pay and benefits and did not require a vaccine,” and (2) remaining in the same position if the employee “agreed to wear personal protective equipment, including a respirator, at all times while on duty, submit to testing for possible diseases when his health condition justified, and keep a log of his temperature.”</p>
<p><i>EEOC v. St. Vincent Hospital and Health Center, Inc.</i></p> <p>Case No. 16-CV-00234 (W.D. Pa. Jan. 5, 2017)</p>	<p>9/22/16</p>	<p><u>Religious Discrimination (Settled With Mixed Results)</u></p> <p>A hospital employer maintained a mandatory vaccination policy, requiring employees to get the influenza vaccine annually. To qualify for a religious-based exemption under the employer’s policy, the employee would need to provide a certification from a clergy person or another third party demonstrating that the employee practices a religion where influenza vaccination “is contraindicated according to doctrine or accepted religious practices.” The employer also required that individuals exempted from the policy wear a face mask when in direct patient contact during flu season. The EEOC filed suit against employer on behalf of six employees who did not get the certifications required by the employer to be exempted from the employer’s policy.</p> <p>The case was settled via consent decree. The employer agree to apply Title VII’s concepts of “religion” and “undue hardship” and not require clergy certification or other proof that the employee’s belief is “official endorsed teaching of any particular religion or denomination.”</p>

Applicable Case	Date Filed	Nature of Claim and Outcome
<p><i>EEOC v. Baystate Medical Center</i></p> <p>Case No. 3:16-cv-30086 (D. Mass. Oct. 30, 2017)</p>	<p>6/6/16</p>	<p><u>Religious Discrimination (Favorable Employer Outcome)</u></p> <p>An employer maintained an influenza immunization policy that required all of its employees to receive an annual flu vaccination. Under this policy, any employee who declines to be vaccinated, for any reason, must wear a mask at all times while working within the employer’s facilities. An employee refused vaccination based on her Christian faith and her belief that “her body is a temple.” The employee wore a mask at work but began to wear her mask improperly, pulling it away from her face when she experienced difficulties communicating with others. The employee’s position did not require her to have patient contact or to work in areas where patients were seen and treated. The employer terminated her employment for failing to wear a mask as required by the employer’s influenza policy. The EEOC filed suit against the employer on the basis of religious discrimination.</p> <p>The district court granted summary judgment in favor of the employer. The court found that because the employer’s influenza policy gave employees two options to choose from—the vaccination or wearing a mask—the mask was itself the employment requirement for which the employee was terminated, and not an accommodation to the vaccination requirement. Thus, the court found that the employee’s claims failed as a matter of law because “there was no conflict between this employment requirement and her religion, nor was her religion the basis for the adverse employment action.”</p>

Applicable Case	Date Filed	Nature of Claim and Outcome
<p><i>EEOC v. Mission Hosp., Inc.</i> Case No. 16-cv-00118-MOC-DLH (W.D.N.C., Aug. 7, 2017)</p> <p><u>Related decisions:</u> 2017 U.S. Dist. LEXIS 124183, 2017 WL 3392783 (W.D.N.C. Aug. 7, 2017), denying the employer’s Motion for Summary Judgment</p>	<p>4/28/16</p>	<p><u>Religious Discrimination (Favorable EEOC Outcome and Settled With Mixed Results)</u></p> <p>A hospital employer had an immunization policy that required employees to receive a flu vaccination annually, by December 1 of each year. The policy also required that employees seeking a religious exemption to the vaccine make a request for exemption by September 1. The EEOC brought suit against the employer on behalf of three employees who were denied the religious exemption due to submitting requests after the hospital’s September 1 deadline. One employee believed that “our bodies are a temple and that God gave us dominion over our bodies” and that “injecting the flu vaccine into her body is morally wrong.” Another believed that “followers of her religion are healed by plants, fruits, and grains.” The third believed that “injecting chemicals and diseases into her veins is not something God intends and that it is wrong.”</p> <p>The district court denied the employer’s motion for summary judgment. The court held that three employees with the unconventional beliefs had “bona fide” religious reasons for requesting exemptions and that “a reasonable jury could find that the defendant was treating individuals differently” due to the fact that the employer allowed employees who did not meet the December 1 deadline a “grace period” but did not afford a similar grace period to those who failed to meet the exemption’s September 1 deadline.</p> <p>The case settled via consent decree. The hospital employer agreed to pay \$89,000 to the employees, change all references to termination in the three employees’ personnel files to “voluntarily resigned,” and provide the three employees with positive letters of recommendation. The hospital also agreed to remove its September 1 deadline for religious and medical exemptions, provide a deadline consistent with CDC recommendations, allow for requests for exemptions to be made up until the deadline for receiving the flu vaccine, and allow the same grace period for medical and religious exemptions as for receiving the flu vaccine.</p>

Applicable Case	Date Filed	Nature of Claim and Outcome
<p><i>Janice Hustvet v. Allina Health System</i> Case No.16-CV-00551 (D. Minn. 2017)</p> <p><u>Related decisions:</u> 283 F. Supp. 3d 734 (D. Minn. 2017), granting summary judgment in favor of the employer, <i>aff'd</i>, 910 F.3d 399 (8th Cir. 2018)</p>	<p>3/3/16</p>	<p><u>Disability Discrimination (Favorable Employer Outcome)</u></p> <p>The hospital employer required employees to have various immunities, including to rubella. An employee who worked with “fragile and immune-compromised” clients did not have immunity to rubella and she refused to take the MMR vaccine because of her concerns that she “had severe cases of mumps and measles—the MM part of the MMR” and that she had “many allergies and chemical sensitivities, such that she needed to limit her exposure.” The employee wished to take a rubella-only vaccine and not the MMR vaccine, but such a vaccine is not available in the United States. The employee’s job was terminated for failing to comply with the employer’s immunization policy. The employee sued the employer on the basis of disability discrimination, unlawful inquiry, and retaliation.</p> <p>The district court granted summary judgment for the employer. The district court dismissed Plaintiff’s disability discrimination claim, finding that Plaintiff failed to meet her burden to show that she was disabled, as there was insufficient evidence in the record to establish that her conditions substantially limited her ability to perform major life activities. The court also found that a reasonable jury could not find that Plaintiff’s claimed limitations are causally related to her concerns about taking the MMR vaccine, as there was no evidence that Plaintiff had severe allergies to any of the vaccine’s components. The district court also granted summary judgment on Plaintiff’s unlawful inquiry claims, finding that Plaintiff was willing to undergo the examination, and thus her failure to complete the examination did not cause her termination. The district court also granted summary judgment to Plaintiff’s retaliation claim, finding that Plaintiff failed to show she engaged in protected conduct by objecting to the requirement that she have immunity to rubella and that even if it were protected conduct, it did not cause her termination.</p> <p>The Eighth Circuit affirmed summary judgment finding that Plaintiff’s record reveals that Plaintiff has “garden-variety allergies,” which is not enough for “reasonable fact-finder to conclude she is disabled.” The appellate court also upheld summary judgment on the unlawful inquiry claim finding that that the hospital’s “decision to force a class of employees (those employees with client contact who merged into the company) to undergo a health screen was job related and consistent with business necessity” and “no more intrusive than necessary.” The</p> <p><i>(continued on next page)</i></p>

Applicable Case	Date Filed	Nature of Claim and Outcome
		<p>appellate court also upheld summary judgment on the retaliation claim because Plaintiff did not establish that the employer terminated her employment because she <i>requested</i> the accommodation. Rather, the employer terminated her “because her job required her to work with potentially vulnerable clients” and she refused to comply with the immunization policy. The appellate court found that Plaintiff did not establish evidence that this legitimate, non-discriminatory reason was pretext.</p>
<p><i>Fallon v. Mercy Catholic Medical Center of Southeastern Pennsylvania</i> Case No. 2-16-CV-00834 (E.D. Pa. 2016)</p> <p><u>Related decisions:</u> 200 F. Supp. 3d 553 (E.D. Pa. 2016), granting the employer’s Motion to Dismiss, <i>aff’d</i>, 877 F. 3d 487 (3d Cir. 2017)</p>	<p>2/22/16</p>	<p><u>Religious Discrimination (Favorable Employer Outcome)</u></p> <p>A medical center employer required employees to be vaccinated against the flu. Employees who received religious or medical exemptions would be required to wear masks. One employee submitted requests for exemptions “on the basis of a strong moral or ethical conviction similar to a religious belief.” He was granted exemptions in 2012 and 2013. However, in 2014 the employer informed the employee that it was changing its policies and asked the employee to provide a letter on official clergy letterhead supporting the exemption request. The employee did not obtain such a letter and instead submitted his exemption request with a lengthy essay detailing his beliefs that the influenza vaccine is ineffective and that his “conscious” compelled him to refuse the vaccine. The employee’s job was terminated for his refusing the flu vaccination.</p> <p>The district court held that Plaintiff’s “stated opposition to vaccinations [was] entirely personal, political, sociological and economic—the very definition of secular philosophy as opposed to religious orientation,” and thus Plaintiff did not state a claim for religious discrimination under Title VII.</p> <p>The Third Circuit affirmed the district court’s dismissal, holding that the employee’s objection to the vaccination, made on the basis of his belief that “one should not harm their [sic] own body and [his strong belief] that the flu vaccine may do more harm than good,” was “a medical belief, not a religious one,” and thus Title VII did not apply.</p>

Applicable Case	Date Filed	Nature of Claim and Outcome
<p><i>Aiken v. Methodist Healthcare Memphis Hospitals</i></p> <p>Case No. 14-02641 (W.D. Tenn. Jan. 13, 2015)</p>	8/19/14	<p><u>Religious Discrimination (Settled With Mixed Results)</u></p> <p>The employer implemented a mandatory flu vaccination policy for all employees working at its facility. The policy notified employees to either receive the vaccine or “provide written documentation from a physician or religious advisor.” Under the policy, exempted employees must wear a surgical mask during flu season. Plaintiff objected to taking the vaccine due to her belief that the vaccines’ manufacturing process used “aborted fetal cell lines” in violation of her Christian beliefs. Plaintiff also stated that she “objected to taking the flu vaccine due to the documented risks associated with the vaccine and its unproven safety in pregnant women.” The employer allegedly asked Plaintiff to have a religious leader or physician sign off on exemption form, which she did not provide. Plaintiff’s job was then terminated for failure to comply with the mandatory flu vaccination policy. Plaintiff filed suit arguing that the employer failed to provide Plaintiff a reasonable accommodation and failed to engage in the interactive process with her. The parties settled the matter before it could be decided.</p>
<p><i>Delgado v. Fulton-DeKalb Hospital Authority</i></p> <p>Case No. 14-CV-01978 (N.D. Ga. Mar. 31, 2015)</p>	6/24/14	<p><u>Religious Discrimination (Settled With Mixed Results)</u></p> <p>The hospital employer required employees to be annually vaccinated against influenza. Plaintiff submitted a request for a religious exemption on the basis of her belief that her “religious tenets prohibit invasive medical procedures such as vaccinations” and that “the injection of toxic chemicals and foreign proteins into the bloodstream is a violation of God’s directive to keep the body/temple holy and free from impurities.” The hospital denied her request, allegedly on the basis that her beliefs were incorrect. Plaintiff also alleged that she was subject to harassment for not following the vaccine mandate. The parties settled the matter before it could be decided.</p>

Applicable Case	Date Filed	Nature of Claim and Outcome
<p><i>Robinson v. Children's Hospital Boston</i></p> <p>Case No. 14-10263 (D. Mass. 2016)</p> <p><u>Related decisions:</u></p> <p>2016 U.S. Dist. LEXIS 46024, 2016 WL 1337255 (D. Mass. Apr. 5, 2016), granting summary judgment in favor of the employer. Appealed, 16-01495, Terminated</p>	<p>2/4/14</p>	<p><u>Disability Discrimination (Favorable Employer Outcome)</u></p> <p>Due to the hospital's highly vulnerably patient population of "some of the most critically ill infants, children, and adolescents in the world" and the Massachusetts Department of Public Health's strong encouragement of vaccination of hospital personnel, the hospital employer decided to require all employees who "work in or access patient-care areas to be vaccinated against the influenza virus to achieve the safest possible environment and to ensure the highest possible care for its patients." The policy only allowed for exemptions for medical reasons, not religious, because the hospital "concluded that additional exemptions would increase the risk of transmission." The hospital did provide accommodations to those with religious concerns to receive a pork-free (gelatin-free) vaccine.</p> <p>Plaintiff's duties required patient interaction and was thus required to be vaccinated under the hospital's policies. Plaintiff refused to be vaccinated on the basis of her religion. Plaintiff believed "many vaccines [were] contaminated" with pork byproduct and "did not feel comfortable receiving the influenza vaccine." The hospital offered Plaintiff a non-gelatin vaccine, but Plaintiff declined it. On the day of the deadline for compliance with the policy, Plaintiff informed the hospital that he had previous had a bad allergic reaction to an influenza vaccine. The hospital encouraged Plaintiff "to seek a medical exemption and granted her a temporary medical exemption while it reviewed her medical records" on the basis of her claimed allergy to the injection, and assisted the employee in looking for another position in an area of the hospital with no patient interaction. Plaintiff was unable to find another position and her position was eventually terminated. The hospital treated this termination "as a voluntary resignation, which left her eligible to re-apply for other Hospital positions in the future."</p> <p>The district court granted summary judgment for the employer hospital, finding that the hospital worked with Plaintiff "several times" to find a reasonable accommodation. The district court also found that exempting the employee from the vaccination would constitute an undue hardship because of the risk to the hospital's vulnerable patient population.</p>

Applicable Case	Date Filed	Nature of Claim and Outcome
<p><i>Good v. Coshocton County Memorial Hospital Association</i></p> <p>Case No. 14-00001</p> <p>(S.D. Ohio Oct. 28, 2014)</p>	1/2/14	<p><u>Religious Discrimination (Settled With Mixed Results)</u></p> <p>The employer implemented a mandatory flu vaccination policy with exemptions permitted for medical or religious reasons. To obtain a religious exemption, employees must provide a form signed by the employee's clergyperson and include a statement about the nature of the religious objection. Plaintiff filed a request in 2012, which was granted. As an accommodation, Plaintiff wore a mask at all times during flu season. In 2013, Plaintiff alleges she made a similar request for exemption on religious grounds, which was denied. Plaintiff alleges she offered to wear a mask at all times at work as an accommodation, which was also denied. Plaintiff's job was terminated for her failure to follow the vaccination policy. The parties settled the matter before it could be decided.</p>
<p><i>Bashista v. St. Joseph Hospital System</i></p> <p>Case No. 14-10001</p> <p>(E.D. Mich. Aug. 22, 2014)</p> <p><u>Related decisions:</u></p> <p>2014 U.S. Dist. LEXIS 117697, 2014 WL 4206891 (E.D. Mich. Aug. 22, 2014), granting the employer's Motion to Dismiss</p>	1/1/14	<p><u>Religious Discrimination (Favorable Employer Outcome)</u></p> <p>Plaintiff's job was terminated for refusing a mandatory flu shot on unspecified religious grounds and their belief that the flu "shot is experimental." Plaintiff brought suit against the hospital employer as well as the CDC and the State of Michigan Department of Community Health (DCH). Plaintiff's complaint contained many conclusory allegations.</p> <p>The district court granted the employer's Motion to Dismiss because Plaintiff failed to plead their claim properly on multiple fronts. The court dismissed the claims against the CDC and DCH under the doctrine of sovereign immunity, as well as because of the lack of employment relationship between these agencies and Plaintiff. The court also dismissed the claim against the employer because Plaintiff had not pled any element of their claim in their complaint or in their response briefing.</p>
<p><i>Lemieux-Lewis v. Hartford Healthcare Corporation</i></p> <p>Case No. 13-cv-01865</p> <p>(D. Conn. Mar. 9, 2015)</p>	12/17/13	<p><u>Religious Discrimination (Settled With Mixed Results)</u></p> <p>Plaintiff worked as an accountant at a medical facility. She alleges she did not work in patient treatment and had very limited contact with patients. The employer implemented a policy mandating that all employees receive the flu vaccine. The policy allowed for religious and medical exemption but stated that employees would have color-coded ID badge tags indicating their "vaccination status." Exempt employees would also have to wear a mask whenever within six feet of an area a patient may be. Plaintiff received a religious exemption to the vaccine mandate, and was required to wear a color-coded ID badge indicating her exempt status. Plaintiff filed suit arguing that the color-coded ID badge and having to wear a mask constituted religious discrimination because it identified her as someone needing a religious exemption and "highlighted her religious beliefs unnecessarily." The parties settled the matter before it could be decided.</p>

Applicable Case	Date Filed	Nature of Claim and Outcome
<p><i>Usack v. Mountain States Health Alliance</i></p> <p>Case No. 13-CV-00278 (E.D. Tenn. Aug. 15, 2014)</p>	<p>10/21/13</p>	<p><u>Religious Discrimination</u></p> <p>A healthcare employer required employees to receive the influenza vaccine. In order to receive a religious exemption, employees must fill out a form provided by the employer and attach a letter from a religious authority. Plaintiff was a nurse who refused to take the vaccine based on her “personally held and/or philosophical objections,” which were beliefs held “outside of belonging to” an organized church or having a state certified religious leader. Specifically, Plaintiff stated on the exemption form that she had “objections to vaccinations, in general, based on [her] personal religious beliefs and [her] relationship with God.” Plaintiff alleges she was terminated for her refusal to take the flu vaccine. The parties settled the matter before it could be decided.</p>
<p><i>Chenzira v. Cincinnati Children’s Hospital Medical Center</i></p> <p>Case No. 1:11-cv-00917 (S.D. Ohio 2012)</p> <p><u>Related decisions:</u></p> <p>2012 U.S. Dist. LEXIS 182139, 2012 WL 6721098 (S.D. Ohio Dec. 27, 2012), denying the employer’s Motion to Dismiss in part such that the religious discrimination claims survive</p>	<p>12/28/11</p>	<p><u>Religious Discrimination (Favorable Employee Outcome and Settled With Mixed Results)</u></p> <p>Plaintiff’s employment was terminated for failing to comply with the employer’s vaccination policy. Plaintiff contends that the termination “violated her religious and philosophical convictions because she is a vegan, a person who does not ingest any animal or animal by-products.” Plaintiff contends that “her practice constitutes a moral and ethical belief which is sincerely held with the strength of traditional religious views.”</p> <p>The district court denied the employer’s Motion to Dismiss in order to afford the employee the opportunity to prove that the employee’s veganism constituted a religious belief, because the court found it “plausible that Plaintiff could subscribe to veganism with a sincerity equating that of traditional religious views.”</p> <p>The parties ultimately settled the matter in mediation before it could be decided.</p>
<p><i>Edwards v. Elmhurst Hospital Center</i></p> <p>Case No. 11 CV 4693 (RRM)(LB) (E.D.N.Y. 2013)</p> <p><u>Related decisions:</u></p> <p>2013 U.S. Dist. LEXIS 31083, 2013 WL 839535 (E.D.N.Y. Feb. 15, 2013), Magistrate judge recommendation that the court grant the employer’s Motion to Dismiss; 2013 U.S. Dist. LEXIS 31082 (E.D.N.Y. Mar. 6, 2013), granting the employer’s Motion to Dismiss with prejudice</p>	<p>9/26/11</p>	<p><u>Disability Discrimination (Favorable Employer Outcome)</u></p> <p>Plaintiff, a health care worker, was required by the New York State Department of Health to receive a flu vaccination as a condition of his employment. Plaintiff objected to the vaccination on the basis of his religious beliefs as a Jehovah’s Witness. Plaintiff alleged that the employer informed him that it would terminate his employment if he refused the vaccine. Consequently, Plaintiff filed suit.</p> <p>The district court dismissed the employee’s claim because he failed to allege any adverse employment action for his refusal of the influenza vaccination. The district court also noted that Plaintiff’s allegations satisfied the first two prongs of the <i>prima facie</i> test—namely that Plaintiff had a “bona fide religious belief conflicting with an employment requirement” and that he had informed his employer of his belief.</p>

APPENDIX B

ENSURING THE SAFETY OF VACCINES IN THE UNITED STATES

(Excerpt from publication by U.S. Food and Drug Administration)¹

Last updated July 2011

- Currently, the United States has the safest, most effective vaccine supply in its history.
- The United States' long-standing vaccine safety system ensures that vaccines are as safe as possible. As new information and science become available, this system is, and will continue to be, updated and improved.
- The U.S. Food and Drug Administration (FDA) ensures the safety, effectiveness, and availability of vaccines for the United States. Before the FDA licenses (approves) a vaccine, the vaccine is tested extensively by its manufacturer. FDA scientists and medical professionals carefully evaluate all the available information about the vaccine to determine its safety and effectiveness.
- Although most common side effects of a vaccine are identified in studies before the vaccine is licensed, rare adverse events may not be detected in these studies. Therefore, the U.S. vaccine safety system continuously monitors for adverse events (possible side effects) after a vaccine is licensed. When millions of people receive a vaccine, less common side effects that were not identified earlier may show up.

| Prelicensure: Vaccine Safety Testing |

The U.S. Food and Drug Administration (FDA) must license (approve) a vaccine before it can be used in the United States. FDA regulations for the development of vaccines ensure their safety, purity, potency, and effectiveness. Before a vaccine is approved by FDA for use by the public, results of studies on safety and effectiveness of the vaccine are evaluated by highly trained FDA scientists and doctors. FDA also inspects the vaccine manufacturing sites to make sure they comply with current Good Manufacturing Practice (cGMP) regulations.

Vaccine Development

Vaccine development begins in the laboratory before any tests in animals or humans are done. If laboratory tests show that a vaccine has potential, it is usually tested in animals. If a vaccine is safe in animals, and studies suggest that it will be safe in people, clinical trials with volunteers are next.

Clinical Trials

Typically, there are three phases of clinical trials. Vaccines that are being developed for children are first tested in adults. FDA sets guidelines for the three phases of clinical trials to ensure the safety of the volunteers.

Phase 1 clinical trials focus on safety and include 20–100 healthy volunteers. In Phase 1, scientists begin to learn how the size of the dose may be related to side effects. If possible at this

early stage, scientists also try to learn how effective the vaccine may be.

If no serious side effects are found in Phase 1, next is Phase 2, which involves several hundred volunteers. This phase includes studies that may provide additional information on common short-term side effects and how the size of the dose relates to immune response.

In Phase 3 studies, hundreds or thousands of volunteers participate. Vaccinated people are compared with people who have received a placebo or another vaccine so researchers can learn more about the test vaccine's safety and effectiveness and identify common side effects.

Clinical trials are conducted according to plans that FDA reviews to ensure the highest scientific and ethical standards. The results of the clinical trials are a part of FDA's evaluation to assess the safety and effectiveness of each vaccine. In addition to evaluating the results of the clinical trials, FDA scientists and medical professionals carefully evaluate a wide range of information including results of studies on the vaccine's physical, chemical, and biological properties, as well as how it is manufactured, to ensure that it can be made consistently safe, pure, and potent.

The trials and all other data must show that the vaccine's benefits outweigh the potential risks for people who will be

76 See U.S. Food and Drug Administration, [Ensuring the Safety of Vaccines in the United States](#) (Last updated July 2011).

recommended to receive the vaccine. Only if a vaccine's benefits are found to outweigh its potential risks does the FDA grant a license for the vaccine, allowing it to be used by the public.

| Postlicensure: Vaccine Safety Monitoring |

After vaccines are licensed, they are monitored closely as people begin using them. The purpose of monitoring is to watch for adverse events (possible side effects). Monitoring a vaccine after it is licensed helps ensure that the benefits continue to outweigh the risks for people who receive the vaccine.

Monitoring is essential for two reasons. First, even large clinical trials may not be big enough to reveal side effects that do not happen very often. For example, some side effects may only happen in 1 in 100,000 or 1 in 500,000 people.

Second, vaccine trials may not include groups who might have different types of side effects or who might have a higher risk of side effects than the volunteers who got the vaccine during clinical trials. Examples of these groups include people with chronic medical conditions, pregnant women, and older adults.

If a link is found between a possible side effect and a vaccine, public health officials take appropriate action by first weighing the benefits of the vaccine against its risks to determine if recommendations for using the vaccine should change.

The Advisory Committee on Immunization Practices (ACIP), a group of medical and public health experts, carefully reviews all safety and effectiveness data on vaccines as a part of its work to make recommendations for the use of vaccines. The ACIP modifies recommendations, if needed, based on safety monitoring.

VAERS

Postlicensure monitoring begins with the Vaccine Adverse Event Reporting System (VAERS), a national system used by scientists at FDA and the Centers for Disease Control and Prevention (CDC) to collect reports of adverse events (possible side effects) that happen after vaccination. Health care professionals, vaccine manufacturers, vaccine recipients, and parents or family members of people who have received a vaccine are encouraged to submit reports to VAERS if they experience any adverse events after getting any vaccine.

Scientists monitor VAERS reports to identify adverse events that need to be studied further. All serious reports are reviewed by medical professionals on a daily basis. VAERS data provide

medical professionals at CDC and FDA with a signal of a potential adverse event. Experience has shown that VAERS is an excellent tool for detecting potential adverse events. Reports of adverse events that are unexpected, appear to happen more often than expected, or have unusual patterns are followed up with specific studies.

VAERS data alone usually cannot be used to answer the question, "Does a certain vaccine cause a certain side effect?" This is mainly because adverse events reported to VAERS may or may not be caused by vaccines. There are reports in VAERS of common conditions that may occur by chance alone that are found shortly after vaccination. Investigation may find no medical link between vaccination and these conditions.

To know if a vaccine causes a side effect, scientists must know whether the adverse event is occurring after vaccination with a particular vaccine more often than would be expected without vaccination. They also need to consider whether the association between the vaccine and the adverse event is consistent with existing medical knowledge about how vaccines work in the body.

VSD

Scientists use CDC's Vaccine Safety Datalink (VSD) to do studies that help determine if possible side effects identified using VAERS are actually related to vaccination. VSD is a network of eight managed care organizations across the United States. The combined population of these organizations is more than 9.2 million people.

Scientists can use VSD in two ways. First, scientists can look back in medical records to see if a particular adverse event is more common among people who have received a particular vaccine. Second, instead of looking back, scientists can use Rapid Cycle Analysis (RCA) to continuously look at information coming into VSD to see if the rate of certain health conditions is higher among vaccinated people. This second approach is new, and it allows results to be obtained much more quickly.

Vaccine Manufacturing

Once a vaccine is licensed, FDA regularly inspects vaccine manufacturing facilities to make sure they are following strict regulations. Vaccines are manufactured in batches called lots, and vaccine manufacturers must test all lots of a vaccine to make sure they are safe, pure, and potent. Vaccine lots cannot be distributed until released by FDA.

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Inspired by you.**