

Designing COVID-19 vaccine mandates in colleges and universities: a roadmap to the 10 key questions

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ABSTRACT

COVID-19 transmission among students, faculty, and staff at US institutions of higher education (IHEs) is a pressing concern, especially with the dominance of the highly contagious Delta variant and emergence of the Omicron variant. From the start of the pandemic to May 26, 2021, >700,000 cases were linked to US colleges and universities. To protect their populations and surrounding communities, IHE administrators are increasingly considering COVID-19 vaccine requirements. Roughly one-quarter of the nearly 4,000 college and university campuses across the US have announced COVID-19 vaccine mandates for students or employees. However, deciding to require vaccination is only the first of multiple decisions, as IHEs face complex issues of how to design and refine their mandates, including whether to require boosters. Mandates vary significantly in stringency, implementation, impact on members of the college or university community, and net benefit to the institution. This essay examines 10 key

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questions that an IHE must face in designing or refining a COVID-19 vaccination mandate. Showing that these 10 questions were carefully considered may be crucial if the institution's mandate is challenged. Ultimately, how an IHE designs its mandate may make the difference between meaningful risk mitigation that advances institutional goals and benefits students, faculty, and staff versus a public health failure that erodes trust, raises equity concerns, threatens to undermine preexisting vaccination requirements, and divides the campus.

KEYWORDS: colleges and universities, COVID-19, ethics, higher education, public health, vaccine mandate

I. IMPORTANCE OF DESIGN IN VACCINE MANDATES

COVID-19 transmission among students, faculty, and staff at US institutions of higher education (IHEs) is a pressing concern, especially with the dominance of the highly contagious Delta variant and emergence of the potentially even more contagious Omicron variant.¹ From the inception of the pandemic to May 26, 2021, >700,000 cases have been linked to US colleges and universities.² Multiple outbreaks of COVID-19 infection occurred across campuses nationally in the fall of 2021.³ IHEs pose specific risks for their populations to the extent they house students in dormitories, offer in-person classes, conduct lab research, sponsor athletic competitions and events, operate academic health centers or medical facilities, and host local, regional, and global collaborators.

To protect their populations and surrounding communities, IHE administrators are increasingly considering COVID-19 vaccine requirements. Roughly one-quarter of the nearly 4000 college and university campuses across the USA have announced COVID-19 vaccine mandates for students or employees.⁴ However, determining whether to require vaccination is only the first of multiple decisions, as IHEs face complex issues

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- 1 See Jonathan Corum & Carl Zimmer, *Tracking Omicron and Other Coronavirus Variants*, N.Y. TIMES, updated Dec. 10, 2021, <https://www.nytimes.com/interactive/2021/health/coronavirus-variant-tracker.html> (accessed Dec. 10, 2021); Paulina Villegas et al., *Preliminary Data Suggest Omicron Is More Transmissible, Causes Milder Disease than Delta*, WHO SAYS, WASH. POST, Dec. 8, 2021, <https://www.washingtonpost.com/nation/2021/12/08/covid-omicron-variant-live-updates/> (accessed Dec. 10, 2021); THE WHITE HOUSE, PRESIDENT BIDEN ANNOUNCES NEW ACTIONS TO PROTECT AMERICANS AGAINST THE DELTA AND OMICRON VARIANTS AS WE BATTLE COVID-19 THIS WINTER, Dec. 2, 2021, <https://www.whitehouse.gov/briefing-room/statements-releases/2021/12/02/fact-sheet-president-biden-announces-new-actions-to-protect-americans-against-the-delta-and-omicron-variants-as-we-battle-covid-19-this-winter/> (accessed Dec. 10, 2021).
 - 2 *Tracking Coronavirus Cases at U.S. Colleges and Universities*, N.Y. TIMES, updated May 26, 2021, <https://www.nytimes.com/interactive/2021/us/college-covid-tracker.html> (accessed Dec. 10, 2021).
 - 3 Chris Quintana & Mike Stucka, 'Astonishingly Risky': COVID-19 Cases at Colleges are Fueling the Nation's Hottest Outbreaks, COM. APPEAL (Sept. 11, 2020), <https://www.commercialappeal.com/story/news/education/2020/09/11/covid-cases-college-us-outbreak-rate-tracker/5759088002/> (accessed Dec. 10, 2021); *Live Updates: Latest News on COVID-19 and Higher Education*, INSIDE HIGHER ED, last updated Dec. 10, 2021, <https://www.insidehighered.com/covid-19-live-updates> (accessed Dec. 10, 2021).
 - 4 See Andy Thomason & Brian O'Leary, *Here's a List of Colleges that Require Students or Employees to be Vaccinated Against Covid-19*, CHRON. HIGHER EDUC. (Dec. 9, 2021), <https://www.chronicle.com/blogs/live-coronavirus-updates/heres-a-list-of-colleges-that-will-require-students-to-be-vaccinated-against-covid-19> (accessed Dec. 10, 2021) (1,141 campuses). For the denominator (total number of campuses), see NAT'L CTR. FOR EDUC. STAT., TABLE 317.10, DEGREE-GRANTING POSTSECONDARY INSTITUTIONS, BY CONTROL AND LEVEL OF INSTITUTION: SELECTED YEARS, 1949–50 THROUGH 2019–20 (2020), https://nces.ed.gov/programs/digest/d20/tables/dt20_317.10.asp?current=yes (accessed Dec. 10, 2021).

Table 1. 10 key questions in designing a COVID-19 vaccine mandate for a US college or university

Questions	Options (some can be combined)
1. Who institutes the mandate?	<ul style="list-style-type: none"> a. College/university leadership b. Governing bodies and legislatures c. Consultation with expert committees d. Consultation with constituencies, including student, staff, and faculty leaders e. Consultation with members of the surrounding community
2. When to start mandate and whether to require boosters after 6 months?	<ul style="list-style-type: none"> a. Allow a grace period and set deadline b. Return to campus, start of semester, mid-semester breaks c. Require initial vaccine series plus booster after 6 months
3. Who to cover?	<ul style="list-style-type: none"> a. Students b. Faculty (including part-time & adjunct), staff, and other employees c. Clinicians and trainees in health care settings d. Others—visitors and public, attendees at events, athletic competitors, collaborators, independent contractors, and members of boards/committees
4. What vaccines to mandate?	<ul style="list-style-type: none"> a. Vaccines fully approved by FDA (Pfizer, to date) b. Vaccines authorized by FDA under EUA (Moderna and Janssen, to date) c. Other vaccines listed by WHO (international students, faculty, etc.)
5. How to support vaccination?	<ul style="list-style-type: none"> a. Education on vaccination and specific vaccines; address questions and concerns b. Easy, fast, and free access to a choice of vaccines c. Educate on and provide/support additional shots as needed (e.g., booster shots)
6. How to document vaccination status?	<ul style="list-style-type: none"> a. Attestation; state dates/type of vaccination; upload CDC vaccination card; download state records; or use state or commercial ‘vaccine passports’ b. Balance ease of implementation with vulnerability to entry of false information c. Protect individual privacy and system security

(Continued)

Table 1. Continued

Questions	Options (some can be combined)
7. What exemptions to allow and with what documentation?	<ul style="list-style-type: none"> a. Medical exemption—scope; document by attestation and specification, or clinician document; protecting privacy b. Religious exemption—whether to allow, with what scope; document by attestation and specification, notarized document or document from religious authority c. Nonreligious conscientious objection exemption—whether to allow, with what scope, what documentation to require
8. How to accommodate exemptions and with what testing?	<ul style="list-style-type: none"> a. Require periodic COVID-19 testing b. Require masking and other measures (e.g., distancing) c. Require remote instead of in-person participation d. Require vaccination as a condition of student enrollment or continued employment in some settings (e.g., health care)
9. How to respond to noncompliance and submission of false information?	<ul style="list-style-type: none"> a. For students (including health sciences students): notice of noncompliance and warning, limit to off-campus virtual participation, offer deferred admission or leave of absence, deny enrollment, suspension, or expulsion b. For faculty and staff (including health care workers): notice of noncompliance and warning, limit to off-campus virtual participation if compatible with duties, offer leave of absence if feasible, or termination (subject to conditions of employment such as tenure and contract rights)
10. What data and feedback to collect; what metrics to use for evaluation, improvement, and ending the mandate?	<ul style="list-style-type: none"> a. Determine what data to collect and metrics to use to evaluate mandate such as: percent vaccinated before vs. after mandate; rates of COVID-19 infections, testing, quarantine, isolation, hospitalization, mortality; percentage seeking and obtaining exemption(s); percentage noncompliant; and costs and savings b. Be transparent and invite feedback c. Continuously monitor state, local, and campus COVID-19 data/trends d. Evaluate regularly to make improvements and decide termination of mandate

of how to design and refine their mandates.⁵ Mandates vary in stringency, implementation, cost, impact on members of the college or university community, and net benefit to the institution.

The goal of this essay is to support systematic public health decisions on college and university campuses by identifying 10 key questions (see Table 1) that an IHE must face in designing or refining a COVID-19 vaccination mandate. Considering these issues carefully is essential to successful implementation. The sheer diversity of institutions—public vs. private, small colleges vs. large universities, and commuter vs. resident campuses, with differing commitments and histories—means that individual IHEs may answer these key questions differently. These questions raise complex issues of law, science, medicine, public health, and university relations, all of which are rapidly evolving. The essay does not aim to fully explicate those issues but rather provides IHE decision makers with a useful roadmap with key landmarks to structure decision making about COVID-19 vaccination mandates.

Unfolding changes in law will undoubtedly affect IHE decisions, requiring leaders to consult their legal counsel. Relevant federal law includes vaccine mandates originally announced by President Biden on September 9, 2021,⁶ which are in the process of implementation⁷ and under substantial challenge. Multiple federal court decisions

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- 5 See CTRS. FOR DISEASE CONTROL AND PREVENTION (CDC), *Guidance for Institutions of Higher Education (IHEs)*, updated Nov. 4, 2021, <https://www.cdc.gov/coronavirus/2019-ncov/community/college-universities/considerations.html> (accessed Dec. 10, 2021); U.S. DEP'T OF EDUC., *ED COVID-19 HANDBOOK, VOL. 3* (2021), <https://www2.ed.gov/documents/coronavirus/reopening-3.pdf> (accessed Dec. 10, 2021); AM. COLL. HEALTH ASS'N, *ACHA Guidelines: Considerations for Reopening Institutions of Higher Education for the Fall Semester 2021*, May 25, 2021, https://www.acha.org/documents/resource/s/guidelines/ACHA_Considerations_for_Reopening_IHEs_for_Fall_2021_5.25.21.pdf (accessed Dec. 10, 2021); AM. COLL. HEALTH ASS'N, *News Announcement, American College Health Association Recommends COVID-19 Vaccination Requirements for All On-Campus College Students in Fall 2021*, Apr. 29, 2021, https://www.acha.org/ACHA/About/ACHA_News/ACHA_Recommends_COVID-19_Vaccination_Requirements_for_Fall_2021.aspx (accessed Dec. 10, 2021). See generally Megan Lowry, *How College and University Leaders Are Getting Their Campuses Vaccinated*, NAT'L ACADS. OF SCIS., ENG'G, AND MED. (Sept. 28, 2021), <https://www.nationalacademies.org/news/2021/09/how-college-and-university-leaders-are-getting-their-campuses-vaccinated> (accessed Dec. 10, 2021).
 - 6 THE WHITE HOUSE, *PATH OUT OF THE PANDEMIC: PRESIDENT BIDEN'S COVID-19 ACTION PLAN*, <https://www.whitehouse.gov/covidplan/> (accessed Dec. 10, 2021); THE WHITE HOUSE, *EXECUTIVE ORDER ON ENSURING ADEQUATE COVID SAFETY PROTOCOLS FOR FED. CONTRACTORS*, Sept. 9, 2021, <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/09/09/executive-order-on-ensuring-adequate-covid-safety-protocols-for-federal-contractors/> (accessed Dec. 10, 2021).
 - 7 See, e.g., SAFER FED. WORKFORCE TASK FORCE, *COVID-19 WORKPLACE SAFETY: GUIDANCE FOR FED. CONTRACTORS AND SUBCONTRACTORS*, Sept. 24, 2021, https://www.saferfederalworkforce.gov/downloads/Draft%20contractor%20guidance%20doc_20210922.pdf (accessed Dec. 10, 2021); Sarah Belger & Hans Riede, *Guidance for Federal Contractors Under President Biden's COVID-19 Executive Order*, QUARLES & BRADY (Oct. 8, 2021), <https://www.quarles.com/publications/guidance-for-federal-contractors-under-president-bidens-covid-19-executive-order/> (accessed Dec. 10, 2021). Additional federal rules announced on Nov. 4, 2021, include: Dep't of Lab., Occupational Safety & Health Admin. (OSHA), *COVID-19 Vaccination and Testing; Emergency Temporary Standard*, 86 Fed. Reg. 61,402 (Nov. 5, 2021) (to be codified at 29 C.F.R. pts. 1910, 1915, 1917, 1918, 1926, 1928), available at <https://www.federalregister.gov/documents/2021/11/05/2021-23643/covid-19-vaccination-and-testing-emergency-temporary-standard> (accessed Dec. 10, 2021); Dep't of Health & Hum. Servs., *Ctrs. for Medicare & Medicaid Servs. (CMS), Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination*, 86 Fed. Reg. 61,555 (Nov. 5, 2021) (to be codified at 42 C.F.R. pts. 416, 418, 441, 460, 482, 483, 484, 485, 486, 491, 494), available at <https://www.federalregister.gov/documents/2021/11/05/2021-23831/medicare-and-medicaid-programs-omnibus-covid-19-health-care-staff-vaccination> (accessed Dec. 10, 2021).

since November 1, 2021, have questioned the constitutionality of federal vaccine mandates and temporarily enjoined their enforcement.⁸ State law is evolving as well.⁹ Most IHEs already required vaccinations for student enrollment before the pandemic (e.g., for measles, mumps, rubella, tetanus, and diphtheria),¹⁰ but state law germane to COVID-19 student vaccinations varies.¹¹ Some states currently ban COVID-19 vaccine mandates in IHEs¹² and multiple lawsuits have been brought challenging vaccination mandates in a range of states.¹³ Federal and state litigation will continue to influence the campus vaccination policies.

While these factors will influence how an IHE addresses the 10 design questions identified below, showing that those design questions were carefully considered may be crucial if the institution's mandate is challenged. In the most influential and highest-level court decision to date on IHE vaccination mandates, Indiana University's detailed attention to its mandate design in the spring of 2021 proved pivotal in the judicial rejection of student legal challenges.¹⁴ Ultimately, how an IHE designs its mandate may make the difference between meaningful risk mitigation that advances institutional goals and benefits students, faculty, and staff versus a public health failure that erodes trust, raises equity concerns, threatens to undermine preexisting vaccination requirements, and divides the campus.

II. DESIGN OPTIONS

IHEs designing or refining a COVID-19 vaccination mandate should address 10 key questions (see Table 1). These questions focus on identifying which leaders should institute the mandate, when it should start and whether boosters should be included, who it should cover, which vaccines should qualify (e.g., for international students), what exemptions should be allowed, how vaccination and exemptions

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- 8 See, e.g., James G. Hodge, Jr., et al., *Amid a Public Health Crisis, the Supreme Court Could Be Poised To Stop Biden's Vaccine Mandates*, BULL. ATOMIC SCIENTISTS (Dec. 10, 2021), <https://thebulletin.org/2021/12/a-mid-a-public-health-crisis-the-supreme-court-could-be-poised-to-stop-bidens-vaccine-mandates/> (accessed Dec. 12, 2021) (describing and linking to prominent federal cases limiting or supporting federal vaccine mandates); James G. Hodge, Jr., Jennifer Piatt & Erica N. White, *Guidance: OSHA's COVID-19 Vaccination Mandate Standard for Large Employers*, THE NETWORK FOR PUB. HEALTH L. (Dec. 9, 2021), <https://www.networkforphl.org/resources/guidance-oshas-forthcoming-rule-and-covid-19-vaccination-mandates/> (accessed Dec. 10, 2021).
 - 9 See, e.g., Jennifer Piatt, *COVID-19 Vaccination Mandates: Recent Court Cases*, THE NETWORK FOR PUB. HEALTH L. (Oct. 26, 2021), <https://www.networkforphl.org/resources/covid-19-vaccination-mandates-recent-cases/> (accessed Dec. 10, 2021).
 - 10 See Leila Barraza et al., *Immunization Laws and Policies Among U.S. Institutes of Higher Education*, 47 J.L. MED. & ETHICS 342 (2019).
 - 11 See Dorit Rubinstein Reiss & John DiPaolo, *COVID-19 Vaccine Mandates for University Students*, N.Y.U. J. LEGIS. & PUB. POL'Y (forthcoming), available at <https://ssrn.com/abstract=3874159> (accessed Dec. 10, 2021).
 - 12 See NAT'L ACAD. FOR STATE HEALTH POL'Y (NASHP), *State Efforts to Ban or Enforce COVID-19 Vaccine Mandates and Passports*, updated Dec. 3, 2021, <https://www.nashp.org/state-lawmakers-submit-bills-to-ban-employer-vaccine-mandates/> (accessed Dec. 10, 2021).
 - 13 See Piatt, *supra* note 9, and *infra* note 15.
 - 14 See *Klaassen v. Trustees of Indiana Univ.*, 1:21-CV-238 DRL, 2021 WL 3073926 (N.D. Ind. July 18, 2021), *aff'd*, 7 F.4th 592 (7th Cir. Aug. 2, 2021), *injunctive relief denied*, No. 21A15, 2021 BL 318520 (U.S. Aug. 12, 2021); see also Amy Howe, *Barrett Leaves Indiana University's Vaccine Mandate in Place*, SCOTUSBLOG (Aug. 12, 2021), <https://www.scotusblog.com/2021/08/barrett-leaves-indiana-universitys-vaccine-mandate-in-place/> (accessed Dec. 10, 2021).

should be documented, what testing and other requirements should apply to exempted individuals, and how to respond in cases of false statements or noncompliance without an exemption. Equally important are what data should be collected and metrics used to evaluate the mandate, refine it, and decide when it should end.

1. Governance and Oversight

College and university presidents have been working with their governing boards and constituents to preserve safety and institutional function since early in the pandemic. In *Klaassen v. Indiana University*, federal courts rejected students' constitutional challenges to Indiana University's COVID-19 vaccine mandate.¹⁵ The university's mandate survived scrutiny in part because its leadership had created an advisory committee of campus experts 'in public health, epidemiology, virology, data modeling and monitoring, risk mitigation, health equity, health sciences, and law'.¹⁶ The federal district court found the university had acted reasonably in adopting the mandate: 'It wasn't a decision reached overnight. It wasn't a decision taken by some fly-by-night committee undetached from the current science, the current progress of the fight against the pandemic, or experience and training in relevant fields of study'.¹⁷ The court also noted widespread support for the mandate among faculty, staff, and student councils.¹⁸ The *Klaassen* decision, which was upheld on appeal in the Seventh Circuit with Supreme Court Justice Amy Coney Barrett later denying injunctive relief, reveals how marshaling expertise, collecting input, and building support for a vaccine mandate can help protect against legal challenges.

Careful consultation with multiple constituencies—from governing boards to faculty, staff, students, and parents—can also surface initial concerns and allow institutional leadership to address them. Such shared governance can reduce the chances of polarization, protest letters, and votes of no confidence. COVID-19 vaccination mandates require cooperation and trust to succeed. An IHE's transparency about relevant data (including trends in the state COVID-19 positivity rate and the history of outbreaks at IHEs), pertinent guidance [including from the Centers for Disease Control and Prevention (CDC), the state department of health, and organizations such as the American College Health Association], and IHE deliberations (including concerns about failing to maintain student, faculty, and staff safety; exposing the surrounding community; dangers to vulnerable family members; and potential disruptions to basic

15 Note that students have challenged vaccine mandates at other universities, but no judicial decisions to date have proven as influential as the decisions in *Klaassen*. See, e.g., *Khanthaphixay v. Loyola Marymount Univ.*, No. 2:21-cv-06000, 2021 WL 4025796 (C.D. Cal. Aug. 9, 2021); *Wade v. Univ. of Connecticut Bd. of Trustees*, No. 3:21-cv-924 (JAM), 2021 WL 3616035 (D. Conn. Aug. 16, 2021); *Harris v. Univ. of Massachusetts Lowell*, No. 1:21-cv-11244, 2021 WL 3848012 (D. Mass. Aug. 27, 2021); *Children's Health Defense, Inc. v. Rutgers, The State Univ. of New Jersey*, No. 21-15333 (ZNQ) (TBJ), 2021 WL 4398743 (D.N.J. Sept. 27, 2021). In some cases, students have succeeded in obtaining injunctive relief. See *Magliulo v. Edward Via Coll. of Osteopathic Med.*, No. 3:21-cv-02304, 2021 WL 3679227 (W.D. La. Aug. 17, 2021); *Dahl v. Bd. of Trustees of Western Michigan Univ.*, No. 1:21-cv-757, 2021 WL 3891620 (W.D. Mich. Aug. 31, 2021). For additional court cases on COVID-19 vaccine mandates, see Piatt, *supra* note 9; Hodge, Jr., et al., *supra* note 8.

16 *Klaassen*, 2021 WL 3073926, at *28.

17 *Id.* at *27–28.

18 *Id.* at *6.

IHE functions such as instruction, research, and athletics) can help to build a shared dialogue.

2. Timing the Onset of the Mandate and Whether to Require Boosters

Some IHEs showed reluctance to mandate vaccination before the start of the 2021–22 academic year because all three US vaccines [Pfizer, Moderna, and Janssen/Johnson & Johnson (J&J)] were available only under emergency use authorizations (EUs). The Food and Drug Administration's (FDA) full approval of Pfizer's vaccine for adult populations on August 23, 2021,¹⁹ alleviated this concern, although vaccine hesitancy and resistance remain extensive across multiple states. With the 2021–22 academic year fully underway, students back on campus, the Delta variant fueling infections across substantial portions of the USA, and the Omicron variant emerging across multiple states, IHEs seeking to adopt a vaccine mandate must act quickly. Institutions will need to announce policy and procedure, create a system to request and upload vaccination information securely, adjudicate requests for exemptions and associated requirements such as periodic testing, and collect data on the system's success or failure.

In setting a deadline by which individuals must be vaccinated or deemed exempt, IHEs must juggle a number of considerations. These include how rapidly vaccination is needed to minimize infection on campus, how soon the community can realistically comply, how much time IHE authorities need to process the documentation of vaccination and requests for exemptions, and what public health preventive measures can be deployed while the mandate is being implemented. Setting deadlines for compliance at the start of a semester or return from extended breaks may help avoid disruption of student, faculty, and staff expectations.

A more challenging question is whether to require not only an initial vaccination series [two doses of Pfizer or Moderna plus 2 weeks, or one dose of Janssen (J&J) plus 2 weeks] but also a booster for those at least 6 months from completing the initial series. With epidemiological evidence accumulating that immunity wanes at approximately the 6-month mark and that a booster is needed to combat the Delta (and likely the Omicron) variant effectively,²⁰ some IHEs are beginning to update vaccination mandates to require a booster, which is consistent with CDC guidance urging boosters for all adults.²¹

3. Determining the Populations Covered

Whether to limit vaccine requirements to students or to include faculty and staff is a central question. Epidemiologically, limiting IHE vaccination requirements to students may not yield desired results, as faculty and staff may create equivalent risks for others.

19 U.S. FOOD & DRUG ADMIN. (FDA), FDA APPROVES FIRST COVID-19 VACCINE, Aug. 23, 2021, <https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine> (accessed Dec. 10, 2021). Because IHE students, faculty, and staff tend to be ≥ 18 years of age, we do not address vaccination of minors.

20 See, e.g., CTRS. FOR DISEASE CONTROL AND PREVENTION (CDC), COVID-19 BOOSTER SHOTS, updated Dec. 9, 2021, <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html> (accessed Dec. 10, 2021); THE WHITE HOUSE, PRESIDENT BIDEN ANNOUNCES NEW ACTIONS, *supra* note 1.

21 See, e.g., Ryan Faircloth, *Carleton, St. Olaf Colleges to Require COVID-19 Booster Shot for Students and Employees*, STAR TRIB. (Dec. 10, 2021), <https://www.startribune.com/carleton-st-olaf-colleges-to-require-covid-19-booster-shot-for-students-and-employees-minnesota/600125850/> (accessed Dec. 10, 2021).

Both faculty and staff interact with students, community members, visitors, research participants, and (in IHEs with academic health centers or other clinical services) patients and their families. While infection risks can be mitigated somewhat through mask and social distancing requirements, if the goal of a vaccination mandate is to substantially reduce infections and increase safety, imposing the mandate exclusively on students may be insufficient.

Extending a mandate to faculty and staff raises various legal concerns. Preexisting state laws imposing IHE vaccine requirements tend to focus on students.²² Some faculty or staff may be covered through specific employment laws, policies, or unions' approval of vaccinations. Standards from the federal Occupational Safety and Health Administration (OSHA) require larger employers, including private universities, to mandate vaccines among employees,²³ subject to certain exemptions (discussed below) and regular testing as well as mask-wearing for employees who are not fully vaccinated. State-run universities may not fall under that federal rule, but state-based OSHA equivalents may apply.²⁴ In addition, existing requirements for federal contractors to be vaccinated have been interpreted to apply to faculty and other employees at IHEs with federal contracts.²⁵ Many large research-oriented universities have already determined that their entire employee base must be vaccinated under this rule.²⁶ Health care workers at IHEs with academic health centers face federal and state vaccine mandates applying solely to health care providers.²⁷

As noted above,²⁸ litigation specifically surrounding federal vaccine mandates has generated considerable uncertainty over IHE employee requirements. Select federal district and appellate courts have temporarily enjoined vaccine mandates from OSHA and CMS as well as requirements applying to federal contractors.²⁹ Ultimate guidance from the US Supreme Court on these issues is forthcoming. Its possible rejection of specific federal vaccination requirements could impact IHEs in the spring of 2022. Even

22 See Barraza et al., *supra* note 10.

23 Dep't of Lab., Occupational Safety and Health Admin. (OSHA), COVID-19 Vaccination and Testing; Emergency Temporary Standard, 86 Fed. Reg. 61,402 (Nov. 5, 2021) (to be codified at 29 C.F.R. pts. 1910, 1915, 1917, 1918, 1926, 1928), available at <https://www.federalregister.gov/documents/2021/11/05/2021-23643/covid-19-vaccination-and-testing-emergency-temporary-standard> (accessed Dec. 10, 2021); see also OCCUPATIONAL SAFETY AND HEALTH ADMIN. (OSHA), EMERGENCY TEMPORARY STANDARD: COVID-19 VACCINATION AND TESTING ETS, U.S. DEP'T OF LAB., <https://www.osha.gov/coronavirus/ets2> (accessed Dec. 10, 2021); Hodge, Jr., Piatt & White, *supra* note 8.

24 Hodge, Jr., Piatt & White, *supra* note 8.

25 See AM. COUNCIL ON EDUC., ISSUE BRIEF, ASSESSING THE IMPACT OF COVID-19 FEDERAL CONTRACTOR REQUIREMENTS ON COLLEGES AND UNIVERSITIES, <https://www.acenet.edu/Documents/Issue-Brief-COVID-19-Guidance-for-Federal-Contractors.pdf> (accessed Dec. 10, 2021).

26 Francie Diep, *Biden's Vaccine Order is Broad. These Campuses are Trying to Apply it Narrowly*, CHRON. HIGHER EDUC. (Oct. 25, 2021), <https://www.chronicle.com/article/bidens-vaccine-order-is-broad-these-campus-are-trying-to-apply-it-narrowly> (accessed Dec. 10, 2021).

27 See THE WHITE HOUSE, PATH OUT OF THE PANDEMIC, *supra* note 7; Dep't of Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs. (CMS), Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61,555 (Nov. 5, 2021) (to be codified at 42 C.F.R. pts. 416, 418, 441, 460, 482, 483, 484, 485, 486, 491, 494), available at <https://www.federalregister.gov/documents/2021/11/05/2021-23831/medicare-and-medicaid-programs-omnibus-covid-19-health-care-staff-vaccination> (accessed Dec. 10, 2021); NASHP, *supra* note 12.

28 See *supra* note 8 and accompanying text.

29 See Hodge, Jr., et al., *supra* note 8.

if the Court rejects federal authority to require vaccines, state-based mandates would remain in place. IHEs may also choose to implement mandates, absent state-based legal restrictions.

Campuses routinely host a wide range of other individuals beyond students, faculty, and staff such as short-term contract workers, athletic teams, research collaborators, family members, guests, and the general public. Including temporary visitors in an IHE vaccination mandate is challenging legally and practically. With such visitors on campus for a limited time, institutions may have to rely on other public health protections such as masking, social distancing, and real-time testing in some cases (e.g., athletics).

4. Listing Qualifying Vaccines

Acceptance of COVID-19 vaccines currently available in the USA for the purposes of IHE mandates should be relatively noncontroversial. Each vaccine has been evaluated, widely administered, and monitored by the FDA and CDC. Each vaccine has also proven highly efficacious in real-world applications. More challenging is deciding what vaccines should qualify when administered to international students and others outside the USA. Multiple COVID-19 vaccines available globally are not authorized or approved by FDA or CDC for domestic use. IHEs may need to consult experts on the acceptability of COVID-19 vaccines recognized by the World Health Organization (WHO) and accorded final status through its regularly updated emergency use listing/prequalification process.³⁰

5. Supporting Vaccine Access and Knowledge

Adequate access to vaccines on college or university campuses is key to successful implementation of vaccine mandates. Offering a choice of free COVID-19 vaccines at convenient times, on- and off-campus, is crucial. To support health equity, IHEs must also address the concerns of persons from historically disadvantaged communities; for some individuals, vaccine hesitancy may arise from past research abuses and institutional distrust. Ensuring ready access, creating tailored educational materials, establishing peer hotlines, committing to transparency in communications, and enlisting trusted ambassadors from the full range of subpopulations within the college or university community will promote inclusion and uptake of vaccines.³¹

30 See WHO, Status of COVID-19 Vaccines Within WHO EUL/PQ Evaluation Process, Oct. 20, 2021, https://extranet.who.int/pqweb/sites/default/files/documents/Status_COVID_VAX_20Oct2021.pdf (accessed Dec. 10, 2021); Lawrence O. Gostin, Jana Shaw & Daniel A. Salmon, *Mandatory SARS-CoV-2 Vaccinations in K-12 Schools, Colleges/Universities, and Businesses*, 326 JAMA 25 (2021); see also SAFER FED. WORKFORCE TASK FORCE, *supra* note 7, at 4 [‘For purposes of this Guidance, people are considered fully vaccinated if they have received COVID-19 vaccines currently approved or authorized for emergency use by [FDA] . . . or COVID-19 vaccines that have been listed for emergency use by [WHO] (e.g., AstraZeneca/Oxford)’]; Dep’t of Lab, Occupational Safety and Health Admin. (OSHA), COVID-19 Vaccination and Testing; Emergency Temporary Standard, 86 Fed. Reg. 61,402 (Nov. 5, 2021) (to be codified at 29 C.F.R. pts. 1910, 1915, 1917, 1918, 1926, 1928), available at <https://www.federalregister.gov/documents/2021/11/05/2021-23643/covid-19-vaccination-and-testing-emergency-temporary-standard> (accessed Dec. 10, 2021), at 476 (defining ‘Fully vaccinated’ with reference to FDA and WHO).

31 See generally CDC, *supra* note 5.

6. Documenting Vaccine Status

Lacking a national approach, documentation of vaccination status is not easy. Existing IHE student vaccination requirements for other communicable conditions (e.g., mumps, measles, and rubella) provide one model but may allow submission of high school vaccination records that do not include COVID-19 vaccinations.³² Documentation methods for university health care workers subject to annual flu or other vaccination requirements offer another approach but may rely on most vaccinations being administered on site. Developing a unified approach across students, faculty, and staff may promote efficiency and control costs.

Documentation may also include self-attestation of vaccination using online forms, uploading an image of one's CDC vaccination card, accessing vaccination certificates through CDC's Vaccine Administration Management System, utilizing digital drivers' licenses to upload vaccination information, submitting a printout from the state Immunization Information System, or using online 'apps' to validate vaccination.³³ Some states like California and New York have developed robust, privacy-sensitive apps;³⁴ Florida, Texas, and 19 other states actually prohibit 'vaccine passports'.³⁵ A call for federal standards to encourage harmonization across states has not succeeded,³⁶ although federal vaccine mandates provide some national standards.³⁷

None of these documentation methods are foolproof. Lax requirements for documentation like self-attestation may be easy to implement but are vulnerable to users reporting incomplete or false information. Random spot checks can lower these risks but require time and effort. More extensive requirements, such as posting CDC vac-

32 See, e.g., MINN. STAT. § 135A.14 (2) (2021).

33 See, e.g., *Latest Guidance Addresses Documenting Vaccination, Other Topics*, FEDWEEK (Sept. 21, 2021), <https://www.fedweek.com/fedweek/latest-guidance-addresses-documenting-vaccination-other-topics/> (accessed Dec. 10, 2021); Tom Frieden, *I Ran the C.D.C. Here's How to Prove that Americans Are Vaccinated*, N.Y. TIMES (Sept. 21, 2021), <https://www.nytimes.com/2021/09/21/opinion/cdc-coronavirus-vaccine.html> (accessed Dec. 10, 2021).

34 See Gostin, Shaw & Salmon, *supra* note 30.

35 See NASHP, *supra* note 12.

36 See Frieden, *supra* note 33.

37 See SAFER FED. WORKFORCE TASK FORCE, *supra* note 7, at 5–6 ("The covered contractor must review its covered employees' documentation to prove vaccination status. Covered contractors must require covered contractor employees to show or provide their employer with one of the following documents: a copy of the record of immunization from a health care provider or pharmacy, a copy of the COVID-19 Vaccination Record Card . . . , a copy of medical records documenting the vaccination, a copy of immunization records from a public health or State immunization information system, or a copy of any other official documentation verifying vaccination with information on the vaccine name, date(s) of administration, and the name of health care professional or clinic site administering vaccine. Covered contractors may allow covered contractor employees to show or provide to their employer a digital copy of such records, including, for example, a digital photograph, scanned image, or PDF of such a record."); Dep't of Lab., Occupational Safety and Health Admin. (OSHA), COVID-19 Vaccination and Testing; Emergency Temporary Standard, 86 Fed. Reg. 61,402 (Nov. 5, 2021) (to be codified at 29 C.F.R. pts. 1910, 1915, 1917, 1918, 1926, 1928), available at <https://www.federalregister.gov/documents/2021/11/05/2021-23643/covid-19-vaccination-and-testing-emergency-temporary-standard> (accessed Dec. 10, 2021), at 61,522–23, 61,552–53 (stating what proof of vaccination will suffice); Dep't of Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs. (CMS), Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61,555 (Nov. 5, 2021) (to be codified at 42 C.F.R. pts. 416, 418, 441, 460, 482, 483, 484, 485, 486, 491, 494), available at <https://www.federalregister.gov/documents/2021/11/05/2021-23831/medicare-and-medicare-programs-omnibus-covid-19-health-care-staff-vaccination> (accessed Dec. 10, 2021), at 61,572, and in scattered sections starting at 61,616 (addressing documentation).

ination cards (despite issues concerning their veracity), can increase data reliability. ‘Apps’ that pull information directly from state Immunization Information Systems may help assure accuracy but can be tricky for some individuals to navigate and are not universally available.

Regardless of the documentation method, collecting enough information to ascertain when individuals were inoculated and with what vaccine may prove important to assess the community’s level of protection. Evidence has emerged that vaccine effectiveness appears to diminish over time. Additional doses or boosters are specifically authorized. In September 2021, CDC initially recommended Pfizer vaccine boosters for older persons and those at heightened risk.³⁸ CDC subsequently expanded eligibility to others.³⁹ Documentation also requires a stringent security system that protects individual privacy and confidentiality through access, use, and disclosure limitations based on existing health information privacy laws and privacy training for those with authorized access.

7. Delimiting and Documenting Exemptions

Vaccine mandates routinely allow medical exemptions for individuals whose physician attests they cannot safely take the vaccine. Federal and state constitutions and statutes, disability protections (e.g., Americans with Disabilities Act), and regulatory guidance [e.g., from the Equal Employment Opportunity Commission (EEOC)] firmly support this exemption⁴⁰ based on identified contraindications, such as a severe allergic reaction to the vaccine or any ingredient. To eliminate efforts to game the system, IHEs should seek expert assessment of claims to medical exemptions to distinguish between medically sound and unsupported claims.

More debate surrounds religious exemptions even though no major religion in the USA opposes COVID-19 vaccination.⁴¹ To date, the US Supreme Court has not

38 CTRS. FOR DISEASE CONTROL AND PREVENTION (CDC), INTERIM CLINICAL CONSIDERATIONS FOR USE OF COVID-19 VACCINES CURRENTLY APPROVED OR AUTHORIZED IN THE UNITED STATES (last updated Dec. 10, 2021), <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Contraindications> (accessed Dec. 10, 2021).

39 *Id.*; CTRS. FOR DISEASE CONTROL AND PREVENTION (CDC), *CDC Expands Eligibility for COVID-19 Booster Shots*, Oct. 21, 2021, <https://www.cdc.gov/media/releases/2021/p1021-covid-booster.html> (accessed Dec. 10, 2021); CTRS. FOR DISEASE CONTROL AND PREVENTION (CDC), *COVID-19 BOOSTER SHOTS*, updated Dec. 9, 2021, <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html> (accessed Dec. 10, 2021).

40 See Reiss & DiPaolo, *supra* note 11; Mark A. Rothstein, Wendy E. Parmet & Dorit Rubinstein Reiss, *Employer-Mandated Vaccination for COVID-19*, 111 AM. J. PUB. HEALTH 1061 (2021). Federal vaccine mandates announced pursuant to the White House plan released Sept. 9, 2021, allow medical exemptions. See THE WHITE HOUSE PATH OUT OF THE PANDEMIC, *supra* note 6; SAFER FED. WORKFORCE TASK FORCE, *supra* note 7; Dep’t of Lab., Occupational Safety & Health Admin. (OSHA), *COVID-19 Vaccination and Testing; Emergency Temporary Standard*, 86 Fed. Reg. 61,402, available at <https://www.federalregister.gov/documents/2021/11/05/2021-23643/covid-19-vaccination-and-testing-emergency-temporary-standard> (accessed Dec. 10, 2021); Dep’t of Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs. (CMS), *Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination*, 86 Fed. Reg. 61,555, available at <https://www.federalregister.gov/documents/2021/11/05/2021-23831/medicare-and-medicare-programs-omnibus-covid-19-health-care-staff-vaccination> (accessed Dec. 10, 2021).

41 See Ruth Graham, *Vaccine Resisters Seek Religious Exemptions. But What Counts as Religious?* N.Y. TIMES, Sept. 11, 2021, updated Sept. 15, 2021, <https://www.nytimes.com/2021/09/11/us/covid-vaccine-religion-exemption.html> (accessed Dec. 10, 2021).

constitutionally required respect for religious exemptions to vaccine requirements under First Amendment principles. On October 29, 2021, the Court declined to consider a legal challenge to Maine's COVID-19 vaccine mandate applying to health care workers which did not include a religious exemption.⁴² Maine and five other states (California, Connecticut, Mississippi, New York, and West Virginia) do not allow religious exemptions to vaccine requirements.⁴³ Apart from constitutional considerations, federal and state statutes (including Religious Freedom Restoration Acts), regulations (e.g., EEOC), and emergency orders may protect workplace and student religious objections.⁴⁴ Public colleges and universities, in particular, should ensure that their vaccine mandates apply neutrally across all religions and allow exemptions where required by law.⁴⁵

The Supreme Court may be poised to reconsider affirmative protections for religious exemptions to vaccine requirements,⁴⁶ consistent with its prior decisions limiting social distancing measures impacting religious institutions.⁴⁷ If the Court constitutionally assures religious exemptions to vaccine mandates, a greater array of students, faculty, and staff may seek them in light of the Court's broad recognition of what constitutes protected religious beliefs.⁴⁸ More extensive uptake of religious exemptions to COVID-19 vaccine requirements risks future outbreaks among campus populations featuring greater numbers of unvaccinated persons. To limit legal challenges and potential outbreaks, documentation of religious exemptions may be restricted to respondents' attestation or notarized statement that they have a sincerely held religious objection.⁴⁹

The availability of an exemption based on nonreligious conscientious objection or personal belief varies by state.⁵⁰ IHEs should consult legal counsel regarding state law,

42 Pete Williams, *Supreme Court Declines to Block Vaccine Mandate for Health Workers in Maine*, NBC NEWS, Oct. 29, 2021, <https://www.nbcnews.com/politics/supreme-court/supreme-court-declines-block-vaccine-mandate-health-workers-maine-n1282757> (accessed Dec. 10, 2021).

43 NAT'L CONF. OF STATE LEGISLATURES (NCSL), *States with Religious and Philosophical Exemptions From School Immunization Requirements*, Nov. 22, 2021, <https://www.ncsl.org/research/health/school-immunization-exemption-state-laws.aspx> (accessed Dec. 10, 2021).

44 See Reiss & DiPaolo, *supra* note 11; Rothstein, Parmet & Reiss, *supra* note 40. Federal vaccine mandates announced pursuant to the White House plan released Sept. 9, 2021, recognize religious exemptions. See the mandates cited in note 40 *supra*.

45 Reiss & DiPaolo, *supra* note 11.

46 See Rothstein, Parmet & Reiss, *supra* note 40; Michelle M. Mello & Wendy E. Parmet, *Public Health Law After Covid-19*, 385 NEW ENG. J. MED. 1153 (2021); Wendy Parmet, *A Dangerous Legal Battle Over Vaccine Mandates Will Continue*, N.Y. TIMES (Oct. 31, 2021), <https://www.nytimes.com/2021/10/31/opinion/supreme-court-vaccine-mandates-covid.html> (accessed Dec. 10, 2021).

47 See James G. Hodge, Jr., & Emily Carey, *Charting the Legality of Religious-based Exemptions to COVID-19 Vaccinations*, BERKLEY F. (Feb. 16, 2021), <https://berkeleycenter.georgetown.edu/responses/charting-the-legality-of-religious-based-exemptions-to-covid-19-vaccinations> (accessed Dec. 12, 2021).

48 See Mello & Parmet, *supra* note 46.

49 See Reiss & DiPaolo, *supra* note 11. Some states and IHEs require a notarized statement to qualify for a religious exemption. See, e.g., MINN. STAT. § 135A.14 (3)(b) (2021); Josh Verges, *Student Seeking Waiver from Vaccine Mandate Should Claim Religious Objections*, UMN Says in Lawsuit, Twin Cities.com, PIONEER PRESS (Oct. 6, 2021), updated Oct. 12, 2021, <https://www.twincities.com/2021/10/06/student-seeking-waiver-from-vaccine-mandate-should-claim-religious-objections-umn-says-in-lawsuit/> (accessed Dec. 11, 2021).

50 IMMUNIZATION ACTION COAL., *State Information: Exemptions Permitted for State Immunization Requirements*, updated May 4, 2021, reviewed May 28, 2021, <https://www.immunize.org/laws/exemptions.asp> (accessed Dec. 10, 2021); NCSL, *supra* note 43.

including the availability and scope of this exemption and what documentation can be requested to support the claim.

8. Accommodating Exemptions and Requiring Preventive Measures

Available exemptions coupled with vaccine hesitancy and resistance present challenges for IHEs seeking to design effective COVID-19 vaccine mandates. Some IHE COVID-19 vaccination mandates are stated in the alternative (either get vaccinated or be subject to measures such as regular testing and required masking).⁵¹ Other IHEs require vaccination as an outright condition of in-person student enrollment.⁵² In accommodating exemptions, the combination of public health measures needed may depend on the exposure risks. Campuses experiencing significant outbreaks may need greater protections. One university that reported >300 cases in the first week of classes, despite a vaccination mandate and high compliance, suspended indoor dining and allowed remote undergraduate classes for 2 weeks.⁵³ Another college reported 50 active cases at the end of the semester, although ‘99 percent of the student body was fully vaccinated’; in response, the college moved to remote instruction, urged students to leave campus, and said that boosters would ‘be required by mid-February.’⁵⁴ Mask mandates, increased surveillance testing, contact-tracing, and temporary exclusion of unvaccinated individuals from in-person activities on campus during outbreaks may also be considered.

9. Responding to Noncompliance and False Statements

Colleges and universities may face student, faculty, or staff failure to comply in a timely and truthful way with system requirements pursuant to vaccination mandates. Clearly stating the deadlines for compliance and consequences of refusals (when no exemption is sought) and false statements will provide notice and communicate institutional commitment to public health goals as well as help insulate against potential liability claims in the event outbreaks arise in the future. Some institutions have already disenrolled students for wrongful noncompliance.⁵⁵ In the *Klaassen* case, Indiana University offered options including a leave of absence.⁵⁶ Ultimately, IHEs have to consider how

51 The mandate imposed by Indiana University and litigated in *Klaassen* placed stringent restrictions on unvaccinated students, but it allowed multiple plaintiffs religious exemptions which then afforded them the alternative of testing, masking, and quarantine. See *Klaassen*, 2021 WL 3073926, at *6 (‘If not vaccinated, students are not permitted on campus, their emails and university accounts are suspended, and their access cards are deactivated. . . . For those who receive exemption from vaccination, . . . [they] must participate in more frequent mitigation testing, quarantine if exposed to someone who has tested positive for COVID-19, wear a mask in public spaces, and return to their permanent address or quarantine if there is a serious outbreak of COVID-19. . . .’).

52 See Lindsay Schnell, *More Colleges Are Requiring the COVID-19 Vaccine. Some Are Starting to Kick Out Unvaccinated Students*, USA TODAY (Aug. 24, 2021), updated Aug. 25, 2021, <https://www.usatoday.com/story/news/education/2021/08/24/some-colleges-and-universities-kicking-unvaccinated-students-out-school/5579106001/> (accessed Dec. 10, 2021).

53 Kate Murphy, *Duke Sets New Campus Restrictions After Rise in COVID Cases Among Vaccinated Students*, NEWS & OBSERVER, updated Aug. 31, 2021, <https://www.newsobserver.com/news/local/education/article253851373.html> (accessed Dec. 10, 2021).

54 Amelia Nierenberg, *Middlebury College in Vermont Moves to Remote Instruction Amid an Outbreak*, N.Y. TIMES (Dec. 9, 2021), updated Dec. 10, 2021, <https://www.nytimes.com/live/2021/12/09/world/omicron-variant-covid#middlebury-college-moves-to-remote-instruction-amid-outbreak> (accessed Dec. 10, 2021).

55 Schnell, *supra* note 52.

to achieve public health goals while avoiding unnecessary punitive actions. Conferring with institutional legal counsel may be needed to ensure that enforcement of vaccine mandates comports with applicable law and the institution's policies, tenure codes, labor contracts, and core values.

10. Collecting Data, Making Adjustments, and Terminating the Mandate

Colleges and universities adopting a vaccine mandate need to determine what data and metrics will be used to assess the effectiveness of the mandate and need for additional measures to promote public health and safety. Even after a vaccine mandate is designed and implemented with high levels of compliance, IHEs can experience outbreaks that call for consideration of additional, layered measures to prevent infection and illness.⁵⁷ Data are equally crucial to assess when the threat has subsided and requirements can be modified or lifted. Ascertaining costs associated with mandates may be needed to justify potential federal or state reimbursements and plan for future crises.

III. DESIGNING SUCCESS

Crafting vaccine mandates for IHEs in a divisive and debilitating pandemic can be daunting. Though colleges and universities have long required student vaccinations for attendance, non-medical faculty and staff have not faced similar requirements. Assuming a decision has been made to mandate COVID-19 vaccination, IHE leaders should address 10 key questions to generate a coherent mandate contributing to campus safety and confidence rather than a poorly conceived failure. IHEs should rely on interdisciplinary expertise, collect data, be transparent, embrace feedback, and steadily refine their approach to implement vaccine mandates successfully.

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Conflicts of Interest

The authors have no financial, personal, academic, or other conflicts of interest in the subject matter discussed in this article. The views expressed are those of the authors and not their institutions.

56 *Klaassen*, 2021 WL 3073926, at *1, *25, *43.

57 *See* Murphy, *supra* note 53.