LEGAL SERVICES

DIVISION OF LEGAL AND RESEARCH SERVICES
LEGISLATIVE AFFAIRS AGENCY
STATE OF ALASKA

(907) 465-2450
LAA.Legal@akleg.gov
120 4th Street, Room 3

State Capitol
Juneau, Alaska 99801-1182
Deliveries to: 129 6th St., Rm. 329

MEMORANDUM April 5, 2021

Pre Supreme Court Decision

SUBJECT: Vaccine liability (Work Order No. 32-LS0463)

TO: Senator Lora Reinbold

FROM: Sandon M. Fisher
Legislative Counsel
-and-
Emily Nauman
Deputy Director

You have asked several questions related to vaccines, each is addressed below.

Does the state have "right to try" legislation? Right to try legislation was enacted in the state under HB 43 from the 30th Legislature. The right to try legislation allows physicians to prescribe investigational drugs or other products to terminally ill patients in certain situations and also limits the liability of the physicians, manufacturers, importers, distributors and distributors who prescribe, transport and administer the investigational drugs or products.[1]

Specifically, AS 08.64.367(c) permits a physician to prescribe, without being subject to disciplinary action, "an investigational drug, biological product, or device, or provid[e] related treatment . . . " in order to sustain the life of a patient who has a terminal illness, is unable to participate in a clinical trial, and has considered approved treatment options and given informed consent.[2] HB 43 also added AS 09.65.325; that statute provides that a

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[1] *See* AS 08.64.367(c); AS 09.65.325.

[2] Under AS 08.64.367(d)(1),

> "investigational drug, biological product, or device" means a drug, biological product, or device that has successfully completed Phase 1 studies of clinical trials for investigation and remains in ongoing clinical trials under Phase 2 or Phase 3 or is in the new drug application process following Phase 3 of clinical trials, but has not been approved for general use by the United States Food and Drug Administration[.]

Under AS 08.64.367(d)(2) "terminal illness" means a disease that, without life-sustaining procedures, will result in death in the near future or a state of permanent unconsciousness

person who administers an investigational drug, biological product, or device, or provides related treatment to a terminally ill person, and a manufacturer, importer, or distributor of the investigational drug, biological product, or device has immunity from damages for injury or death if the person was acting in good faith and exercising reasonable care.

Does Alaska law require informed consent to administer a vaccine? The Alaska State Medical Board has adopted the American Medical Association's *Code of Medical Ethics*.[3] The *Code of Medical Ethics* declares that "[i]nformed consent to medical treatment is fundamental in both ethics and law."[4] The *Code of Medical Ethics* goes on to detail how physicians should obtain informed consent:

> The process of informed consent occurs when communication between a patient and physician results in the patient's authorization or agreement to undergo a specific medical intervention. In seeking a patient's informed consent (or the consent of the patient's surrogate if the patient lacks decision-making capacity or declines to participate in making decisions), physicians should:
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> (A) Assess the patient's ability to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision.
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> (B) Present relevant information accurately and sensitively, in keeping with the patient's preferences for receiving medical information. The physician should include information about:
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> i. the diagnosis (when known);
>
> ii. the nature and purpose of recommended interventions;
>
> iii. the burdens, risks, and expected benefits of all options, including forgoing treatment.
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> (C) Document the informed consent conversation and the patient's (or surrogate's) decision in the medical record in some manner. When the patient/surrogate has provided specific written consent, the consent form should be included in the record.[5]

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from which recovery is unlikely.

[3] *State Medical Board Frequently Asked Questions*, available at: https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/StateMedicalBoard/FrequentlyAskedQuestions.aspx#ethicsCode (last accessed Feb. 15, 2021).

[4] *American Medical Association, Code of Medical Ethics 2.1.1*, available at: https://www.ama-assn.org/system/files/2019-06/code-of-medical-ethics-chapter-2.pdf (last accessed March 31, 2021).

[5] *Id.*

Alaska's Code of Civil Procedure assigns health care providers liability for failure to obtain informed consent. AS 09.55.556(a) provides:

> (a) A health care provider is liable for failure to obtain the informed consent of a patient if the claimant establishes by a preponderance of the evidence that the provider has failed to inform the patient of the common risks and reasonable alternatives to the proposed treatment or procedure, and that but for that failure the claimant would not have consented to the proposed treatment or procedure.

In analyzing an informed consent claim, the court will consider the patient's perspective to determine the scope of the health care provider's duty:

> We have previously recognized that '[t]he informed consent doctrine is based on the principle that every human being of adult years and sound mind has a right to determine what shall be done to his or her own body.' Alaska Statute 09.55.556 describes the basic duty to obtain informed consent by requiring that a health care provider 'inform the patient of the common risks and reasonable alternatives to the proposed treatment or procedure.' We have emphasized that the scope of this duty must be viewed from the patient's perspective, not the doctor's; in keeping with this view, we have construed the statute to 'measure [ ] the physician's duty of disclosure by what a reasonable patient would need to know in order to make an informed and intelligent decision.'[6]

Thus, in general, a health care provider can be held liable for failure to obtain informed consent, if, but for that failure, the patient would not have consented to the proposed treatment or procedure. However, as discussed below, there are specific provisions in federal law relating to informed consent, claims for vaccine-related injuries, and protection from liability under some circumstances that must be considered.

The Department of Health and Social Services provides on its website a COVID-19 vaccine informed consent form for the use of dispensing clinics.[7]

Is the COVID-19 vaccine an experimental vaccine? Currently, there are three COVID-19 vaccines approved for use in the United States. It is my understanding that the vaccines currently being administered were approved by the U.S. Food and Drug Administration (FDA) through the issuance of an emergency use authorization (EUA). For the FDA to

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[6] *Harrold v. Artwohl*, 132 P.3d 276, 280 (Alaska 2006) (footnotes omitted).

[7] DHSS COVID 19 Consent Form, accessed on March 3, 2021 at: http://dhss.alaska.gov/dph/Epi/id/SiteAssets/Pages/HumanCoV/COVID_Vaccine_Consent.pdf.

issue an EUA the secretary of the Department of Health and Social Services must have declared an applicable public health emergency.[8]

Can a manufacturer, healthcare provider, or the state be held liable if there are adverse reactions to a vaccine? The federal government is primarily responsible for regulating vaccines and operates the National Vaccine Program, which has two relevant components: the National Vaccine Injury Compensation Program (VICP) and the Countermeasures Injury Compensation Program (CICP). Under federal law COVID-19 vaccines are classified as "countermeasures[9] The Health Resources and Services Administration publishes a comparison of the two programs,[10] but for purposes of this work order the main point is that the VICP covers vaccines routinely administered to children and pregnant women while the CICP covers COVID-19 vaccines.

For vaccines administered under the VICP, a federal statute explicitly tasks the Director of the National Vaccine Program with being responsible for the "safety and efficacy testing of vaccines."[11] Similarly, another federal statute declares that any person pursuing compensation under the VICP for vaccine-related injury or death must file their claim in the United States Court of Federal Claims.[12] And yet a third statute instructs the Director of the National Vaccine Program to "make health practitioners and the public aware of potential adverse reactions and contraindications to vaccines."[13] As part of that mandate, the federal government creates and disseminates "vaccine information materials" for all vaccines covered by the VICP.[14] The material must contain "in understandable terms:" (1)

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[8] 21 U.S.C. § 360bbb-3.

[9] *See* 42 U.S.C. § 247d-6d(i)(1) and *Public Readiness and Emergency Preparedness Act*, Public Health Emergency, https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx (last accessed January 26, 2021). For the definition of "vaccine" in the Alaska Statutes, see AS 18.09.990(11).

[10] Available at *Comparison of Countermeasures Injury Compensation Program (CICP) to the National Vaccine Injury Compensation Program (VICP)*, Health Resources and Services Administration, https://www.hrsa.gov/cicp/cicp-vicp (last accessed January 26, 2021).

[11] 42 U.S.C. § 300aa-2(a)(3).

[12] 42 U.S.C § 300aa-11(a)(1). A person may file a civil suit filed in state court against a vaccine administrator or manufacturer, but the damages would, generally speaking, be limited to $1,000. *Id.* at § 300aa-11(a)(2)(A).

[13] 42 U.S.C. § 300aa-2(a)(6).

[14] 42 U.S.C. § 300aa-26(a).

a concise description of the vaccine's benefits, (2) a concise description of the risks associated with the vaccine, (3) "a statement of the availability of the National Vaccine Injury Compensation Program"; and (4) any other information the Secretary of Health and Human Services deems relevant.[15] Each health care provider administering a VICP-covered vaccine must provide a copy of this material "to the legal representatives of any child or to any other individual to whom such provider intends to administer such vaccine . . . , supplemented with visual presentations or oral explanations, in appropriate cases."[16] The materials "shall be provided prior to the administration of such vaccine."[17]

Turning to the CICP (which, again, covers the COVID-19 vaccines), federal law declares that people administering a "countermeasure" "shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration" of the countermeasure.[18] Another federal statute declares that no state can enact a law that contradicts CICP statutes:

> **Preemption of State law**
> During the effective period of a declaration under subsection (b), or at any time with respect to conduct undertaken in accordance with such declaration, no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that--
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> > (A) is different from, or is in conflict with, any requirement applicable under this section; and
> > (B) relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this chapter, or under the Federal Food, Drug, and Cosmetic Act.[19]

Consequently, it is unlikely that a manufacturer, health care provider, or the state can be

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[15] 42 U.S.C. § 300aa-26(c).

[16] 42 U.S.C. § 300aa-26(d).

[17] *Id.*

[18] 42 U.S.C. §§ 247d-6d(a)(1) and (i)(2).

[19] 42 U.S.C. § 247d-6d(b)(8).

held liable for adverse reactions to a COVID-19 vaccine.

Is the term "vaccine" defined by state law? Yes. The term vaccine is defined for purposes of the statewide immunization program in AS 18.09.990(11):

> "vaccine" means a preparation of killed microorganisms, living attenuated organisms, living fully virulent organisms, or other substances that are administered to humans for the purpose of producing or artificially increasing specific immunity to life-threatening and disabling diseases.

Can an employer require an employee to be vaccinated as condition of employment? It is likely that an employer can require its employees to be vaccinated as a condition of employment. The U.S. Supreme Court has recognized the power of states to place the good of the public over personal liberties in the context of vaccine mandates.[20] Private employers, of course, are not subject to the same standards as the government; however the Court has indicated a willingness to enforce vaccine mandates despite civil liberties challenges. Importantly, it appears the vaccines required in those cases were approved vaccines, not ones dispensed under an EUA. However, that may not ultimately change the analysis.

While neither the U.S. Equal Employment Opportunity Commission (EEOC) nor the U.S. Center for Disease Control and Prevention (CDC) have specifically stated that employers may mandate vaccination, there are indicators that such a mandate would be legally permissible. Most importantly, the EEOC has confirmed that, if the employer can show that based on the unique circumstances of the work environment, a failure to be vaccinated would pose a "direct threat" to the health or safety of other co-workers or third parties with whom they interact, there appears to be support for upholding mandatory vaccination programs.[21] Importantly, the EEOC has also clarified that a direct threat

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[20]Long prior to the adoption of many federal employment laws, in 1905, the Supreme Court of the United States upheld Massachusetts' decision to mandate the vaccination of all citizens in response to the smallpox epidemic. *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11 (1905). In the years since, several courts—state and federal—have upheld mandatory influenza vaccine programs in the health care setting and in the context of assisted living facilities, even when the employee objected to the vaccination under state or federal employment law.

[21] The employer must show that an unvaccinated employee would pose a direct threat due to 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." The EEOC requires employers to conduct an individualized assessment to determine whether a "direct threat" exists, and has identified the following four factors to consider: (1) the duration of the risk; (2) the nature and severity of the potential harm; (3) the likelihood that the potential harm will occur; and (4) the imminence of the potential harm. EEOC

would include a determination that an unvaccinated individual will expose others to the virus at the worksite.[22]

The Occupational Safety and Health Act (OSHA) may also allow an employer to require vaccination. A rule known as the general duty clause, in sec. 5(a)(1) of the Occupational Safety and Health Act, requires that an employer keep its workplace free from any recognized hazards that cause or are likely to cause death or serious physical harm to employees.[23] To cite an employer for a general duty clause violation, the Secretary of the Department of Labor must demonstrate that (1) the employer failed to keep its workplace free from a hazard to which employees were exposed; (2) the hazard is recognized; (3) the hazard was likely to cause death or serious physical harm; and (4) there was a feasible and economically viable way to correct the hazard. Because COVID-19 is recognized as a hazard that is likely to cause death or serious physical harm, and vaccinations that have been shown to be safe and effective are readily available, an employer could cite the OSHA general duty cause in defense of a policy requiring employees to be vaccinated before entering the workplace.

Without a state or federal court case that has clearly resolved this issue the EEOC guidance may be the best available resource at present. This is a rapidly changing area of law, and the information in this memorandum may become obsolete.

If we may be of further assistance, please advise.

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- struck down OSHA Not Gives Authority

Supreme Court Rules in favor of individual rights

Struck illegal E.O. Down

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guidance issued December 16, 2020, available at https://www.eeoc.gov/ newsroom/eeoc-issues-updated-covid-19-technical-assistance-publication-3.

[22] If an employer determines that an individual who cannot be vaccinated due to disability poses a direct threat at the worksite, the employer must then determine whether it can provide a reasonable accommodation (an accommodation that does not cause undue hardship to the employer) that would eliminate or reduce this risk so the unvaccinated employee does not pose a direct threat. *Id.*

[23] 29 U.S.C. § 654(a)(1).