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March 1, 2022

Dr. Umair Shah, Secretary
Department of Health
Cheryl Strange, Secretary
Department of Corrections

Re: Clallam Bay Correctional Center Error

Dear Secretaries Shah and Strange:

On February 11, 2022, the Department of Corrections announced its staff had erroneously injected the monoclonal antibody known as REGEN COV into at least twenty-four people at Clallam Bay Correctional Center on or about February 10, 2022. DOC's press release about this error is attached. It may be that the Department of Health has already launched an investigation on its own initiative or at DOC's request, but if not, DOH must do so.[1]

We are copying the Pharmacy Quality Assurance Commission[2] because it may want to independently investigate what appear to be three errors with respect to this incident:

- Storage of medication error
- Dispensing of medication error
- Administration of medication error

DOH has licensing authority over health care staff at DOC facilities. DOH has the statutory responsibility to investigate instances where licensed health care staff may have engaged in unprofessional conduct. Unprofessional conduct is broadly defined and includes:

> Incompetence, negligence, or malpractice which results in injury to a patient or which creates an unreasonable risk that a patient may be harmed.

RCW 18.180.130(4).[3]

[1] We note that REGEN COV is not ordinarily an injectable medication. It is usually administered IV.

[2] We note that Dr. William Hayes is a Commission Board member. Dr. Hayes should recuse himself from any aspect of an investigation or review of these incidents. We assume that Board Member Hayes is the same Dr. Hayes that is employed by DOC. If this is not the case, we withdraw any objection to Dr. Hayes' participation.

[3] This may not be the only category of unprofessional conduct a DOH investigation could reveal. An investigation could reveal other instances of unprofessional conduct as defined in the statute.

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While DOC was quick to claim that no one at CBCC who was injected with REGEN COV was "seriously" harmed, that alone does not forgive the error or relieve DOH of its duty to investigate. The mistake described in the press release appears to be a textbook description of the creation of "an unreasonable risk that a patient may be harmed" even if DOH discovers that no patient *was* harmed.

Moreover, as of January 24, 2022, the FDA imposed limits on REGEN COV's use because it is not effective against the Omicron variant. In other words, not only did DOC staff inject the CBCC victims with a drug by mistake, but they were injected with a drug that was not currently FDA-authorized for administration.[4]

DOH should make an independent determination that no CBCC victim was harmed. Since nearly all of the victims of this error are incarcerated and at least one victim is a DOC employee and thus dependent on DOC for their livelihood, they are especially vulnerable.

This is not the first COVID-19 vaccine-related mishap in a Washington prison. On or about April 30, 2021, DOC staff administered expired Moderna vaccine to ten people at the Monroe Correctional Complex. It may be that DOH investigated that error, but if not, DOH should do so now.[5]

DOC being permitted to investigate its staff *alone* is unacceptable. DOH is the sole authority empowered to take action against the license of any licensed health care professional involved in these incidents. DOC might decide, for example, to discharge a health care professional involved in these errors, but without a DOH investigation, a person who had engaged in unprofessional conduct could simply move on to employment in another health care setting.

[4] The FDA's January 24, 2022 press statement said this about REGEN COV:

> In light of the most recent information and data available, today, the FDA revised the authorizations for two monoclonal antibody treatments – bamlanivimab and etesevimab (administered together) and REGEN-COV (casirivimab and imdevimab) – to limit their use to only when the patient is likely to have been infected with or exposed to a variant that is susceptible to these treatments.
>
> Because data show these treatments are highly unlikely to be active against the omicron variant, which is circulating at a very high frequency throughout the United States, these treatments are not authorized for use in any U.S. states, territories, and jurisdictions at this time. In the future, if patients in certain geographic regions are likely to be infected or exposed to a variant that is susceptible to these treatments, then use of these treatments may be authorized in these regions.

https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-limits-use-certain-monoclonal-antibodies-treat-covid-19-due-omicron

[5] The Pharmacy Quality Assurance Commission may likewise wish to investigate this incident.

Please advise us whether DOH will conduct investigations into both incidents.

Sincerely,

COLUMBIA LEGAL SERVICES

/s/Amy Crewdson
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Tony Gonzalez
Laurel Jones
Nick Straley

Attorneys at Law

Attachment
cc: Pharmacy Quality Assurance Commission