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November 16, 2009

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Comments on the Nebraska Department of Correction Services proposed Execution Protocol, Title 69, Nebraska Administrative Code, Chapter 11.

Dear Mr. Green,

We are writing to comment on the Nebraska Department of Correction Services' (NDCS) proposed Execution Protocol. Undersigned Megan McCracken is the Eighth Amendment Resource Counsel for the Death Penalty Clinic. Undersigned Jennifer Moreno is the Clinic's Eighth Amendment Fellow and Staff Attorney. The Clinic created and administers the website, www.lethalinjection.org, and has been involved in lethal injection litigation nationwide.

The following comments do not purport to address all of the deficiencies in the new protocol. We note at the outset that our ability to submit a completely informed comment is restricted by the NDCS's failure to include specific details about many aspects of the execution process and its failure to include information in the rulemaking record, as required by the APA. Accordingly, we do not have all of the information necessary to fully comment on the proposed regulations.

Nebraska Should Remove Pancuronium Bromide and Potassium Chloride from the Execution Protocol

On November 13, 2009, the State of Ohio announced a new lethal injection protocol that uses an intravenous injection of a single anesthetic drug. The new Ohio protocol will no longer use pancuronium bromide, a paralyzing drug, or the excruciatingly painful potassium chloride to execute inmates. With this new protocol, Ohio has taken a significant step towards eliminating the risk that inmates will suffer excruciating pain during executions. The Nebraska protocol calls for the administration of pancuronium bromide and potassium chloride, two very dangerous and unnecessary drugs that should be removed from the protocol.

Administration of pancuronium bromide and/or potassium chloride to a conscious person would be torturous. In an execution by lethal injection performed pursuant to the NDCS' Execution Protocol, there is a risk that the condemned inmate will not be adequately anesthetized by the anesthetic drug and then will experience the pain and suffering caused by pancuronium bromide and potassium chloride. There are many reasons why the first drug could fail to render the inmate deeply anesthetized, but perhaps the most significant is failed or faulty IV access. The safety of an execution by lethal injection rests in large part on the ability of the IV Team to set a proper, functioning IV that delivers the full dose of the anesthetic drug into the inmate's circulation. If the IV is in any way faulty, an incomplete dose could be delivered, and the inmate would not be adequately anesthetized prior to experiencing paralysis and cardiac arrest. To further complicate matters, once the pacuronium has been administered, it becomes extremely difficult to determine whether the inmate has been anesthetized. In contrast, a protocol that does not use pancuronium and potassium poses no risk of excruciating pain and suffering to the condemned inmate, even if the IV is faulty.

As discussed below, there are numerous deficiencies in the execution protocol proposed by Nebraska. These deficiencies are exacerbated by the inclusion of pancuronium bromide and potassium chloride in the lethal injection procedure. The lack of clear training and qualification requirements for the IV team, the failure to include clear instructions on how to carry out many aspects of the execution process, and the lack of contingency planning, among others, all increase the risk that the inmate will be insufficiently anesthetized and suffer immensely.

Nebraska should follow the lead of Ohio and remove pancuronium bromide and potassium chloride from the execution protocol. As shown by Ohio's adoption of a single anesthetic procedure, these dangerous drugs are unnecessary to the execution process and only serve to increase the risk that executions will not be humane.

Execution Team Qualification

The Execution Protocol fails to specify the qualifications required for membership on the execution team. Our primary concern lies with the IV Team, which appears to be responsible for all aspects of the lethal injection procedures. As the September 15, 2009 botched execution attempt of Romell Broom in Ohio made clear, whether a lethal injection execution will be carried out in a manner that ensures that the inmate will not experience grievous pain and suffering depends in large part on the competence of the IV Team. Because the execution protocol requires the administration of pancuronium bromide and potassium chloride, it is crucial that the IV Team be qualified, experienced, and able to set a functioning IV and reliably deliver the anesthetic drug. However, the protocol's qualification requirements for the IV Team are vague and do not require licensure, experience, or formal training.

Although the protocol specifies that members of the IV team shall be "shall have successfully completed training as an emergency medical technician" it does not require that team members be licensed and credentialed EMTs, either currently or at any time in the past. § 004.03. IV team members are also required to have received training in venipuncture, catheter placement, and phlebotomy, among other things, but there is no indication that team members will be formally trained medical professionals (EMTs or otherwise). By the terms of the protocol, IV Team members could be NDCS employees who have received internal instruction. If it is the case that NDCS intends to provide instruction to current employees, instead of selecting licensed medical professionals, the protocol should, at a minimum, specify the qualifications of the trainers to ensure team member are adequately trained. A vague requirement of "training" without specifying what the term actually means is meaningless and does not satisfy the APA's requirement that the proposed regulation provide meaningful elucidation of the agency's plan to effectuate the mandate of the statute.

The protocol also does not require IV members to have current credentials or specific experience performing the tasks required of them during an execution (preparing drugs and syringes, setting IVs, administering drugs), or to perform them as part of their regular jobs. If the members of the IV Team do not regularly perform these activities, they will not possess sufficient skill to perform the tasks reliably and competently during an execution. One need only look to the lethal injection protocols of other states to see examples of team member qualifications that are clear and provide assurances that the personnel carrying out the technical and medical aspects of the procedure are qualified and competent to do so. Protocols in other states typically require at least one year of experience as a doctor, nurse, or EMT and current employment in the relevant medical field. In the absence of this type of specific requirement, the proposed Execution Protocol is deficient and fails to guarantee that the IV team will be qualified to perform executions competently and safely. The procedures should be rewritten to specify the required credentials, skills, training, and experience of the personnel who will be selected for the IV Team.

Finally, the Director of the NDCS has full discretion to appoint and remove members of the IV Team. § 003. However, the Director is not required to have any medical knowledge or training that would qualify him or her to evaluate the competency of medical personnel to carry out executions. This makes it all the more important that the protocol clearly establish the qualification requirements to ensure that member of the IV team are competent.

<u>Execution Team Duties</u>

For the reasons stated below, the Execution Protocol is deficient as a guideline for performing executions by lethal injection. It fails to inform members of the Execution Team of the specific steps they must take to carry out the execution safely and appropriately; it lacks contingency plans; and does not specify the chain of command in the event that problems do arise.

A. Crucial information is missing from the Execution Protocol.

The Execution Protocol is missing information that is both basic and crucial, and without which members of the Lethal Injection Team cannot actually carry out an execution. The protocol lacks clear instructions for the preparation of the lethal drugs, provides no information on the type of IV that will be set, and does not provide an adequate standard for the consciousness check.

1. The protocol lacks clear instructions for the preparation of the drugs.

Whether or not an execution by lethal injection will be humane turns on the successful administration of a proper dose of sodium pentothal. The protocol's omission of the directions for preparing this drug is a fundamental flaw and creates great danger for condemned inmates. Lethal injection protocols in many other states contain clear instructions for these procedures. Here, the proposed protocol does not specify the concentration at which the thiopental will be mixed, how many syringes of each drug will be prepared, including how many extra syringes of all three drugs will be prepared, and how the syringes will be labeled and stored from the time of preparation until administration.

If the IV Team prepares the sodium pentothal at too low a concentration, the dose could be too small, and the inmate might not be adequately anesthetized before the second and third drugs are administered and/or might not remain anesthetized throughout the procedure. If the IV Team prepares the sodium pentothal at a concentration that is too high – higher than the standard clinical concentration of 2.5% – the inmate could suffer significant pain upon administration of the drug.

2. The protocol lacks information on the type of IV to be set.

The Execution Protocol is silent on the type of IV the IV Team Leader will set. The protocol directs the Team Leader to "establish a functioning intravenous line capable of administering the lethal substance . . . into a vein of the condemned inmate." § 005.05(4). However, the protocol does not indicate what type of IV to set, how many functioning lines must be set, whether there are preferred sites for IV access and how long the IV team can attempt to set an IV before abandoning the process. As discussed above, IV access is essential to ensuring a humane execution because the line must deliver the anesthetic drug or the inmate will suffer grievously when the second and third drugs are administered. Failing to include such important information in the protocol risks that the IV team will not have sufficient guidelines on the type of IV to set and be forced to make decisions that are outside of their qualifications and experience.

Protocols in other states require execution teams to first attempt to set a peripheral IV and describe the medical training and experience required of the person who will perform the task. As explained above, there is no guarantee in the Execution Protocol that the IV Team Leader will possess medical training and experience. For this reason, if the protocol requires a peripheral IV, there is no assurance that the team will know how

to select an appropriate IV site or to set the IVs using medical procedures. Alternatives to peripheral IV access are placement of a central line in the subclavian or jugular veins or a femoral line in the groin. All three are medical procedures that must be performed by a doctor or specialized nurse. If the NDCS contemplates one of IV access alternatives, the protocol must clarify the level of training and qualifications of the medical personnel who will perform it.

Without information on the type of IV to be set, it is impossible to assess whether NDCS is prepared to obtain IV access in a safe and reasonable manner. The protocol should provide clear guidelines to ensure that the IV Team is not forced to make decisions that exceed their expertise and increase the chance that an execution will be inhumane.

3. The consciousness check standard is inadequate to ensure unconsciousness

After the administration of thiopenthal, the Warden is called upon to "reasonably verify" that the inmate has been rendered unconscious before the IV Team administers the next two drugs. § 005.02(4). This requirement is vague and inadequate to assure that the inmate will be properly anesthetized by the thiopental and not regain consciousness during the execution. The only way to ensure that the inmate remains in a deep state of unconsciousness is to have a person trained and experienced in assessing consciousness monitor the inmate throughout the entire process. Alternatively, the protocol can be revised to remove the paralytic and potassium chloride and eliminate the risk of extreme pain and suffering.

A 3 gram dose of thiopental, if properly delivered into the circulatory system, will render the inmate deeply anesthetized, which is appropriate, given that the next two drugs will paralyze him and then cause cardiac arrest. However, if the thiopental is inadequately delivered the inmate could be unconscious but only lightly anesthetized at the time of the consciousness check. It is crucial that the inmate is rendered deeply unconscious by thiopental, and remains so throughout the administration of pancuronium and potassium until death. If the inmate regains consciousness, the paralytic will mask any signs of pain and suffering caused by the second and third drugs. Only someone with appropriate training and equipment will be able to ensure deep anesthesia and detect signs of consciousness in a paralyzed person and take appropriate steps.

The proposed protocol only requires a consciousness check after the administration of thiopental by the Warden, who is questionably qualified to assess consciousness. As described below, the IV Team Leader trains the Warden, but the protocol does not indicate whether the IV Team Leader is qualified to perform the training or what specific training the Warden receives. The protocol does not require any subsequent monitoring to ensure that the inmate remains unconscious by qualified medical personnel. Without these important safeguards, the protocol is inadequate because it does not ensure that the inmate will be rendered and remain unconscious throughout the entire procedure.

B. The Execution Protocol provides no contingency plans

The Execution Protocol fails to guide the Lethal Injection Team in the event that an execution does not proceed as planned. The omission of contingency planning is a disturbing and unacceptable deficiency in the protocol that places condemned inmates at great risk or pain and suffering. Moreover, it puts the IV Team in the untenable position of having responsibility for an execution, but insufficient information to perform its tasks safely and appropriately.

The protocol acknowledges that problems can arise during an execution and directs the IV Team Leader to "be prepared to correct any issues with respect to the intravenous line or condemned inmate's vascular system," without providing any guidance. § 005.05(7). As discussed above, the qualifications of the IV team are not sufficient to ensure that they are capable of correcting problems as they arise and the protocol should explicitly plan for foreseeable problems.

Numerous things can go wrong during an execution. While several contingencies may have no deleterious effect for the inmate, a few – failed IVs that deliver drugs outside the vein, IV lines that leak or clog, or a failed dose of sodium pentothal – are almost certain to result in extreme anguish.

The September 2009 botched execution attempt of Romell Broom highlights the need to have a contingency plan. There, the execution team struggled for over two hours to find suitable veins in the arms and legs of Broom but were unable to do so. P. Krouse, *Strickland stops execution after team can't access veins*, Cleveland Plain Dealer, Sept. 16, 2009 (Attachment A). The execution was discontinued when Broom was granted a reprieve by Gov. Strickland. Id. The IV access problems in Ohio can happen in any state that uses lethal injection, and the possibility increases when execution personnel are untrained and inexperienced. In addition to IV access, numerous other states have experienced problems with various stages of the lethal injection process. *See generally*, Brief for Michael Morales et al. as Amici Curiae in Support of Petitioners, Baze v. Rees, No. 07-5439, 533 U.S. ___ (2008) (Attachment B).

At a minimum, the Execution Protocol must anticipate the foreseeable contingencies that would lead to pain and suffering for the condemned inmate and provide instructions for how the Lethal Injection Team should respond.

1. IV Access

In addition to providing no information on the type of IV that will be set, the protocol provides no instruction on what to do in the event that IV access is not possible. Section 005.05(2) provides for an assessment of the inmate's veins at least 48 hours prior to the execution. However, the protocol does not indicate what happens if the assessment reveals that the inmate has no good vein sites. Additionally, there is no information on what happens if the IV Team Leader is unable to set a functioning IV line at the start of an execution.

Lethal injection protocols from other states specify placement of two peripheral IV lines as the default for IV access. They call for a vein assessment by a qualified medical practitioner to determine the best sites for the peripheral IVs; the interior elbow (antecubital fossa) is the most common location. As a backup to peripheral IV access, several protocols call for placement of a central or femoral line, but only if medical personnel who are qualified by law and have experience setting such lines are present to perform the procedure.

2. IV Line Failure

The Execution Protocol fails to plan for the foreseeable scenario of IV line failure during an execution. We cannot comment on specific deficiencies in the protocol, because it does not specify the set up of the IV lines, including the length of the line and the position of the inmate. However, there is a risk of line failure and leakage with any setup. This risk increases if the IV lines are lengthy and require extensions in the line. There is also increase risk of failure or line entanglement if the inmate is moved after the IV's are set and the lines are connected. A line could fail because the IV catheter is set improperly in the inmate's veins, creating excessive backpressure in the line. Finally, there is the very real possibility that an IV line will fail for reasons that are not clear, and that the drugs administered through the line simply will not work.

The Execution Protocol does not contemplate or address any of these scenarios. It does not require that someone watch the lines during the administration of the drugs. It does not require that the personnel on the IV Team have experience administering IV drugs and therefore can recognize and troubleshoot a blocked or failed line. It does not require continuous monitoring of the inmate to assure that he remains deeply anesthetized by the thiopental throughout the execution. Additionally, the protocol does not direct the IV Team in the event of complete IV line failure during the execution. Most other protocols we have seen require the setting of two functioning IV lines and detailed instructions of what to do in the event that the primary IV line fails.

IV line failure is extremely problematic because it risks that the anesthetic will be improperly administered, but that the second and third drugs will be delivered, causing extreme pain. As previously stated, if the second and third drugs were removed from the protocol, the effects of a failed IV line would be much less serious and would not risk a torturous execution.

3. IV Catheter Errors

The Checklist also does not address the possibility that the IVs will be set incorrectly or migrate after insertion, resulting in IV catheters that push the drugs into an inmate's flesh rather than his circulatory system. This is a real risk that has resulted in horribly botched executions in other states. The Execution Protocol must put in place procedures that will identify a failed IV (and all of the other contingencies addressed here) and specify what the IV Team should do in response. Additionally, the protocol is

unclear about whether the IV Team Members are in the same room with the inmate and in a position to ensure that the IVs function throughout the process and that the drugs are administered correctly.

C. Unclear Chain of Command

The protocol fails to clearly lay out the chain of command during an execution, which increases the possibility of an ineffective response if problems arise. The protocol states that the Director "shall direct the administration of all substance to the prisoner in accordance with the prisoner" but it is unclear if the Director supervises the administration of the drugs or simply signals for the IV Team Leader to begin, thus turning over the entire procedure to him or her. § 005.01(5). The IV Team Leader is charged with correcting any "issues with respect to the intravenous line or condemned inmate's vascular system", but this is not a clear indication the IV Team Leader is the ultimate decision-maker in the event of differing opinions or unanticipated situations. §005.05(7). Because the protocol does not detail the chain of command, should a problem occur during an execution, no one is empowered to make the immediate and informed decisions necessary to prevent a cruel execution.

D. Conclusion

The Execution Protocol is inadequate because it lacks critical information about the manner in which lethal injections will be administered, and it fails to lay out contingency plan or a clear chain of command for the Execution Team. The problems described above, as well as others, can be addressed through appropriate planning, recruiting and training of appropriate personnel for the IV Team, and redrafting of the protocol. Without these changes, however, the protocol is deficient as a guideline for executions by lethal injection. Finally, by unnecessarily including pancuonium and potassium chloride in the protocol, the consequence of any of the above inadequacies in the protocol are incalculably greater. By employing an anesthetic only procedure, Nebraska could eliminate the risk of one of the above problems resulting in a torturous execution.

<u>Execution Team Training</u>

The Execution Protocol provides insufficient information about Execution Team Member training requirements and the qualification of trainers. Without clear requirements, the protocol cannot guarantee that team members will be engaged in meaningful training activities that prepare them for participation in executions and to deal with foreseeable problems.

The Execution Protocol requires the execution team to train every six months when there is no execution scheduled. § 006.01.01. The protocol does not provide any information about what training activities the team members will be engaged in, who leads the trainings and what their qualifications are, or whether or not team members are evaluated. The protocol allows the IV Team and the Escort Team to train separate from

the Director, Warden and Staff Communicator when no execution has been scheduled. Id. The protocol provides no information on what separate training activities these team members will undertake or whether they will be evaluated.

After an execution has been scheduled, the Execution Team as a whole is required to train together weekly and "engage in one or more drills that in which all members enact their individual responsibilities." § 006.02.01. Again, the protocol is silent on what drills are performed, who supervises or provides training, and whether or not team members are evaluated. However, the protocol does specify that the IV Team does not practice setting IVs or preparing the drugs. § 006.02.01. If members of the IV Team do not perform these tasks as part of their day jobs, which they are not required to do, and are not required to practice them during training sessions, it is possible they do not ever practice these skills. It is unacceptable that the IV Team may not ever set an IV or prepare the drugs until called on to do so during an execution.

Finally, the protocol calls for the IV Team Leader to train the Warden to perform the consciousness check. § 006.02.02. As described above, all we know about the IV Team Leader is that he or she has completed some form of EMT training and training related to various aspects of setting an IV and administering drugs. § 004.03. However, nothing in the protocol indicates that the IV Team Leader is qualified to train another person to assess consciousness.

The Execution Team training requirements in the protocol fail to ensure that team members will be sufficiently trained to competently perform executions because the protocol lacks specific information on training activities, the qualification of individuals providing the training, and whether or not there is an evaluation of Team Member performance. Furthermore, the IV Team is never required to practice the crucial elements of the execution procedure: setting IVs and preparing drugs. These omissions in the protocol increase the chance that the Execution Team will be unprepared to carry out humane executions.

Allowance for Modification to the Protocol

We are troubled that the Execution Protocol grants the Director of the NDCS the authority to modify the protocol. §001. The protocol does not specify the circumstances under which the Director can make changes to the protocol or whether there are any guidelines the Director must follow when making changes. Furthermore, any changes to the protocol would require compliance with the Administrative Procedures Act (APA), which requires that rules and regulations be "adopted in substantial compliance with the provisions of the act." Neb. Rev. Stat. §84-906(2) (2008). These provisions include providing public notice and opportunity for public comment. Neb. Rev. Stat. §84-906.02. It would subvert the APA to permit the Director to make changes to the protocol at any time, for any reason, without compliance with the APA process.

Failure to Comply with the Requirements of the APA

The NDCS has not complied with the requirements of the APA most notably by failing to disclose the actual fiscal impact of the proposed protocol and by failing to include all the required material in the rulemaking record. The APA requires that rules be adopted in "substantial compliance" with the act. Neb. Rev. Stat. §84-906(2) (2008). As a result of these procedural deficiencies, the NDCS has failed to meet this standard and has also hindered the ability of the public to make meaningful comments on the proposed regulation.

A. Failure to disclose the actual fiscal impact of the proposed Execution Protocol

The NDCS' has erroneously claimed that adoption of the proposed regulations will have minimal fiscal impact. The NDCS is required to make an assessment of the estimated economic impact of the proposed regulation on the State agency, political subdivisions, and the regulated public. Neb. Rev. Stat. §§ 84-906.01(2)(h), 84-907.06, 84-907. When the notice of the proposed regulations was published on September 25, 2009, the NDCS declared that the proposed regulations will have no fiscal impact. This claim is absurd on its face. The public has a right to know how much it will cost taxpayers to administer the death penalty by lethal injection. This is critically important as Nebraska struggles with a state budget shortfall of $334 million. *See* Josh Funk, *Nebraska Governor Proposes Widespread Budget Cuts*, Associated Press, November 3, 2009 (Attachment C).

We have attached as Attachment D a letter submitted by Jeanne Woodford, the former Warden of San Quentin Prison in California, in response to California's proposed lethal injection regulations in June 2009. In her letter, Former Warden Woodford revealed that executions by lethal injection, carried out at San Quentin, cost between $70,000 and $200,000 per execution**.** This includes expenses related to extra security measures in and around the prison, hundreds of hours of overtime due to training of execution team members and the extra prison personnel required to work on the day of scheduled executions, and costs related to demonstrations leading up to and on the day of an execution. While specific costs in Nebraska may vary, it cannot be the case that the proposed regulations will have no economic impact at all, aside from minimal equipment costs.

Carrying out the proposed regulations will impose a significant fiscal burden on the state of Nebraska. Until the NDCS, in compliance with the APA, conducts an assessment of the costs, the full economic impact is unknown. However, at a minimum, the proposed regulations will require expenditures in the following ways:

1. Staff Time

The proposed regulations will require hundreds, possibly thousands of hours of staff time to implement. The DPSCS must calculate and disclose the cost of this staff time. Many, if not all, of the personnel who must implement the regulation are paid by

the state. Thus, the time these staff members spend implementing every aspect of the proposed regulations must be calculated and the cost of this labor must be disclosed. Under the proposed regulations, non-Department employees might be selected to take part in executions and the cost of recruitment, selection and compensation for that personnel must be disclosed. In addition, any likely overtime expenses—which are much more costly to the NDCS than regular staff expenses—must be identified.

Specifically, the NDCS must disclose the cost of the following staff time required by the proposed regulations:

a. The proposed regulations require, at minimum, The Director of the NDCS, the Warden of the Nebraska State Penitentiary, the Staff Communicator, at least 7 members of the Escort Team, and two members of the IV Team. §003. In addition, during the time that these individuals are preparing, training, and carrying out their duties under the proposed regulations, they will be removed from their regular assignments. Additional staff will be needed to cover their regular work assignments for this time.

b. Staff time is needed for the Director to screen and select applicants for the Execution Team. §003.

c. Staff time is required to complete execution team training required by §006.

2. Operations and Material Costs

The proposed regulations impose other significant operations and materials cost on the state that the NDCS must calculate and disclose. Specifically, the NDCS must disclose:

a. The cost of establishing an execution chamber suitable for lethal injection executions. Nebraska has not previously carried out executions by lethal injection and this Execution Protocol will require NDCS to modify existing facilities or establish a new chamber.

b. The cost of increased security at the prison leading up to and on the day of the execution.

c. The cost of services of the coroner, who is required to pronounce death. § 008.02.05.

d. The costs of the drugs and other necessary equipment.

3. Litigation Costs

Because of the substantive deficiencies of the proposed regulations, the state will incur potentially hundreds of thousands of dollars in litigation expenses spent defending the protocol in court. Thus, at a bare minimum, there will be additional litigation costs incurred by the State that would not be incurred but for the adoption of these lethal injection procedures. The NDCS must calculate and disclose the expected costs under the various possible litigation scenarios, including to other state departments such Nebraska Attorney General's Office.

B. Failure to include required information in the rulemaking file.

NDCS has failed to include all the material required by the APA in the rulemaking record. Section 84-906 of the APA requires the NDCS to maintain an official rulemaking record and make it available for public inspection. In addition to numerous other materials, the NDCS is required to include "all written petitions, requests, submissions and comments received by the agency and all other written materials prepared by and for the agency in connection with the proposal or adoption of the rule or regulation." §84-906(2)(c). This section requires NDCS to produce a substantial amount of material for inclusion in the rulemaking file, which it has not done.

To date, the NDCS has only disclosed the minimum notices and fiscal impact statements prepared by NDCS to after the protocol was developed. The NDCS is required to disclose *anything* sent to NDCS or prepared by NDCS "in connection with" the proposed regulation, and not merely the forms required to initiate the rulemaking process. The NDCS has not included any material it prepared or received during the time spent researching and developing the proposed regulation. At minimum, the NDCS is required to include the material it received and prepared when reviewing the protocols from other states. It was well publicized that NDCS officials were researching protocols in other jurisdictions, specifically Kentucky and Texas and possibly others. *See* Nate Jenkins, *Nebraska Consulting with Other States on Death Penalty,* Associated Press, August 10, 2009 (Attachment E). Additionally, in December 2008, the Nebraska Attorney General prepared a report for the Governor, *Lethal Injection as a Constitutional Method of Enforcing a Sentence of Death,* that discussed, among other things, material to be included in a written protocol. To the extent that NDCS relied upon or used any of the information contained in the report, they must make it available in the rulemaking file. NDCS has violated the APA by failing to make all the required material available to the public.

Section 94-907 of the APA also requires the agency to include "draft copies or working copies of all rules and regulations to be adopted . . ." in the rulemaking file. The NDCS has not made any material available that pre-dates the notice of rulemaking filed on September 25, 2009. It is highly unlikely that the draft Execution Protocol that accompanied the notice of rulemaking was the first and only draft produced by the agency in preparation for rulemaking. This is particularly important because interested members of the public cannot fully comment on the proposed protocol without access to

earlier drafts that may provide information on alternatives the agency considered and rejected during the development of the proposed protocol.

The NDCS has violated the APA by not including the statutorily required materials in the rulemaking file. Failing to include everything received or prepared "in connection" with the proposed rule as well as earlier drafts not only violates the requirements of the APA but also hinders public participation in the current public comment process.

Use of Pancuronium Bromide to Paralyze Inmates Before Executing Them

We wish to expand upon our objection to the NDCS's decision to paralyze condemned inmates with pancuronium bromide prior to executing them with potassium chloride. As previously discussed, the use of pancuronium bromide is unnecessary and dangerous, and creates a substantial risk that executions in Nebraska will be excruciatingly painful and torturous.

The state of Ohio recently announced that it has removed these dangerous drugs from its execution protocol, in favor of the administration of a single anesthetic. By modifying its protocol, Ohio has recognized that it is unnecessary to paralyze inmates or administer potassium chloride. Nebraska should follow Ohio's example and remove these drugs from the protocol and eliminate the serious risks involved with paralyzing inmates prior to injecting them with potassium chloride.

Citations to the assertions made in this section of the comment can be found in Ty Alper, Anesthetizing the Public Conscience: Lethal Injection and Animal Euthanasia, 35 Ford. Urb. L.J. 817 (2008), which is attached to this comment as Attachment F. This section of our comment is adapted from this article.

A. The problem with pancuronium in the lethal injection procedure

The proposed procedures call for the serial administration of three drugs. The drugs are, in the following order, sodium pentothal, pancuronium bromide, and potassium chloride. The first drug is intended to anesthetize the inmate so he does not experience the effects of the second and third drugs. The second drug paralyzes him, and the third drug stops his heart, killing him. The use of pancuronium, the second drug, presents a serious problem. Because pancuronium paralyzes the inmate during the execution process, the inmate may experience excruciating pain and suffering but be unable to cry out or even blink an eyelid to let anyone know if the anesthesia has failed. Because pancuronium masks the ability of a lay observer to discern whether the anesthetic drug has been properly delivered, it is very difficult or impossible, in most cases, to know whether the lethal injection execution has been "botched." Pancuronium virtually ensures that the execution looks "peaceful" when it may have been anything but.

Moreover, the pain and suffering that an inmate will experience if not properly anesthetized is extreme. Because pancuronium is a paralytic that restricts the ability of

the respiratory muscles to contract, it causes asphyxiation. The third drug, potassium chloride, causes excruciating pain that has been likened to the feeling of having one's veins set on fire. Experts who have testified in lethal injection cases have unanimously agreed that it would be unconscionable to inject either drug into a person who was not adequately anesthetized.

Litigation on behalf of death row inmates has exposed problems at every step of the process, including the mixing of the drugs; the setting of the IV lines; the administration of the drugs; and the monitoring of their effectiveness. At each step, discovery has revealed untrained and unreliable personnel working with inadequate equipment under poorly designed conditions, including the improper mixing and preparation of the anesthetic; unreliable screening of execution team members; lack of training and supervision of execution team members; inadequate and poorly designed physical facilities; and inconsistent and unreliable recordkeeping.

B. Background and history on curare-based paralytic drugs

To fully comprehend the dangers of pancuronium, and the reasons why it is widely condemned in the practice of animal euthanasia, it is instructive first to consider briefly its origins and history, which we briefly describe here, and ask that the DPSCS take into account.

Pancuronium belongs to a class of drugs called neuromuscular blocking agents. Many of these drugs are derived from, or are synthetic versions of, curare, a highly poisonous extract from certain woody vines that grow in South America. They are often referred to as "curariform" drugs, because they have a curare-like effect. Neuromuscular blocking agents interfere with the transmission of nerve impulses at the receptor sites of all skeletal muscle. In lay terms, these drugs paralyze all voluntary muscles in the body, including the diaphragm, which is necessary to breathe. Unless a person under the influence of a neuromuscular blocking agent is assisted by an artificial breathing mechanism (such as a ventilator), he or she will suffocate to death.

For centuries, indigenous tribes in South America used curare (which is also known as ourara, woorari, wourali, and urali) to make poison-tipped hunting arrows. They combined bark scrapings from certain vines with viscous substances such as snake or ant venom, boiled the mixture for days, and let it cool into a dark, heavy paste, into which they dipped their arrows. Animals struck with these arrows were paralyzed, and eventually suffocated from respiratory paralysis. Curare was particularly effective when hunting monkeys and other animals that lived high in the trees; once shot with a curare-tipped arrow, the animals lost their grip and fell to the ground. Indigenous hunters assessed the strength of their curare based upon how many trees a monkey could jump to after being poisoned. A monkey shot with "one-tree curare" could only leap to one tree before falling; poisoned by a weaker, "three-tree curare," a monkey could leap to as many as three trees in an effort to escape before collapsing to the ground.

Although used in hunting for centuries, curare came to the attention of physiologists in the mid-nineteenth century, particularly among those who practiced vivisection, the dissection of a living animal for medical experimentation. The influential French physiologist Claude Bernard, who needed a way to keep the animals still and cooperative—but alive—while experimenting on them, pioneered the use of curare in vivisection. After discovering its paralyzing properties, Bernard routinely used the drug during vivisection to immobilize his subjects.

It was through the use of curare in vivisection that people began to consider the implications of what curare did *not* do, namely serve any anesthetic function. While curare inhibits all voluntary movement, it does nothing at all to affect consciousness, cognition, or the ability to feel pain. In 1864, Bernard described an animal under the influence of curare as corpse-like, but quite alive:

> In this motionless body, behind that glazing eye, and with all the appearance of death, sensitiveness and intelligence persist in their entirety. The corpse before us hears and distinguishes all that is done around it. It suffers when pinched or irritated, in a word, it has still consciousness and volition, but it has lost the instruments which serve to manifest them.

In 1868, the Swedish physiologist A. F. Holmgren condemned curare as "the most cruel of all poisons." Its use, he wrote,

> changes [one] instantly into a living corpse, which hears and sees and knows everything, but is unable to move a single muscle, and under its influence no creature can give the faintest indication of its hopeless condition. The heart alone continues to beat.

Not surprisingly, the use of curare during animal experimentation was controversial; indeed, its use led to the passage of anti-vivisection laws in Great Britain at the end of the nineteenth century. Testifying before the Royal Commission of 1875, an investigative body created to examine the morality of vivisection, one witness described the experience of a dog subjected to vivisection while paralyzed by curare. Curare, he testified, was used to

> render [the] dog helpless and incapable of any movement, even of breathing, which function was performed by a machine blowing through its windpipe. All this time, however, its intelligence, its sensitiveness, and its will, remained intact . . . . In this condition the side of the face, the interior of the belly, and the hip, were dissected out . . . continuously for ten consecutive hours . . . .

In the 1940s, surgeons began to utilize curare in surgery as a way of relaxing the muscles and aiding in certain delicate procedures. Anesthesiologists hailed the advent of curariform drugs in surgery, because their paralytic properties obviated the need for massive, and potentially dangerous, doses of anesthesia to control unwanted movement. Instead of using deep anesthesia to restrict muscle movement, curare-induced paralysis

accomplished the same goal without the accompanying danger of general anesthesia. The drug quickly became a staple in operating rooms, allowing surgeons to work with improved surgical field and without fear of involuntary muscle contraction.

But while paralytic agents have their place in modern surgery, their inherent danger remains. Dr. Harold Griffith, a Canadian doctor who was the first to use curare on human beings to assist with surgery, published his findings in 1942. While extolling the virtues of curare in the surgical setting, he also warned that it is a "dangerous poison, and should only be used by experienced anesthetists in well-equipped operating rooms." Any time paralytic drugs are used in surgery, the necessity of adequately maintained anesthesia is that much more important, as the drugs restrict the patient's ability to verbally communicate sensation, or physically respond to assessments of anesthetic depth. If the anesthesia wears off during surgery, and the patient is paralyzed, the consequences can be horrific. This phenomenon, referred to as anesthesia awareness, is well-known in the annals of surgery and is a major concern of the anesthesiology profession.

C. Rejection of paralytics by veterinary and animal welfare communities

Decades of review and study have led to a consensus in the veterinary and animal welfare communities with respect to the safest and most humane method of animal euthanasia. That method is an anesthetic-only procedure involving an overdose of the barbiturate sodium pentobarbital. Tens of thousands of animals are euthanized every day by means of this procedure, which has been used in the United States for more than sixty years. According to the AVMA's guidelines, an overdose of pentobarbital is the "preferred method" of euthanizing dogs, cats, and large animals such as horses. In addition to the AVMA, every major American animal rights organization strongly recommends—or requires—the use of pentobarbital in animal euthanasia.

The ease with which the anesthetic-only procedure can be administered is an important consideration. The vast majority of animal euthanasia takes place not in the offices of veterinarians but in animal shelters, where millions of dogs and cats are euthanized each year. Euthanasia in shelters is performed by shelter workers who are not formally trained in veterinary medicine. By developing a procedure with no risk of pain, and a wide margin for error, the veterinary community has accounted for the difficulty posed by relatively untrained personnel administering the lethal procedure. For example, the Euthanasia Training Manual of the Humane Society of the United States is purposefully written in lay terms in recognition of the need for a "more instructive and less technical guide for shelter euthanasia technicians" than the AVMA guidelines, which are written by and for veterinarians. With that purpose in mind, the Humane Society Manual states that pentobarbital is the "best possible method of euthanasia currently available."

Not only does the Humane Society agree with the AVMA that the anesthetic-only procedure is the preferred method for animal euthanasia, but it expressly condemns the use of curariform drugs like the one used in human lethal injections. The foreword to the

Euthanasia Training Manual states that "[i]t is our moral and ethical duty to ensure that we work to end these practices: drowning, poisoning, shooting, gassing, or injecting animals with curare-based or paralytic substances." The Manual later deems "inhumane" the use of "any combination of sodium pentobarbital with a neuromuscular blocking agent." The Humane Society also condemns the use of T-61, a euthanasia solution that combines an anesthetic with a neuromuscular blocking agent, because it "can cause animals intense pain after administration and a curare-like paralysis of respiration (suffocation) before the animal loses consciousness."

Curariform drugs are mentioned only briefly in the AVMA guidelines, and almost always with disapproval. For example, the use of neuromuscular blocking agents alone to achieve death is "unacceptable" and "absolutely condemned." The history of this provision in the guidelines suggests that veterinary experts were concerned with curare's long association with conscious paralysis and suffocation. In short, no AVMA-approved method of euthanasia includes a paralytic, and nowhere in the AVMA guidelines is a three-drug formula like the one used in human lethal injection even contemplated, let alone approved.

D. State animal euthanasia laws and legislative history

There are only eight states whose animal euthanasia laws would even arguably allow the use of a procedure like the one used in human lethal injection executions. These states are essentially silent on the method to be used. Typical is Indiana, which mandates simply that the method shall be "reasonably humane." While eight states are silent on the issue, forty-two states (including Maryland) have enacted statutes and/or regulations that either implicitly or explicitly ban the use of neuromuscular blocking agents, such as pancuronium, in animal euthanasia.

The legislative history of the statutes banning the use of curariform drugs in animal euthanasia is striking, both for what it reveals, and for what it does not reveal. In some states, these laws were the product of intense lobbying by animal rights groups, who argued for the ban in terms quite similar to the arguments of death row inmates challenging the use of neuromuscular blocking agents in lethal injection procedures. In other states, pentobarbital was mandated because it was widely recognized to be the safest and most humane method of euthanasia. In still other states, the legislative or regulatory move either to ban neuromuscular blocking agents or mandate pentobarbital was utterly uncontroversial, as it reflected the virtually unanimous consensus of the veterinary and animal welfare communities.

In 1987, both houses of the New York Legislature overwhelmingly passed a bill to ban the use of "T-61, curare, any curariform drug, any neuromuscular blocking agent or any other paralyzing drug" in animal euthanasia, and allow animal shelters access to sodium pentobarbital. Once the bill was passed, then-Governor Mario Cuomo received an outpouring of letters and memoranda from doctors and animal rights activists, urging him to sign the bill into law, which he eventually did. Much of the debate focused on the use of the drug T-61, which is a combination of anesthetic and paralytic. T-61 is no longer

available in the United States and is strongly condemned by the Humane Society of the United States because, "if improperly administered, T-61 can cause animals intense pain after administration and a curare-like paralysis of respiration (suffocation) before the animal loses consciousness." At the time, however, shelters had to use T-61 because they were not able to procure sodium pentobarbital which, like thiopental used in human lethal injections, is a controlled substance. New York's law, like similar laws of other states, gave shelters access to sodium pentobarbital. In any event, the concerns about T-61 and other curariform drugs, reflected in New York's legislative history, are echoed in the concerns with pancuronium today.

For example, a group of doctors, including anesthesiologists, wrote to Governor Cuomo to describe what could happen if an animal euthanized using a combination of an anesthetic and a paralytic did not receive an adequate dose of the anesthetic:

> In the case of a paralyzed, awake animal who did not volunteer and does not know what is happening, the experience is undoubtedly terrifying, even in the absence of pain. If pain is present, it can be even more terrifying and more painful than would ordinarily be assumed, since pain and fear can be synergistic.

Others wrote to the governor, noting that the New York State Department of Health banned the use of curariform drugs or agents with curariform activity in the destruction of animals in laboratory settings. Dozens of local animal welfare organizations weighed in as well, one noting that "we favor this law since it would also prohibit the use of . . . drugs containing paralytic agents, which can cause acute suffering before an animal dies." Another letter pleaded that "[a]nimal organizations have put their hearts and souls into securing a bill which would mean that animal shelters could obtain sodium pentobarbital to be used only to humanely euthanize dogs and cats."

The legislative testimony in support of the bill by Representative Arthur Kremer is particularly on point:

> MR. KREMER: The objections that have been raised to the use of this drug [T-61] are based upon adequate scientific research that has shown the use of this particular drug causes animals to die in what is considered a torturous manner, and sodium pentobarbital is a more humane manner in which the animal could be euthanized . . .
>
> MR. DAVIDSEN: You mentioned the word "torturous"?
>
> MR. KREMER: When an animal is paralyzed prior to dying, I think you put that animal, if you will, through a much more difficult death than you would with sodium pentobarbital.

The legislative history of the Connecticut statute also reflects concerns that the use of curariform drugs in animal euthanasia increases the potential for a torturous death. In that state, the original version of a proposed bill would only permit a licensed

veterinarian to administer euthanasia by a "lethal injection." Although the legislative history reflects an overwhelming support for the bill, several animal welfare advocates urged the legislators to include a list of drugs to be used in lethal injections, for fear that some individuals might use curariform drugs instead of sodium pentobarbital. One of the advocates, the president of the Northeastern Connecticut Animal Rescue, Inc., warned that pet shops may be tempted to use succinylcholine chloride, a neuromuscular blocking agent, and that animals would be paralyzed and "die[] of suffocation while fully conscious." She continued: "Please do not assume that the phrase 'lethal injection' is adequate to prevent the animal's suffering. Drugs other than sodium pentobarbital are NOT humane alternatives." The legislature concurred and amended the bill, so that the language signed into law permits euthanasia only "by lethal injection of sodium pentobarbital."

E. Nebraska animal euthanasia law

The use of curariform drugs such as those Nebraska proposes using to execute human beings is not permitted under Nebraska law for use in the euthanasia of animals.

In 1999, Nebraska legislators passed the Controlled Substances Welfare Act ["the Act"] to allow animal welfare organizations to obtain proper controlled substances for the purpose of humane euthanasia. Neb. Rev. Stat. § 54-2502. The Act authorizes animal welfare organizations to form agreements with "collaborating veterinarians" in order to obtain and administer euthanizing drugs. Neb. Rev. State. § 54-2504. Euthanizing drugs are defined to include "sodium pentobarbital or any controlled substance for the purpose of humane euthanasia." Neb. Rev. Stat. §§ 54-2503.

Neither Nebraska nor federal law define any curariform drug as a "controlled substance." In Nebraska, a "controlled substance" is defined as "a drug, biological, substance, or immediate precursor in Schedules I to V of section 28-405." Neb. Rev. Stat. § 28-401. There are no curariform drugs among the substances enumerated in Nebraska Statutes section 28-405. Similarly, curariform drugs are not listed among the "controlled substances" enumerated by federal statute. *See* 21 U.S.C. 812. Furthermore, although pancuronium and pancuronium bromide (the most common curariform drugs used in human lethal injections) do require prescriptions according to the U.S. Food and Drug Administration, the agency does not characterize them as "controlled substances."

Therefore, because the Nebraska statute authorizing animal welfare organizations to obtain and administer euthanizing drugs defines those drugs to include only sodium pentobarbital or other "controlled substances," curariform drugs are not "euthanizing drug[s]," and animal welfare organizations are not permitted to obtain or administer them to euthanize animals. In practice, it is sodium pentobarbital that Nebraska veterinarians and animal shelter workers use to humanely euthanize animals.

F. The NDCS should reconsider the use of a drug that has been long rejected by the veterinary and animal welfare communities

There is no reason for the NDCS to paralyze inmates with pancuronium before executing them. It is a barbaric practice that needlessly risks a horrifying and painful death. The DPSCS should review and consider the considered expertise of the veterinary and animal welfare communities and conclude that pancuronium has no place in a humane lethal injection process.

G. The NDCS should reconsider the use of a drug that has been rejected by medical ethicists and critical care providers for use in end of life care

At the end-of-life stage, a physician's focus turns from curing or restoring health to ensuring patient comfort during the dying process. The physician has an obligation to provide care that relieves physical pain. Neuromuscular blocking agents, such as pancuronium bromide, possess no sedative or pain-relieving properties and therefore serve no palliative function for a dying patient. At the same time, the use of such drugs brings significant risks to the patient.

Neuromuscular blocking agents can paralyze the patient's diaphragm and cause a patient to asphyxiate. In addition, neuromuscular blocking agents can mask the physical signs that doctors look for when attempting to identify whether a dying patient is suffering pain. For example, drugs like pancuronium bromide may suppress the visual signs of acute air hunger associated with the withdrawal of a ventilator, leaving the patient to endure the agony of suffocation in silence and isolation.

In addition, neuromuscular blocking agents like pancuronium bromide can mask the signs of severe pain. When a patient is paralyzed, he is unable to display any of the behavioral cues that allow a physician to assess his pain levels. See, *e.g.*, Robert D. Truog, et al., *Recommendations for End-Of- Life Care in the Intensive Care Unit: The Ethics Committee of the Society of Critical Care Medicine*, 29 Crit. Care Med. 2332, 2345 (2001). For example, the presence of a neuromuscular blocking agent will suppress the visual signs of acute air hunger associated with the withdrawal of a ventilator as well as other signs of pain and suffering. *Id*. When the attending physicians cannot identify these signs of suffering, they cannot administer the further sedatives or analgesics that are needed to ensure the patient's comfort.

Other tools available for assessing pain, moreover, are insufficient substitutes for the patient's behavioral clues. For example, monitoring a patient's blood pressure or heart rate may give some sign of the patient's level of comfort, but these tests can be unreliable due to the physiologic instability of dying patients. Without physical signs such as grimaces or gasps, which are masked by neuromuscular blockers, physicians, the most highly trained of a patient's caregivers, may be unable to provide an acceptable level of palliative care to their patients.

In light of these concerns raised above, the Ethics Committee of the Society of Critical Care Medicine has concluded, consistent with established guidelines for critical care physicians and the overwhelming consensus in the medical community, that the risks to the patient are too great to justify administering neuromuscular blocking agents in end-

of-life care. *See id.* For the same reasons, in addition to all of the other reasons discussed above, DPSCS should not include pancuronium bromide as a component of its execution protocol.

Conclusion

Thank you for your consideration of these comments. Please do not hesitate to contact either one of us if we can answer any further questions that you may have.

Sincerely,

Megan McCracken Jen Moreno

Encl.

Attachments A – F.