IN DISTRICT COURT FOR DOUGLAS COUNTY, NEBRASKA

STATE OF NEBRASKA, Appellee, vs. CAREY DEAN MOORE, Appellant.	)))))))))	Docket 106 Page 55 **SUCCESSOR MOTION FOR POSTCONVICTION RELIEF**

INTRODUCTION

The Defendant, CAREY DEAN MOORE, moves pursuant to Neb. Rev. Stat. §§ 29-3001 *et. seq*. (Reissue 2008) for an evidentiary hearing as required by *State v. Silvers*, 255 Neb. 702, 587 N.W.2d 325 (1998), and the order from the Nebraska Supreme Court dated April 21, 2011. Thereafter, Mr. Moore requests that this court vacate the sentences of death and impose terms of life for both convictions.

On January 24, 2011, the State requested the Nebraska Supreme Court schedule Mr. Moore's execution and that it be conducted by lethal injection. Nebraska's current lethal injection protocol did not exist during any of Mr. Moore's prior legal proceedings and was adopted following passage of LB 36, Neb Laws 2009 as a consequence of the Nebraska Supreme Court's decision in *State v. Mata*, 275 Neb. 1, 745 N.W.2d 229 (2008) (*Mata II*) (The existing electrocution protocol held unconstitutional under Neb. Const. Art. I, § 9). None of the grounds for relief alleged in this motion could have been raised by Mr. Moore in any previous proceedings.

After appointment of counsel on February 16, 2011, Mr. Moore requested that jurisdiction over the case be remanded to the district court for an evidentiary hearing, or that he be allowed to submit evidence directly to the Nebraska Supreme Court on the issue of the unconstitutionality of the Nebraska lethal injection protocol. The Nebraska Supreme Court's order dated April 21, 2011, specifically held that:

> There is no procedure in the Nebraska Supreme Court in which to hold an evidentiary hearing or adjudicate the merits of the claims challenging Nebraska's lethal injection statutes or execution protocol. . . .
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> We recognize that there may be factual differences among lethal injection statutes and protocols of the various states that give rise to a constitutional challenge. But in those circumstances, the condemned prisoner should follow the procedures such as have been used in other states to obtain an evidentiary hearing. . . .
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> In Florida, a death row inmate filed a 'successor post-conviction' action, under the 'newly discovered evidence' provisions of Fla. R. Crim. Pro. 3.851, in which he challenged the constitutionality of Florida's lethal injection protocol. *Ventura v. State*, 2 So.3d 194 (Fla. 2009). See also, *Schwab v. State*, 995 So.2d 922 (Fla. 2008).

The factual basis for relief as alleged in this motion were not available at the time of Defendant's prior direct appeals, motions for postconviction relief, and/or petitions for federal habeas corpus relief. See, *State v. Ryan*, 257 Neb. 635, 601 N.W.2d 473 (1999); *State v. Otey*, 236 Neb. 915, 464 N.W.2d 352 (1991). Whereas resetting a date for execution might be viewed as a "ministerial" act, changing the method of execution is not. Failure to conduct an evidentiary hearing would violate the Due Process Clause of the Fourteenth Amendment to the United States Constitution.

Mr. Moore further shows that said sentences of death are void or voidable under specific provisions of the Nebraska Constitution and/or the United States Constitution by reason of the following facts:

FACTUAL ALLEGATIONS: PROCEDURAL HISTORY

1. Mr. Moore has been convicted in the above entitled case of two counts of first degree murder that occurred on or about August 22, 1979 (Van Ness homicide), and August 26, 1979 (Helgeland homicide).

2. He is currently in the custody of the Nebraska Department of Correctional Services as a result of said convictions pending his judicial execution currently scheduled for June 14, 2011.

3. Contemporaneous with the filing of this motion, Mr. Moore has moved for a stay of execution with the Nebraska Supreme Court[1].

4. The Nebraska substantive law of first degree murder in effect in August 1979, and at all times relevant to the proceedings provided as follows:

   a. Neb. Rev. Stat. § 28-303 (Reissue 1995) required that:

      > The determination of whether murder in the first degree shall be punished as a Class I (death) or Class IA (life w/o parole) felony **shall be made pursuant to sections 29-2520 to 29-2524.** (Emphasis added.)

   b. Neb. Rev. Stat. § 29-2522 (1) (Reissue 1995) required that:

      > After hearing all of the evidence and arguments in the sentencing proceeding, the judge or judges shall fix the sentence at either death or life imprisonment, . . . If an order is entered sentencing the defendant to death, **a date for execution shall not be fixed until after the conclusion of the appeal provided for in section 29-2525.** (Emphasis added.)

   c. Neb. Rev. Stat. § 29-2528 (Reissue 1995) required that:

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[1] *Otey v. State*, 240 Neb. 813, 485 N.W.2d 153 (1992).

> In all cases when the death penalty has been imposed by the district court, the Supreme Court shall, after consideration of the appeal, order the prisoner to be discharged, a new trial to be had, or **appoint a day certain for the execution of the sentence**. (Emphasis added.)

d. Neb. Rev. Stat. 29-2532 (Reissue 1995)[2] in effect at the time of the murders and during all of the subsequent sentencing proceedings relevant to these proceedings required that:

> The mode of inflicting the punishment of death, in **all cases, shall be by causing to pass through the body of the convicted person a current of electricity of sufficient intensity to cause death**, and the application of such current shall be continued until such convicted person is dead. . . . A crime punishable by death **must be punished according to the provisions herein made and not otherwise**. (Emphasis added.)

5. On April 14, 1980, Mr. Moore was found guilty of two counts of first degree murder following a bench trial, Judge Clark presiding.

6. On June 20, 1980, Mr. Moore was sentenced to death by a three judge panel (J. Clark, J. Stanley, J. Martin). The death sentences were based in significant part upon the panel's interpretation of the language "manifested exceptional depravity by ordinary standards of morality and intelligence" and finding the existence of the second prong of aggravating circumstance (1)(d)[3].

7. On January 29, 1982, the Nebraska Supreme Court affirmed Mr. Moore's convictions and sentences on direct appeal. *State v. Moore*, 210 Neb. 457, 316 N.W.2d 33 (1982) (C.J. Krivosha and J. White, concurring in affirming the convictions, dissenting from imposition of death), *cert. denied*, *Moore v. State*,

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[2]LB 268, § 17, Neb. Laws 1973.

[3]Neb. Rev. Stat. § 29-2523 (1)(d) (Reissue 1995).

456 U.S. 984, 102 S.Ct. 2260 (1982) (*Moore I*).

8. On June 1, 1982, the Nebraska Supreme Court entered an order directing that Mr. Moore be executed on _____, 1982, "by causing the passage of an electrical current through the body of Carey Dean Moore until dead. . . . as provided by law." (*Death warrant #1*)

9. On June 29, 1982, Mr. Moore filed a motion for postconviction relief pursuant to Neb. Rev. Stat. § 29-3001 *et seq*.

10. On July 14, 1982, the Nebraska Supreme Court entered a stay of Mr. Moore's execution.

11. On May 6, 1983, the motion for postconviction relief was denied by the Douglas County district court after appointment of counsel and an evidentiary hearing.

12. On June 8, 1984, the Nebraska Supreme affirmed the denial of postconviction relief. *State v. Moore*, 217 Neb. 609, 350 N.W.2d 14 (1984) (*Moore II*) (CJ Krivosha dissenting as to the sentencing proceedings).

13. On October 24, 1984, the Nebraska Supreme Court entered an order directing that Mr. Moore be executed on December 4, 1984, "by causing the passage of an electrical current through the body of Carey Dean Moore until dead. . . . as provided by law." (*Death warrant #2*)

14. On November 14, 1984, Mr. Moore filed with the United States District Court for Nebraska a petition for a writ of habeas corpus pursuant to 28 U.S.C. § 2254.

15. On November 15, 1984, the US District Court issued a stay of execution.

16. On September 20, 1988, Mr. Moore's petition for federal habeas corpus was granted as to the death sentences only, based upon the unconstitutional

interpretation of the second prong of aggravating circumstance 1(d). The State unsuccessfully appealed the grant of the habeas corpus relief. *Moore v. Clarke*, 904 F.2d 1226 (8th Cir. 1984), *rehrg denied*, 951 F.2d 895 (8th Cir. 1991)[4], *cert denied*, 504 U.S. 930, 112 S.Ct. 1998 (May 18, 1992.) (*Moore III*).

17. After the grant of Mr. Moore's motion for federal habeas corpus relief became final on May 18, 1992, the federal writ gave the State 60 days to initiate re-sentencing proceedings. The State ignored the requirements of the federal writ and attempted to have the Nebraska Supreme Court conduct the re-sentencing. This procedure was intended to prevent the case from being returned to the district court for a sentencing hearing before a new three-judge panel.

18. On July 9, 1993, the Nebraska Supreme Court held that it had the statutory and constitutional authority to re-sentence Mr. Moore, but in the interest of "judicial economy" the case would be remanded to the district court for re-sentencing. *State v. Moore*, 243 Neb. 679, 502 N.W.2d 227 (1993) (*Moore IV*)[5],

19. On June 29-30, 1994, and October 14, 1994, a re-sentencing hearing was held before a three judge panel (J. Buckley, J. Rist, J. Quist) in the district court.

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[4]While the State's appeal was still pending before the Eighth Circuit, the United States Supreme Court approved a limiting construction of a similar Arizona death penalty statute. *Walton v. Arizona*, 497 U.S. 639, 110 S.Ct. 3047 (1990); *Lewis v. Jeffers*, 497 U.S. 764, 110 S.Ct. 3092 (1990). After careful consideration of *Walton v. Arizona* and *Lewis v. Jeffers*, the Eighth Circuit reaffirmed its earlier holding that 1(d) was unconstitutional. The United States Supreme Court denied the State's petition for certiorari.

[5]In *State v. Reeves*, 258 Neb. 511, 535, 604 N.W.2d 151, 168 (2000), the Nebraska Supreme Court expressly disapproved of *Moore IV*, and held that as an appellate court it was without original jurisdiction to re-sentence a capital defendant and this its earlier holdings to the contrary were "clearly erroneous."

20. On April 21, 1995, Mr. Moore was again sentenced to death based in significant part upon a finding of the second prong of aggravating circumstance (1)(d) as to both murders. The panel made the unique and unprecedented determination that, as a matter of law, the statutory language "manifested exceptional depravity by ordinary standards of morality and intelligence[6]" would be interpreted to include "the purposeful selection of a particular victim on the basis of the specific characteristic of age". (Sentencing order, p. 11).

21. On September 27, 1996, the Nebraska Supreme Court affirmed Mr. Moore's death sentences and for the first (and only) time expanded the existing *Palmer* five factor test by approving application of the 1(d) aggravating circumstances to cases involving, "[T]he killer's cold, calculated planning of the victim's death, as exemplified by experimentation with the method of causing the victim's death or

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[6]The first attempt at a limiting construction of the "exceptional depravity" prong of 1(d) by the Nebraska Supreme Court was that it meant "so coldly calculated as to indicate a state of mind totally and senselessly bereft of regard for human life," or involved "unresisting victims." *State v. Harper*, 208 Neb. 568, 579, 304 N.W.2d 663, 668 (1981); *State v. Rust*, 197 Neb. 528, 539, 250 N.W.2d 867, 874 (1977); *State v. Holtan*, 197 Neb. 544, 547, 250 N.W.2d 876, 880 (1977). It was not until *State v. Palmer*, 224 Neb. 282, 320, 399 N.W.2d 706, 731-32 (1986), that the Nebraska Supreme Court fashioned a more specific five-factor test stating:

> [W]e hold that "exceptional depravity" in a murder exists when it is shown, beyond a reasonable doubt, that the following circumstances, either separately or collectively, exist in reference to a first degree murder: (1) apparent relishing of the murder by the killer; (2) infliction of gratuitous violence on the victim; (3) needless mutilation of the victim; (4) senselessness of the crime; or (5) helplessness of the victim.

In *Joubert v. Hopkins*, 75 F.3d 1232 (8th Cir.1996), the Eighth Circuit suggested in *dicta* that the *Palmer* five factor test for "exceptional depravity" was constitutional. However, the reversal of Joubert's grant of habeas relief was based on a procedural bar and not the merits of the constitutional claim.

by the purposeful selection of a particular victim on the basis of specific characteristics such as race, gender, creed, sexual orientation, disability, or age." *State v. Moore*, 250 Neb. 805, 820, 553 N.W.2d 120, 132 (1996), *cert. denied*, *Moore v. State*, 520 U.S. 1176, 117 S.Ct. 1448 (1997)[7]. *(Moore V*).

22. On December 23, 1996, Mr. Moore's motion to stay issuance of the mandate was denied and the mandate issued.

23. Under clearly established existing Nebraska law, the issuance of the December 23, 1996 mandate defined the date ending all of Mr. Moore's direct appeals. His case became "final[8]" for purposes of any subsequent attempt at statutory changes mitigating his punishment. E.g., *State v. Randolph*, 186 Neb. 297, 183 N.W.2d 225 (1971). Any change of this "final" judgment date would require that Mr. Moore's convictions and/or sentences be vacated in a subsequent collateral postconviction or federal habeas action[9].

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[7]This newly expanded interpretation of aggravator 1(d) in *Moore* was rejected three years later by the Nebraska Supreme Court in *State v. Palmer*, 257 Neb. 702, 719-21, 600 N.W.2d 756, 770-72 (1999), when it returned to the original *Palmer* five factor test without consideration of these new *Moore* "factors."

[8]A sentence becomes a final judgment upon the entry of the mandate by an appellate court following the decision on a direct appeal. *Jones v. Clarke*, 253 Neb. 161, 568 N.W.2d 897 (1997); *State v. Warner*, 192 Neb. 438, 222 N.W.2d 292 (1974). Nether the Nebraska courts nor the Nebraska Legislature have jurisdiction to mitigate punishment after a sentence becomes "final". *Duff v. Clarke*, 247 Neb. 345, 526 N.W.2d 664 (1995); *Boston v. Black*, 215 Neb. 701, 340 N.W.2d 401 (1983).

[9]See, e.g., *State v. Lotter*, 266 Neb. 245, 261-62, 664 N.W.2d 892, 908 (2003) applying analysis from *Teague v. Lane*, 489 U.S. 288, 109 S.Ct. 1060 (1989), and holding that the benefit of the Supreme Court's *Ring* decision would not apply during postconviction to a capital case that was "final."

24. On March 3, 1997, the Nebraska Supreme Court entered an order directing that Mr. Moore be executed on May 9, 1997, "by causing the passage of an electrical current through the body of Carey Dean Moore until dead. . . . as provided by law." (*Death warrant #3*)

25. On April 30, 1997, Mr. Moore filed a *pro se* motion for postconviction relief and requested appointment of counsel[10].

26. On May 5, 1997, the district court denied Mr. Moore's request for appointment of counsel and the motion for postconviction relief without an evidentiary hearing. However, on this same date the Nebraska Supreme Court entered a stay of Mr. Moore's scheduled execution.

27. On April 2, 1999, the Nebraska Supreme Court affirmed the district court's denial of postconviction relief. *State v. Moore*, 256 Neb. 553, 591 N.W.2d 86 (1999), *cert denied*, *Moore v. Nebraska*, 120 S.Ct. 459 (1999) (*Moore VI*).

28. On October 5, 1999, Mr. Moore filed with the United States District Court for Nebraska a petition for writ of habeas corpus pursuant to 28 U.S.C. § 2254.

29. On October 14, 1999, the Nebraska Supreme Court entered an order directing that Mr. Moore be executed on January 19, 2000, "by causing the passage of an electrical current through the body of Carey Dean Moore until dead. . . . as provided by law." (*Death warrant #4*)

30. On November 24, 1999, the US District Court entered a stay of execution.

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[10]This was Mr. Moore's first opportunity to challenge the ineffectiveness of counsel under the Sixth and Fourteenth Amendments to the United States Constitution at the re-sentencing proceedings held in 1994 through 1995.

31. On November 14, 2000, Mr. Moore's petition for federal habeas relief in regards to the unconstitutional application of the contradictory definitions of aggravator 1(d) under the Eighth and Fourteenth Amendments to the United States Constitution was denied. *Moore v. Kinney*, 119 F.Supp.2d 1022 (D. Neb. 2002).

32. On November 22, 2000, the stay entered by the US District Court was extended while Mr. Moore pursued an appeal to the Eighth Circuit Court of Appeals.

33. On appeal, a panel of the Eighth Circuit Court of Appeals initially determined that the *Palmer* five factor test remained unconstitutional and held:

> Contrary to the state's argument, *Joubert* cannot be cited for the proposition that the Eighth Circuit approved a "broader definition of exceptional depravity than was employed in resentencing Moore." Appellee's Brief at 14. In light of the fact that this court found the exceptional depravity prong of aggravator § 29-2523(1)(d) unconstitutionally vague in 1990 when the sentencing panel applied it to Moore in 1980, it remains unconstitutionally vague. *Moore v. Kinney*, 278 F.3d 774, 782 (8th Cir. 2002)

34. On February 10, 2003, the State's motion for rehearing *en banc* was granted, the original panel decision vacated, and the denial of habeas relief affirmed in *Moore v. Kinney*, 320 F.3d 767 (8th Cir. 2003) (J. Heaney, McMillian, Bye, Melloy, Smith dissenting), *cert. denied*, *Moore v. Kinney*, 539 U.S. 530, 123 S.Ct. 2580 (2003).

35. A review of the docket entries in US District Court case, *Moore v. Kinney*, 4:99 cv 3263, using PACER does not show that any order has been entered vacating the stay extended by the federal district court on November 22, 2000[11].

[11]Mr. Moore would note that his attorney's review of the federal docket conflicts with the factual assertions made by Attorney General Bruning in the affidavit dated January 24, 2011, and the letter from Denise Lucke attached to AG Bruning's affidavit as Exhibit C.

36. On July 26, 2004, Mr. Moore filed for state postconviction relief on the grounds that Nebraska's judicial electrocution protocol was unconstitutional under the Eighth and Fourteenth Amendments to the United States Constitution and Neb. Const. Art. I, § 1, 9, and 14.

37. On August 31, 2004, Mr. Moore's request for appointment of counsel and his motion for postconviction relief were denied without an evidentiary hearing.

38. On June 28, 2006, the Nebraska Supreme Court affirmed and held that all Defendant's claims were procedurally barred. *State v. Moore*, 272 Neb. 71, 718 N.W.2d 537 (2006). On January 16, 2007, the United States Supreme Court denied certiorari *Moore v. State*, 549 U.S. 1171, 127 S.Ct. 1134 (2007).

39. On March 21, 2007, the Nebraska Supreme Court entered an order that Mr. Moore be executed on May 8, 2007, "by causing the passage of an electrical current through the body of Carey Dean Moore until dead. . . . as provided by law." (*Death warrant #5*)

40. Mr. Moore filed no state or federal proceedings to delay or stay his execution.

41. On May 2, 2007, the Nebraska Supreme Court *sua sponte* stayed Mr. Moore's pending judicial electrocution while it considered the constitutionality of judicial electrocution in the case of *State v. Mata* (Case No. S-05-1868).

FACTUAL ALLEGATIONS: PASSAGE OF LB 36, NEB LAWS (2009)

42. It is undisputed that since at least 1999, there have been numerous bills introduced in the Nebraska Legislature to change Nebraska's required method of judicial execution to provide for lethal injection as an alternative to electrocution[12]. None of these bill were ever passed into law.

43. On September 5, 2003, the Nebraska Supreme Court in *State v. Mata*, 266 Neb. 668, 702, 668 N.W.2d 448, 478-79 (2003) (*Mata I*) strongly suggested that the Legislature make statutory changes to Neb. Rev. Stat. § 29-2523 (Reissue 1995) in order to authorize execution by a method other than electrocution.

44. After *Mata I*, the Nebraska Legislature took no action to change the method of judicial execution from electrocution.

45. On February 8, 2008, in *State v. Mata*, 275 Neb. 1, 745 N.W.2d 229 (2008) (*Mata II*), the Nebraska Supreme Court affirmed the conviction, but held that electrocution as the sole method of conducting a judicial execution was "cruel and unusual punishment" under Neb. Const. Art. I, § 9. The Court then stated:

> Thus, although we affirm the judgment, we decline to "appoint a day certain for the execution of the sentence" and stay Mata's execution. When the State moves that an execution date be set, in addition to the other requirements for such a motion, the State should allege, and be prepared to demonstrate, that a constitutionally acceptable method of carrying out Mata's sentence is available.

[12]See e.g., LB 52, 96th Legislature, First Session (1999), LB 62, 97th Legislature, First Session (2001); LB 356, 97th Legislature, First Session (2001), LB 1281, 97th Legislature, Second Session (2002), LB 2, 97th Legislature, Third Special Session (2002), LB 526, 98th Legislature, First Session (2003).

46. On April 7, 2008, the State's motion for rehearing in *Mata* was denied and the decision became "final." The State took no further legal action challenging the holding that the Nebraska procedure for electrocution was unconstitutional under Neb. Const. Art I, § 9.

47. The 100th Nebraska Legislature was in session at the time *Mata II* was decided on February 8, 2008. The Legislature took no action to change the method of conducting a judicial execution from electrocution before adjourning *sine die* on April 17, 2008.

48. The Governor took no action to call the Legislature into special session to address the issue of method of execution after it adjourned on April 17, 2008.

49. On January 8, 2009 (eleven months after *Mata II*, and twenty four months after Mr. Moore's last judicial proceeding), Speaker Flood introduced LB 36 before the 101st Legislature which directed the Nebraska Department of Correctional Services (hereinafter referred to as "DCS") to conduct judicial execution through the intravenous injection of a "substance or substances" that would cause death.

50. On May 28, 2009, LB 36 as amended, was passed by the Legislature and signed by the Governor. LB 36, Neb. Laws 2009 (hereinafter referred to as "LB 36") did not contain the "emergency" clause and took effect on August 30, 2009 (eighteen and a half months after the decision in *Mata II*).

51. Under the plain language of LB 36, DCS cannot conduct any judicial execution without a protocol specifying the substance or substances to be employed. LB 36 did not state whether DCS must follow the rule-making procedures set forth in

the Administrative Procedures Act[13].

52. In so far as relevant to this motion for postconviction relief, LB 36 amended Neb. Rev. Stat. § 29-2532 (now codified at Neb. Rev. Stat. § 83-964 (2010 Cum. Supp.) to provide as follows:

> A sentence of death shall be enforced by the intravenous injection of a substance or substances in a quantity sufficient to cause death. **The lethal substance or substances shall be administered in compliance with an execution protocol created and maintained by the Department of Correctional Services**. . . . (Emphasis added.)

53. LB 36 further amended Neb. Rev. Stat. § 29-2532 (now codified at Neb. Rev. Stat. § 83-965 (2010 Cum. Supp.) to direct as follows:

> (2) The director shall create, modify, and maintain a written execution protocol describing the process and procedures by which an execution will be carried out consistent with this section. The director shall (a) select the substance or substances to be employed in an execution by lethal injection, (b) **create a documented process for obtaining the necessary substances**, (c) designate an execution team composed of one or more executioners and any other personnel deemed necessary to effectively and securely conduct an execution, (d) describe the respective responsibilities of each member of the execution team, (e) describe the training required of each member of the execution team, and (f) perform or authorize any other details deemed necessary and appropriate by the director.
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> (3) The execution protocol shall require that the first or only substance injected be capable of rendering the convicted person unconscious and that a determination sufficient to reasonably verify that the convicted person is unconscious be made before the administration of any additional substances, if any. (Emphasis added.)

54. LB 36 provided no guidelines, procedures, standards, or policies specifying whether the lethal substance should be a fast or slow acting poison, opiate,

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[13]Neb. Rev. Stat. §§ 84-901 *et seq*. (Reissue 2008), *McAllister v. Nebraska Dep't of Corr. Servs*., 253 Neb. 910, 573 N.W.2d 143 (1998).

barbiturate, benzodiazepine, arsenic, cyanide, mercury, methanol, ethylene glycol, warfarin, atropine, organophosphate, shell fish toxin, digitalis, snake venom, bacterial toxin, potassium chloride, sulfuric acid, other toxic substance, or a carcinogen like dimethylnitrosamine[14].

55. LB 36 did not specify the time necessary between the injection of the substance into the condemned prisoner and when he or she should be rendered unconscious, whether the substance may or may not inflict unnecessary pain, whether the substance shall cause brain or heart/respiratory death as defined by Neb. Rev. Stat. § 71-7202 (Reissue 2003), or whether death can be caused by suppression of the condemned prisoner's nervous system, paralysis of the diaphragm, seizure of the heart, shock, massive hemorrhaging, kidney failure, liver failure, or other physiological mechanism that will terminate life.

56. LB 36 did not authorize DCS to obtain the lethal substances from foreign pharmaceutical manufacturer and/or distributors who were not registered with the FDA and DEA, or allow DCS to obtain lethal substances in violation of federal statutes and administrative regulations.

57. On September 28, 2009, the Department of Correctional Services began rule making procedures to develop a lethal injection protocol under the Nebraska Administrative Procedures Act.

58. On February 10, 2010 (twenty four months after the decision in *Mata II*), Title 69, Chpt 11, was signed by the Governor and became effective.

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[14] *State v. Harper*, 208 Neb. 568, 304 N.W.2d 663 (1981).

59. Title 69, Chpt 11 developed by DCS is the protocol for lethal injection (hereinafter "execution protocol") intended to be applied to Mr. Moore and provides, in relevant part, as follows:

008 Lethal Substances

008.01 Identification. Executions shall be accomplished by the intravenous injection of the following substances into the condemned inmate by the method described in this protocol.

008.01.01 Sodium thiopental
008.01.02 Pancuronium bromide
008.01.03 Potassium chloride

008.02 Administration of the lethal substances. The lethal substances shall be administered to the condemned inmate by the mechanism described in this protocol. They shall be administered in the following order and dosages.

008.02.01 Sodium thiopental will initially be administered in one 3 gram dose. There will be a waiting period of at least one minute between the administration of the sodium thiopental and conducting the consciousness checks. If unconsciousness is not verified by the Warden after the administration of the initial dose, additional 3 gram doses will be administered and consciousness checks conducted after the administration of each dose until unconsciousness is verified.

008.02.02 Once unconsciousness is verified, pancuronium bromide will be administered in one dose of 50 mg/100 ml.

008.02.03 Once the pancuronium bromide has been administered, potassium chloride will be the third lethal substance administered in one dose of 240 Meq.

008.02.04 A 50cc saline flush will be administered following each injection of a lethal substance.

008.02.05 If the coroner does not pronounce the condemned inmate dead at the conclusion of this process, the Director shall order the execution process repeated in the manner

described by this protocol.

009 Procurement and inventory of lethal substances

009.01 The Director shall purchase two complete sets of the described lethal substances unless the Director determines that additional quantities should be kept in inventory.

009.02 The described lethal substances shall be purchased through the Department Pharmaceutical Supervisor or through some other appropriate source.

009.03 The purchase of the lethal substances will be treated as the purchase of high security items and their receipt and delivery are not subject to standard business delivery procedures, but will be delivered directly into the custody of the Director.

009.04 The Director shall document the order and receipt of the lethal substances and provide for their maintenance and storage.

009.05 The inventory of lethal substances will be reviewed every six months and also immediately upon receipt of an execution order from the Nebraska Supreme Court.

009.06 Expired lethal substances will be cleared from inventory and replaced.

60. Title 69, Chpt 11 does not authorize DCS to obtain the lethal substances from unregistered foreign pharmaceutical manufacturer and/or distributors in violation of federal statutes and administrative regulations.

FACTUAL ALLEGATIONS: SODIUM THIOPENTAL

61. Sodium Thiopental ("thiopental") is an intravenously administered, ultra-short-acting barbiturate intended to assist in the induction of general anesthesia. It was developed in the 1930s by Abbott Laboratories, Inc. ("Abbott"). Thiopental was among the most frequently used anesthetics from the 1930s through the 1970s.

62. Abbott produced thiopental in the United States until approximately 2004, when Abbott spun off a new company called Hospira, Inc. ("Hospira").

63. Hospira stopped producing thiopental in 2009.

64. In January 2011, Hospira announced its decision to permanently discontinue production of thiopental. No other firm located in the United States manufactures thiopental. It has not been available in the United States since 2009.

65. Thiopental is ultra-short-acting, even when it is fully potent and properly administered. The anesthetic effects can take effect and wear off within just a few minutes. Due to its ultra-short-acting nature, thiopental is generally considered inappropriate for maintaining a surgical state of unconsciousness and is now used only to induce anesthesia for purposes of intubation.

66. Propofol (which was originally developed under the trade name Diprivan) was developed in the late 1970s and first approved by FDA in 1989. In late 2008, another similar short-acting anesthetic drug called fospropofol disodium was approved by FDA (under the brand name Lusedra).

67. Since the introduction of propofol, the use of thiopental in the United States has declined to a minimal level.

FACTUAL ALLEGATIONS: DCS PURCHASE OF CONTROLLED SUBSTANCE FROM KAYEM PHARMACEUTICALS, MUMBIA, INDIA FOR USE IN MR. MOORE'S EXECUTION

68. At the time of the adoption of Title 69, Chpt 11, it appears that DCS was unaware of the fact that the sole United States distributor of sodium thiopental approved by the FDA and DEA was Hospira, and that there might be a problem with a domestic shortage of the drug.

69. On April 7, 2010, DCS received a letter from Hospira expressing their disapproval of the use of Hospira manufactured drugs for the purposes of lethal injection. A copy of the letter is attached as Exhibit "A".

70. On approximately August 31, 2010, DCS learned through email communications with Andrew Welsh-Huggins of the Associated Press that Hospira was the only US supplier of sodium thiopental and that there was a shortage of the drug.

71. On September 3, 2010, DCS advised the AP reporter that DCS had no supply of sodium thiopental with which to conduct a judicial execution. The relevant emails are attached as Exhibit "B."

72. On September 27, 2010, DCS advised Catharine Huddle of the Lincoln Journal Star, that it did not have a supply of sodium thiopental, but that the substance was "on order." DCS did not indicate where it had placed the order.

73. On October 29, 2010, Dr. Diane Booker, Interim Pharmacy Director at DCS, sent an email to the departments of corrections in several other states stating:

> I have been given a task to obtain some Sodium Pentothal by any means available, be it Great Britain or Canada or anywhere. So, does anyone know where I might start looking? This request is coming down from our Director of Corrections here in Nebraska. Any help would be greatly appreciated.

74. On November 2, 2010, Dr. Booker forwarded an email to Steve Urosevich, Pharmacy Director at DCS, with the information she had learned from Stephanie Zepeda, Director of Pharmacy Services for the Texas Department of Corrections and Chris Bina, Federal Bureau of Prisons. The emails are attached as Exhibit "C." This information included the following:

> I would also like to mention that the American Board of Anesthesiologists has stated that it will censure anesthesiologists that participate in lethal injections. There was an article in the Washington Post regarding this in May 2010. I don't know if this will trickle over to other health care professions involvement but wouldn't be surprised.
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> Though not specifically addressed in the Washington Post article provided by Stephanie, there could also be potential licensure and legal implications for healthcare professionals with obtaining non-FDA approved medications from overseas.

Chris [Bina of FBOP]

> I would suggest looking for another product with similar actions. An anesthesiologist could be consulted. Switching to another anesthetic may be difficult for some states because the current execution procedures were adopted after lengthy court proceedings and changing drugs could take time and invite lawsuits.
>
> Hospira is the only manufacturer in the US that I am aware. Speculation of true reason for shortage since Hospira had sent a letter to Ohio DOC objecting to use of its product in lethal injections.
>
> The Food and Drug Administration says there are no FDA-approved manufacturers of sodium thiopental overseas. See attached interesting article in Washington Post from 10/27/10 where Arizona stated they obtained it from Britain.
>
> Sorry I couldn't be more help.

[Stephanie Zepeda]

75. On approximately November 11, 2010, Mr. Urosevich had telephone and email contact with Chris Harris, who represented himself to be the "Director Sales &

Marketing" for Kayem Pharmaceuticals Pvt. Ltd. (hereinafter "Kayem"). The purpose of these communications was for DCS to place an order for a quantity of sodium thiopental for use in conducting lethal injections. The email from Mr. Urosevich to Mr. Harris is attached as Exhibit "D."

76. On November 24, 2010, the Robert Houston, Director of DCS, authorized payment to Kayem for the purchase of "Thiopental Sodium" as evidenced in an invoice dated November 13, 2010. Ex "E."

77. There were a series of email communications between Mr. Harris and Inga Hookstra, Controller at DCS, regarding how to make payment for 500 grams of sodium thiopental. Kayem needed to complete a number of forms, including and ACH Enrollment Form and IRS Form W-9. Because Kayem did not have a US bank account, payment ultimately had to be made by check.

78. On November 29, 2010, Mr. Harris stated in email to DCS, "Will speak to my person in the US when company is setup and bank account is opened if we can setup an ACH account there." Upon information and belief, Mr. Moore alleges that the person in the US referred to by Mr. Harris is "Wayne Atwater" of Steuben, Maine.

79. On or about November 29, 2010, DCS sent a check to Kayem in the amount of $2,056.15. (Ex "F").

80. On December 8, 2010, Kayem sent 500 vials of "Thiopentone injection IP[15] 1Gm "thiosol Sodium"" by air freight to DCS through United States customs broker,

[15]"IP" means Indian Pharmacopoeia.

Phil Patterson at 1200 Harney St., Omaha, Nebraska. Mr. Navneet Verma of Kayem completed a "Certificate of Origin" stating that the controlled substance shipped to the DCS was "Thiopentone injection IP 1Gm "thiosol Sodium" and "Manufactured by: Neon Laboratories Ltd, Mumbai, India." (Ex "G").

81. The package of controlled substances was held by Mr. Patterson until clearance was obtained from customs and FDA.

82. On January 6, 2011, the FDA released it's lien on the package, but stated:

> COMMENT: FDA releases this shipment, which is being· imported by or on behalf of the state correctional authorities. In keeping with established practice, FDA **does not review or approve products for the purpose of lethal injection**. FDA has **not** reviewed the products in this shipment to determine their **identity, safety, effectiveness, purity or any other characteristics.**
> . . .
> These products are released. This notice does **not constitute assurance that the product released complies with all provisions of the Food, Drug, and Cosmetic Act, or other related Acts, and does not preclude action should the product later be found violative**. (Emphasis added.) (Ex "H").

83. On January 7, 2011, Mr. Houston, Director of DCS, signed for the receipt of 497 units (1 gm) of "Thiopentone Injection I.P." (Ex "I")

84. On January 24, 2011, the Attorney General requested an execution date be set for Mr. Moore. DCS intends to use as the first drug at his judicial execution, the controlled substance "Thiopentone injection IP 1Gm "thiosol Sodium"" obtained from Kayem as detailed *ante*.

FACTUAL ALLEGATIONS: BACKGROUND AND STATUS OF KAYEM PHARMACEUTICAL, PVT., LTD, MUMBIA, INDIA

85. The efficacy of any controlled substance intended to induce unconsciousness in the condemned prisoner is essential under the Eighth Amendment to the United States Constitution[16] and Neb. Const. Art I, § 9.

86. The entire statutory and regulatory structure administered by the FDA and DEA is intended to assure that drugs used for human consumption are of the quality and quantity represented by the manufacturer and will perform as intended.

87. If there has been compliance with the statutory and regulatory requirements of the FDA and DEA, then there is a presumption as to the efficacy of the drugs.

88. There is a compelling interest on the part of the Nebraska courts which has ordered Mr. Moore's execution, DCS which is statutorily tasked with carrying out the death sentence, the individual 'executioner' responsible for injecting the lethal chemicals into the body of Mr. Moore, and obviously Mr. Moore, that the drugs used to cause his death comply with established regulatory and statutory standards regarding the efficacy of the drugs involved[17].

89. It is undisputed that DCS did not obtain its quantity of Thiopentone injection IP 1Gm "thiosol Sodium" from a foreign manufacturer or distributor registered,

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[16] *Baze v. Rees*, 553 U.S. 35, 53, 128 S. Ct. 1520, 1533 (2008) ("It is uncontested that, failing a proper dose of sodium thiopental that would render the prisoner unconscious, there is a substantial, constitutionally unacceptable risk of suffocation from the administration of pancuronium bromide and pain from the injection of potassium chloride."

[17] It should be noted that the Nebraska Attorney General's Office in advocating for Mr. Moore's lethal injection, has no legal, ethical, or moral responsibility in either imposing the original death sentence or conducting the actual killing of Mr. Moore.

inspected, and approved by the DEA and FDA.

90. In addition to the legal issue of whether LB 36 and Title 69, Chpt 11 authorized DCS to use lethal chemicals from unregistered foreign manufacturers and distributors, there is a factual question regarding whether Kayem, its director, and sales personnel have the level of competence, professionalism, and credibility to be DCS's source of one of the essential lethal drugs.

91. Kayem's physical facility is located at 2 Green Field CHS. Ltd., Laxman Mhatre Road, Marian Colony, Borivali (W), Mumbai, 400 103, Maharashtra, India. It is in a residential neighborhood on the ground floor of an apartment building. There are two small rooms. One serves as an office and the other is a storage room. There is no air conditioning or climate control at this building. The affidavit of Sophie Walker is attached with photographs and is incorporated herein by reference. (Ex "J").

92. Kayem does not appear to be involved in the direct formulation of any medications with the possible exception of Indian herbal remedies to alleviate symptoms of arthritis, upper respiratory infections, constipation, hemorrhoids, and inadequate male sexual performance (Celebration). Kayem's primary business activity appears to be the production of tablets, capsules, ointments, and injectable products as a subcontractor for other generic drug companies located in India. The primary country receiving Indian manufactured drugs from Kayem appears to be Angola.

93. The current director/owner of Kayem is Navneet Verma of Mumbia, India. Mr. Verma originally formed and operated Kay Kay Sales Corp., which he described

as a “Dealer in Pharmaceutical Products.” Kay Kay Sales was “acquired” by Mr. Verma’s company, Kayem Pharmaceutical Pvt., Ltd..

94. According to Mr. Verma, Kay Kay Sales and Kayem are “very much in the business of exporting of various Generic Drugs to Africa, including Thiopental Sodium and also export of Ayurvedic Products as the legitimate vocation/trade.”

95. Mr. Verma has admitted that Kayem is not registered with either the DEA or FDA as a foreign pharmaceutical manufacturer or distributor. (Ex “K”). Mr. Verma has written to Mr. Moore’s counsel that:

> Whereas “Thiosol -Thiopental Sodium’ under export is a duly registered product within the meaning of the India FDA for its domestic marketing and accordingly we have informed the buyer that the shipment of Thiopental Sodium shall be from the running stock of the Indian Market.”

96. In an April 19, 2011, article of the Sunday Guardian (of India), Mr. Verma stated:

> [T[he drug is really used in India for treating the poor, "slum dwellers" as he put it. The major difference is that the Indian pharma authorities recognise it as an essential drug, while the US treats it as a barbiturate. The Kayem MD [marketing director] said that he was still receiving enquiries from the US states but "now that I have jacked up the price I don't think they will go ahead". (Ex “L”).

97. Wayne Atwater was listed as the Director of Sales for Kayem on its website http://www.kayempharma.com/ with an address of 7260 Azure Drive, Suite 140-860, Las Vegas, NV 89130.

98. Wayne Atwater and Anthony (Tony) Atwater are the same person.

99. Mr. Atwater is also the owner of Atwater Concrete Inc., located in Ellsworth and Steuben, Maine. His primary business is pouring concrete foundations, slabs, patios, and walkways. (Ex “M”).

100. Kayem’s Las Vegas address is in actuality a mail forwarding service called

"Mostly Mail" located in a shopping mall. The advertised services at this location are mail boxes, notary, document shredding, EBAY services, and FedEx/ Airborne/DHL package servicing. Photos of the “Mostly Mail” location are attached and incorporated herein. (Ex “N”).

101. The Nevada Secretary of State identifies "GG International" as Kayem's "registered agent" located at 7260 Azure Drive, Suite 140-860, Las Vegas, NV 89130 with Wayne Atwater, Chris Harris, Mahendra P. Jain, and Navneet Sahay Verma as managers. "GG International" is the "registered agent" for over 1700 LLC clients, the majority of which have been revoked, dissolved, or in default.

102. Kayem is not registered as a corporation doing business in Nebraska. GG International appears to provide LLC licensing services under a variety of internet addresses and names, including "Same Day Corp" and "Nevada LLC Services." However, the checks for LLC licensing services from these companies are all to be paid to "GG International."

103. Upon information and belief, Mr. Moore alleges that the substances provided to DCS by Kayem, where similar to (perhaps identical to) the package as shown in Ex “O” and “P”.

104. In an April 20, 2011 email to Mr. Moore’s attorney, Mr. Verma describes Mr. Harris and Mr. Atwater in extremely unflattering terms[18], to include the following:

> Now to throw light on the transaction pertaining to sale of Thiopental Sodium to this department, we have to summarize as under;

[18]NOTE: The emails of Mr. Verma, Mr. Harris, & Mr. Atwater contain numerous misspellings, typos, and other grammatical errors. These errors have not been corrected and the contents of the correspondence is reproduced exactly as received.

a) One Mr. Chris Harris a.k.a Mr Christopher Harris of resident 145 B , Prashanti Building, Bosepukur Road, Kolkatta 700 019 – Indian Citizen under passport No G 9575846 AND EMAIL id (KNOWN TO US) : Chris Harris" <chrisharris85@gmail.com>, has approached (Copy marked as Annexure – II hereof) us through our websearch claiming himself to be a "Pharmacy Broker" to market our facility including our Ayurvedic products throughout the world and have started using a designation as " Director - Sales & Marketing" and joined in operation of our Bank Account as one of the Authorized Signatory with Axis Bank bearing No.910020038604067 Axis Bank, Gariahat, Kolkatta, since the month of July-September 2010 in order to monitor recovery of his sales proceeds.

b) To this extent the said Mr Chris Harris has procured a Order from One M/sECO Pharma Ltee Capital Pharmacy 57 SSR Street, Port Louis Mauritius to whom we have exported Generic Medication and received payments through confirmed Letter of Credit. He also procured multiple orders from Europe and various other countries where we have exported to the extent of value received.

c) **In pursuit of his marketing activity he has referred to us his acquaintance name Mr Wayne Atwater a.k.a Mr Tony Atwater a resident of Stebun Maine, USA** under Social Security No 004-76-6629.

d) Later on the said **Mr Chris Harris has required us to induct him in our Board of Director by amendment to the records of Registrar of Companies which we have declined in view of his gradual aggressive involvement in activities detrimental our interest**.

e) **By this time the said Mr Chris Harris & Mr Wayne Atwater of their own have surreptitiously and without taking the Company mandate and in disagreement to the provision of Indian Law have applied to the Secretary of State Nevada to incorporate a Company in the Name & Style of " Kayem Pharmaceutical LLC , wherein our Passport Numbers were used which we came know when we got information that a Company has been floated by this Duo**.

f) The justification given by the duo was that only by formation of a Corporate entity in USA, we will get the relevant approvals to market of our Ayurvedic Product and ironically these justification was given to us (Directors of Kayem Pharmaceutical Pvt Ltd) only after incorporation of this Kayem Pharmaceutical LLC. Further **to our utter dismay we have been made a party to the equity of a Company whereas we have never remitted a single penny for its incorporation including hiring of an Agent G.G. International and whereas this entity was formed by the private money of this duo**.

g) **This sudden and abrupt formation of Company by this duo has given rise to suspicion about the some eminent deceit by the hands of this duo** and thus we have asked for a Deed of Guarantee (Copy attached and marked Annexure - IIi hereof) wherein all the constituent were required to keep each other safe and indemnified and the compliance of Local US Law was the sole obligation of Mr Wayne Atwater resident of Maine USA under Social Security No 004-76-6629 as the Principal Officer .

h) Through the said Deed of Guaranty the said Mr Wyane Atwter has been authorized to operate Bank Account since he has required to receive our Export proceeds from future parties to facilitate speedy collection.

I) **By this time the intention of this Duo was clear to us as they wanted to make quick money even getting themselves in the unethical practices and which are detrimental to Kayem Pharmaceutical Pvt Ltd - India**.

j) **The situation was further got aggravated when we tried we approached directly to Mr Steve Urosoveich** - Chief Operating Officer of Department of Correction to understand the status of our participation in Tendering process of their regular **Formulary requirements which was a precondition of our export of Thiopental Sodium to them vide mail dated the 6th January 2011 wherein the said Mr Ursovich has categorically advised us to route our query through Mr Chis Harris , this has solicited Mr Harris ire who required for an explanation from us , the matter further worsened when we have asked the said Mr Urosvich on dated 14.03.2011 to issue us an official certificate that we have supplied them 'Thiopental Sodium" so that we may use this certificate with other Institutions in Africa as a testimony of our credential as Exporter the reply was again laconic and discouraging and with an instruction to route every correspondence through Mr. Chris Harris as if The Department has not dealt with a Company but with a Pharmacy Broker " Chris Harris" –** Copy of both the mails attached and marked Annexure - IV hereto. These two mails clearly establishes the fact this sale of Thiopental Sodium in country of USA through Department of Correction was purely a transaction between the said department and Mr Chris Harris wherein we have been utilized by both the parties for their respective gains.

k) After cessation of our relations this Duo, **the Duo has mounted a website as http://www.kayempharma.org with same design and content to deceive our Customers and to the detriment of our reputation. They have further posted various Sex enhancement products on multiple B2B Portal including www.Alibaba.com with a sole intention to tarnish our image and to avenge themselves for the severance of our relation prompted by us as a proactive measures to prevent further complications.**

l) **We (Kayem Pharmaceutical Pvt Ltd) is also evaluating the proposition to initiate legal proceeding against this Duo for breach of trust and warranty of authority including interalia defrauding bonafide Indian Merchant**.

m) The Name of Chris Harris from our website has been removed with a purpose to exhibit all concerned that he is no longer with us.

n) Therefore, it is to confirm that **the entire transaction arisen out of the sale of Thiopental Sodium was between Mr Chris Harris and Mr Steve Urosvich and our role was merely supply of Thiopental Sodium on the advice of Chris Harris –Pharmacy Broker and on receipt of Payement by the Importer** – the Government Consumer in a legitimate course of our trade and only upon receipt of advance in our name. to this extent we enclose the Copy of Treasury warrant No 19902946 dated 29th November 2010 (Copy attached & marked Annexure- V hereof)

105. On April 23, 2011, Mr. Harris sent an email to Mr. Moore's attorney refuting the statements made by Mr. Verma set forth in the above paragraph as follows:

a. First **I did not approach Kayem or Navneet. Navneet approached me through GIL from Altcharge.com** . And since I was doing marketing for other companies he offered me to join Kayem as a partner.

b. Yes I did procure multiple orders for Kayem as that was my part to bring in business for the company. I was to be inducted into the board of Kayem and also be paid a % which I did not receive & have realized was not inducted into the board of directors of Kayem as Navneet Verma wanted to keep all profits to himself. **After realizing this and coming to know of how he was planning to cut Tony out of the profit sharing I decided to remove myself from the company**.

c. Yes **I had referred Tony (Wayne Atwater) to Navneet as Tony was going to take care of the marketing of the company websites and also help in marketing the Herbal Range in the US. And for later getting the company products registered in the US for which the LLC was setup by Tony and was to get 12.5% of gross sales**.

d. As for being inducted into the board that was to be done and decided when I joined the company in August 2010 and also 50% ownership of the Brand Celebration was to be given to me. Which towards the end I realized was not going to happen as Navneet kept giving excuses for delays. And **I like a fool trusted him and was going all out to market the company products.** And all

sales of every item was informed to him as he was to take care of the legality of export items. Even all payments we to Kayem.

e. The LLC was formed with the full knowledge of Navneet and mails are attached where he has even mention how the LLC is to function after setup. **And as finalized with Tony Kayem was to pay Tony 12.5% of gross sales. But later Navneet later said to pay Tony 10% and even told me to get all future US order payments into Kayem's India account so Tony would not have to be paid anything. This I immediately informed Tony of how Navneet was wanting to defraud him. And We both decided to leave Kayem.** Also how could we setup the LLC without the signatures and documents they (Navneet & Mahinder) provided? This very fact they gave all they documents, signed the contract and even gave the details of how the LLC is to function proves they were 100% aware of it and were in agreement of the LLC being formed.

f. I agree that Kayem did not pay for the setup of the LLC as that was to be paid by Tony. And if it is to his utter dismay that he was made a party to the LLC why has he not resigned from it. In fact Tony has even sent him a mail asking for his resignation which has not been done and till date 23rd April 2011 the LLC details are mentioned on the Kayem website. Also how could we setup the LLC without the signatures and documents they provided? This very fact they gave all they documents, signed the contract and even gave the details of how the LLC is to function proves they were 100% aware of it and were in agreement of the LLC being formed.

g. This Deed which was signed by all of us was just as a security. If you will see all transactions (documentation, export and even the funds came into the bank account controlled by Navneet) **Tony and myself were just doing marketing for the company for which the LIONS share of profit was benefited by Navneet**. So if we planned to deceive anyone then no funds should have gone into Kayem's India account. **This proves that Navneet is just full of Shit**.

h. [NO RESPONSE]

I. **If quick money was to be made by Tony and Me why would all payments come to Kayem's accounts. This proves what a bunch of lies Navneet is concocting**.

j. As the department of Corrections has only been dealing with me hence they wanted all correspondence to be routed through me. As Navneet would deal with his Angola party and I would not interfere as that would confuse the buyer. As for him asking for a certificate I had told Navneet that we cannot ask the department of corrections for a Certificate as we are not their regular supplier and have just

worked with them on a very small order. But Navneet wanted to highlight it that he was a Supplier to the department which Kayem is not. In fact **when Nebraska first placed they order Navneet even put it up on the Kayem website that Kayem was a supplier to the Department of corrections for which I was told by Steve (Nebraska) to remove as we are not a regular supplier**. In fact Navneet would call me daily asking me to contact other states to buy the Sodium Thiopental.

k. As for deceiving customers. Navneet had kept my name and details on the Kayem website even after I had informed him to remove it as I was no more with the company. He even sent a mail at that time to Steve and marked a copy to me just to show I was with the company. After sending him repeated mails and threatening with legal action he finally removed my details but till date has the LLC details on the site. I have even mentioned on my website www.harrispharmallp.com that we have no connection with Kayem. My website is still not complete as we are still in the process of getting all the licenses for my company Harris Pharma LLP & getting the Harris Atwater LLC setup. That is why we have not picked up any orders till now. We will be having all our licenses ready in 20 days and then will start marketing for our company.

l. He is evaluating if to initiate legal proceedings against us. Makes me laugh. I have threatened him with legal action if my details were not removed from his websites www.kayempharma.com and www.kaykayhealthcare.com My contact number +1-2394945670 is still on his Kaykay website. As for defrauding **it is he who has defrauded me as all proceeds he has kept for himself.** And all details of invoices are in the public domain so you can check where the funds were paid into.

m. This has been done only after I threatened legal action against them if my details were not removed. And my US number is still on his www.kaykayhealthcare.com website.

n. If the person in charge of sales for a company is called a broker then there should be a broker fee. Which broker works for free as all proceeds went into the account of Kayem. (Emphasis added)

106. In his first email on April 27, 2011, Mr. Verma described Mr. Harris and Mr. Atwater as "Drug Peddlers" who had been sending him threatening mails, including the following:

From: tony atwater [mailto:ath202000@yahoo.com]
Sent: 27 April 2011 04:36

To: navneet@kayempharma.com
Subject: llc

Navneet **you piece of shit thief**, you should take the Nevada address off your website as I have told them about your fraud and it is closed. You **little cock sucking lier!** You say you have no idea about the starting of the llc but yet you still use the address? **MORON**

Tony Atwater (Emphasis added)

107. In a second email on April 27, 2011, Mr. Verma advised Mr. Moore's attorney that:

> Secondly, **we are extremely thankful that we have been saved from the blackmail of these Drug Peddlers who were exercising coercion on us for the sake of Foreign Orders** and we are filing various Legal recourses here in India since the jurisdiction is in India. (Emphasis added)

108. In a third email on April 27, 2011, Mr. Verma advised Mr. Moore's counsel as follows:

> 2. Mr Christopher Harris has been recommended to us by one Mr Gil Vazquez, Business development of Altcharge.com a Bank[19] who provides Merchant Account for E-Commerce in the month of July 2010 to develop our Export business of Generic Medicines.
>
> 3. We have also obtained a confirmation from Mr Ike Khan a resident citizen of Florida USA[20] who has introduced us to the said Altcharge .com in course of his business as Merchant Bank Broker, about the authenticity of this recommended persons of Altcharge. Mr Ike Khan was instrumental in obtaining a Merchant account with said Altcharge for our proposed E-Commerce Site (which is in fact a non-starter business proposition as of now). Copy of the said mail attached.
>
> 4. Since July –August 2010 the said Mr Chris Harris has came to us on the

[19]Altcharge is not a "bank," but basically an electronic check cashing service (similar to PayPal). It's target client base includes high risk clients, such as foreign internet pharmacies and sellers of adult DVDs.

[20]This was apparently Ike Khan of ikekhan.com who advertizes maid services, door hanging, Florida tours, A1 Realty, A1 Lending, and Ace Financial.

recommendation of said Mr Gil Vazuez of Altcahrge (email ID: gil@altcharge.com; Phone (800)851-2004 ext 202 Fax -(702) 926-6898) and have procured a few Orders and put a precondition that he will procure future orders on a permanent basis only when he is made a partner to our firm and accordingly asked us to induct him in our Board of Directors.

5. This request had never been materialised since **his subsequent behaviour in his dealing in a very non-transparent manner had engender a sense of suspicion and deceit and have alarmed us for bigger complications** in future.

6. All the matter post exportation of Thriopental Sodium to Nebraska & South Dakota has been mentioned to you in our mail dated 20th April,2011.

7. For the sake of argument, may we ask - Has Mr Chris Harris- Director Sales & Marketing ever got any Letter of Appointment or the Resolution effecting his induction in our Company? If he has , when he has resigned and whether the same has been complied with the provisions of the Registrar of Companies- India or not?

8. However all these matters pertains to our internal issues which are the subject of our Indian court and which we are seriously agitating here with jurisdictional court. And **we confirm this blatant exploitation of Indian Merchants by the hands of this so called "Pharmacy Broker/ Drug Peddlers shall no longer be tolerated and shall be put to a logical** end which we assure of this.

9. This is also an irony that within a span of Five months i.e from July-August 2010 to January 2011 , the guy swiftly procures orders of "Thiopental Sodium"- alone and that too for the prisons of USA knowing its end use but not disclosing the same to the Exporter Company to which **he pretends to be a Director and further to the worst of irony the Prison Officials also decline to talk to the actual exporter** , as if it was a transaction, a closely guarded secret, between two individuals- A Pharmacy Broker & a State Department . Immediate upon the conclusions of these two exports and upon coming the matter under public debate, **these brokers runs away from the Company by citing a false pretext**, looking for another supplier of "Thiopental Sodium" for the prisons of USA. Pl refer current positing of http://www.alibaba.com/product-free/114542262/sodium_thiopental.html A common understanding is that one joins in Board of Director of Company as an executive Officer for at least a longer period of time to make prosper the company/association for a permanent return. **This transaction clearly indicates a greater conspiracy where in a bonafide Indian merchant is being defrauded in the hands of this so called "Pharmacy Broker"** . Does it not sound or bacons for greater conspiracy. Normally if anybody joins in the Company as Promoter Director he remains with the company

or even complies with the applicable provisions of Law for subscribing in the share capital of the Company or for his severance with the said Company but in current case it is a few mails which entitles these guy to become a Promoter Director and on the very one day entitles him to quit. This **all are a sham which we are going to address here in India through the remedy available in in court of Law**. (Emphasis added.)

109. Although Mr. Verma and Mr. Harris, assert in their communications with Mr. Urosevech and Mr. Moore's counsel that the export to DCS was legal under United States law, Mr. Verma has admitted that it is not properly registered under the FDA Act to provide controlled substance into the United States market.

From: Navneet Verma [mailto:navneet@kayempharma.com]
Sent: 21 April 2011 11:41
To: 'David Zeiger'
Subject: RE:

Dear Mr David

In view of your enquiry and our mail dated the April12th,2011, we confirm that we shall not able to help you in this context since sale of Thiopental Na to Jails/Prisons has a serious conflict with our Ethos and secondly **our products are not registered in USA for market (pursuant to Sec 355(j) of USFDA Act) nor we intend to engage in ourselves at this point of time oblige by selling an unregistered products in a regulated market unless the buyer obtains relevant permissions for import of our Drugs in USA**.

Therefore, we are extremely sorry to help you in this context.

Best regards

From: David Zeiger [mailto:David.Zeiger@PriorityCo.com]
Sent: 21 April 2011 03:47
To: Navneet Verma
Subject: RE:

Hi Navneet,

My companies website is www.priorityco.com PPI is a nationwide pharm wholesaler primarily to acute care hospitals. PPI has been in business for over 30 years and is licensed in 44 States as a wholesaler. Our primary distribution center

is in San Diego, California and the Salt Lake City DC will open shortly.

I am interested in selling Thiopental Na to the US prison system as both you and Hospira have dropped the product understanding it is a political issue secondary to low dollar volume.

I would only be interested if Kaye continues to supply PPI with product on an ongoing basis.

Hope this helps,
Priority Pharmaceuticals, Inc.
Dave Zeiger, Pharm.B/CEO
4040 Sorrento Valley Blvd, Su D
San Diego, Calif. 92121-1415
1-858 -761-1886 M
Fax to E-mail 1-858-952-5566

From: Navneet Verma [mailto:navneet@kayempharma.com]
Sent: Tuesday, April 12, 2011 11:16 PM
To: David Zeiger
Cc: Doug Hartel (letrah@charter.net); 'doug.hartel' (doug.hartel@hartelinternational.com)
Subject: Re:

Dear Mr David

We are thankful to receive your enquiry, we confirm That we are manufacturer of Thiopental Sodium**. Our Product is not registered in USA for its domestic distribution**, what we have exported to the Prison (Nebraska & South Dakota) was meant to in-house usage and hopefully within the provision of Sec 510 of USFDA Act.

Subsequent upon the oppositions of Death Penalty opponents and in line our belief we have declared that we will not sell to any body who is intending to use this product as Lethal Injection or its misuse.

In view of your enquiry and to commence any further discussions on this matter, we shall be obliged to have a complete detail of your Organization together with its market standing and the purpose to buy this Product.

Thanking you
Regards,
Navneet Verma
Managing Director & CEO (Emphasis added.)

FACTUAL ALLEGATIONS: FEDERAL CONTROLLED SUBSTANCE LAWS

110. Sodium thiopental is a Schedule III controlled substance under the Federal Drug Controlled Substances Act[21] (hereinafter "FDCA"). i.e., Drug Code Number (code 2100). Substances intended to induce general anesthesia are "drugs" within the meaning of the FDCA and are subject to FDA regulation.

111. The provision of LB 36, § 11[22], that excludes obtaining, dispensing, or administering controlled substances for the purposes of conducting a lethal injection from Nebraska Uniform Controlled Substances Act or various professional licensing acts does not, and cannot, limit the scope of federal law[23].

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[21]21 U.S.C. § 801 *et seq*. See 21 U.S.C. § 321(g)(1); see also, e.g., FDA Guidelines For The Clinical Evaluation Of General Anesthetics. Substances intended to induce general anesthesia are "drugs" under the FDCA even when they are used as part of a process designed to cause death. See FDA Compliance Policy Guide § 650.100 (FDA "considers products used for animal euthanasia to conform to the definition of drug under [21 U.S.C. § 201(g)(1)(C)] since they are clearly intended to affect the function of the body by inducing death."); see also *United States v. Articles of Drug . . . Labeled in Part . . . Beuthanasia* D, No. 77-0-396, Food Drug Cosm. L. Rep. (CCH) P38265 (D. Neb. Aug. 1, 1979) (upholding FDA's position that pentobarbital sodium is a "drug" when used during animal euthanasia). See 21 U.S.C. § 321(g)(1)(C); see also *Chaney v. Heckler*, 718 F.2d 1174, 1182 (D.C. Cir. 1983) (holding that drugs used during lethal injection are subject to regulation under the FDCA), *rev'd on other grounds sub. nom Heckler v. Chaney*, 470 U.S. 821 (1985).

[22]Codified at Neb. Rev. Stat. § 83-966 (2010 Cum. Supp.)

[23]In *Gonzales v. Raich*, 545 U.S. 1, 17, 125 S. Ct. 2195, 2205-06, (2005), the Supreme Court held that the provisions of the FDCA were constitutional under U.S. Const. Art. I, § 8 and enforceable against the petitioners, even when California had legalized the distribution of medical marijuana as a matter of state law. The Court noted:

> Our case law firmly establishes Congress' power to regulate purely local activities that are part of an economic "class of activities" that have a substantial effect on interstate commerce. See, e.g., *Perez*, 402 U.S., at 151, 91 S.Ct. 1357; *Wickard v. Filburn*, 317 U.S. 111, 128-129, 63 S.Ct.

112. Under the supremacy clause of Art. VI, § 2 of the United States Constitution, Nebraska state law is superseded to the extent that it conflicts with federal law. *Felder v. Casey*, 487 U.S. 131, 108 S.Ct. 2302 (1988); *Whitehead Oil Co. v. City of Lincoln*, 245 Neb. 680, 515 N.W.2d 401 (1994).

113. Neither the Legislature in adopting LB 36, nor DCS in adopting Title 69, Chpt 11, intended that controlled substances to be used for lethal injection should (or could) be obtained by DCS in violation of the FDCA.

Federal Drug Control Act and the Food & Drug Administration (FDA)

114. It is a violation of federal law under the FDCA to "introduce or deliver for introduction into interstate commerce[24]" any unapproved new drug, or any drug that is misbranded or adulterated, as those terms are defined in the FDCA. 21

82, 87 L.Ed. 122 (1942). As we stated in *Wickard*, "even if appellee's activity be local and though it may not be regarded as commerce, it may still, whatever its nature, be reached by Congress if it exerts a substantial economic effect on interstate commerce." *Id*., at 125, 63 S.Ct. 82. We have never required Congress to legislate with scientific exactitude. When Congress decides that the " 'total incidence' " of a practice poses a threat to a national market, it may regulate the entire class. See *Perez*, 402 U.S., at 154-155, 91 S.Ct. 1357 (" '[W]hen it is necessary in order to prevent an evil to make the law embrace more than the precise thing to be prevented it may do so' "(quoting *Westfall v. United States*, 274 U.S. 256, 259, 47 S.Ct. 629, 71 L.Ed. 1036 (1927))). In this vein, we have reiterated that when " 'a general regulatory statute bears a substantial relation to commerce, the *de minimis* character of individual instances arising under that statute is of no consequence.' " E.g., *Lopez*, 514 U.S., at 558, 115 S.Ct. 1624 (quoting *Maryland v. Wirtz*, 392 U.S. 183, 196, n. 27, 88 S.Ct. 2017, 20 L.Ed.2d 1020 (1968); emphasis deleted).

[24]Importation of a drug amounts to introduction or delivery for introduction of that drug into interstate commerce. See 21 U.S.C. § 321(b)(1) ("The term 'interstate commerce' means . . . commerce between any State or Territory and any place outside thereof . . . .").

U.S.C. § 355(a); 21 U.S.C. § 331(d); 21 U.S.C. § 331(a). The importing of an unapproved new drug, a misbranded drug, or an adulterated drug is a federal crime punishable as a misdemeanor or felony under 21 U.S.C. § 333(a). The importing of an unapproved new drug is also prohibited by FDA regulations. 21 C.F.R. § 314.410(a)(1). The importing of any drug—new, old, approved or unapproved—is prohibited by FDA regulations unless the drug is listed with FDA and was produced at a registered foreign drug establishment. *Id*. § 207.40(b).

115. As used in the FDCA, a drug is an "unapproved new drug" if:

a. It is not generally recognized as safe and effective ("GRAS/E"), as that phrase is used in the FDCA's "new drug" definition. Compare 21 U.S.C. § 321(p), with The Unapproved Universe, Deborah M. Autor, Esq., Director, Office of Compliance, Center for Drug Evaluation and Research, FDA, at 7 (Jan. 9, 2007),("The agency believes it is not likely that any currently marketed prescription drug is GRAS/E.").

b. It is not covered by either of the FDCA's "grandfather" provisions. Compare 21 U.S.C. § 321(p) (1938 clause), and Pub. L. No. 87-781 § 107, 76 Stat. 781, 788-89.

c. Because thiopental is not GRAS/E and is not grandfathered, thiopental is a "new drug" within the meaning of the FDCA. See 21 U.S.C. § 321(p); see also 36 Fed Reg. 6609-10 (Apr. 7, 1971) (FDA pronouncement that thiopental sodium in suppository form is a "new drug" under 21 U.S.C. § 321(p) and that a "new drug application is required from any person marketing such drug without approval").

d. Like any new drug, thiopental requires FDA approval before it may be lawfully introduced into interstate commerce or delivered for introduction into interstate commerce. 21 U.S.C. § 355(a).

e. Despite its long history, thiopental sodium for injection has never been approved by FDA or otherwise evaluated by FDA for safety or effectiveness.

116. As used in the FDCA, a drug can be "misbranded" for numerous reasons, including as follows:

a. A drug is misbranded if its labeling fails to include adequate warnings or required information about side effects and contraindications. 21 U.S.C. §§ 352(f)(2), 352(n).

b. A drug is also misbranded if it was manufactured by a foreign firm that has not registered with FDA. 21 U.S.C. §§ 352(o), 360(l).

c. A drug is misbranded if it is not listed with FDA. 21 U.S.C. §§ 352(o), 360(j).

d. A prescription drug is misbranded if its labeling fails to prominently display the symbol "Rx only." 21 U.S.C. § 353(b)(4)(A); see 21 C.F.R. § 201.16; cf. *In re Canadian Imp. Antitrust Litig.*, 385 F. Supp. 2d 930, 933 (D. Minn. 2005) ("Section 353(b)(4) does not allow for the substitution of another country's "equivalent" symbol for the United States' "Rx only" symbol."), aff'd 470 F.3d 785 (8th Cir. 2006).

117. The controlled substance imported by DCS from Kayem to be used for lethal injection is a "misbranded" drug for each of the reasons discussed in the paragraph above. First, the labeling for imported thiopental fails to include many of the warnings, side effects, and/or contraindications that were provided by Abbott and Hospira. For instance, the labeling for imported thiopental fails to warn that thiopental is habit forming and fails to identify at least six potential drug-drug interactions. Second, imported thiopental is not listed with FDA. Third, the imported controlled substance was manufactured and distributed by an unregistered foreign source. Finally, the substance is a prescription drug and the labeling fails to display the "Rx only" symbol.

118. As used in the FDCA, the term "adulterated" refers to more than just the purity of a product. A drug is adulterated if its composition varies in any respect from the

standard formulation established by the official United States Pharmacopeia[25]. Assuming that the controlled substance from Kayem is not counterfeit, they may have been produced according to the standards established by the Indian Pharmacopeia (I.P.) or British Pharmacopeia (BP). as denoted on the packaging as "I.P." There is no evidence that the substance provided by Kayem is in compliance with the official United State Pharmacopeia (U.S.P.) which defines thiopental sodium for injection as containing "not less than 93.0 percent and not more than 107.0 percent of the labeled amount of C11H17N2NaO2S."

119. Even if not pharmacologically deficient, drugs are deemed "adulterated" under the FDCA if they are not manufactured in accordance with FDA's current good manufacturing practice ("cGMP") regulations[26]. If the process used to produce the drug does not conform to FDA's cGMP regulations, the drug is adulterated under the law even if the drug is not chemically flawed in any way[27].

120. It is simply unknown and cannot be confirmed whether the controlled substances imported by DCS from Kayem were produced in accordance with FDA's cGMP

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[25]See 21 U.S.C. §§ 351(b) (a drug is adulterated if "its strength differs from, or its quality or purity falls below, the standard set forth" "in an official compendium"), 321(j) (the term "official compendium" means "the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them"). Upon information and belief, the imported thiopental at issue in this litigation is adulterated within the meaning of 21 U.S.C. § 351(b).

[26]See 21 U.S.C. § 351(a)(2)(B); see also *Vermont v. Leavitt*, 405 F. Supp. 2d 466, 473 (D. Vt. 2005).

[27] See *Nutritional Health Alliance v. FDA*, 318 F.3d 92, 100 n.9 (2d Cir. 2003) (collecting cases).

regulations. The FDA has not inspected the Kayem or Neon facilities and/or processes used to manufacture or package the controlled substance, and there exists photographic evidence that Kayem's facilities and/or processes are deficient.

121. FDA has long maintained that even state governments are in violation of federal law when they import unapproved drugs. FDA has repeatedly sent letters to state and local governments warning that public programs seeking to import foreign prescription drugs would violate federal law, including:

a. In August 2003, FDA advised the California Attorney General that any state program that sought to purchase lower-cost drugs from Canada would be illegal.

b. In November 2003, FDA stated that a program proposed by the Governor of Illinois to allow senior citizens to purchase drugs from Canada "would be in direct conflict with [the FDCA]."

c. In February 2004, FDA informed the State of Minnesota that a website encouraging citizens to obtain prescription drugs from Canada was "unwise," "unsafe," and "illegal[]."

d. In March 2004, FDA informed the Governor of New Hampshire that endorsing any program to purchase drugs from Canada would "undermine one of our nation's key consumer protection statutes [i.e., the FDCA]." FDA further warned that any drugs purchased from Canada "will clearly be illegal in virtually all instances.". FDA also asserted that employees of New Hampshire's Department of Corrections were not qualified to determine whether a particular vendor of foreign drugs was a permissible source of imports.

e. In April 2004, FDA sent a follow-up letter decrying a nascent program established by the New Hampshire State Police Laboratory that purported to assess whether Canadian drugs were equivalent to FDA-approved products in terms of potency and purity. FDA found such efforts wholly lacking because they could not "reveal if a foreign drug is expired, contaminated, was stored under adverse or inappropriate conditions, or is counterfeit."

f. Between 2004 and 2008, when multiple jurisdictions were considering drug importation programs, FDA sent numerous similar letters to local and state government officials around the country.

122. In addition to sending warning letters to state government officials, FDA has denied several formal citizen petitions that sought FDA's permission to import unapproved new drugs.

a. In October 2003, FDA received a petition requesting that FDA "use its enforcement discretion to allow importation of Canadian versions of drugs that are [FDA-approved]." Petition of the City of Springfield, Mass. dated Oct. 7, 2003, Docket No. 2003P-0479, Doc. No. FDA-2003-P-0238-0002. FDA denied that petition on August 9, 2004, on the ground that the agency lacked authority to implement such a policy:

> [T]he petition requests that FDA ignore the will of Congress and sanction the complete and systematic violation of the statutory provisions that FDA was created to enforce. FDA cannot simply substitute its (or your) judgment over the judgment of Congress as expressed in the Act.

b. In December 2003, FDA received a petition from the State of Vermont requesting that FDA "waive or revoke the current FDA interpretation of statutes and regulations that prohibit" Vermont from establishing a program "to obtain prescription medications from sources in Canada." Petition of the State of Vermont dated Dec. 4, 2003, Docket No. 2003P-0479, Document No. FDA-2003-P-0238-0005. FDA denied the petition on August 4, 2004, on the ground that Vermont's "proposal would not be consistent with . . . [FDA's] statutory responsibility to protect the nation's drug supply." The United States District Court for the District of Vermont agreed with FDA and dismissed Vermont's complaint with prejudice. See *Vermont v. Leavitt*, 405 F. Supp. 2d 466, 474 (D. Vt. 2005) ("There is no question that Vermont's proposed program would violate the FDCA.").

c. Similar FDA refusals to condone the illegal importation of unapproved drugs have been upheld by other federal courts. See, e.g., *Montgomery County Md. v. Leavitt*, 445 F.Supp. 2d 505 (D. Md. 2006) (upholding FDA's denial of a similar request made by Montgomery County, Maryland); *Andrews v. United States* HHS, No. 04-0307, 2005 U.S. Dist. LEXIS 5710 (D.D.C. Mar. 31, 2005) (upholding HHS's refusal to certify that Canadian prescription drugs pose the same risks as FDA-approved products).

d. The FDA has launched successful enforcement actions against firms that sought to import unapproved new drugs. See, e.g., *United States v. Rx Depot, Inc.*, 290 F. Supp. 2d 1238, 1240 (N.D. Okla. 2003) (entering a preliminary injunction against a firm and its principals where the firm's business was to assist "individuals in procuring prescription medications from pharmacies in Canada"); *United States v. Genendo Pharmaceutical, N.V.*, 485 F.3d 958, 960 (7th Cir. 2007) (affirming seizure and condemnation of drugs offered for import, as well as permanent injunctive relief where a firm was "obtaining prescription drugs overseas and importing them into the United States for resale").

123. On January 4, 2011, FDA issued a statement regarding its role in the importation of unapproved thiopental from unregistered foreign manufacturers and distributors. FDA stated that it did not verify the identity, potency, safety, or effectiveness of these controlled substances, nor did it claim that importation from foreign unregistered manufacturers and distributors were imported legally. Rather, the FDA simply stated that it would defer enforcement authority to other law enforcement agencies.

Federal Drug Control Act and the Drug Enforcement Agency (DEA)

124. A central feature of the FDCA is its "closed system" of distribution in which all persons in the "legitimate distribution chain" of controlled substances must register with DEA. The FDCA created three categories of registrants: " manufacturer," "distributor," and "practitioner." Each category has distinct requirements for registration with DEA. See 21 U.S.C. § 823(a) (criteria for " manufacturer" registration), 21 U.S.C. § 823(b) (criteria for "distributor" registration), 21 U.S.C. § 823(f) (criteria for "practitioner" registration). A "manufacturer" is authorized to engage in "[t]he production, preparation, propagation, compounding, or processing of a drug." *Id*. A "distributor" is

authorized to "deliver (other than by administering or dispensing) a controlled substance." *Id*. Manufacturers, distributors and dispensers are required to register with the Attorney General under the provisions of 21 U.S.C. § 822(b). The Attorney General, in turn, has delegated the registration authority to the DEA. See 28 C.F.R. § 0.100(b).

125. Federal law requires that prior to the introduction of a new drug in the United States market, a manufacturer must file a New Drug Application (NDA) with the FDA. See 21 U.S.C. § 355(b)(1). The FDCA requires that a NDA include information and reports on the drug's safety, composition, and manufacturing process. *Id*. The manufacturer is required to submit proposed labeling, patent information, and samples of the drug for testing. *Id.* After receiving the submissions, the FDA reviews the application and renders a decision on the NDA.

126. To market a generic drug in the United States, a manufacturer must file an Abbreviated New Drug Application (ANDA). 21 U.S.C. § 355(j). As part of an ANDA, the manufacturer is required to show that the FDA has previously approved the active ingredient(s) of its generic product. 21 U.S.C. § 355(j)(2)(A)(ii). The generic drug must be bio-equivalent to the originally approved (pioneer) drug and the proposed labeling must be the same as that of the pioneer drug. 21 U.S.C. § 355(j)(2)(A)(iv & v). The generic drug manufacturer must affirm that it is not infringing on a patent for the pioneer drug. 21 U.S.C. § 355(j)(2)(A)(vii).

127. As a matter of law, unapproved drugs are of unknown quality, lack evidence of

effectiveness, and present increased risks of impurity or subpotency. See generally Guidance for FDA Staff And Industry: Marketed Unapproved Drugs—Compliance Policy Guide, § 440.100 (June 2006), FDA's Concerns About Unapproved Drugs, ("The Agency has serious concerns that drugs marketed without required FDA approval may not meet modern standards for safety, effectiveness, quality, and labeling.").

128. Unapproved foreign drugs are presumptively unsafe and ineffective. FDA has previously stated that such products are also highly likely to be adulterated. See, e.g., *In re Canadian Import Antitrust Litigation*, 470 F.3d 785 (8th Cir. 2006) ("FDA's Office of Compliance has cautioned that '[d]rugs from foreign countries do not have the same assurance of safety as drugs actually regulated by the FDA,' due to the risk that counterfeit or unapproved drugs will be sent to consumers, and also because '[w]ithout regulation of repackaging, storage conditions, and many other factors, drugs delivered to the American public from foreign countries may be very different from FDA approved drugs with respect to formulation, potency, quality, and labeling.'") see also Importing Prescription Drugs, ("FDA cannot ensure the safety and effectiveness of products that are not FDA-approved and come from unknown sources and foreign locations, or that may not have been manufactured under proper conditions. These unknowns put patients' health at risk if they cannot be sure of the product's identity, purity, and source.")

129. FDA's experience teaches that foreign products are often not just adulterated, but actually counterfeit. In 2004, FDA took action against 4 foreign websites that

claimed to be able to ship drugs that were equivalent to FDA-approved drugs. In reality, those foreign websites were shipping products into the United States that were from unknown sources, were of unknown safety and efficacy, and did not include an active pharmaceutical ingredient. See FDA News Release, Feb. 12, 2004. The risk of purchasing an adulterated and/or counterfeit drug increases greatly when products are sourced online or from small distributors. See, e.g., FDA Initiative to Combat Counterfeit Drugs, ("[S]ome smaller wholesalers also knowingly or unknowingly take higher risks by obtaining drugs that may not have a clear "pedigree" traceable back to a legitimate manufacturer."); *id*. ("Counterfeit drugs . . . enter the U.S. market via disguised imports from other countries."). Moreover, as is the case here, the purchase of small lots from small distributors for uses which the country of origin would consider illegal or contrary to public policy raises the risk of adulteration and counterfeiting.

130. The DEA registration held by the Nebraska Department of Correctional Services does not authorize it to directly import drugs from a foreign supplier. 21 C.F.R. 1301 *et. seq*., 21 C.F.R. 1201.13.

FACTUAL ALLEGATIONS: DANGERS OF 'BOTCHED' EXECUTIONS

131. The public record is replete with instances of botched executions where the subject was not rendered unconscious through the injection of the purported sodium thiopental. For instance:

a. During the execution of Angel Diaz, which occurred in Florida in December 2006, the condemned prisoner spent 30 minutes gasping for air, grimacing, and trying to speak after the fatal drugs had been administered.

b. During the execution of Joseph Clark in Ohio in May 2006, the condemned prisoner actually raised his head off the gurney and spoke for several minutes after the thiopental had begun to flow, with witnesses reporting cries of pain for almost 10 minutes.

c. A federal district court found evidence that six of thirteen condemned prisoners executed by California between 1999 and 2006 remained conscious when the paralytic was administered. *Morales v. Hickman*, 415 F. Supp. 2d 1037, 1045 (N.D. Cal. 2006).

d. Another federal district court found, based on eyewitness accounts, that at least five condemned prisoners executed by the State of North Carolina had experienced pain and suffering well beyond the administration of thiopental. *Brown v. Beck*, No. 06-3018, 2006 U.S. Dist. LEXIS 60084, at 16-18 (E.D.N.C. Apr. 7, 2006).

e. A third federal district court found, again based on eye witness accounts, that several condemned prisoners executed by the State of Arkansas had remained conscious during their executions. *Nooner v. Norris*, No. 06-96183, 2006 U.S. Dist. LEXIS 96183, at 7-8 (E.D. Ark. June 26, 2006), *rec'd. on other grounds*, 491 F.3d 804 (8th Cir. 2007).

f. A federal appellate judge recently concluded that two of the four most recently executed prisoners in Tennessee were not properly anesthetized by thiopental prior to the administration of the other two drugs. *West v. Ray*, No. 10-6196, 2010 U.S. App. LEXIS 23043, at 16-18 (6th Cir. 2010) (Nelson Moore, J., dissenting) ("Tennessee's lethal-injection protocol has become, in practice, death by suffocation.").

132. There is a compelling interest on the part of the judicial branch, executive branch, and Mr. Moore that Nebraska's first lethal injection not be botched because DCS cut corners by obtaining controlled substances of unknown efficacy from a foreign distributor and manufacturer not inspected, registered, or approved by the FDA or DEA.

GROUNDS FOR RELIEF

GROUND ONE: THE LEGISLATURE THROUGH PASSAGE OF LB. 36, NEB. LAWS (2009) CHANGED MR. MOORE'S SENTENCE THAT WAS "FINAL" BY MITIGATING THE METHOD OF EXECUTION FROM ELECTROCUTION TO LETHAL INJECTION IN VIOLATION OF THE EXCLUSIVE COMMUTATION POWER OF THE BOARD OF PARDONS CREATED IN NEB. CONST. ART IV, § 13, AND VIOLATES THE SEPARATION OF POWERS PROVISIONS OF NEB. CONST. ART. II, § 1.

133. Mr. Moore incorporates by reference the allegations set forth in ¶ 1 through 132, above in this ground for relief.

134. Effective October 1, 1913, the Nebraska Legislature amended Nebraska statutes to provide that for capital offenses all executions would no longer be conducted by hanging, but by "causing to pass through the body of the convicted person a current of electricity of sufficient intensity to cause death, and the application of such current shall be continued until such convicted person is dead," Neb. Cons. Stat. § 10214 (1922).

135. Since at least 1973[28], until August 30, 2009, Nebraska law has stated in no uncertain terms that, "The mode of inflicting the punishment of death, **in all**

[28]LB 268, § 17, Neb. Laws (1973).

cases," shall be by the continuous passage of a current of electricity "**and not otherwise**[29]." (Emphasis added).

136. The Nebraska law in effect prior to August 30, 2009, made absolutely no provisions for any other method of judicial execution in the event that electrocution was held to be unconstitutional. The sole "remedy" available to the State was for the condemned prisoner to be sentenced to a term of life without parole, the alternate statutory sentencing option available under Neb. Rev. Stat. § 28-303 (Reissue 1995) and Neb. Rev. Stat. § 29-2320 through 29-2324 (Reissue 1995).

137. The Nebraska Legislature does not have the constitutional authority under Neb. Const. Art. II, § 1, through passage of LB 36, Neb. Laws 2009, to change a death sentence required to be conducted by electrocution once the judgment and sentence in the case became "final" before LB 36 took effect on August 30, 2009.

138. Although the Legislature and the Nebraska courts have the authority to mitigate a sentence through statutory changes that take effect while a case is pending on direct appeal under *State v. Randolph*, 186 Neb. 297, 183 N.W.2d 225 (1971) and its progeny[30], the constitutional authority to mitigate by commutation can only be exercised by the Nebraska Board of Pardons after a judgment and

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[29] Neb. Rev. Stat. § 29-2532 (Reissue 1995).

[30] *Jones v. Clarke*, 253 Neb. 161, 568 N.W.2d 897 (1997); *State v. Schrein*, 247 Neb. 256, 526 N.W.2d 420 (1995); *State v. Warner*, 192 Neb. 438, 222 N.W.2d 292 (1974).

sentence has become "final[31]."

139. The Nebraska Supreme Court has clearly and repeatedly held that neither the Nebraska courts nor the Legislature have the power to mitigate or commute a sentence after that sentence has become "final" without improperly invading the authority of the Board of Pardons under Neb. Const. Art. IV, § 13 and violating Neb. Const. Art. II, § 1. *State v. Bainbridge*, 249 Neb. 260, 543 N.W.2d 158 (1996) (Court's authority to reduce previously imposed 15 year license suspension under Neb. Rev. Stat. § 60-6,209 (Reissue 1993) held unconstitutional); *State v. Jones*, 248 Neb. 117, 532 N.W.2d 293 (1995) (Neb. Rev. Stat. § 29-2931 (Cum. Supp.1994), which provided the trial judge authority to reduce the sex offender's sentence by placing him on probation with the condition that he enroll in an approved aftercare treatment program or modify the original sentence to allow earlier eligibility for parole held unconstitutional.); *State v. Philipps*, 246 Neb. 610, 521 N.W.2d 913 (1994) (Neb. Rev. Stat. § 29-2308.01 (Reissue 1989), which provided that the sentencing court may reduce a sentence it had previously imposed within 120 days after imposition or receipt of mandate held unconstitutional).

GROUND TWO: THE LEGISLATURE THROUGH PASSAGE OF LB. 36, NEB. LAWS (2009) ABDICATED AND DELEGATED TO THE EXECUTIVE BRANCH (DCS) ITS EXCLUSIVE LEGISLATIVE RESPONSIBILITY TO DETERMINE THE PARTICULAR QUANTITY AND TYPE OF DRUG(S) TO BE USED IN LETHAL INJECTION IN VIOLATION OF THE SEPARATION OF POWERS PROVISIONS OF NEB. CONST. ART. II, § 1.

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[31] *Duff v. Clarke*, 247 Neb. 345, 526 N.W.2d 664 (1995); *Boston v. Black*, 215 Neb. 701, 340 N.W.2d 401 (1983).

140. Mr. Moore incorporates by reference the allegations set forth in ¶ 1 through 139, above in this ground for relief.

141. The plain language of LB 36 delegates to DCS, an agency of the Executive Branch, the legislative responsibility to determine the guidelines, procedures, protocol, standards, or policies associated with the selection, quantities, sequence, and obtaining of controlled substances to be used in conducting a lethal injection.

142. The delegation of legislative responsibility to the executive branch violates Neb. Const. Art. II, § 1, and the decisions in *Lincoln Dairy v. Finigan*, 170 Neb. 777, 104 N.W.2d 227 (1960), *Clemens v. Harvey*, 247 Neb. 77, 525 N.W.2d 185 (1994), and their progeny[32].

GROUND THREE: DCS HAS EXCEEDED THE SCOPE OF THE RULE MAKING AUTHORITY GRANTED BY LB 36 BY INTERPRETING LB 36 AND TITLE 69, CHPT 11 SO AS TO ALLOW DCS TO OBTAIN SODIUM THIOPENTAL FROM A FOREIGN UNREGISTERED DISTRIBUTOR AND MANUFACTURER TO BE USED FOR LETHAL INJECTION IN VIOLATION OF NEB. CONST. ART II, § 1 AND THE DUE PROCESS CLAUSE OF THE FOURTEENTH AMENDMENT TO THE UNITED STATES CONSTITUTION.

143. Mr. Moore incorporates by reference the allegations set forth in ¶ 1 through 142, above in this ground for relief.

144. The actions of DCS in obtaining sodium thiopental from an unregistered foreign distributor and manufacturer exceeded the scope of DCS authority under Title

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[32]See also, *State v. Salyers*, 239 Neb. 1002, 1005, 480 N.W.2d 173, 176 (1992) ("[T]he fixing of terms and conditions of probation is a judicial duty and function and cannot be delegated to anyone, including a probation officer."); *State v. Collins*, 1 Neb. App. 596, 510 N.W.2d 330 (1993) (The district court improperly delegated to the probation office the determination of the amount of restitution owed.)

69, Chpt 11, and exceeded the scope and authority granted to DCS under LB 36.

145. It could not, and was not, the intent of the Legislature that in obtaining the controlled substances to be used for a lethal injection, DCS could obtain the essential anesthetic necessary to induce unconsciousness from an unregistered foreign distributer working out of a two room apartment in a residential neighborhood in Mumbia, India.

146. It could not, and was not, the intent of the Legislature that DCS could obtain the controlled substances outside the normal registration and importation requirements of the federal statutory and regulatory scheme of the FDA and DEA.

147. The actions of DCS in the manner in which it obtained the sodium thiopental to be used to execute Mr. Moore exceeds the authority granted to the executive branch in LB 36 and is in violation of Neb. Const. Art. II, § 1 and the Due Process clause of the Fourteenth Amendment to the United States Constitution.

GROUND FOUR: THE USE OF SODIUM THIOPENTAL OF UNKNOWN EFFICACY OBTAINED FROM A FOREIGN UNREGISTERED DISTRIBUTOR AND MANUFACTURER FOR LETHAL INJECTION CREATES AN UNJUSTIFIED RISK OF A BOTCHED EXECUTION IN VIOLATION OF PROHIBITION AGAINST CRUEL AND UNUSUAL PUNISHMENT CONTAINED IN NEB. CONST. ART I, § 9 AND THE EIGHTH AMENDMENT AND DUE PROCESS CLAUSE OF THE FOURTEENTH AMENDMENT TO THE UNITED STATES CONSTITUTION.

148. Mr. Moore incorporates by reference the allegations set forth in ¶ 1 through 147, above in this ground for relief.

149. The actions of DCS in obtaining the sodium thiopental as alleged in this motion to be used to execute Mr. Moore, involves a known and unjustified risk that a substance of unknown and untested efficacy will be used that may result in a botched judicial execution in violation of the prohibition against cruel and unusual punishment under Neb. Const. Art. I, § 9, and the Eighth and Fourteenth Amendments to the United States Constitution.

GROUND FIVE: THE REPEAL OF ELECTROCUTION AS THE SOLE METHOD OF EXECUTION AND INTRODUCTION OF LETHAL INJECTION AS THE SOLE METHOD THROUGH LB 36 AND PROTOCOL CREATED BY DCS AFTER MR. MOORE'S CRIME WAS COMMITTED VIOLATES THE *EX POST FACTO* PROHIBITION OF NEB. CONST. ART I, § 16, ART I, § 10 OF THE UNITED STATES CONSTITUTION, AND THE DECISION IN *Calder v. Bull*, 3 Dall. 386 (1798) AND ITS PROGENY.

150. Mr. Moore incorporates by reference the allegations set forth in ¶ 1 through 149, above in this ground for relief.

151. Nebraska law in effect in August 1979 (time of the homicides), made electrocution the sole method of conducting a judicial execution. There have been five death warrants prior to January 2011, directing that Mr. Moore's death be caused by electrocution.

152. Electrocution as the sole method of execution in Nebraska was statutorily repealed by LB 36, Neb. Laws (2009) effective August 30, 2009. There was no "savings clause" to LB 36 regarding application of electrocution as an option to lethal injection to cases that were "final" on August 30, 2009.

153. LB 36 introduced lethal injection as the sole method of execution after August

30, 2009, with the new protocol signed by the Governor on January 24, 2010[33].

154. On its face and as applied to Defendant, LB 36 violates the Ex Post Facto clauses of Neb. Const. Art. I, § 16, Art I, § 10 of the United States Constitution, and the decision in *Calder v. Bull*, 3 Dall. 386 (1798), and it's progeny, in that LB 36 has attempted to retroactively:

a. Direct the Nebraska Supreme Court to modify a final criminal judgment by ordering a judicial execution by a different method than was required at the time of the offense. See, LB 37 § 7.

b. Create a new method of judicial execution through lethal injection based on the injection of substances and a protocol to be developed by DCS at some point after August 30, 2009. See, LB 36 § 10-12.

c. Create a new statutory rule that for any case in which a method of judicial execution has already been found unconstitutional and the case is final because of entry of a mandate following direct appeal, the "death sentence shall remain in force until the sentence can be lawfully executed by any valid method of execution." See, LB 36, § 13.

WHEREFORE Mr. Moore moves that he be granted an evidentiary hearing on his Motion for Postconviction Relief and that, following said hearing, Mr. Moore's death sentences be vacated and set aside.

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[33] *Washington v. Dowling*, 109 So. 588 (Fla. 1926) (State habeas petition granted as to death by electrocution where Legislature repealed statute in effect at time of offense which stated that, "[P]unishment by death **shall in all cases** be inflicted by hanging the convict by the neck until he be dead," and passed new statute stating, "Punishment of death **shall in all cases** be inflicted by causing to pass through the body of the convict a current of electricity of sufficient intensity to cause immediate death, and the application of such current must be continued until such convict is dead."(Emphasis added.); *Simborski v. Wheeler*, 121 Conn. 195, 183 A. 688 (1936) (The method of the prisoner's execution was to be conducted by law in effect at time of the offense (hanging), and could not be conducted by subsequent statutes providing for electrocution as sole method.).

Respectfully submitted,

Carey Dean Moore, Defendant

By: _____

Jerry L. Soucie, Bar # 16163
Nebraska Commission on Public Advocacy
P.O. Box 98932
140 N. 8th St., Suite 240
Lincoln, NE 68516
Attorney for Defendant, Carey Dean Moore

VERIFICATION

STATE OF NEBRASKA)
) SS.
COUNTY OF JOHNSON)

CAREY DEAN MOORE, being first duly sworn upon oath deposes and states that he is the Defendant in the above-entitled action, he has read the forgoing Successor Motion for Postconviction Relief, knows the contents thereof, and that the allegations contained therein are true as he verily believes.

_____
Carey Dean Moore
Inmate # 32947
Tecumseh Correctional Facility
P.O. Box 900
Tecumseh, NE 68542

SUBSCRIBED AND SWORN to before me this ____ day of May, 2011.

_____
NOTARY PUBLIC

CERTIFICATE OF SERVICE

I, Jerry L. Soucie, hereby certify that on this ____ day of May, 2011, a true and correct copy of the foregoing was hand delivered to the Office of the Attorney General, State Capitol Room 2115, Lincoln, NE 68509-8920 and copy to the Office of the Douglas County Attorney, ATTN: Don Kleine, 100 Hall of Justice, 1701 Farnam St., Omaha, NE 68183.

By: _____
Jerry L. Soucie, Bar # 16163
Attorney for Defendant, Mr. Moore

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