JS 44 (Rev. 06/17)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Fresenius Kabi USA, LLC, Plaintiff

(b) County of Residence of First Listed Plaintiff State of Illinois
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Mark A. Christensen, James M. Bausch, Nathan D. Clark
Cline Williams Wright Johnson & Oldfather, L.L.P.
1990 US Bank Bldg, 233 So. 13th St., Lincoln, NE 68508;402-474-6900

DEFENDANTS

State of Nebraska; The Nebraska Department of Correctional Services; and Scott Frakes, in his Office Capacity as Director of the Nebraska Department of Correctional Services

County of Residence of First Listed Defendant Lancaster
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*
Nebraska Attorney General
2115 State Capitol
Lincoln, NE 68509

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☒ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☒ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. Sections 1331 and 1332

Brief description of cause:
Action for Injunction /Preliminary Injunction

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☐ Yes ☒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

IN THE SUPREME COURT OF THE STATE OF NEBRASKA

State of Nebraska,
Appellee,
v.
Carey Dean Moore,
Appellant.

Case No. S-95-0485.

EXECUTION WARRANT

TO: THE NEBRASKA DIRECTOR OF CORRECTIONAL SERVICES

THIS MATTER came on for consideration on the 27th day of June, 2018, for the fixing of a date of execution and issuance of a death warrant for appellant, Carey Dean Moore.

WHEREUPON, appellant was tried and convicted before the District Court for Douglas County, Nebraska, and sentenced to death for each of two convictions of first degree murder; appellant's sentences of death, upon resentencing by a three-judge panel of the District Court for Douglas County, were affirmed by this Court on September 27, 1996, following mandatory direct review as provided by Neb. Rev. Stat. § 29-2525 (see *State v. Moore*, 250 Neb. 805, *as modified by* 251 Neb. 162 (1996));

WHEREUPON, it appearing to the Court that no stay has issued by a court of the United States prohibiting the fixing of an execution date, nor is there pending any action in the courts of the State of Nebraska challenging appellant's conviction or sentence;

WHEREUPON, the Court finds that Tuesday, August 14, 2018, shall be set as the date of execution;

IT IS THEREFORE ORDERED, ADJUDGED, AND DECREED that Tuesday, August 14, 2018, is hereby fixed as the date to carry said sentence of death into execution.

000095367NSC

EXHIBIT A

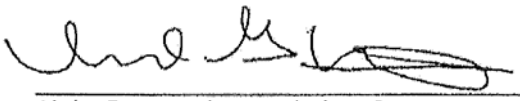
IT IS FURTHER ORDERED that Scott R. Frakes, Director of the Nebraska Department of Correctional Services, shall proceed on Tuesday, August 14, 2018, between the hours of 12:01 a.m. and 11:59 p.m., to carry said sentence of death into execution by administering to appellant, Carey Dean Moore, an intravenous injection of a substance or substances in a quantity sufficient to cause death, as provided by law.

IT IS FURTHER ORDERED that you, the Director of Correctional Services, shall make return of the manner of your execution of this warrant and your proceedings thereon to the Clerk of the District Court for Douglas County, Nebraska.

IT IS FURTHER ORDERED that the Clerk of the Nebraska Supreme Court shall forthwith prepare and certify under her hand and seal of this Court a full, true, and current copy of this Warrant, and cause the same to be delivered to the Director of Correctional Services.

DATED this 5th day of July, 2018.

BY THE COURT:



Chief Justice Michael G. Heavican

STATE OF NEBRASKA
NEBRASKA SUPREME COURT

I, Pamela J. Kraus, Deputy Clerk of the Nebraska Supreme Court, hereby certify the above and foregoing two (2) pages to be a full and true copy of the Execution Warrant of Carey Dean Moore, filed by said Supreme Court in the above-entitled action on this 5th day of July, 2018.

IN WITNESS WHEREOF, I hereunto set my hand and affix the official seal of the Supreme Court of the State of Nebraska this 5th day of July, 2018.

Pamela J. Kraus, Deputy Clerk
Nebraska Supreme Court

Fresenius Kabi, LLC

SCHEDULE OF RESTRICTED PRODUCTS (6.22.2018)

Diprivan (Propofol)

NDC #	Description
63323026910	Diprivan 100mg 10mL SDV (10pk)
63323026929	Diprivan 200 mg 20mL SDV 10pk
63323026937	Diprivan 200 mg 20mL SDV 10pk NovaPlus
63323026950	Diprivan 500 mg 50mL SDV
63323026957	Diprivan 500 mg 50mL SDV NovaPlus
63323026959	Diprivan 500 mg 50mL SDV Premier
63323026965	Diprivan 1 g 100mL SDV
63323026967	Diprivan 1 g 100mL SDV NovaPlus
63323026969	Diprivan 1g 100mL SDV Premier
63323026970	Diprivan 200mg 20mL SDV HPG
63323026977	Diprivan 500mg 50mL SDV HPG
63323026978	Diprivan 1g 100mL SDV HPG
63323026994	Diprivan 200 mg 20mL SDV 10pk Premier

Dilaudid (Hydromorphone Hydrochloride)

NDC #	Description
76045000905	Dilaudid 0.5mg 0.5mL PFS Simplist
76045000910	Dilaudid 1mg 1mL PFS Simplist
76045001010	Dilaudid 2mg 1mL PFS Simplist
76045001110	Dilaudid 4mg 1mL PFS Simplist
63323085225	Hydromorphone Hydrochloride 1 mg 1 mL Vial
63323085325	Hydromorphone Hydrochloride 2 mg 1 mL Vial
63323085410	Hydromorphone Hydrochloride 4 mg 1 mL Vial
63323085110	Hydromorphone Hydrochloride 10 mg 1 mL Vial **HPF**
63323085115	Hydromorphone Hydrochloride 50 mg 5 mL Vial **HPF**
63323085150	Hydromorphone Hydrochloride 500 mg 50 mL **HPF**

Midazolam Hydrochloride

NDC #	Description
63323041110	Midazolam HCl 10mg 10mL MDV
63323041112	Midazolam HCl 2mg 2mL MDV
63323041125	Midazolam HCl 5mg 5mL MDV Pack of 25
63323041202	Midazolam HCl 10mg 2mL MDV
63323041205	Midazolam HCl 25mg 5mL MDV
63323041210	Midazolam HCl 50mg 10mL MDV
63323041225	Midazolam HCl 5mg 1mL MDV Pack of 25
76045000120	Midazolam 2mg 2mL PF PFS Simplist
76045000210	Midazolam 5mg 1mL PF PFS Simplist
76045000320	Midazolam10mg 2mL PF PFS Simplist

EXHIBIT B

Morphine Sulfate

NDC #	Description
76045000410	Morphine Sulfate 2mg 1mL PFS Simplist
76045000510	Morphine Sulfate 4mg 1mL PFS Simplist
76045000610	Morphine Sulfate 5mg 1mL PFS Simplist
76045000710	Morphine Sulfate 8mg 1mL PFS Simplist
76045000810	Morphine Sulfate 10mg 1mL PFS Simplist
63323045201	Morphine Sulfate 2 mg 1 mL Vial
63323045401	Morphine Sulfate 4 mg 1 mL Vial
63323045501	Morphine Sulfate 5 mg 1 mL Vial
63323045801	Morphine Sulfate 8 mg 1 mL Vial
63323045101	Morphine Sulfate 10 mg 1 mL Vial

Potassium Chloride

NDC #	Description
63323096505	Potassium Chloride 10mEq 5mL SDV
63323096510	Potassium Chloride 20mEq 10mL SDV
63323096520	Potassium Chloride 40mEq 20mL SDV
63323096730	Potassium Chloride 60mEq 30mL MDV

Rocuronium Bromide

NDC #	Description
63323042605	Rocuronium Bromide 50mg 5mL MDV
63323042610	Rocuronium Bromide 100mg 10mL MDV

Vecuronium Bromide

NDC #	Description
63323078110	Vecuronium Bromide 10mg Vial
63323078220	Vecuronium Bromide 20mg Vial

Cisatracurium Besylate

NDC #	Description
63323041605	Cisatracurium Besylate 10 mg 5 mL
63323041710	Cisatracurium Besylate 20 mg 10 mL
63323041820	Cisatracurium Besylate 200 mg 20 mL

DEA PERPETUAL INVENTORY

DEA/Control Number: RN0414184

Tax Identifying Number: 4704912334201

Nebraska State Penitentiary / 4201 South 14th Street / Lincoln, NE 68502

Item Description: Potassium Chloride

Unit of Measure: 30 mL (2meq/ml) 8/18

Date	Location	Quantity Received	Quantity Used	Balance
10/12/17	NSP IV Room	25	—	25

October 12, 2017

EXHIBIT C

DEA PERPETUAL INVENTORY

DEA/Control Number: ~~RN0414184~~ FN2576108 8/16/18

Tax Identifying Number: 4704912334201

Nebraska State Penitentiary / 4201 South 14th Street / Lincoln, NE 68502

Item Description: Cisatracurium

Unit of Measure: 20 mL 10/18

Date	Location	Quantity Received	Quantity Used	Balance
10/12/17	NSP EV Room	10	—	10

FRESENIUS KABI

Fresenius Kabi USA, LLC

Three Corporate Drive
Lake Zurich, IL 60047
T 847-550-2300
T 888-391-6300
www.fresenius-kabi.us

July 24, 2018

The Honorable Pete Ricketts
Governor of Nebraska
Office of the Governor
1445 K Street
Lincoln, Nebraska 68509-4848
pete.ricketts@nebraska.gov

Nebraska's Improper Acquisition of Lethal Injection Drugs

Dear Governor Ricketts:

I understand that Nebraska has set an execution date for August 14, 2018, and intends to use potassium chloride and/or other medicines manufactured by Fresenius Kabi as part of the state's lethal-injection protocol. While Fresenius Kabi takes no position on capital punishment, we oppose the use of our lifesaving products for this purpose. We have contracts in place with distributors and wholesalers of our products that prohibit the sale to states for executions, and so any acquisition by a state for this purpose would be in contravention of these contracts, and thus illegal and improper. In addition, our pharmaceutical products are approved by the U.S. Food and Drug Administration solely for patient care.

I have written to your predecessor on more than one occasion regarding lethal injection, and I'd like to take this opportunity once again to remind you and your administration of the public health consequences of using our medicines in lethal injection, as it can have a severely negative impact on Nebraska hospitals and the patients who rely on them.

I am copying Attorney General Doug Peterson and Director of Correctional Services Scott Frakes, as well as officials at the FDA who have been involved in this issue and have an ongoing interest in drug shortages. Potassium chloride is on the FDA's drug shortage list today.

Fresenius Kabi USA is the U.S. arm of a European company that specializes in medicines and technologies – including injectable drugs – used in hospitals and clinics across Nebraska and the United States.

EXHIBIT E

Our products are used widely in surgeries, and to treat people with cancer and other serious diseases. Our products are administered to patients hundreds of millions of times a year to heal, cure and reduce pain and suffering. To our knowledge, our medicines have never been used in an execution. In the United States, medical doctors, hospitals and other health care professionals have been vocal in opposing the use of our products in lethal injection, as this could result in shortages that would harm patients in Nebraska and nationwide.

At issue is European Union regulation 1352/2011, which prevents trade in products that could be used for capital punishment or torture. It is because of this regulation that drugs such as sodium thiopental, which were previously used in lethal injection, are now in short supply, or virtually unavailable in the United States. The EU can be expected to add more drugs to its list of trade-restricted products if these drugs are used in executions, or distribution controls for drugs like these are deemed inadequate.

You may be aware that other drug manufacturers and wholesalers have resorted to legal action in other states to enforce their rights and prevent their products from use in executions. Fresenius Kabi is considering all legal options in Nebraska on behalf of the patients that could be harmed by drug shortages.

We therefore respectfully demand that pursuant to open record act NE Code § 84-712 (2017), you immediately disclose the quantities, lot numbers, inventory logs, and invoices for any Fresenius Kabi drugs the state may have acquired for executions, and that you return any such drugs to us without delay. We will provide a full refund. We have asked for the return of our products from Nebraska in the past, and the state has refused. At that time, Nebraska had repealed the death penalty, had no scheduled executions, and assured us the products would be used solely for patient care. Now, it seems the state may have improperly or illegally diverted medicines for use in executions, against our contracts and policies.

I would be happy to discuss this matter with you further, or to provide you or your staff with more information. I greatly appreciate your leadership in this matter, and I look forward to hearing from you as soon as possible.

Sincerely,

John Ducker
President and CEO

cc: Doug Peterson, Attorney General, State of Nebraska
Office of the Attorney General, 2115 State Capitol, Lincoln, NE 68509
(402) 471-2683

Scott R. Frakes, Director, Nebraska Department of Correctional Services
P.O. Box 94661, Lincoln, NE 68509-4661
(402) 471-2654

The Honorable Scott Gottlieb, Commissioner, U.S. Food and Drug Administration
10903 New Hampshire Avenue, Silver Spring, MD 20993

Rebecca K. Wood, J.D.
Chief Counsel, U.S. Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993

Lauren Silvis, Chief of Staff, U.S. Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993

Capt. Valerie Jensen, R.Ph., Associate Director, Drug Shortages Program,
Center for Drug Evaluation and Research, U.S. Food and Drug Administration
10903 New Hampshire Avenue, Silver Spring, MD 20993

FRESENIUS KABI

Fresenius Kabi USA, LLC

Three Corporate Drive
Lake Zurich, Illinois 60047
T 847-550-2300
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www.fresenius-kabi.us

December 27, 2016

Mr. Mark Boyer
Associate Legal Counsel
Nebraska Department of Correctional Services
P.O. Box 94661
Lincoln, NE 68509-4661

RE: Proposed Revisions to Nebraska's Execution Protocol and Implications for Public Health

Dear Mr. Boyer:

I am writing on behalf of Fresenius Kabi, a manufacturer of injectable medicines and medical technologies that are used in hospitals across Nebraska and the United States to care for patients who have critical conditions.

I have read with interest and concern Nebraska's proposed revision to its execution protocol. Specifically, the state's plan that "the proposed, revised protocol does not identify the substance(s) to be used or the detailed method in which they will be administered" as this may have unintended public health consequences for Nebraskans and patients across the United States.

Please know that Fresenius Kabi takes no position on capital punishment. Our interest is to avoid unintended drug shortages and ensure that the lifesaving medicines we supply remain immediately available to patients – a goal I know you share.

Our concern is the potential use of certain of our products in lethal injection. This would be an improper use of these products, which are intended to save lives, and could have far-reaching negative consequences on public health due to European Union regulation 1352/2011, which prevents trade in products that could be used for capital punishment or torture. The EU has already used this regulation to ban the export of strong barbiturates and other drugs that are, or could be, used in executions. We want to avoid similar restrictions on our products as this would result in great harm to patients.

To satisfy EU concerns, Fresenius Kabi put in place distribution controls several years ago to prevent the sale or distribution of certain drugs for use in carrying out executions (see attachment). As you know, most pharmaceutical companies and their distributors have since implemented similar controls. If the EU perceives these controls to be inadequate, it could move to impose trade restrictions on needed drugs, including commonly used anesthesia drugs that doctors rely on every day in Nebraska.

EXHIBIT F

The anesthesia drug propofol, for example, is the most widely used medicine for inducing general anesthesia. It is administered more than 55 million times a year in the U.S. alone and more than 80 percent of the propofol used in the United States is manufactured in Europe. If the EU were to ban its export, it would put surgical procedures at risk nationwide.

I encourage you to speak directly to state medical associations and professional groups, especially anesthesiologists and hospitals, about the potential impact to medical and surgical care if propofol were suddenly in very short supply. Additional information can be found at www.propofol-info.com.

We have written to, and have had discussions about this with many state officials as well as the FDA and its Office of Drug Shortage, with the U.S. Department of Health and Human Services, and members of the Unites States Congress and their staffs. In 2013 I wrote to then-Governor Heinemann and others (see attachment) expressing similar concerns. To date, propofol has never been used in lethal injection.

As Nebraska works to revise its execution protocol, I am asking for your assurance that Nebraska will not use Fresenius Kabi medicines as execution agents, and that the state will not consider propofol as a lethal injection agent due to the severely negative consequences the resulting shortage would have on public health following EU sanctions.

I know we share a common goal of assuring that patients have unrestricted access to lifesaving medicines, and I would be happy to discuss this matter further with you or any Nebraska officials or provide their staffs with more information.

Sincerely,

John Ducker
President and CEO

Attachments (2)

cc: The Honorable Pete Ricketts
Governor of Nebraska
P.O. Box 94848
Lincoln, NE 68509-4848

Courtney Phillips
Chief Executive Officer
Nebraska Department of Health & Human Services
P.O. Box 95026
Lincoln, Nebraska 68509-5026

Thomas L. Williams, M.D.
Chief Medical Officer
Director of the Division of Public Health
Nebraska Department of Health & Human Services
P.O. Box 95026
Lincoln, Nebraska 68509-5026

###

FRESENIUS KABI

Fresenius Kabi USA, LLC

Three Corporate Drive
Lake Zurich, Illinois 60047
T 847-550-2300
T 888-391-6300
www.fresenius-kabi.us

November 29, 2013

AUTHORIZED DISTRIBUTORS FOR RESTRICTED PRODUCTS

Effective December 1, 2013, Fresenius Kabi USA, LLC has added **rocuronium bromide** and **potassium chloride** to its Authorized Distributor program for restricted products.

The Authorized Distribution program is designed to ensure access to key drugs for patient care while preventing their sale and distribution for lethal injection.

While Fresenius Kabi takes no position on capital punishment, the company opposes the use of its products for this purpose, and therefore does not sell certain drugs to correctional facilities.

In addition to rocuronium bromide and potassium chloride, **midazolam** and **Diprivan® (propofol)** are already included in this program. Please see below for our current list of authorized distributors for restricted products.

If you have any questions, feel free to contact your distributor, or Fresenius Kabi customer service at 888-386-1300.

Drug	Authorized Distributors
Diprivan® (propofol)	• AmerisourceBergen Drug Corporation • Besse Medical, a division of ASD Specialty Healthcare, Inc. • Cardinal Health • Cesar Castillo, Inc. • DMS Pharmaceutical Group • H.C. Pharmacy Central, Inc. • H.D. Smith Wholesale Drug and Smith Medical Partners, LLC • HMPG Pharmacy • Henry Schein, Inc. • Kaiser Foundation Hospitals • McKesson Corporation • Morris and Dickson Co., LLC • Oncology Supply, a division of ASD Specialty Healthcare, Inc. • PharMEDium Services, LLC • Priority Healthcare distribution, Inc. d/b/a Curascript SD Specialty Distribution • PSS World Medical, Inc.
Midazolam	• AmerisourceBergen Drug Corporation • Cardinal Health • Cesar Castillo, Inc. • DMS Pharmaceutical Group • H.C. Pharmacy Central, Inc. • H.D. Smith Wholesale Drug and Smith Medical Partners, LLC • Henry Schein, Inc. • HMPG Pharmacy • McKesson Corporation • Morris and Dickson Co., LLC • PharMEDium Services, LLC • Priority Healthcare distribution, Inc. d/b/a Curascript SD Specialty Distribution
Potassium Chloride	• AmerisourceBergen Drug Corporation • Cardinal Health • Cesar Castillo, Inc. • DMS Pharmaceutical Group • H.C. Pharmacy Central, Inc. • H.D. Smith Wholesale Drug and Smith Medical Partners, LLC • HMPG Pharmacy • McKesson Corporation • Morris and Dickson Co., LLC • Oncology Supply, a division of ASD Specialty Healthcare, Inc. • PharMEDium Services, LLC

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Fresenius Kabi USA, LLC

Three Corporate Drive
Lake Zurich, Illinois 60047
T 847-550-2300
T 888-391-6300
www.fresenius-kabi.us

Drug	Authorized Distributors
Rocuronium Bromide	• AmerisourceBergen Drug Corporation • Cardinal Health • Cesar Castillo, Inc. • DMS Pharmaceutical Group • H.C. Pharmacy Central, Inc. • H.D. Smith Wholesale Drug and Smith Medical Partners, LLC • HMPG Pharmacy • McKesson Corporation • Morris and Dickson Co., LLC • PharMEDium Services, LLC

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December 23, 2013

The Honorable Dave Heineman
Governor of Nebraska
Office of the Governor
P.O. Box 94848
Lincoln, Nebraska 68509-4848

Choosing a Lethal Injection Protocol
Propofol and Implications for Public Health

Dear Governor Heineman:

I read with interest a recent news article in the *Lincoln Journal Star* that Nebraska, like other states, is considering changing its lethal injection protocol because its supply of sodium thiopental is expiring and the drug is unavailable for capital punishment.

I wrote to you in September about the drug Propofol and why it shouldn't be used for lethal injection. Since I haven't received a response, I would like to take the opportunity to remind you about this important matter that impacts the public health of Nebraskans and patients across the United States. I am copying Attorney General Jon Bruning and Director of Correctional Services Michael Kenney, as well as officials at HHS and FDA who have been involved in this issue and have an ongoing interest in drug shortages.

Fresenius Kabi USA is the U.S. arm of a European company that specializes in medicines and technologies – including injectable drugs like Propofol – used in hospitals and clinics across Nebraska and the United States.

Propofol is an anesthetic used widely in surgeries to induce general anesthesia. It is administered more than 50 million times a year in the United States. To our knowledge, this drug has never been used in an execution anywhere. In the United States, hospitals and anesthesiologists have been vocal in opposing the use of Propofol in lethal injection, as this would result in a shortage that would harm patients and physicians nationwide.

At issue is European Union regulation 1352/2011, which prevents trade in products that could be used for capital punishment or torture. It is because of this regulation that drugs such as sodium thiopental, which were previously used in lethal injection, are now in short supply, or virtually unavailable in the United States. The EU can be expected to add

Propofol to its list of trade-restricted products if the drug is used in an execution. More than 85 percent of Propofol used in the United States is manufactured in Europe. The result would be a severe and harmful shortage of Propofol affecting millions of patients. You and your staff can learn more about this issue at an informational web site we created: www.propofol-info.com.

You may be aware that state of Missouri considered using Propofol in an execution earlier this year. It decided against this following the objections of physicians, hospitals, medical and public interest groups, and drug manufacturers including Fresenius Kabi. By choosing a different drug, Missouri Governor Jay Nixon successfully avoided a public health crisis.

Please know that Fresenius Kabi takes no position on capital punishment. We are deeply sympathetic to the victims of violent crime. We are, however, extremely concerned about the harm to patient care that a shortage of Propofol would cause.

We therefore respectfully request that you exclude Propofol from your execution plans. I encourage you to speak directly to your state medical associations and professional groups, especially anesthesiologists and hospitals, about the potential impact to medical and surgical care if Propofol were in short supply.

We have written to, and have had discussions about this issue with many state officials as well as the FDA and its Office of Drug Shortage, with the U.S. Department of Health and Human Services, and with many members of Congress and their staffs.

The clinical and safety profile of Propofol make it a drug of choice that contributes to the care of millions of patients every year. We are asking for your commitment to protect patients by not permitting Propofol to be used in lethal injection.

I would be happy to discuss this matter with you further, or to provide you or your staff with more information. I greatly appreciate your leadership in this matter, and I look forward to hearing from you.

Sincerely,

John Ducker
President and CEO

cc: Jon Bruning, Attorney General, State of Nebraska
Office of the Attorney General,

Michael Kenney, Director, Nebraska Department of Correctional Services

The Honorable Margaret A. Hamburg, M.D., Commissioner,
U.S. Food and Drug Administration

Sally Howard, J.D., FDA Deputy Commissioner for Policy Planning and Legislation

Lisa Barclay, J.D., Chief of Staff, U.S. Food and Drug Administration

Capt. Valerie Jensen, R.Ph., Associate Director, Drug Shortages Program,
Center for Drug Evaluation and Research, U.S. Food and Drug Administration

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September 25, 2013

The Honorable Dave Heinemann
Governor of Nebraska
State Capitol
Second Floor NE
Lincoln, NE 68509-4848

Propofol and Lethal Injection – Implications for Public Health

Dear Governor Heinemann:

I am writing on behalf of Fresenius Kabi. We are a manufacturer of injectable medicines and medical technologies that are used in hospitals across Nebraska and the United States to care for patients who have critical conditions.

We are aware that some states are considering changes to their lethal injection protocols, because certain drugs have become unavailable due largely to European Union regulation 1352/2011, which prevents trade in products that could be used for capital punishment or torture.

As it has already done with barbiturates, the EU has stated it will add Propofol, a drug we manufacture, to its list of trade-restricted products if the drug is used in an execution. The result of this would be a severe and harmful shortage of Propofol affecting patients and medical professionals across the United States. More than 85 percent of Propofol used in the United States is manufactured in Europe. Propofol is the most widely used medicine for inducing general anesthesia. It is administered more than 50 million times a year in the United States alone.

Please know that Fresenius Kabi takes no position on capital punishment. We are deeply concerned, however, about the potential harm to patient care that a shortage of Propofol would cause.

We therefore respectfully request that you exclude Propofol from your execution plans. To help professionals learn more about this issue, we created an informational web site (www.propofol-

info.com) that includes links and background that might be helpful to you and your staff. In addition, I encourage you to speak directly to state medical associations and professional groups, especially anesthesiologists and hospitals, about the potential impact to medical and surgical care if Propofol were suddenly in very short supply.

We have written to, and have had discussions about this with many state officials as well as the FDA and its Office of Drug Shortage, with the U.S. Department of Health and Human Services, and with members of Congress and their staffs.

The clinical and safety profile of Propofol make it a drug of choice that contributes to the care of millions of patients every year. We are asking for your commitment to protect patients by not permitting Propofol to be used in lethal injection.

I would be happy to discuss this matter further with you, or to provide you or your staff with more information. Please don't hesitate to contact me to discuss this important issue. I greatly appreciate your leadership in this matter.

Sincerely,

John Ducker
President and CEO

cc: The Honorable Kathleen Sibelius, Secretary, Health and Human Services
The Honorable Margaret A. Hamburg, M.D., Commissioner, U.S. Food and Drug Administration
Sally Howard, J.D., FDA Deputy Commissioner for Policy Planning and Legislation
Lisa Barclay, J.D., Chief of Staff, U.S. Food and Drug Administration
Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research
Capt. Valerie Jensen, R.Ph., Associate Director, Drug Shortages Program, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

AMA

Capital Punishment

Physicians must not participate in a legally authorized execution.

Code of Medical Ethics Opinion 9.7.3

Debate over capital punishment has occurred for centuries and remains a volatile social, political, and legal issue. An individual's opinion on capital punishment is the personal moral decision of the individual. However, as a member of a profession dedicated to preserving life when there is hope of doing so, a physician must not participate in a legally authorized execution.

Physician participation in execution is defined as actions that fall into one or more of the following categories:

(a) Would directly cause the death of the condemned.

(b) Would assist, supervise, or contribute to the ability of another individual to directly cause the death of the condemned.

(c) Could automatically cause an execution to be carried out on a condemned prisoner.

These include, but are not limited to:

(d) Determining a prisoner's competence to be executed. A physician's medical opinion should be merely one aspect of the information taken into account by a legal decision maker, such as a judge or hearing officer.

(e) Treating a condemned prisoner who has been declared incompetent to be executed for the purpose of restoring competence, unless a commutation order is issued before

treatment begins. The task of re-evaluating the prisoner should be performed by an independent medical examiner.

(f) Prescribing or administering tranquilizers and other psychotropic agents and medications that are part of the execution procedure.

(g) Monitoring vital signs on site or remotely (including monitoring electrocardiograms).

(h) Attending or observing an execution as a physician.

(i) Rendering of technical advice regarding execution.

and, when the method of execution is lethal injection:

(j) Selecting injection sites.

(k) Starting intravenous lines as a port for a lethal injection device.

(l) Prescribing, preparing, administering, or supervising injection drugs or their doses or types.

(m) Inspecting, testing, or maintaining lethal injection devices.

(n) Consulting with or supervising lethal injection personnel.

The following actions do not constitute physician participation in execution:

(o) Testifying as to the prisoner's medical history and diagnoses or mental state as they relate to competence to stand trial, testifying as to relevant medical evidence during trial, testifying as to medical aspects of aggravating or mitigating circumstances during the penalty phase of a capital case, or testifying as to medical diagnoses as they relate to the legal assessment of competence for execution.

(p) Certifying death, provided that the condemned has been declared dead by another person.

(q) Witnessing an execution in a totally nonprofessional capacity.

(r) Witnessing an execution at the specific voluntary request of the condemned person, provided that the physician observes the execution in a nonprofessional capacity.

(s) Relieving the acute suffering of a condemned person while awaiting execution, including providing tranquilizers at the specific voluntary request of the condemned person to help relieve pain or anxiety in anticipation of the execution.

(t) Providing medical intervention to mitigate suffering when an incompetent prisoner is undergoing extreme suffering as a result of psychosis or any other illness.

No physician should be compelled to participate in the process of establishing a prisoner's competence or be involved with treatment of an incompetent, condemned prisoner if such activity is contrary to the physician's personal beliefs. Under those circumstances, physicians should be permitted to transfer care of the prisoner to another physician.

Organ donation by condemned prisoners is permissible only if:

(u) The decision to donate was made before the prisoner's conviction.

(v) The donated tissue is harvested after the prisoner has been pronounced dead and the body removed from the death chamber.

(w) Physicians do not provide advice on modifying the method of execution for any individual to facilitate donation.

AMA Principles of Medical Ethics: I

American Society of Anesthesiologists®

Statement on Physician Nonparticipation in Legally Authorized Executions

Committee of Origin: Ethics

(Approved by the ASA House of Delegates on October 18, 2006, and reaffirmed on October 26, 2016)

1) Execution by lethal injection has resulted in the incorrect association of capital punishment with the practice of medicine, particularly anesthesiology.
2) Although lethal injection mimics certain technical aspects of the practice of anesthesia, *capital punishment in any form is not the practice of medicine.*
3) Because of ancient and modern principles of medical ethics, legal execution should not necessitate participation by an anesthesiologist or any other physician.
4) ASA continues to agree with the position of the American Medical Association on physician involvement in capital punishment. ASA strongly discourages participation by anesthesiologists in executions.

EXHIBIT H

THE AMERICAN BOARD OF ANESTHESIOLOGY, INC.
A Member Board of the American Board of Medical Specialties
Advancing the Highest Standards of the Practice of Anesthesiology

Commentary (May 2014)

Anesthesiologists and Capital Punishment

The majority of states in the United States authorize capital punishment, and nearly all states utilize lethal injection as the means of execution. However, this method of execution is not always straightforward (1), and, therefore, some states have sought the assistance of anesthesiologists (2).

For decades the American Medical Association (AMA) has been opposed to physician involvement in capital punishment on the grounds that physicians are members of a profession dedicated to preserving life when there is hope of doing so (3). Effective February 15, 2010, the American Board of Anesthesiology (ABA) has incorporated the AMA Code of Medical Ethics, Opinion E-2.06 (June 2000), regarding physician participation in capital punishment into its own professional standing policy. Specifically, it is the ABA's position that an anesthesiologist should not participate in an execution by lethal injection and that violation of this policy is inconsistent with the Professional Standing criteria required for ABA Certification and Maintenance of Certification in Anesthesiology or any of its subspecialties. As a consequence, ABA certificates may be revoked if the ABA determines that a diplomate participates in an execution by lethal injection (4). What constitutes participation is clearly defined by the AMA's policy.

The ABA has not taken this action because of any position regarding the appropriateness of the death penalty. Anesthesiologists, like all physicians and all citizens, have different personal opinions about capital punishment. Nonetheless, the ABA, like the AMA, believes strongly that physicians should not be involved in capital punishment. The American Society of Anesthesiologists has also supported the AMA's position in this regard (5), as have others including the American Nurses Association (ANA) and National Association of Emergency Medical Technicians (NAEMT). (6,7,8).

Patients should never confuse the death chamber with the operating room, lethal doses of execution drugs with anesthetic drugs, or the executioner with the anesthesiologist. Physicians should not be expected to act in ways that violate the ethics of medical practice, even if these acts are legal. Anesthesiologists are healers, not executioners.

In conclusion, the ABA's policy on capital punishment is intended to uphold the highest standards of medical practice and encourage anesthesiologists and other physicians to honor their professional obligations to patients and society.

Sincerely,

Jeffrey Andrews MD

J. Jeffrey Andrews, M.D.
Secretary

4208 Six Forks Road, Suite 1500
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Fax: (866) 999-7503
Website: www.theABA.org

EXHIBIT I

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7. Position statement by the ANA, Nurses Role in Capital Punishment, January 28, 2010.

8. NAEMT position statement on EMT and Paramedic Participation in Capital Punishment, June 9, 2006.

Position Statement

Nurses' Role in Capital Punishment

Effective Date: January 28, 2010

Status: Revised Position Statement

Originated By: ANA Committee on Ethics, 1983, rev. 1988 Revised by: ANA Center for Ethics and Human Rights

Adopted By: ANA Board of Directors

Related Past Action:
1. *Code of Ethics for Nurses with Interpretive Statements*, 2001
2. ANA Position Statements (1983,1984,1988): *Nurses' Participation in Capital Punishment*
3. House of Delegates Resolution on Acts of Torture and Abuse (2005)

Supersedes: ANA Position Statements (1983,1984,1988): *Nurses' Participation in Capital Punishment*

Purpose: This position statement addresses the nursing profession and the role of nurses in capital punishment. It provides a brief historical overview of the previous position statements as well as supportive background material related to capital punishment. Recommendations for nurses are presented with reference to ethical concepts, including, but not limited to, the ethic of care, justice, respect for persons, nonmaleficence, beneficence, and fidelity.

Statement of ANA position: The American Nurses Association (ANA) is strongly opposed to nurse participation in capital punishment. Participation in executions, either directly or indirectly, is viewed as contrary to the fundamental goals and ethical traditions of the nursing profession.

Definitions of Capital Punishment:

EXHIBIT J

Capital punishment "penalizes those convicted of certain classes of crimes by killing them" (US Supreme Court, 2009). Capital punishment is "The sentence of death for a serious crime." (Garner, 2004, p. 223).

History/previous position statements: The ANA's Committee on Ethics first adopted a position statement addressing capital punishment in 1983. This version was revised by the ANA Center for Ethics and Human Rights and approved by the ANA's Board of Directors in 1988 and again in 1994. These statements referred to the *Code of Ethics for Nurses* (ANA, 1985). There was also a House of Delegates Resolution on Acts of Torture and Abuse in 2005 that addressed the activities of nurses in correctional settings.

Supportive Material: Health care professionals, including nurses, continue to be called upon to participate in capital punishment including the use of lethal injection, among others. Currently, 35 states have legalized the death penalty. Fifteen states plus the District of Columbia do not support capital punishment (Death Penalty Information Center, 2010). Fifty nine countries retain the death penalty. In 2008 the United States was one of five countries with the highest rate of executions. "Together they carried out (93%) of all executions worldwide." (Amnesty International, 2008).

In 1972, the U. S. Supreme Court ruled in *Furman v. Georgia* that capital punishment violated the Constitution's Eighth and Fourteenth Amendments protecting individuals against "cruel and unusual punishments". The moratorium on the death penalty remained in place until 1976 when the Supreme Court upheld a death-sentence in *Gregg v. Georgia*, ruling that the death penalty does not, in all cases, violate the Eighth and Fourteenth Amendments. This ruling was supported in the *Baze v. Rees* Supreme Court case in 2008, which ruled that the lethal injection "cocktail" did not violate the Eighth or Fourteenth amendment, and was not deemed cruel and unusual punishment.

The United Nations General Assembly (2007) adopted a resolution, calling for "States that still maintain the death penalty: To establish a moratorium on executions with a view to abolishing the death penalty" (Item 2.*d*).

Professional and international organizations such as the American Medical Association (2000), American Psychiatric Association (2008), American Society of Anesthesiologists (2006), American Public Health Association (2001), American Correctional Health Services Association (1996), World Medical Association (2000), National Commission on Correctional Health Care (2008) and International Council of Nurses (2006a, 2006b) address the role of health care professionals in capital punishment. In summary, the health care professionals' participation in capital punishment is a breach of professional ethics.

Historically, the role of the nurse has been to promote, preserve, and protect human health. The ANA *Code of Ethics for Nurses with Interpretive Statements* states that ethics is "the foundation of nursing.... and has a history of concern for the welfare of the sick, injured, and vulnerable and for social justice" (ANA, 2001, p. 5). This array of concerns extends to the community and "encompasses the ...protection, promotion, and restoration of health" (p. 5). The Code of Ethics is grounded in the basic principles of respect for persons, nonmaleficence, beneficence, and justice, and stipulates that "nurses act to change those aspects of social structures that detract from health and well-being" (p. 5). Addressing end of life care, the Code states, nurses may not act [to alleviate pain] "with the sole intent of ending a patient's life" (p. 8). The obligation to refrain from causing death is longstanding and should not be breached even when legally sanctioned.

The ANA's Position Statement on Ethics and Human Rights (1991) addresses the intersection of ethics and human rights stating that "the principle of justice is one point at which issues of ethics and human rights intersect" (p. 1). This statement includes discussion of "first generation rights, such rights include: ...freedom from torture, and from cruel, inhuman or degrading treatment or punishment" (p. 1).

The ANA's *Social Policy Statement 3rd Edition* places the nurse in a position of public trust to ensure the patient is supported in goals of health and healing. "All registered nurses are educated in the art and science of nursing, with the goal of helping individuals, …… to attain, maintain, and restore health, or to experience a dignified death" (ANA, 2010, p.19). In those

cases where the corrections nurse has a relationship with a prisoner as a patient, the nurse will offer comfort care at the end of life, and if requested, help the prisoner prepare for the execution, but will not take part in it.

The ANA document *Corrections Nursing: Scope and Standards of Practice* (2007) states:

> It is inappropriate for nurses to be involved in the security aspects of the facility and disciplinary decisions or committees. Correctional nurses must be vigilant in maintaining a healthcare role and not participate in non-therapeutic court-ordered procedures such as but not limited to body entry searches or executions by lethal injections, performed solely for correctional purposes and without informed consent. (p. 8)

The scope of practice indicates "the registered nurse in the corrections environment is bound by the profession's *Code of Ethics for Nurses with Interpretive Statements* (ANA, 2001)" (ANA, 2007, p. 14). It continues, stating "Nursing practice must be balanced with the goals of corrections and the incarcerated person's rights to appropriate health care" (ANA, 2007, p. 11).

> The corrections nurse is expected to demonstrate integrity and highly ethical and moral practice, appreciating the legally mandated obligation to deliver nursing care regardless of the individual's circumstances or offenses. The basic concept of patient advocacy may be foreign to the corrections environment and may need to be regularly reaffirmed by the corrections nurse. (ANA, 2007, p. 12)

The ANA is opposed to all forms of participation by nurses in capital punishment, by whatever means, whether under civil or military legal authority. Participation in capital punishment is inconsistent with the ethical precepts of justice, nonmaleficence, and beneficence, and the values and goals of the nursing profession. The ethical principle of nonmaleficence requires that nurses act in such a way as to prevent harm, not to inflict it. The act of participating in capital punishment clearly inflicts harm; nurses are ethically bound to abstain from any activities in carrying out the death penalty process. Nurses must not participate in capital punishment, whether by chemical, electrical, or mechanical means. Consistent with this

directive is a standard of the National Commission on Correctional Health Care (NCCHC) prohibiting correctional health services staff from participation in inmate executions (2008).

Nurses, in their professional roles, including advanced practice, should not take part in assessing the prisoner or the equipment; supervising or monitoring the procedure or prisoner; procuring, prescribing or preparing medications or solutions; inserting the intravenous catheter; injecting the lethal solution; attending or witnessing the execution; or pronouncing the prisoner dead. Nurses should not train paraprofessionals in any of the activities listed above for the purpose of their use in capital punishment. The NCCHC specifies that health services staff do not assist, supervise or contribute to the ability of another to directly cause death of an inmate (2008).

The ANA recognizes that the endorsement of the death penalty remains a personal decision and that individual nurses may have views that are different from the official position of the profession. Regardless of the personal opinion of the nurse on the appropriateness of capital punishment, it is a breach of the ethical traditions of nursing, and the Code of Ethics to participate in taking the life of any person. The fact that capital punishment is currently supported in many segments of society does not override the obligation of nurses to uphold the ethical mandates of the profession.

Recommendations: In keeping with the nursing profession's commitment to caring, the preservation of human dignity and rights, the ethical principles of justice, nonmaleficence, beneficence, and fidelity, and the trust that the public has placed in registered nurses, the ANA recommends that:

1. Nurses abide by the Code of Ethics and the Scope and Standards of Professional Nursing Practice in correctional facilities prohibiting nurses from assuming any role in the capital punishment of a prisoner.

2. Nurses strive to preserve the human dignity of prisoners regardless of the nature of the crime they have committed.

3. Nurses act to protect, promote, and restore health of prisoners and provide comfort care at the end of life if requested, including pain control, anxiety relief or procuring services of a chaplain.

4. Nurses abide by the social contract to facilitate healing, and avoid participation in capital punishment — where the intent is to cause death.

5. Nurses who are invited to witness an execution must not represent themselves as a nurse nor assume any nursing role in that execution.

6. Nurse administrators provide a work environment that allows nurses to abide by the recommendations of the American Correctional Health Services Association and the ANA.

7. Nurses scrutinize policies and procedures guiding their practice to ensure there are no contradictions in performance expectations.

8. Nurses help colleagues balance moral burdens with professional ethics when specific death penalty cases cause moral turmoil.

9. Nurse researchers design studies to explore the meaning of participation, motivating factors, consequences of non-participation and fears of patient abandonment in the context of capital punishment.

10. Nurses continue to be involved in national and international dialogue on political, scientific, ethical, legal, social and economic perspectives leading to legislation that would abolish the death penalty.

11. Nurses as individuals and as a professional community maintain awareness that any nurse participation could contribute to the public's acceptance of the death penalty and their non-participation may, in fact, contribute to rejection of the death penalty.

12. Nurse educators should include and emphasize the knowledge and skills needed to act upon the above recommendations, especially the boundaries of direct and indirect participation.

Summary: The ANA is opposed to nurse participation in any phase of capital punishment. The *Code of Ethics for Nurses with Interpretive Statements* (ANA, 2001) addresses the fundamental values of the nursing profession. Participation of nurses in capital punishment is contrary to ethical precepts of the Code and *Nursing's Social Policy Statement: 3rd Edition* (ANA, 2010).

The document, *Corrections Nursing: Scope and Standards of Practice* (2007), specifically states that nurses' participation in executions by lethal injection is inappropriate. While many states still have a legalized death penalty, nurses should strive for social changes which recognize the human dignity of all individuals and uphold rights to be free from cruel and unusual punishment. Many professional and international organizations have addressed their concerns about the imposition of capital punishment and have issued codes, position statements, or policies stating opposition to the execution of prisoners.

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MARCH 30, 2015

Share:

APhA House of Delegates Adopts Policy Discouraging Pharmacist Participation in Execution

WASHINGTON, DC – The American Pharmacists Association (APhA) House of Delegates today voted to adopt a policy discouraging pharmacist participation in executions. The House of Delegates met as part of the 2015 APhA Annual Meeting & Exposition, APhA2015, in San Diego.

The policy states: "The American Pharmacists Association discourages pharmacist participation in executions on the basis that such activities are fundamentally contrary to the role of pharmacists as providers of health care."

APhA Executive Vice President and CEO, Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA, stated, "Pharmacists are health care providers and pharmacist participation in executions conflicts with the profession's role on the patient health care team. This new policy aligns APhA with the execution policies of other major health care associations including the American Medical Association, the American Nurses Association and the American Board of Anesthesiology.

This new policy statement joins two policies previously adopted by the APhA House of Delegates:

Pharmacist Involvement in Execution by Lethal Injection (2004, 1985)

1. APhA opposes the use of the term "drug" for chemicals when used in lethal injections.
2. APhA opposes laws and regulations which mandate or prohibit the participation of pharmacists in the process of execution by lethal injection.

Byline
M. Spinnler

"The American Pharmacists Association discourages pharmacist participation in executions on the basis that such activities are fundamentally contrary to the role of pharmacists as providers of health care."

EXHIBIT K

APHA
AMERICAN PUBLIC HEALTH ASSOCIATION
For science. For action. For health.

Participation of Health Professionals in Capital Punishment

Date: Jan 01 1985 | **Policy Number:** 8521
Key Words: Capital Punishment, Public Health Workforce

The American Public Health Association,

Noting that at least 37 states have enacted statutes which authorize death as a possible penalty for certain crimes; and

Whereas such state-sanctioned executions can include, and in some instances are required by state statute to include, the participation of medical professional personnel in a variety of roles, including: determination that the condemned prisoner is physically healthy and mentally competent to be executed;[1,2] and

Whereas medical professional personnel may aid in the preparation of the prisoner for execution, and, in the case of execution by lethal injection, inject the lethal substance or supervise its injection by others, monitoring the administration of execution and observing the condemned prisoner throughout the execution, examining the prisoner following administration of the method of execution, and declaring that said procedures have in fact been sufficient to kill the prisoner; and

Whereas there is no expert consensus that any of the methods now used for such state-imposed executions will produce death without pain or suffering and in several instances said methods have in fact merely inflicted wounds and injuries but have not been sufficient to cause immediate death;[3,5] and

Whereas even participation of medical personnel in the capacity of certifying that death has occurred includes the possibility that said professional shall be required to inform the executioner that the prisoner is not yet dead and that additional punishment is needed to cause the prisoner's death;[6-8] and

Whereas participation of medical personnel in the administration of torture or inhumane or degrading treatment, whether pursuant to statutory mandate or by passive supervision of others administering such treatment, is internationally condemned as contrary to the laws of humanity;[9-12] and

Whereas professional standards of health care have always forbidden the use of medical knowledge and skill for purposes of injury;[13-16] therefore

Resolves that health personnel, as members of a profession dedicated to preserving life when there is hope of doing so, should not be required nor expected to assist in legally authorized executions.

References/Footnotes

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2. Frod v. Wainwright, 752 F.2d 526 (11th Cir. 1985). (application for rehearing en banc pending). (2 to 1 panel decision, following 1950 opinion of Supreme Court, finding that minimum due process is provided by Florida state procedure provides only for governor to appoint three psychiatrists to review prisoner's sanity, without further review by other medical professionals or the courts.)
3. Chaney v Heckler, 718 F.2d 1174 (D.C. Cir. 1983). See also Heckler v. Chaney, 53 LW 4385, March 19, 1985. (Supreme Court refused 9 to 0 to require Food and Drug Administration to review substances used in state executions.)
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EXHIBIT L

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7. Louisiana ex rel. Francis v. Resweber, 329 US 459 (1947). (Supreme Court ruled 4 to 4 that the State of Louisiana could attempt to execute Francis after a first attempt at electrocution, involving two jolts of electricity, had failed.)

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9. Curran WJ, Casscells W: The ethics of medical participation in capital punishment by intravenous drug injection. N Engl J Med 1980;302:226-230. (Earlier discussion of medical ethics involved in lethal injections, but discusses in greater detail the history of medical participation in state executions, ethical considerations, international ethical principles; cites professional association standards and resolutions.)

10. Gardner MR: Executions and indignities—an eighth amendment assessment of methods of inflicting capital punishment. Ohio State Law J 1978;39:(1)96-130. (Describes case law and social evolution of definitions of "cruel and unusual punishment;" describes step-by-step preparation and procedures for electrocution at p 126.)

11. Branucci: New cruel and unusual punishments inflicted: the original meaning. 57 Cal. L Rev. 839 (1969).

12. Ulmer NC: Doctors and the death penalty: hippocratic or hypocritical? Christianity and Crisis 1981;41:(6)109-110. (Commentary on AMA's resolutions against participation in executions but permitting certification of death following execution.)

13. Resolution of American Medical Assocation, Chicago, 1981.

14. Resolution of American Psychiatric Association, Washington, DC.

15. Resolution of Human Rights Advocacy Committee, Florida State Hospital, December 6, 1984. (Letter to Marcia Beach, Chairperson, Florida Statewide Human Rights Committee.)

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IACP
INTERNATIONAL ACADEMY OF COMPOUNDING PHARMACISTS

Protecting, Promoting & Advancing Pharmacy Compounding

IACP BOARD UPDATES POSITION ON COMPOUNDING FOR LETHAL INJECTIONS

In March of 2013, the **Colorado Department of Corrections Director Tom Clements** contacted 97 compounding pharmacies in that state with an unusual request: "I am reaching out to compounding pharmacies throughout the state of Colorado in order to comply with state law that the CDOC acquire sodium thiopental or other equally or more effective substance to cause death." That represented the first instance in what would become a more and more frequent question for the Academy and its members – how and should a compounding pharmacist be involved in the preparation of drugs for lethal injection?

The **International Academy of Compounding Pharmacists (IACP) Board of Directors** established a formal policy, pointing out the well-recognized **Pharmacist's Conscience Clause** as a guiding principle and identifying the unilateral decision by pharmaceutical companies to restrict the sales of their products to Departments of Correction. Additionally, the Academy recommended a series of self-assessment questions for a compounding pharmacist to consider when requested to be involved in a capital punishment case when commercially manufactured drugs were intentionally withheld. Those included: verifying the legality of preparing a dispensing a drug that will knowingly cause harm with a state Board of Pharmacy, confirming that professional and business practice insurance covers such compounding, and to assess the potential impact on the individual staff members, and the pharmacy's security and reputation from potential negative publicity surrounding the controversy of capital punishment.

Over the past year, as supplies of manufactured drugs for capital punishment dwindled and more states sought compounded preparations as an alternative, five state legislatures have taken up bills that would provide for confidentiality to potential pharmacy suppliers. That has been in direct response to media attention, court challenges, and reports of so-called "botched" executions that alleged the compounded medications used were "deficient" in quality.

After much consideration, and recognizing that more and more IACP members are asking for guidance and a clear position to assist them, the Academy's Board of Directors has updated its position with the following statements:

While the pharmacy profession recognizes an individual practitioner's right to determine whether to dispense a medication based upon his or her personal, ethical and religious beliefs, IACP discourages its members from participating

BREAKING NEWS MORE

1/30/2018
IACP Urges Congress to Protect Patient Access to Compounded Medications

1/30/2018
Energy & Commerce's Subcommittee on Health Pharmacy Compounding Hearing THIS MORNING at 11 am EST

1/29/2018
Energy & Commerce's Health Subcommittee to Hold Pharmacy Compounding Hearing on Tuesday, January 30

IACP CALENDAR MORE

8/1/2018 » 8/3/2018
Essentials of Nonsterile Compounding

8/3/2018 » 8/5/2018
Essential Elements of Compounded Sterile Preparations

EXHIBIT M

in the preparation, dispensing, or distribution of compounded medications for use in legally authorized executions.

The issue of compounded preparations being used in the execution of prisoners sentenced to capital punishment continues to be a topic of significant interest. It is important to first understand the origin of this issue: states are turning to compounded preparations for this purpose because the companies that manufacture the products traditionally used have unilaterally decided to stop selling them for use in executions. IACP believes that a national discussion needs to be conducted on whether a pharmaceutical manufacturer can restrict the use of FDA-approved products only to purposes that adhere to their corporate values.

Pharmacy, and compounding in particular, is a profession of healing and care that is focused on individual patients and providing the best and most appropriate medications at all times.

INTERNATIONAL ACADEMY OF COMPOUNDING PHARMACISTS
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Missouri City, TX 77459
P: 281.933.8400; F: 281.495.0602

POSITION PAPER

American College of Physicians Ethics Manual

Third Edition*

Medicine, law, and social values are not static and must be re-examined periodically. This edition of the ACP Ethics Manual covers emerging issues in medical ethics and revisits some old issues. The overview of the evolution of medical ethics, which appeared in previous editions of the Manual, has been eliminated to allow more space for the consideration of today's ethical dilemmas. Other changes include a revised chapter on end-of-life care, discussion of physician-assisted suicide, revised sections on conflicts of interest and on medical risk to the physician and patient, given developments in human immunodeficiency virus (HIV) infection and the acquired immunodeficiency syndrome (AIDS), and discussion of sexual contact between physician and patient. A statement on disclosure of errors and a section on care of the physician's family have also been added. The sections on confidential information told by a patient's family or friend to the physician; on physician-pharmaceutical industry relations; on physicians in training; and on the impaired physician have been expanded. Sections on advertising, peer review, and resource allocation have been revised. The literature of biomedical ethics expands at a rate that does not allow a bibliography to remain current, so an exhaustive list of references or suggested readings is not included in this manual. Instead, only cited references are listed.

Annals of Internal Medicine. 1992;117:947-960.

The *ACP Ethics Manual* is designed to facilitate the process of making ethical decisions in clinical practice and medical research. Because ethics must be understood within a historical and cultural context, the second edition of the *Manual* included a brief overview of the cultural, philosophical, and religious underpinnings of modern medical ethics. In this third edition, we refer the reader to that overview (1) and to other sources (2-5) that more fully explore the rich heritage of medical ethics.

The *Manual* raises ethical issues and presents general guidelines. In applying these guidelines, physicians should consider individual circumstances and use their best judgment. Physicians are morally as well as legally accountable, and the two may not be concordant. Segregation and slavery, for example, were once legal in this country but are never morally defensible. Physicians must keep in mind the distinctions and potential conflicts between legal and ethical obligations when making clinical decisions and must seek counsel when concerned about the potential legal consequences of ethical decisions. We refer to the law in this manual for illustrative purposes only; these references should not be taken as a statement of the law, which can vary from state to state, or of the legal consequences of a physician's actions.

The law does not always establish positive duties (what one should do) to the extent that professional (especially medical) ethics does. Our current understanding of medical ethics is based on the principles from which these positive duties emerge. The relative value of such principles, and conflicts among them, often account for the ethical dilemmas physicians must face.

These principles include beneficence—the duty to promote good and prevent harm to patients; nonmaleficence—the duty to do no harm to patients; and respect for a patient's autonomy—the duty to protect and foster an individual's free and uncoerced choices (6). From the principle of respect for autonomy are also derived the rules for truth-telling, disclosure, and informed consent.

In addition, considerations of justice guide the physician's role as citizen and in societal decisions about resource allocations. The principle of distributive justice demands that we seek the morally correct distribution of benefits and burdens in society. Determining that distribution, especially when allocating resources to health care, is the focus of intense debate in our society. More than ever, concerns about justice challenge the traditional role of physician as patient advocate.

A broad consensus is emerging that the U.S. health care system does not serve all of its citizens well and that major reform is needed. Any such reform, constrained by growing concerns that our resources are limited, faces important issues of priority and equity. Health care costs will be a major focus, and our society's values will be tested in decisions about resource allocations.

These issues attract widespread public attention, and their debate is covered regularly in the press. Increasingly, government, through legislation, administrative action, or judicial decision, is involved in medical ethics. It is crucial that a responsible physician perspective be heard as these societal decisions are made.

The decision to update this manual was prompted by the continued emergence of complex ethical issues not

* Members of the Ethics Committee for the 1991-92 term who developed this third edition of the manual were Edwin P. Maynard, MD, *Chair;* Karen Coblens, MD; Errol D. Crook, MD; Lee Dunn, Jr., JD, LLM; Arthur W. Feinberg, MD; Lloyd W. Kitchens, Jr., MD; Bernard Lo, MD; William A. Reynolds, MD; Gerald E. Thomson, MD; and Susan W. Tolle, MD. Staff editors were Lois Snyder, JD, and Janet Weiner, MPH. Additional staff contributions were made by H. Denman Scott, MD (Senior Vice President, Health and Public Policy), Linda Johnson White (Director, Department of Scientific Policy), and Linda J. Sowers. Approved by the Board of Regents on 10 July 1992.

EXHIBIT N

privileges, and duties pertinent to the patient-physician relationship and has the right to require that physicians be competent and knowledgeable and that they practice with consideration for the patient as a person.

Obligations of the Physician to Society

Physicians have obligations to society that in many ways parallel their obligations to individual patients. Physicians' conduct, both as professionals and as individual citizens, should merit the respect of the community.

All physicians must fulfill the profession's collective responsibility to be advocates for the health of the public. Physicians should protect the public's health by reporting diseases, as required by law, to the responsible authority. They should support public health endeavors that provide the general public with accurate information about health care and comment on medical subjects within their areas of expertise to keep the public properly informed. Physicians should regard interacting with the news media to provide accurate information as an obligation to society and an extension of medical practice.

Physicians should help the community recognize and deal with social and environmental causes of disease. They should work toward ensuring access to health care for all individuals and help correct deficiencies in the availability, accessibility, and quality of health services in the community.

Resource Allocation

Medical care is delivered within social and institutional systems that must take overall resources into account. Increasingly, decisions about resource allocations challenge the physician's traditional role as patient advocate. There have always been limits to this advocacy role; for example, a physician is not obligated to lie to third-party payers for a patient nor to provide all treatments, no matter how futile. Resource allocation pushes these limits further, by asking physicians to consider the best interests of all patients as well as the best interests of each patient. The just allocation of resources presents the physician with ethical dilemmas that cannot be ignored. There is agreement on two fundamental rules:

1. Physicians have a responsibility to use all health-related resources in a technically appropriate and efficient manner. They should plan work-ups carefully and avoid unnecessary testing, medications, operations, and consultations.

2. Decisions on resource allocations must not be made in the context of an individual patient-physician encounter but must be part of a broader social process. Physicians participating in decisions at the policy level should stress the value of health to our society and should base allocations on medical need, cost-effectiveness of treatments, and proper distribution of benefits and burdens in our society.

Relationship of the Physician to Government

The physician should help develop health policy at the local, state, and national levels by expressing views as an individual and as a professional. Through professional activities and associations, as well as through the political process, physicians should participate in health policy decisions. These include societal decisions about the distribution of resources between health care and other social goods and about the various methods for delivering health care, in assuring that no sick person is denied essential medical care.

Physicians must resist being a party to abuses of human rights. Under no circumstances is it ethical for a physician to be used as an instrument of government to do anything to weaken the physical or mental resistance of a human. Neither should a physician participate in, or tolerate, cruel or unusual punishment or disciplinary activities beyond those permitted by the United Nations Standard Minimum Rules for the Treatment of Prisoners (30).

Participation by physicians in the execution of prisoners, except to certify death, is unethical.

Relationship of Physicians to Other Health Professionals

The interests of the patient have primacy in all aspects of the patient-physician relationship. The attending physician should act as an advocate and coordinator of care for the patient and should assume appropriate responsibility, especially when other health professionals help. The physician should collaborate only with competent health professionals when sharing the care of a patient.

All health professionals share a commitment to work together to serve the patient's interests. The best patient care is often a team effort, and mutual respect, cooperation, and communication should govern this effort. Even though health professionals have special areas of expertise, each member of the patient care team has equal moral status. When a health professional has major ethical objections to an attending physician's order, both should discuss the matter thoroughly. Mechanisms should be available in hospitals to resolve differences of opinion among members of the patient care team.

Ethics Committees and Ethics Consultants

Ethics committees and consultants contribute to achieving patient care goals primarily by developing educational programs in the institution, coordinating institutional resources, providing a forum for discussion among medical and hospital professionals, and assisting institutions to develop sound policies and practices. Although it is generally agreed that neither ethics committees nor consultants should have decision making authority, they can advise physicians on ethical matters.

Medicine and the Law

Physicians should remember that all citizens are equal under the law, and being ill does not diminish the right or expectation to be treated equally. Stated another way, illness does not, in and of itself, change a

WORLD MEDICAL ASSOCIATION

WMA RESOLUTION ON PHYSICIAN PARTICIPATION IN CAPITAL PUNISHMENT

Adopted by the 34th World Medical Assembly, Lisbon, Portugal, September/October 1981
and amended by the 52nd WMA General Assembly, Edinburgh, Scotland, October 2000
and the 59th WMA General Assembly, Seoul, Korea, October 2008

RESOLVED, that it is unethical for physicians to participate in capital punishment, in any way, or during any step of the execution process, including its planning and the instruction and/or training of persons to perform executions.

The World Medical Association

REQUESTS firmly its constituent members to advise all physicians that any participation in capital punishment as stated above is unethical.

URGES its constituent members to lobby actively national governments and legislators against any participation of physicians in capital punishment.

EXHIBIT O

21.12.2011 EN Official Journal of the European Union L 338/31

COMMISSION IMPLEMENTING REGULATION (EU) No 1352/2011

of 20 December 2011

amending Council Regulation (EC) No 1236/2005 concerning trade in certain goods which could be used for capital punishment, torture or other cruel, inhuman or degrading treatment or punishment

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EC) No 1236/2005 of 27 June 2005 concerning trade in certain goods which could be used for capital punishment, torture or other cruel, inhuman or degrading treatment or punishment [1], and in particular Article 12(2) thereof,

Whereas:

(1) Regulation (EC) No 1236/2005 imposes a prohibition on exports of goods which have no practical use other than for the purpose of capital punishment, torture and other cruel, inhuman or degrading treatment or punishment and controls on exports of certain goods that could be used for such purpose. It respects the fundamental rights and observes the principles recognised by the Charter of Fundamental Rights of the European Union, in particular respect for and protection of human dignity, the right to life and the prohibition of torture and inhumane and degrading treatment or punishment.

(2) In some recent cases medicinal products exported to third countries have been diverted and used for capital punishment, notably by administering a lethal overdose by means of injection. The Union disapproves of capital punishment in all circumstances and works towards its universal abolition. The exporters objected to their involuntary association with such use of the products they developed for medical use.

(3) It is therefore necessary to supplement the list of goods subject to trade restrictions to prevent the use of certain medicinal products for capital punishment and to ensure that all Union exporters of medicinal products are subject to uniform conditions in this regard. The relevant medicinal products were developed for, inter alia, anaesthesia and sedation and their export should therefore not be made subject to a complete prohibition.

(4) It is also necessary to broaden the ban on trade in electric-shock belts to cover similar body-worn devices such as electric shock sleeves and cuffs which have the same impact as electric-shock belts.

(5) It is necessary to prohibit trade in spiked batons which are not admissible for law enforcement. While the spikes are capable of causing significant pain or suffering, spiked batons do not appear more effective for riot control or self-protection than ordinary batons and the pain or suffering caused by the spikes is therefore cruel and not strictly necessary for the purpose of riot control or self-protection.

(6) Changes in the numbering of certain parts of the Combined Nomenclature (CN) have occurred after Regulation (EC) No 1236/2005 was adopted and the relevant CN codes should be updated accordingly.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Committee on Common Rules for Exports of Products.

(8) In order to ensure that the measures provided for in this Regulation are effective, this Regulation must enter into force immediately,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II and Annex III to Regulation (EC) No 1236/2005 shall be replaced by the texts in Annex I and Annex II, respectively.

Article 2

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

It shall not apply to products listed in point 4.1 of Annex III for which an export declaration has been lodged prior to its entry into force.

[1] OJ L 200, 30.7.2005, p. 1.

EXHIBIT P

This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaties.

Done at Brussels, 20 December 2011.

For the Commission
The President
José Manuel BARROSO

ANNEX I

'ANNEX II

List of goods referred to in Articles 3 and 4

Introductory Note:

The "CN codes" in this Annex refer to codes specified in Part Two of Annex I to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (1).

Where "ex" precedes the CN code, the goods covered by Regulation (EC) No 1236/2005 constitute only a part of the scope of the CN code and are determined by both the description given in this Annex and the scope of the CN code.

Note: this list does not cover medical-technical goods

CN code	Description
	1. **Goods designed for the execution of human beings, as follows:**
ex 4421 90 98 ex 8208 90 00	1.1. Gallows and guillotines
ex 8543 70 90 ex 9401 79 00 ex 9401 80 00 ex 9402 10 00 ex 9402 90 00	1.2. Electric chairs for the purpose of execution of human beings
ex 9406 00 38 ex 9406 00 80	1.3. Air-tight vaults, made of e.g. steel and glass, designed for the purpose of execution of human beings by the administration of a lethal gas or substance
ex 8413 81 00 ex 9018 90 50 ex 9018 90 60 ex 9018 90 84	1.4. Automatic drug injection systems designed for the purpose of execution of human beings by the administration of a lethal chemical substance
	2. **Goods designed for restraining human beings, as follows:**
ex 8543 70 90	2.1. Electric-shock devices which are intended to be worn on the body by a restrained individual, such as belts, sleeves and cuffs, designed for restraining human beings by the administration of electric shocks having a no-load voltage exceeding 10 000 V
	3. **Portable devices allegedly designed for the purpose of riot control, as follows:**
ex 9304 00 00	3.1. Batons or truncheons made of metal or other material having a shaft with metal spikes

(1) OJ L 256, 7.9.1987, p. 1.'

ANNEX II

'ANNEX III

List of goods referred to in Article 5

Introductory Note:

The CN codes in this Annex refer to codes specified in Part Two of Annex I to Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff.

Where "ex" precedes the CN code, the goods covered by Regulation (EC) No 1236/2005 constitute only a part of the scope of the CN code and are determined by both the description given in this Annex and the scope of the CN code.

CN code	Description
	1. Goods designed for restraining human beings, as follows:
ex 9401 61 00 ex 9401 69 00 ex 9401 71 00 ex 9401 79 00 ex 9401 80 00 ex 9402 90 00 ex 9403 20 20 ex 9403 20 80 ex 9403 50 00 ex 9403 70 00 ex 9403 81 00 ex 9403 89 00	1.1. Restraint chairs and shackle boards *Note:* This item does not control restraint chairs designed for disabled persons
ex 7326 90 98 ex 8301 50 00 ex 3926 90 97	1.2. Leg-irons, gang-chains, shackles and individual cuffs or shackle bracelets *Note:* This item does not control "ordinary handcuffs". Ordinary handcuffs are handcuffs which have an overall dimension including chain, measured from the outer edge of one cuff to the outer edge of the other cuff, between 150 and 280 mm when locked and have not been modified to cause physical pain or suffering
ex 7326 90 98 ex 8301 50 00 ex 3926 90 97	1.3. Thumb-cuffs and thumb-screws, including serrated thumb-cuffs
	2. Portable devices designed for the purpose of riot control or self-protection, as follows:
ex 8543 70 90 ex 9304 00 00	2.1. Portable electric shock devices, including but not limited to, electric shock batons, electric shock shields, stun guns and electric shock dart guns having a no-load voltage exceeding 10 000 V *Notes:* 1. This item does not control electric shock belts and other devices as described in item 2.1 of Annex II. 2. This item does not control individual electronic shock devices when accompanying their user for the user's own personal protection.
	3. Portable equipment for dissemination of incapacitating substances for the purpose of riot control or self-protection and related substances, as follows:
ex 8424 20 00 ex 9304 00 00	3.1. Portable devices designed or modified for the purpose of riot control or self-protection by the administration or dissemination of an incapacitating chemical substance *Note:* This item does not control individual portable devices, even if containing a chemical substance, when accompanying their user for the user's own personal protection.
ex 2924 29 98	3.2. Pelargonic acid vanillylamide (PAVA) (CAS RN 2444-46-4)
ex 2939 99 00	3.3. Oleoresin capsicum (OC) (CAS RN 8023-77-6)

CN code	Description
	4. Products which could be used for the execution of human beings by means of lethal injection, as follows:
ex 2933 53 90 [(a) to (f)]	4.1. Short and intermediate acting barbiturate anaesthetic agents including, but not limited to:
	(a) amobarbital (CAS RN 57-43-2
ex 2933 59 95 [(g) and (h)]	(b) amobarbital sodium salt (CAS RN 64-43-7)
	(c) pentobarbital (CAS RN 76-74-4)
	(d) pentobarbital sodium salt (CAS 57-33-0)
	(e) secobarbital (CAS RN 76-73-3
	(f) secobarbital sodium salt (CAS RN 309-43-3)
	(g) thiopental (CAS RN 76-75-5)
	(h) thiopental sodium salt (CAS RN 71-73-8), also known as thiopentone sodium
	Note:
	This item also controls products containing one of the anaesthetic agents listed under short or intermediate acting barbiturate anaesthetic agents.'