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108TH CONGRESS
2D SESSION

H. R. 3870

To amend the Public Health Service Act, the Federal Food, Drug, and Cosmetic Act, and the Controlled Substances Import and Export Act to provide grants to States to establish prescription drug monitoring programs, to impose requirements respecting Internet pharmacies, to require manufacturers to implement chain-of-custody procedures, to restrict an exemption respecting the importation of controlled substances for personal use, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 2, 2004

Mr. NORWOOD (for himself and Mr. STRICKLAND) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Public Health Service Act, the Federal Food, Drug, and Cosmetic Act, and the Controlled Substances Import and Export Act to provide grants to States to establish prescription drug monitoring programs, to impose requirements respecting Internet pharmacies, to require manufacturers to implement chain-of-custody procedures, to restrict an exemption respecting the importation of controlled substances for personal use, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Prescription Drug Abuse Elimination Act of 2004''.

SEC. 2. PRESCRIPTION DRUG MONITORING PROGRAM.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding after section 399N the following:

''SEC. 399O. PRESCRIPTION DRUG MONITORING PROGRAM.

''(a) PRESCRIPTION DRUG.—For purposes of this section, the term 'prescription drug' means—

''(1) a drug that is included in schedule II, III, or IV of section 202(c) of the Controlled Substances Act; or

''(2) a drug that is—

''(A) subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act; and

''(B) identified for purposes of this section by the Secretary as potentially subject to abuse, diversion, and misuse.

''(b) GRANTS.—The Secretary shall make a grant to each State that submits an application in accordance with subsection (k) for the purpose of establishing a prescription drug monitoring program described in this section.

''(c) REPORTING REQUIREMENTS.—A funding agreement for a grant under this section is that the State involved shall comply with the following:

''(1) The State shall require dispensers to report each dispensing in the State of a prescription drug to an ultimate user or research subject.

''(2) A State may exclude from the reporting requirement of this section—

''(A) the direct application of a prescription drug to the body of an ultimate user or research subject;

''(B) the dispensing of a prescription drug in a quantity limited to an amount adequate to treat the ultimate user or research subject involved for 48 hours or less; or

''(C) the application or dispensing of a prescription drug in accordance with an exclusion identified by the Secretary under subsection (i)(2).

''(3) Subject to paragraph (5), the information to be reported under this section with respect to the dispensing of a prescription drug shall include the following:

''(A) Drug Enforcement Administration Registration Number of the dispenser.

''(B) Drug Enforcement Administration Registration Number and name of the practitioner who prescribed the drug.

''(C) Name, address, and telephone number of the ultimate user or research subject.

''(D) Identification of the drug by a national drug code number.

''(E) Quantity dispensed.

''(F) Estimated number of days for which such quantity should last.

''(G) Number of refills ordered.

''(H) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

''(I) Date of the dispensing.

''(J) Date of origin of the prescription.

''(4) The State shall specify an electronic format for the reporting of information under this section and may waive the requirement of such format with respect to an individual dispenser.

''(5) The State may meet the requirements of paragraphs (3) and (4) by requiring that information be reported under this section in accordance with the current version of the telecommunications format for controlled substances of the American Society for Automation in Pharmacy.

''(d) DATABASE.—A funding agreement for a grant under this section is that the State involved shall comply with the following:

''(1) The State shall establish and maintain an electronic database containing the information reported to the State under this section.

''(2) The database must be searchable by any field or combination of fields.

''(3) The State shall include reported information in the database in a timely and efficient manner, with appropriate safeguards for ensuring the accuracy and completeness of the database.

''(4) The State shall take appropriate security measures to protect the integrity of, and access to, the database.

''(e) REQUIRED AVAILABILITY OF INFORMATION.—Subject to subsection (g), a funding agreement for a grant under this section is that the State involved, with respect to the database established by the State under subsection (d), shall comply with the following:

''(1) The State, taking into consideration the criteria established by the Secretary under subsection (i)(1), shall notify appropriate authorities responsible for drug diversion investigation if informa-

tion in the database indicates a potential unlawful diversion or misuse of a prescription drug.

''(2) The State shall provide for sharing of information on a specific individual in the database with each State that—

''(A) maintains a database established under subsection (d); and

''(B) agrees to use the information in accordance with the requirements of this section.

''(3) The State shall automatically share information reported to the State under this section with another State if—

''(A) such other State maintains a database under subsection (d); and

''(B) the information concerns—

''(i) the dispensing of a prescription drug to an ultimate consumer or research subject who resides in such other State; or

''(ii) the dispensing of a prescription drug prescribed by a practitioner whose principal place of business is located in such other State.

''(f) OPTIONAL AVAILABILITY OF INFORMATION.—Subject to subsection (g), a funding agreement for a grant under this section is that the State involved, with respect

to the database established by the State under subsection (d), may choose to comply with any of the following:

''(1) On request, the State may make available information on a specific individual from the database to any dispenser or practitioner who certifies that the requested information is for the purpose of providing pharmaceutical or medical treatment, or evaluating the need for such treatment, with respect to a bona fide patient.

''(2) On request, the State may make available information on a specific individual from the database to any local, State, or Federal law enforcement authority responsible for prescription drug diversion investigation that requests the information and certifies that—

''(A) the requested information relates to an active criminal investigation or proceeding involving the unlawful diversion or misuse of a prescription drug; and

''(B) the authority has reasonable cause to conclude that such information will further the purpose of the investigation or assist in the proceeding.

''(3) On request, the State may make available information on a specific individual from the data-

base to any health care professional licensing authority that requests the information and certifies that the requested information relates to an active investigation or proceeding involving the unlawful diversion or misuse of a prescription drug, and the authority has reasonable cause to conclude that such information will further the purpose of the investigation or assist in the proceeding. Information made available to a health care professional licensing authority under this paragraph shall be limited to those individuals licensed, regulated, or disciplined by the authority.

''(4) The State may make available information on a specific individual from the database to dispensers, practitioners, law enforcement authorities responsible for prescription drug diversion investigation, and health care professional licensing authorities in accordance with paragraphs (1), (2), and (3), irrespective of whether such dispensers, practitioners, or authorities are from another State.

''(5) On request, the State may make available information on a specific individual from the database to that specific individual with appropriate identification and procedures.

''(g) LIMITATION.—With respect to information in a database established under subsection (d), a funding agreement for a grant under this section is that—

''(1) the State involved shall limit the release of information pursuant to subsections (e) and (f) to the minimum necessary to accomplish the intended purpose of such release;

''(2) after the passage of 18 months from the date of the dispensing of a drug, the State involved will make information on such dispensing available only to the extent required by court order; and

''(3) except as inconsistent with the provisions of this section, the State involved will comply with section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033) (concerning the confidentiality of individually identifiable health information) and any regulation promulgated under such section.

''(h) QUALITY IMPROVEMENT PROGRAM.—A funding agreement for a grant under this section is that the State involved shall operate a continuous quality improvement program to ensure the State's compliance with this section and to improve the State's prescription drug monitoring program.

''(i) AUTHORITY OF SECRETARY.—

''(1) NATIONAL CRITERIA.—The Secretary shall establish criteria for determining whether information in a database established under subsection (d) indicates a potential unlawful diversion or misuse of a prescription drug.

''(2) EXCLUSIONS.—The Secretary may identify instances (in addition to those described in subparagraphs (A) and (B) of subsection (c)(2)) in which a State may exclude from the reporting requirement of this section the application or dispensing of a prescription drug.

''(j) ADVISORY COUNCIL.—A funding agreement for a grant under this section is that the State involved shall comply with the following:

''(1) The State shall establish an advisory council to assist in the establishment and implementation of a prescription drug monitoring program under this section.

''(2) The State shall ensure that the membership of the advisory council includes the following:

''(A) A representative of the primary State agency responsible for law enforcement.

''(B) A representative of the primary State agency responsible for health care.

''(C) A health care practitioner with a specialty in pain medicine licensed in the State to prescribe drugs.

''(D) A pharmacist licensed in the State.

''(E) A prosecutor experienced in criminal prosecution of drug diversion cases.

''(F) A member representing the public at large.

''(k) APPLICATION.—For purposes of subsection (b), an application is in accordance with this subsection if—

''(1) the application contains each funding agreement in this section;

''(2) with respect to such funding agreements, the application provides assurances of compliance satisfactory to the Secretary; and

''(3) the application is in such form, is made in such manner, and contains such information as the Secretary determines to be necessary to carry out this section.

''(l) DEFINITIONS.—For purposes of this section:

''(1) The term 'bona fide patient' means an individual who is a patient of the dispenser or practitioner involved.

''(2) The term 'dispense' means to deliver a prescription drug to an ultimate user or research

subject by, or pursuant to the lawful order of, a practitioner, irrespective of whether the dispenser uses the Internet or other means to effect such delivery.

''(3) The term 'dispenser' means a physician, pharmacist, or other individual who dispenses a prescription drug to an ultimate user or research subject.

''(4) The term 'ultimate user' means a person who has lawfully obtained, and who possesses, a prescription drug for his or her own use, for the use of a member of his or her household, or for the use of an animal owned by him or her or by a member of his or her household.

''(m) AUTHORIZATION OF APPROPRIATIONS.—

''(1) IN GENERAL.—There is authorized to be appropriated to carry out this section $10,000,000 for fiscal year 2005 and each subsequent fiscal year.

''(2) STARTUP GRANTS.—For the purpose of awarding grants under this section to assist with the initial costs of establishing a prescription drug monitoring program, there is authorized to be appropriated $25,000,000 for the period of fiscal years 2005 through 2009. Such authorization of appro-

priations is in addition to the authorization of appropriations in paragraph (1).''.

SEC. 3. INTERNET PHARMACIES.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 503A the following:

''SEC. 503B. INTERNET SALE OF PRESCRIPTION DRUGS.

''(a) IN GENERAL.—

''(1) PROHIBITIONS.—Subject to paragraph (2), it is a violation of this section—

''(A) for any person to sell a prescription drug in interstate commerce through an Internet site—

''(i) if the Internet site is an illegal Internet pharmacy under subsection (b);

''(ii) if the person fails to comply with the treating provider verification requirements of subsection (c);

''(iii) if the person fails to submit the notices required by subsection (d); or

''(iv) if the person fails to comply with the reporting requirements applicable to the person under a State prescription drug monitoring program established with a

grant under section 399O of the Public Health Service Act; or

''(B) for any person to own or operate an illegal Internet pharmacy in interstate commerce.

''(2) EXCEPTION.—Any person who sells a prescription drug through an Internet site, or who owns or operates an Internet pharmacy, is deemed to meet the requirements of this section for purposes of such sale, ownership, or operation if the Internet site or Internet pharmacy is certified by the National Association of Boards of Pharmacy's Verified Internet Pharmacy Practice Sites program.

''(b) INTERNET PHARMACY REQUIREMENTS.—

''(1) IN GENERAL.—For purposes of this section:

''(A) The term 'Internet pharmacy' means an Internet site that is used primarily to sell prescription drugs in interstate commerce.

''(B) The term 'illegal Internet pharmacy' means an Internet pharmacy that fails to comply with this subsection.

''(2) REQUIREMENTS.—An Internet pharmacy shall provide to any individual who accesses the pharmacy the following information:

"(A) The street address and telephone number of—

"(i) the Internet pharmacy's place of business; and

"(ii) the Internet pharmacy's supervising pharmacist.

"(B) All States in which the Internet pharmacy is licensed or otherwise authorized to dispense prescription drugs.

"(C) If the Internet pharmacy makes referrals to, or solicits on behalf of, a practitioner or a group of practitioners for prescription services—

"(i) the name, street address, and telephone number of such practitioner or group; and

"(ii) each State in which each practitioner involved is licensed or otherwise authorized to prescribe drugs.

"(D) A statement that the Internet pharmacy will dispense prescription drugs only upon a showing of a prescription.

"(c) TREATING PROVIDER VERIFICATION REQUIREMENTS.—The treating provider verification requirements of this subsection are as follows:

''(1) IN GENERAL.—Subject to paragraph (2), a person may sell a prescription drug in interstate commerce through an Internet site only if—

''(A) the sale is in accordance with a prescription of the treating provider of the patient involved;

''(B) the seller verifies the prescription in accordance with paragraph (3);

''(C) the seller maintains a record of direct communications in accordance with paragraph (4); and

''(D) the seller complies with the prohibition of paragraph (5) against alteration of the prescription.

''(2) LIMITATION.—The treating provider verification requirements of this subsection apply with respect to a prescription drug only if—

''(A) the prescription drug is included in schedule II, III, or IV of section 202(c) of the Controlled Substances Act; or

''(B) the Secretary for purposes of this section identifies the prescription drug as potentially subject to abuse, diversion, and misuse.

''(3) VERIFICATION REQUIREMENT.—

''(A) REQUIREMENT.—A seller verifies a prescription in accordance with this paragraph if—

''(i) the patient involved or the patient's treating provider presents the prescription, directly or by facsimile or electronic mail, to the seller; or

''(ii) the seller verifies the prescription by direct communication with the treating provider involved.

''(B) INFORMATION.—When seeking verification of a prescription under subparagraph (A)(ii), a seller shall provide to the treating provider the following information:

''(i) Patient's full name and address.

''(ii) Identification of the drug by a national drug code number.

''(iii) Quantity to be dispensed.

''(iv) Date of patient request.

''(v) Date and time of verification request.

''(vi) Name of contact person at seller's company, including facsimile and telephone number.

"(C) VERIFICATION EVENTS.—A prescription is verified under subparagraph (A)(ii) only if one of the following occurs:

"(i) The treating provider confirms the prescription is accurate by direct communication with the seller.

"(ii) The treating provider informs the seller that the prescription is inaccurate and provides the accurate prescription.

"(iii) The treating provider fails to communicate with the seller within 48 hours, or a similar time as defined by the Commissioner of Food and Drugs, after receiving from the seller the information described in subparagraph (B).

"(D) INVALID PRESCRIPTION.—If a treating provider informs a seller before the deadline under subparagraph (C)(iii) that the prescription is inaccurate or expired, the seller shall not fill the prescription. The treating provider shall specify the basis for the inaccuracy or invalidity of the prescription. If the prescription communicated by the seller to the treating provider is inaccurate, the treating provider shall correct it.

''(4) RECORD REQUIREMENT.—A seller shall maintain a record of all direct communications with a treating provider regarding the sale of a prescription drug, including verification of the prescription involved.

''(5) NO ALTERATION.—A seller may not alter a prescription for a prescription drug. Notwithstanding the preceding sentence, if the same prescription drug is manufactured by the same company and sold under multiple labels to individual providers, the seller may fill the prescription with a prescription drug manufactured by that company under another label.

''(6) DEFINITIONS.—In this subsection:

''(A) The term 'direct communication' includes communication by telephone, facsimile, or electronic mail.

''(B) The term 'seller' means a person that sells a prescription drug in interstate commerce through an Internet site.

''(C) The term 'treating provider' means—

''(i) a health care provider who has performed a documented patient evaluation of the individual involved (including a patient history and physical examination) to

establish the diagnosis for which the prescription drug involved is prescribed, has discussed with the individual his or her treatment options and the risks and benefits of treatment, and maintains contemporaneous medical records on the individual;

''(ii) a health care provider who is providing care in consultation with a health care provider described in clause (i) and who has access to the medical records of the patient involved; or

''(iii) a health care provider who is providing care as part of an on-call or cross-coverage arrangement with a health care provider described in clause (i).

''(d) STATE NOTICE REQUIREMENTS.—A person that sells a prescription drug in interstate commerce through an Internet site shall provide to each State authority that licenses or otherwise authorizes the person to dispense the prescription drug the following information:

''(1) A statement that the person is selling prescription drugs through an Internet site.

''(2) The name, Internet address, street address, and telephone number of the person's business for selling such drugs.

''(e) DEFINITION.—In this section, the term 'prescription drug' means a drug subject to section 503(b).''.

(b) INCLUSION AS PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by inserting after paragraph (k) the following:

''(l) The sale of a prescription drug, or the ownership or operation of an illegal Internet pharmacy, in violation of section 503B.''.

(c) LINKS TO ILLEGAL INTERNET PHARMACY.—Section 302 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 332) is amended by adding at the end the following:

''(c) In the case of a violation of section 503B relating to an illegal Internet pharmacy, the district courts of the United States and the United States courts of the Territories shall have jurisdiction to order a provider of an interactive computer service to remove, or disable access to, a site violating such section, or a link to a site violating such section, that resides on a computer server that such provider controls or operates. Such relief shall—

''(1) be available only after provision to the provider of notice and an opportunity to appear;

''(2) not impose any obligation on the provider to monitor its service or to affirmatively seek facts indicating activity violating section 503B;

''(3) specify the provider to which the relief applies; and

''(4) specifically identify the location of the site or link to be removed, or to which access is to be disabled.''.

SEC. 4. DISTRIBUTION AND LABELING OF DRUGS.

(a) DRUG PEDIGREE AMENDMENTS.—Paragraph (1) of section 503(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)) is amended—

(1) in subparagraph (A), by striking ''Each person who is engaged in the wholesale distribution of a drug subject to subsection (b) and who is not the manufacturer or an authorized distributor of record of such drug shall'' and inserting ''Subject to subparagraph (C), each person who is engaged in the wholesale distribution of a drug subject to subsection (b) shall''; and

(2) by adding after subparagraph (B) the following:

''(C) Subparagraph (A) applies to the manufacturer of a drug or the authorized distributor of record of a drug only if—

''(i) the drug is included in schedule II of section 202(c) of the Controlled Substances Act; or

''(ii) the Secretary designates the drug for purposes of this subparagraph, taking into consideration the impact to public health that would result from counterfeiting or diversion of the drug, the price of the drug, the volume of the drug, the dosage form of the drug, the clinical uses of the drug, the history of counterfeiting or diversion of the drug, and whether products similar to the drug have a history of counterfeiting or diversion.''.

(b) CHAIN-OF-CUSTODY REQUIREMENTS.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) (as amended by section 3) is amended—

(1) in section 502, by adding at the end the following:

''(w) If it is a drug with respect to which the manufacturer, importer, distributor, or retailer fails to comply with the chain-of-custody requirements of section 503C.''; and

(2) by inserting after section 503B the following:

"SEC. 503C. CHAIN-OF-CUSTODY REQUIREMENTS.

"(a) IN GENERAL.—Not later than January 1, 2006, the Secretary shall promulgate chain-of-custody requirements applicable to each manufacturer, importer, distributor, and retailer of a prescription drug.

"(b) MANUFACTURERS.—The chain-of-custody requirements promulgated under this section shall require each manufacturer of a prescription drug—

"(1) to incorporate a unique identifier into the packaging or labeling of the drug;

"(2) to track the drug through the point of delivery to the retailer of the drug; and

"(3) to maintain, either directly or through a contractor, a database on the movement of the drug.

"(c) IMPORTERS, DISTRIBUTORS, AND RETAILERS.—The chain-of-custody requirements promulgated under this section shall require each importer, distributor, and retailer of a prescription drug to assist in the tracking of the drug under this section by reporting the receipt of the drug to the manufacturer.

"(d) PRESCRIPTION DRUG.—In this section, the term 'prescription drug' means a drug subject to section 503(b).

''(e) EFFECTIVE DATE.—The chain-of-custody requirements promulgated by the Secretary under this section shall take effect on January 1, 2008.''.

(c) GRANTS FOR COMMUNITY PHARMACISTS.—The Secretary of Health and Human Services may make grants to community pharmacists to assist such pharmacists to comply with tracking requirements imposed on such pharmacists by drug manufacturers, importers, or distributors as a result of the amendments made by subsection (b).

SEC. 5. RESTRICTION ON PERSONAL USE EXEMPTION FOR IMPORTING CONTROLLED SUBSTANCES.

Paragraph (2) of section 1006(a) of the Controlled Substances Import and Export Act (21 U.S.C. 956(a)) is amended by striking ''may not import the controlled substance'' and all that follows and inserting ''may not import the controlled substance into the United States—

''(1) in an amount that exceeds 50 dosage units of the controlled substance; or

''(2) in the case of a controlled substance in schedule II, III, or IV, more than 1 time during any 30-day period.''.

SEC. 6. WORKING GROUP ON PHARMACEUTICAL COUNTERFEITING.

(a) ESTABLISHMENT.—The Secretary of Health and Human Services (in this section referred to as the ''Secretary''), acting through the Commissioner of Food and Drugs, shall convene a working group (in this section referred to as the ''working group'') to conduct a study and submit a report on pharmaceutical counterfeiting.

(b) MEMBERS.—The Secretary shall invite to serve as members of the working group representatives of the following:

(1) Domestic regulatory agencies.

(2) Domestic and international law enforcement officials.

(3) Multinational organizations, such as the World Trade Organization and the World Health Organization.

(4) The United States Trade Representative.

(5) The pharmaceutical industry.

(6) Trade associations.

(c) STUDY.—The study conducted by the working group on pharmaceutical counterfeiting shall consider the following:

(1) How to enhance supply-chain security.

(2) Consumer education on counterfeiting issues.

(3) Employing technology designed to frustrate organized and sophisticated criminals intent on compromising the world's drug supply.

(4) How industry could assist law enforcement by analyzing suspected counterfeit drugs to determine authenticity.

(5) How industry can collaborate on issues related to pharmaceutical counterfeiting without revealing trade secrets or other confidential information.

(d) REPORT.—Not later than 2 years after the date of the enactment of this Act, the working group shall submit a report to the Congress on the results of the study conducted under this section, including recommendations on measures to reduce or eliminate problems associated with pharmaceutical counterfeiting.

SEC. 7. BASELINE RESEARCH ON PRESCRIPTION DRUG ABUSE.

(a) RESEARCH.—The Secretary of Health and Human Services shall conduct research on issues related to prescription drug abuse, including the following:

(1) Enhancing existing public use surveys and other sources so as to provide appropriate baseline data and data on the natural history and context of prescription drug use in order to evaluate the extent

and nature of potential problems and guide corrective actions which reduce the problems without unintentionally hindering patient access.

(2) The phenomenon of iatrogenic addiction, including the actual incidence and prevalence of iatrogenic addiction, the factors that modulate the risk of such addiction, and the extent to which concern about iatrogenic addiction impacts health care delivery.

(3) Development of postapproval surveillance approaches that can detect and address potential risks of abuse and misuse, including risks in diverse patient populations that did not previously appear at risk for diversion or abuse, and in geographic regions that have been relatively absent from risk.

(4) Methods to better translate new ideas about terminology, diagnosis, and management of addiction diseases into clinical practice at the primary care and specialist levels.

(5) Reliable, useful assessment tools for addiction in the clinical setting of initial and ongoing treatment of conditions requiring the use of controlled substances.

(6) Development of better methods of ensuring patient adherence to prescribed drug regimens.

(7) Relative contributions of genetic, psychosocial, environmental, and behavioral factors to addiction to prescription opioids.

(b) REPORT.—Not later than 2 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to the Congress a report on the results of the research conducted under this section.

SEC. 8. DATABASE FOR DRUG ABUSE MORTALITY REPORTING.

Section 505 of the Public Health Service Act (42 U.S.C. 290aa–4) is amended—

(1) in subparagraph (B) of subsection (c)(1), by striking ", as indicated in reports by coroners"; and

(2) by adding at the end the following:

"(e) With respect to the activities of the Administrator under subsections (a) and (c)(1)(B) relating to the collection of data on the number of deaths occurring as a result of substance abuse, the Administrator—

"(1) shall expand and intensify collection activities to maintain a comprehensive, national database on such deaths; and

"(2) shall require medical examiners, coroners, and other appropriate persons to report to the Ad-

ministrator for purposes of collecting data on such deaths.''

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