(ii) be conducted by an approved entity (as defined in subparagraph (B)) in accordance with generally accepted auditing principles.

(B) DEFINITION OF APPROVED ENTITY.—For purposes of subparagraph (A), the term ''approved entity'' means an entity that is—

(i) approved by the Secretary of the Treasury;

(ii) approved by the Governor of the State; and

(iii) independent of any agency administering activities funded under this section.

(C) SUBMISSION.—Not later than 30 days following the completion of an audit under this subsection, a State shall submit a copy of the audit to the State legislature and to the Secretary of the Treasury.

(D) REPAYMENT AND PENALTY.—Each State or recipient of any proceeds of grant funds made available under this section shall pay to the United States amounts ultimately found by the approved entity under paragraph (1)(A) not to have been expended in accordance with this section plus 10 percent of such amount as a penalty, or the Secretary of the Treasury may offset such amounts plus the 10 percent penalty against any amount that the State or recipient, respectively, may be eligible to receive under this section.

(2) REQUIREMENTS FOR SINGLE AUDITS.—The provisions of chapter 75 of title 31, United States Code, shall apply to the audit requirements of this section.

(3) STATE REPORTS.—

(A) IN GENERAL.—A State shall prepare a comprehensive report regarding the activities carried out with amounts received by the State under this section.

(B) REQUIREMENTS.—Reports prepared under this subsection—

(i) shall be in accordance with generally accepted accounting principles, including the provisions of chapter 75 of title 31, United States Code;

(ii) shall include the results of the most recent audit conducted in accordance with the requirements of paragraph (1); and

(iii) shall be in such form and contain such other information as the State deems necessary—

(I) to provide an accurate description of such activities; and

(II) to secure a complete record of the purposes for which amounts were expended in accordance with this section.

(C) AVAILABILITY OF REPORTS.—A State shall make copies of the reports required under this subsection available for public inspection within the State. Copies also shall be provided upon request to any interested public agency, and each such agency may provide such agency's views on such reports to Congress.

(4) SUPERVISION.—

(A) IN GENERAL.—

(i) REQUIREMENT.—The Secretary of the Treasury shall supervise the amounts received under this part in accordance with clause (ii).

(ii) LIMITATION.—The supervision by the Secretary of the Treasury shall be limited to—

(I) making grant payments to the States;

(II) approving the entities referred to in paragraph (1)(B); and

(III) withholding payment to a State based on the findings of such an entity in accordance with paragraph (1)(C)(ii).

(B) SPECIAL RULE.—No administrative officer or agency of the United States, other than the Secretary of the Treasury shall supervise the amounts received by the States under this section or the use of such amounts by the States.

(5) PROHIBITION.—With the exception of the Department of the Treasury as provided for in this section, no Federal department or agency may promulgate regulations or issue rules regarding this section.

(6) COMPLIANCE.—If the Secretary of the Treasury determines that a State, or a recipient of any proceeds of grant funds made available under this section, has failed to comply with a provision of this section, the Secretary of the Treasury shall notify the Governor of the State and shall request the Governor to secure compliance with such provision. If, not later than 60 days after receiving such notification, the Governor fails or refuses to secure compliance, the Secretary of the Treasury may take such action as the Secretary determines necessary to secure compliance.

(c) CONDITIONS ON USE OF FUNDS.—

(1) IN GENERAL.—Notwithstanding any other provision of law, grant funds made available under this section and the proceeds of the grant funds may not be used to promote, disseminate, sponsor, or produce any project or production that—

(A) denigrates the religious objects or religious beliefs of the adherents of a particular religion; or

(B) depicts or describes, in a patently offensive way, sexual or excretory activities or organs.

(2) STRICT APPLICATION.—The prohibition described in paragraph (1) shall be strictly applied without regard to the content or viewpoint of the project or production.

(d) ALLOTMENT OF FUNDS.—

(1) RESERVATION FOR ADMINISTRATIVE COSTS.—From the sum appropriated under subsection (g) the Secretary shall reserve not more than $1,000,000 for the administrative costs of the Department of the Treasury.

(2) MINIMUM ALLOTMENT.—From the sum appropriated under subsection (g) and not reserved under paragraph (1), the Secretary first shall allot—

(A) $500,000 to each State; and

(B) $200,000 to each of the Commonwealth of Puerto Rico, Guam, American Samoa, the United States Virgin Islands, and the Commonwealth of the Northern Mariana Islands.

(3) ALLOTMENT OF REMAINDER.—From the sum appropriated under subsection (g), not reserved under paragraph (1), and not allotted under paragraph (2), the Secretary shall allot to each State an amount that bears the same relation to the sum as the population of the State bears to the population of all States.

(4) STATE ADMINISTRATIVE COSTS.—A State may use not more than 15 percent of the funds allotted under paragraph (3) for administrative costs.

(5) DEFINITION OF STATE.—Notwithstanding subsection (e) and for the purposes of paragraphs (2)(A) and (3), the term ''State'' means each of the several States of the United States and the District of Columbia.

(e) DEFINITIONS.—In this section:

(1) ARTS.—The term ''arts'' includes, but is not limited to, music (instrumental and vocal), dance, drama, folk art, creative writing, architecture and allied fields, painting, sculpture, photography, graphic and craft arts, costume and fashion design, motion pictures, television, radio, film, video, tape and sound recording, the arts related to the presentation, performance, execution, and exhibition of such major art forms, all those traditional arts practiced by the diverse peoples of this country, and the study and application of the arts to the human environment.

(2) GOVERNOR.—The term ''Governor'' means the chief executive officer of a State.

(3) PRODUCTION.—The term ''production'' means plays (with or without music), ballet, dance and choral performances, concerts, recitals, operas, exhibitions, readings, motion pictures, television, radio, film, video tape and sound recordings, and any other activities involving the execution or rendition of the arts.

(4) PROJECT.—The term ''project'' means programs organized to carry out this section, including programs to foster American artistic creativity, to commission works of art, to create opportunities for individuals to develop artistic talents when carried on as a part of a program otherwise included in this definition, and to develop and enhance public knowledge and understanding of the arts. Such term includes, where appropriate, rental or purchase of facilities, purchase or rental of land, and acquisition of equipment. Such term also includes the renovation of facilities if the amount of the expenditure of Federal funds for such purpose in the case of any project does not exceed $250,000.

(5) SECRETARY.—The term ''Secretary'' means the Secretary of the Treasury.

(6) STATE.—The term ''State'' means any of the several States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the United States Virgin Islands, and the Commonwealth of the Northern Mariana Islands.

(f) REPORT BY INSPECTOR GENERAL.—The Inspector General of the Department of the Treasury shall submit to Congress a report describing the extent to which States and the recipients of any proceeds of grant funds made available under subsection (a) comply with the requirements of this section.

(g) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $100,060,000 for fiscal year 1998.

ASHCROFT (AND OTHERS) AMENDMENT NO. 1188

Mr. ASHCROFT (for himself, Mr. HELMS, Mr. BROWNBACK, Mr. SESSIONS, and Mr. INHOFE) proposed an amendment to the bill, H.R. 2107, supra; as follows:

Beginning on page 96, strike line 14 and all that follows through page 97, line 8.

THE FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997 PRESCRIPTION DRUG USERS FEE REAUTHORIZATION ACT OF 1997

HUTCHINSON AMENDMENT NO. 1189

(Ordered to lie on the table.)

Mr. HUTCHINSON submitted an amendment intended to be proposed by him to the bill, S. 830, supra; as follows:

In lieu of the matter proposed to be inserted, insert the following:

SEC. . APPLICATION OF FEDERAL LAW TO THE PRACTICE OF PHARMACY COMPOUNDING.

Section 503 (21 U.S.C. 353) is amended by adding at the end the following:

''(h)(1) Sections 501(a)(2)(B), 502(f)(1), 502(l), 505, and 507 shall not apply to a drug product if—

''(A) the drug product is compounded for an identified individual patient, based on a medical need for a compound product—

''(i) by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or a licensed physician, on the prescription order of a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or

''(ii) by a licensed pharmacist or licensed physician in limited quantities, prior to the

receipt of a valid prescription order for the identified individual patient, and is compounded based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product that have been generated solely within an established relationship between the licensed pharmacist, or licensed physician, and—

''(I) the individual patient for whom the prescription order will be provided; or

''(II) the physician or other licensed practitioner who will write such prescription order; and

''(B) the licensed pharmacist or licensed physician—

''(i) compounds the drug product using bulk drug substances—

''(I) that—

''(aa) comply with the standards of an applicable United States Pharmacopeia or National Formulary monograph; or

''(bb) in a case in which such a monograph does not exist, are drug substances that are covered by regulations issued by the Secretary under paragraph (3);

''(II) that are manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)); and

''(III) that are accompanied by valid certificates of analysis for each bulk drug substance;

''(ii) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopeia or National Formulary monograph and the United States Pharmacopeia chapter on pharmacy compounding;

''(iii) only advertises or promotes the compounding service provided by the licensed pharmacist or licensed physician and does not advertise or promote the compounding of any particular drug, class of drug, or type of drug;

''(iv) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective;

''(v) does not compound a drug product that is identified by the Secretary in regulation as presenting demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and

''(vi) does not distribute compounded drugs outside of the State in which the drugs are compounded, unless the principal State agency of jurisdiction that regulates the practice of pharmacy in such State has entered into a memorandum of understanding with the Secretary regarding the regulation of drugs that are compounded in the State and are distributed outside of the State, that provides for appropriate investigation by the State agency of complaints relating to compounded products distributed outside of the State.

''(2)(A) The Secretary shall, after consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by States in complying with paragraph (1)(B)(vi).

''(B) Paragraph (1)(B)(vi) shall not apply to a licensed pharmacist or licensed physician, who does not distribute inordinate amounts of compounded products outside of the State, until—

''(i) the date that is 180 days after the development of the standard memorandum of understanding; or

''(ii) the date on which the State agency enters into a memorandum of understanding under paragraph (1)(B)(vi), whichever occurs first.

''(3) The Secretary, after consultation with the United States Pharmacopeia Convention Incorporated, shall promulgate regulations limiting compounding under paragraph (1)(B)(i)(I)(bb) to drug substances that are components of drug products approved by the Secretary and to other drug substances as the Secretary may identify.

''(4) The provisions of paragraph (1) shall not apply—

''(A) to compounded positron emission tomography drugs as defined in section 201(ii); or

''(B) to radiopharmaceuticals.

''(5) In this subsection, the term 'compound' does not include to mix, reconstitute, or perform another similar act, in accordance with directions contained in approved drug labeling provided by a drug manufacturer.''.

NOTICES OF HEARINGS

COMMITTEE ON ENERGY AND NATURAL RESOURCES

Mr. MURKOWSKI. Mr. President, I would like to announce for the information of the Senate and the public that the nominations hearing previously scheduled before the full Committee on Energy and Natural Resources on Thursday, September 18, 1997, at 9:30 a.m. will now take place at 9 a.m. in room SE–366 of the Dirksen Senate Office Building in Washington, DC.

For further information, please call Camille Flint at (202) 224–5070.

PERMANENT SUBCOMMITTEE ON INVESTIGATIONS

Ms. COLLINS. Mr. President, I would like to announce for the information of the Senate and the public that the Permanent Subcommittee on Investigations of the Committee on Governmental Affairs, will hold hearings on ''Emerging Securities Fraud: Fraud In The Micro-Capital Markets.''

This hearing will take place on Monday, September 22, 1997, at 1:30 p.m. in room 342 of the Dirksen Senate Office Building. For further information, please contact Timothy J. Shea of the subcommittee staff at 224–3721.

ADDITIONAL STATEMENTS

ENHANCED OIL RECOVERY PROJECTS PROGRESS

• Mr. DOMENICI. Mr. President, in 1989, I stood on the Senate floor and urged the Senate to enact tax incentives for enhanced oil recovery techniques.

At that time, I told my colleagues that traditional drilling techniques were leaving behind 70 percent of the resource when traditional drilling and pumping was completed. To me, this was wasteful, foolish, and unnecessary.

It is wasteful to leave the oil behind.

It is foolish because the United States has a growing appetite for energy. We are currently importing close to half of the energy we use from an area of the world renowned for political instability.

It is unnecessary because we have the technology to recover the resource if we would use enhanced oil recovery techniques.

In 1989, I also told the Senate that it would be possible to recover another 20 billion barrels of oil from our same oil fields of existing wells if enhanced oil recovery techniques were used. Since our known recoverable reserves at that time were in the neighborhood of 28 billion barrels, the potential was, and still is, significant.

At that time, the Department of Energy conducted extensive studies showing that if a 15-percent investment tax credits were enacted, it could result in the recovery of additional reserves for as little cost to the Treasury as $1 per additional barrel recovered—assuming $20 per barrel oil.

For each and every dollar of Federal revenue invested in EOR incentives, the trade deficit would be reduced by $24 to $76 dollars according to the same DOE studies.

States with significant EOR potential include California, Texas, New Mexico, and Oklahoma. Other States with reserves include Arkansas, Colorado, Florida, Illinois, Kansas, Louisiana, Mississippi, Montana, North Dakota, Utah, and Wyoming.

In 1990, the Congress enacted tax incentives to encourage enhanced oil recovery so that more of this vast resource could be recovered and put to good use. I am proud to have been the primary sponsor of that legislation.

As a Senator, one of the greatest rewards is seeing a new law make the world a better place. During the August recess I had this rewarding experience. I also saw the predictions of the theoretical studies proven up in the real world.

I toured the Texaco enhanced oil recovery project located in Buckeye, NM. The technical name of the project is the ''Central Vacuum Unit CO_2 project.''

This particular oil field was discovered in 1929. Primary oil recovery techniques were used until 1977. Beginning in 1977, the field was transformed into a waterflood operation. Waterflood is a secondary oil recovery technique. The waterflood technology sustained and enhanced production for awhile, but it was evident that either the oil wells in the field would be shut-in and the field-shut down leaving behind a significant amount of oil, or enhanced oil recovery methods could prolong economic levels of production. One very promising enhanced oil recovery technique involves injecting the wells with CO_2.

CO_2 injection is an enhanced oil recovery technique eligible for a 15-percent Federal investment tax credit. Using CO_2 is going to significantly extend the life of this mature field by more than 20 years. The project will recover an additional 20 million barrels of oil and 23 billion cubic feet of gas that otherwise would have been left behind.