IMPROVING PREDICTABILITY AND TRANSPARENCY IN DEA AND FDA REGULATION

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRTEENTH CONGRESS

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C O N T E N T S

IMPROVING PREDICTABILITY AND TRANSPARENCY IN DEA AND FDA REGULATION

MONDAY, APRIL 7, 2014

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 3:00 p.m., in room 2123, Rayburn House Office Building, Hon. Joseph R. Pitts (chairman of the subcommittee) presiding.

Members present: Representatives Pitts, Burgess, Whitfield, Shimkus, Murphy, Blackburn, Lance, Griffith, Bilirakis, Ellmers, Upton (ex officio), Pallone, Dingell, Green, Barrow, and Waxman (ex officio).

Staff present: Clay Alspach, Chief Counsel, Health; Gary Andres, Staff Director; Noelle Clemente, Press Secretary; Paul Edattel, Professional Staff Member, Health; Sydne Harwick, Legislative Clerk; Robert Horne, Professional Staff Member, Health; Carly McWilliams, Professional Staff Member, Health; Heidi Stirrup, Policy Coordinator, Health; John Stone, Counsel, Health; Ziky Ababiya, Democratic Staff Assistant; Eric Flamm, Democratic FDA Detailee; Elizabeth Letter, Democratic Press Secretary; Karen Lightfoot, Democratic Communications Director and Senior Policy Advisor; and Karen Nelson, Democratic Deputy Staff Director, Health.

Mr. PITTS. The subcommittee will come to order.

The Chair will recognize himself for an opening statement.

OPENING STATEMENT OF HON. JOSEPH R. PITTS, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Today's legislative hearing focuses on three bills designed to improve the predictability and transparency in Drug Enforcement Administration and Food and Drug Administration regulation.

H.R. 4069, the Ensuring Patient Access and Effective Drug Enforcement Act, introduced by Representatives Marino and Blackburn, will facilitate greater collaboration between industry stakeholders and regulators in an effort to combat our Nation's prescription drug abuse epidemic.

[The information follows:]

I

113TH CONGRESS
2D SESSION

H. R. 4069

To improve enforcement efforts related to prescription drug diversion and abuse, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 18, 2014

Mr. MARINO (for himself and Mrs. BLACKBURN) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To improve enforcement efforts related to prescription drug diversion and abuse, 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 "Ensuring Patient Access and Effective Drug Enforcement Act of 2013".

SEC. 2. REGISTRATION PROCESS UNDER CONTROLLED SUBSTANCES ACT.

(a) DEFINITIONS.—

(1) CONSISTENT WITH THE PUBLIC HEALTH AND SAFETY.—Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended by adding at the end the following:

"(j) In this section, the phrase 'consistent with the public health and safety' means having a substantial relationship to this Act's purpose of preventing diversion and abuse of controlled substances.".

(2) IMMINENT DANGER.—Section 304(d) of the Controlled Substances Act (21 U.S.C. 824(d)) is amended—

(A) by striking "(d) The Attorney General" and inserting "(d)(1) The Attorney General"; and

(B) by adding at the end the following:

"(2) In this subsection, the term 'imminent danger' means a significant and present risk of death or serious bodily harm that is more likely than not to occur in the absence of an immediate suspension order.".

(b) CRIMINAL BACKGROUND CHECKS AND DRUG TESTING FOR EMPLOYEES WITH ACCESS TO CONTROLLED SUBSTANCES.—

(1) REQUIREMENTS.—Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended

by inserting before subsection (j) (as added by subsection (a)(1)) the following:

"(i)(1) The Attorney General shall require all registrants under subsections (a), (b), (d), or (e), as a condition of such registration—

"(A) to obtain a criminal background check on each of the registrant's employees who has or will have access to facility areas where controlled substances under the registrant's possession or control are stored, such as a cage, vault, or safe; and

"(B) to perform drug testing on each such employee in accordance with Federal and State law.

"(2) The criminal background checks required by paragraph (1) shall be obtained—

"(A) periodically, but not more frequently than every 2 years, for all employees of the registrant who are described in paragraph (1)(A); and

"(B) at the time of hire, for such employees who are hired after the date of enactment of the Ensuring Patient Access and Effective Drug Enforcement Act of 2013.

"(3) The term 'drug testing' means testing designed to detect the illegal use of a controlled substance.".

(2) CONFORMING CHANGE.—Section 304(a) of the Controlled Substances Act (21 U.S.C. 823(a)) is amended—

(A) in paragraph (4), by striking "or" at the end;

(B) in paragraph (5), by striking the period at the end and inserting "; or"; and

(C) by adding at the end the following:

"(6) has failed to comply with the requirements under section 303(i) (relating to criminal background checks and drug testing).".

(3) ALTERNATIVE CIVIL PENALTY FOR FAILURE TO COMPLY WITH CRIMINAL BACKGROUND CHECK AND DRUG TESTING REQUIREMENTS.—

(A) PROHIBITED ACT.—Section 402(a) of the Controlled Substances Act (21 U.S.C. 842(a)) is amended—

(i) in paragraph (14), by striking "or" at the end;

(ii) in paragraph (15), by striking the period at the end and inserting "; or"; and

(iii) by inserting after paragraph (15) the following:

"(16) who is a registrant to fail to comply with the requirements under section 303(i) (relating to criminal background checks and drug testing);".

(B) MAXIMUM CIVIL PENALTY OF $10,000.—Subsection (c)(1)(B) of the Controlled Substances Act (21 U.S.C. 842(c)(1)(B)) is amended by striking "paragraph (5) or (10)" and inserting "paragraph (5), (10), or (16)".

(4) REGULATIONS, GUIDANCE.—The Attorney General of the United States shall finalize such regulations and guidance as the Attorney General deems necessary to carry out the amendments made by this subsection.

(5) APPLICABILITY.—The amendments made by this subsection shall apply beginning on the date that is 2 years after the date of enactment of this Act.

(c) OPPORTUNITY TO SUBMIT CORRECTIVE ACTION PLAN PRIOR TO REVOCATION OR SUSPENSION.—Section 304(c) of the Controlled Substances Act (21 U.S.C. 824(c)) is amended—

(1) by striking "(c) Before" and inserting "(c)(1) Before"; and

(2) by adding at the end the following:

"(2) Before revoking or suspending a registration pursuant to section 303, the Attorney General shall—

"(A) provide—

"(i) notice to the registrant of the grounds for revocation or suspension; and

"(ii) in the case of any such grounds consisting of a violation of law, a specific citation to such law;

"(B) give the registrant an opportunity to submit a corrective action plan within a reasonable period of time to demonstrate how the registrant plans to correct the grounds for revocation or suspension; and

"(C) determine whether—

"(i) in light of the plan, revocation or suspension proceedings should be discontinued or deferred; or

"(ii) additional changes need to be made in the corrective action plan.".

SEC. 3. COMBATING PRESCRIPTION DRUG ABUSE WORKING GROUP.

(a) ESTABLISHMENT.—There is established the Combating Prescription Drug Abuse Working Group (referred to in this section as the "Working Group").

(b) MEMBERSHIP.—

(1) APPOINTMENT.—

(A) IN GENERAL.—Not later than 180 days after the date of the enactment of this Act, the President shall appoint each member of the Working Group.

(B) COMPOSITION.—The Working Group shall be composed of not more than 20 members and shall include at least 1 and not more than 3 of each of the following:

(i) Public policy experts.

(ii) Representatives of the Drug Enforcement Administration.

(iii) Representatives of the Food and Drug Administration.

(iv) Representatives of the Office of National Drug Control Policy.

(v) Representatives of patient groups.

(vi) Representatives of pharmacies.

(vii) Representatives of manufacturers of drugs.

(viii) Representatives of wholesale distributors of drugs.

(ix) Representatives of hospitals, physicians, and other health care providers.

(x) Representatives of State attorneys general.

(xi) Representatives of law enforcement officials, including local law enforcement officials.

(xii) Representatives of health benefits plans and entities that provide pharmacy benefits management services on behalf of a health benefits plans.

(2) CO-CHAIRS.—The co-chairs shall be elected by the members of the Working Group. The Working Group shall select for election from the members of the Group two individuals, of whom—

(A) one shall be a representative of the Federal Government or a State government; and

(B) one shall be a representative of a non-governmental entity.

(3) TERM; VACANCIES.—Each member shall be appointed for the life of the Working Group. Any vacancy in the Working Group shall not affect the powers of the Working Group and shall be filled in the same manner in which the original appointment was made.

(4) PAY PROHIBITED.—Members of the Working Group shall serve without pay.

(c) MEETINGS.—The Working Group shall meet at the call of the co-chairs. The Working Group shall conduct at least two public meetings, at which the Working Group shall provide opportunity for public comment.

(d) DUTIES OF THE WORKING GROUP.—

(1) IN GENERAL.—The Working Group shall—

(A) review and report to Congress on Federal initiatives with respect to efforts to reduce prescription drug diversion and abuse;

(B) identify gaps and opportunities with respect to ensuring the safe use of prescription drugs with the potential for diversion and abuse;

(C) examine recommendations to transfer one or more controlled substances from schedule III to schedule II under the Controlled Substances Act (21 U.S.C. 801 et seq.) to evaluate—

(i) the effectiveness of such a transfer in reducing diversion and abuse; and

(ii) any effect of such a transfer on access to prescription drugs for legitimate medical purposes; and

(D) make recommendations on specific ways to reduce the diversion and abuse of prescription drugs.

(2) REPORT.—

(A) IN GENERAL.—Not later than one year after the date of the enactment of this Act, the Working Group shall issue a report to Congress that describes the efforts of the Working Group to prevent or reduce prescription drug diversion and abuse to ensure that patients continue to have access to medications.

(B) RECOMMENDATIONS.—The report described in subparagraph (A) shall include specific recommendations for the Drug Enforcement Administration, the Food and Drug Administration, and other Federal and State agencies, as appropriate, and shall address the following topics:

(i) Systems for prescription drug monitoring.

(ii) Illegal prescription drug Internet sites and facilities that distribute and fill prescriptions indiscriminately.

(iii) Facilitating proper disposal of prescription drugs.

(iv) Identifying active geographic areas in which prescription drug abuse is prevalent.

(v) Ensuring access to prescription drugs for legitimate medical purposes.

(vi) Improving collaboration among Federal agencies, especially the Drug Enforcement Administration and the Food and Drug Administration, for purposes of coordinating prevention and enforcement efforts to reduce prescription drug diversion and abuse.

(vii) Improving collaboration among Federal agencies and State agencies for purposes of coordinating prevention and enforcement efforts to reduce prescription drug diversion and abuse.

(viii) The resource needs for law enforcement with respect to prescription drug abuse.

(ix) The need for education of providers, patients, parents, and youth on prescription drug abuse.

(x) Development of abuse-resistant prescription drug products.

(xi) Recommendations for reducing robberies, burglaries, and cargo theft of prescription drugs.

(e) POWERS OF THE WORKING GROUP.—

(1) HEARINGS.—The Working Group may, for the purpose of carrying out this section, hold hearings, sit and act at times and places, take testimony, and receive evidence as the Working Group considers necessary.

(2) INFORMATION FROM FEDERAL AGENCIES.—The Working Group may secure directly from any Federal department or agency such information as the Working Group considers necessary to carry out this section. Upon the request of the co-chairs of the Working Group, the head of such department or agency shall furnish such information to the Working Group in a timely manner.

(f) TERMINATION OF THE WORKING GROUP.—The Working Group shall terminate two years after the date on which the members are appointed under subsection (b).

○

Mr. PITTS. H.R. 4250, the Sunscreen Innovation Act, introduced by Representatives Whitfield and Dingell, seeks to expedite the FDA's approval process for active ingredients in sunscreens that have long been approved for use in places like Europe, Canada, and other countries to ensure that U.S. consumers have access to the safest, most effective sunscreens available.

[The information follows:]

I

113TH CONGRESS
2D SESSION

H. R. 4250

To amend the Federal Food, Drug, and Cosmetic Act to provide an alternative process for review of safety and effectiveness of nonprescription sunscreen active ingredients and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 13, 2014

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

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide an alternative process for review of safety and effectiveness of nonprescription sunscreen active ingredients 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 "Sunscreen Innovation Act".

SEC. 2. REGULATION OF NONPRESCRIPTION SUNSCREEN ACTIVE INGREDIENTS.

Subchapter A of chapter V (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

"SEC. 524B. PROCEDURES FOR CLASSIFYING SUNSCREEN ACTIVE INGREDIENTS.

"(a) IN GENERAL.—The Secretary shall review and determine whether nonprescription sunscreen conditions are generally recognized as safe and effective and shall ensure that any such conditions that are marketed in the United States are appropriately labeled.

"(b) DEFINITIONS.—

"(1) ACTIVE INGREDIENT.—The term 'active ingredient' means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or function of the body of humans or animals. The term includes components that may undergo chemical change in the manufacture of a drug and may be present in a drug in a modified form intended to furnish the specified activity or effect.

"(2) SUNSCREEN ACTIVE INGREDIENT.—The term 'sunscreen active ingredient' means an active ingredient that absorbs, reflects, or scatters radi-

ation in the ultraviolet range at wavelengths from 290 to 400 nanometers.

"(3) SUNSCREEN CONDITION.—The term 'sunscreen condition' means a sunscreen active ingredient (or a combination of sunscreen active ingredients), dosage form, dosage strength, or route of administration, marketed for a specific nonprescription use.

"(c) CRITERIA FOR ELIGIBILITY.—To be eligible for review under this section, a sunscreen condition shall—

"(1) not be included in the stayed sunscreen monograph; and

"(2) have been marketed as a nonprescription sunscreen condition in the United States or at least 1 other country, or marketed as a cosmetic or dietary supplement in 1 or more counties other than the United States—

"(A) for a minimum of 5 continuous years; and

"(B) in sufficient quantity, as determined by the Secretary based upon the information submitted under subparagraphs (D) and (E) of subsection (d)(1) and, if applicable, subsection (d)(2)(A)(ii).

"(d) APPLICATION FOR ELIGIBILITY.—

"(1) IN GENERAL.—A sponsor of a nonprescription sunscreen condition described in subsection (c) desiring to market such condition in the United States may submit an application to the Secretary, in such manner and containing such information as required by the Secretary, including the following:

"(A) Basic information about the sunscreen condition (including a description of each active ingredient, pharmacologic class, intended nonprescription use, nonprescription strength and dosage form, route of administration, and directions for use).

"(B) A detailed chemical description of the sunscreen active ingredient that includes a full description of the drug substance, including its physical and chemical characteristics, the method of synthesis (or isolation) and purification of the drug substance, and any specifications and analytical methods necessary to ensure the identity, strength, quality, and purity of the drug substance, including reference to the current edition of the official National Formulary, the United States Pharmacopeia, or foreign compendiums, where applicable.

"(C) A list of each country in which the sunscreen condition has been marketed.

"(D) The cumulative total number of dosage units sold for each dosage form of the sunscreen condition, including total weight of the active ingredient, package size for each dosage form in which the condition is marketed as nonprescription, and an estimate of the minimum number of potential consumer exposures to the condition.

"(E) The use pattern (according to the label) for each country in which the sunscreen condition is marketed and any changes in use pattern that have occurred over time.

"(F) A list of all countries in which the sunscreen condition has been withdrawn from marketing or in which an application for nonprescription marketing approval has been denied and an explanation for such withdrawal or application denial.

"(2) SUNSCREEN CONDITIONS THAT HAVE NOT BEEN MARKETED IN THE UNITED STATES FOR 5 CONTINUOUS YEARS.—

"(A) IN GENERAL.—In the case of an application with respect to a nonprescription sun-

screen condition that has not been marketed in the United States for 5 continuous years, in addition to the information required under paragraph (1), the sponsor shall submit the following information for each country in which the sunscreen condition has been marketed:

"(i) The manner in which the sunscreen condition has been marketed to consumers. If the sunscreen condition is marketed to consumers as a nonprescription pharmacy only condition, the Secretary may require supplemental information.

"(ii) A description of the population demographics and the source from which this information has been compiled, to ensure that the sunscreen condition's use can be reasonably extrapolated to the population of the United States.

"(iii) A description of the country's system for identifying adverse drug experiences, especially those found in nonprescription marketing experience, including method of collection if applicable.

"(iv) A statement of how long the sunscreen condition has been marketed in

each country and how long the current product labeling has been in use, accompanied by a copy of the current product labeling, including a translation into English of any labeling that is not in English, and a statement of whether the current product labeling has been authorized, accepted, or approved by a regulatory body in each country where the condition is marketed.

"(v) A list of all countries where the sunscreen condition is marketed as a prescription drug only and an explanation for such restriction.

"(B) SUNSCREEN CONDITIONS THAT HAVE BEEN MARKETED IN MORE THAN 5 COUNTRIES.—

"(i) IN GENERAL.—In the case of a sunscreen condition that has been marketed as a nonprescription sunscreen in more than 5 countries, with a minimum of 5 continuous years of marketing in at least one such country, the sponsor—

"(I) may submit information in accordance with clauses (i) through

(iv) of subparagraph (A) with respect to only 5 such countries, including—

"(aa) the country with a minimum of 5 continuous years of nonprescription marketing;

"(bb) the country with the longest duration of marketing; and

"(cc) the country with the most support for marketing, such as a large volume of sales with cultural diversity among users of the product; and

"(II) shall explain the basis for the countries selected under subclause (I); and

"(III) shall provide information from more than 5 countries if such information is needed to support the application.

"(ii) REQUIREMENT.—If the sunscreen condition meets the criteria under items (aa) through (cc) of clause (i)(I) in 1 or more countries listed in section 802(b)(1)(A), at least 1 such country shall

be included among the 5 countries selected under such clause (i)(I).

"(3) PENDING APPLICATIONS.—The requirements of this subsection shall not apply to a sunscreen condition deemed eligible for review of safety and effectiveness by publication of a notice of eligibility in the Federal Register prior to the date of enactment of the Sunscreen Innovation Act. Applications for such sunscreen conditions shall be considered in accordance with subsection (g).

"(e) PUBLIC AVAILABILITY.—If a condition is found eligible under subsection (d), the Secretary shall make the application publicly available, with redactions for confidential commercial information or trade secret information, and any other information exempt from disclosure pursuant to section 1905 of title 18, United States Code, section 552(b) of title 5, United States Code, or section 301(j) of this Act. Applications shall remain confidential during the Secretary's consideration of eligibility.

"(f) NEW SUNSCREEN CONDITION APPLICATION.—

"(1) ELIGIBILITY DETERMINATION.—Not later than 60 days after the submission of an eligibility application under subsection (d), the Secretary shall determine if the sunscreen condition is eligible for further review for safety and effectiveness. In the

case of a sunscreen condition determined to be eligible, the Secretary shall publish a notice of eligibility in the Federal Register, and provide interested persons an opportunity to submit published and unpublished data related to the safety and effectiveness of the sunscreen condition for its intended nonprescription uses, in accordance with paragraph (2). In the case of a sunscreen condition determined not eligible, the Secretary shall issue a letter to the sponsor, which shall be made publicly available.

"(2) SAFETY AND EFFECTIVENESS DATA SUBMISSIONS.—

"(A) IN GENERAL.—Within 60 days of the publication in the Federal Register of an application deemed eligible, as described in paragraph (1), the sponsor and other interested parties shall submit safety and effectiveness data to the Secretary for further review, as described in subparagraph (B).

"(B) REQUIRED SUBMISSIONS REGARDING DATA.—Submissions under this paragraph shall include the following:

"(i) HUMAN SAFETY DATA.—

"(I) INDIVIDUAL ACTIVE COMPONENTS.—With respect to individual

active components, controlled studies, partially controlled or uncontrolled studies, documented case reports, pertinent marketing experiences that may influence a determination as to the safety of each individual active component, and pertinent medical and scientific literature.

"(II) COMBINATIONS OF INDIVIDUAL ACTIVE COMPONENTS.—With respect to combinations of the individual active components, controlled studies, partially controlled or uncontrolled studies, documented case reports, pertinent marketing experiences that may influence a determination as to the safety of combinations of the individual active component, and pertinent medical and scientific literature.

"(ii) EFFICACY DATA.—

"(I) INDIVIDUAL ACTIVE COMPONENTS.—With respect to individual active components, controlled studies, partially controlled or uncontrolled

studies, documented case reports, pertinent marketing experiences that may influence a determination on the efficacy of each individual active component, pertinent medical and scientific literature.

"(II) COMBINATIONS OF INDIVIDUAL ACTIVE COMPONENTS.—With respect to combinations of the individual active components, controlled studies, partially controlled or uncontrolled studies, documented case reports, pertinent marketing experiences that may influence a determination on the efficacy of combinations of the individual active components, and pertinent medical and scientific literature.

"(iii) DATA SETTING FORTH MEDICAL RATIONALE AND PURPOSE.—A summary of the data and views setting forth the medical rationale and purpose (or lack thereof) for the sunscreen condition and the scientific basis (or lack thereof) for the conclusion that the condition has been proven safe and effective for the intended use. If

there is an absence of controlled studies in the material submitted, an explanation as to why such studies are not considered necessary must be included.

"(iv) OFFICIAL DRUG MONOGRAPH.—An applicable United States Pharmacopoeia or National Formulary for the sunscreen active ingredient or a proposed standard for inclusion in an article to be recognized in an official drug monograph for the active ingredient, including information showing that the official or proposed compendial monograph for the active ingredient is consistent with the active ingredient used in the studies establishing safety and effectiveness and with the active ingredient marketed in the nonprescription product to a material extent and for a material time. If differences exist between the official or proposed compendial monograph for the active ingredient and the active ingredient that is the subject of the application, sponsor shall explain such differences.

"(v) ADVERSE DRUG EXPERIENCES.—A list of all serious adverse drug experi-

ences, as defined by the Secretary, from each country where the condition has been or is currently marketed as a prescription drug or as a nonprescription drug or product.

"(C) OPTIONAL ANIMAL SAFETY DATA.—In addition to the information required under subparagraph (B), the sponsor may submit information with respect to animal safety data, including controlled studies and partially controlled or uncontrolled studies, in the case of an application for individual active components, and controlled studies and partially controlled or uncontrolled studies in the case of an application for combinations of individual active components.

"(D) CONFIDENTIALITY OF SUBMISSIONS.—The Secretary shall make data and information submitted by the sponsor, or pursuant to a notice requesting safety and effectiveness data published in the Federal Register, publicly available, with redactions for confidential commercial information or trade secret information, and any other information exempt from disclosure pursuant to section 1905 of

title 18, United States Code, section 552(b) of title 5, United States Code, or section 301(j) of this Act.

"(3) NEW SUNSCREEN CONDITION APPLICATION SUBMISSION TO THE ADVISORY COMMITTEE.—Not later than 30 days after the end of the public comment period described in paragraph (2), the Secretary shall submit the application and the safety and effectiveness data submitted under paragraph (2) to the Nonprescription Drugs Advisory Committee (referred to in this section as the 'advisory committee') for review.

"(g) PENDING SUNSCREEN CONDITION APPLICATIONS.—Not later than 30 days after the date of enactment of the Sunscreen Innovation Act, the Secretary shall submit to the advisory committee all safety and effectiveness data submitted with respect to each application for review of sunscreen conditions that the Secretary had determined, prior to the date of enactment of the Sunscreen Innovation Act, to be eligible for review of safety and effectiveness and for which the information required under subsection (f)(2) has been submitted to the Secretary prior to such date of enactment.

"(h) REVIEW AND RECOMMENDATION FOR NONPRESCRIPTION SUNSCREEN CONDITION.—

"(1) IN GENERAL.—The Secretary shall require the advisory committee to evaluate the safety and effectiveness data submitted in accordance with subsection (f)(2) or (g).

"(2) STANDARDS.—In evaluating a nonprescription sunscreen condition under paragraph (1), the advisory committee shall use the regulations in effect at the time of the application, including regulations with respect to—

"(A) the safety of the nonprescription sunscreen condition;

"(B) the effectiveness of the nonprescription sunscreen condition;

"(C) the benefit-to-risk ratio of the nonprescription sunscreen condition; and

"(D) the labeling of the nonprescription sunscreen condition.

"(3) COMMUNICATIONS BETWEEN ADVISORY COMMITTEE AND OTHER INDIVIDUALS WHO SUBMIT DATA.—The advisory committee shall have the authority to communicate with the sponsor and other individuals who submit data during the advisory committee's review, including requesting clarification or additional information.

"(4) RECOMMENDATIONS.—

"(A) IN GENERAL.—For each such submission under subsection (f)(3) or (g), the advisory committee shall make one of the following recommendations to the Secretary:

"(i) The sunscreen condition is generally recognized as safe and effective (including any or all indications), including nonprescription sunscreen conditions for which a new drug application has been approved by the Secretary.

"(ii) Insufficient information has been provided to support a recommendation that the sunscreen condition is generally recognized as safe and effective (including any or all indications).

"(iii) The sunscreen condition is not generally recognized as safe and effective to be marketed or sold unless an application with respect to such condition is approved under section 505(b).

"(B) TIMING.—The advisory committee shall make a recommendation under subparagraph (A) not later than 180 days after the advisory committee receives the application and

data submitted under subsection (f)(3) or subsection (g).

"(C) RESUBMISSION OF DATA.—If the advisory committee recommends that insufficient information has been provided, in accordance with subparagraph (A)(ii), the advisory committee shall make such recommendation not later than 180 days after the date on which such additional information is submitted.

"(i) DETERMINATION BY THE CENTER FOR DRUG EVALUATION AND RESEARCH.—

"(1) IN GENERAL.—The Center for Drug Evaluation and Research shall respond to the recommendations of the advisory committee under subsection (h)(4) as follows:

"(A) In the case of a recommendation by the advisory committee described in clause (i) of subsection (h)(4), not later than 45 days after the advisory committee issues the recommendation, the Center for Drug Evaluation and Research shall issue a determination affirming or denying the recommendation of the advisory committee. If the Center for Drug Evaluation and Research affirms the recommendation of the advisory committee, or if

the Center for Drug Evaluation and Research takes no action regarding the recommendation within 45 days of receiving such recommendation, the nonprescription sunscreen condition shall be generally recognized as safe and effective, not misbranded, and permitted to be marketed and sold in accordance with all applicable rules and regulations for over-the-counter drugs.

"(B) In the case of a recommendation described in clause (ii) of such subsection, the Center for Drug Evaluation and Research shall issue a determination affirming or denying the recommendation of the advisory committee, to be made publicly available, within 45 days of receiving the recommendation, and inform the sponsor that the sponsor must submit additional information to the advisory committee in order to continue the review by the advisory committee.

"(C) In the case of a recommendation described in clause (iii) of such subsection, the Center for Drug Evaluation and Research shall issue a determination affirming or denying the recommendation of the advisory committee, to

be made publicly available, within 45 days of receiving such recommendation, and indicate whether such sunscreen condition determined to be not generally recognized as safe and effective to be marketed and sold unless an application with respect to such condition is approved under section 505(b), or whether additional data must be submitted to the advisory committee.

"(2) SUPERVISORY REVIEW OF DETERMINATION.—

"(A) IN GENERAL.—Any person may request a supervisory review of a determination of the Center for Drug Evaluation and Research to not accept a recommendation of an advisory committee. Such review may be conducted at the next supervisory or higher level above the individual who made the determination.

"(B) REQUEST FOR SUPERVISORY REVIEW.—A request described in subparagraph (A) shall be made to the Secretary not later than 30 days after such decision and shall indicate in the request whether such person seeks an in-person meeting or a teleconference. The Secretary shall schedule an in-person or tele-

conference review, if so requested, not later than 30 days after such request is made. The Secretary shall issue a decision to the person requesting a review under this paragraph not later than 45 days after the meeting.

"(C) STANDARD OF SUPERVISORY REVIEW.—The Secretary shall be authorized to overturn a determination of the Center for Drug Evaluation and Research not to accept a recommendation of the advisory committee if the supervisory review results in a decision by the reviewer that the individual who made the determination did not provide reasonable and sufficient substantive support for the decision to disregard the advisory committee's recommendation.

"(D) SUPERVISORY REVIEW DECISION.—If the Secretary overturns a determination by the Center for Drug Evaluation and Research not to accept a favorable recommendation of an advisory committee, the nonprescription sunscreen condition shall be generally recognized as safe and effective, not misbranded, and permitted to be marketed and sold in accordance with all ap-

plicable rules and regulations for over-the-counter drugs.

"(E) FINAL AGENCY ACTION.—A decision made through supervisory review shall constitute final agency action subject to judicial review.

"(j) REPORTS.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of the Sunscreen Innovation Act, on March 1, 2015, and every 2 years thereafter, the Secretary shall issue a report to Congress describing actions taken under this section.

"(2) CONTENTS.—The reports under paragraph (1) shall include—

"(A) a review of the progress made in issuing in a timely manner decisions on the safety and effectiveness for sunscreen conditions for applications pending as of the date of enactment of the Sunscreen Innovation Act, including the number of pending applications—

"(i) reviewed and the decision times for each application, measured from the date of original eligibility application submission by the sponsor;

"(ii) resulting in a determination of generally recognized as safe and effective and not misbranded;

"(iii) resulting in a determination of not generally recognized as safe and effective and not misbranded and the reasons for such determinations; and

"(iv) for which a determination has not been made, an explanation for the delay, a description of the current status of each such application, and the length of time such applications have been pending, measured from the date of original eligibility application submission by the sponsor;

"(B) a review of the progress made in issuing in a timely manner a decision on safety and effectiveness for sunscreen condition applications submitted after the date of enactment of the Sunscreen Innovation Act, including the number of such applications—

"(i) reviewed and the decision times for each application;

"(ii) resulting in a determination of generally recognized as safe and effective and not misbranded; and

"(iii) resulting in a determination of not generally recognized as safe and effective and not misbranded and the reasons for such determinations;

"(C) a description of the staffing and resources relating to the costs associated with the review and decisionmaking pertaining to applications;

"(D) a review of the progress in meeting the deadlines with respect to processing applications under this section;

"(E) to the extent the Secretary determines appropriate, recommendations for process improvements in the handling of pending and new applications; and

"(F) recommendations for expanding the applicability of this section to nonprescription active ingredients or conditions that are not related to the sunscreen category of over-the-counter drugs.

"(3) METHOD.—The Secretary shall publish the reports required under this subsection in the manner

the Secretary determines to be the most effective for efficiently disseminating the report, including publication of the report on the Internet website of the Food and Drug Administration.

"(k) RULES OF CONSTRUCTION.—

"(1) AUTHORITY TO WITHDRAW OR SUSPEND.—Nothing in this section shall be construed to alter the Secretary's authority to withdraw or suspend from the market a drug that the Secretary determines to be unsafe or ineffective.

"(2) OTHER CONDITIONS.—Nothing in the section shall affect the Secretary's authority to review nonprescription conditions other than sunscreen conditions.".

SEC. 3. SUNSCREEN TESTING AND LABELING.

Not later than 180 days after the date of enactment of this Act, the Secretary shall issue determinations with respect to—

(1) the appropriate testing and labeling requirements for sunscreens sold as an aerosol; and

(2) whether sunscreen may contain a label indicating a sun protection factor greater than 50.

○

Mr. PITTS. And H.R. 4299, the Improving Regulatory Transparency for New Medical Therapies Act, which Ranking Member Pallone and I introduced.

Mr. Pallone and I introduced H.R. 4299, which seeks to improve the transparency and consistency of DEA's scheduling of new FDA-approved drugs under the Controlled Substances Act, CSA, and its registration process for manufacturing controlled substances for use in clinical trials. Ultimately, this will allow new and innovative treatments to get to patients who desperately need them faster. It now takes on average well over a billion dollars and 14 years from the time a drug is discovered to the time of approval.

[The information follows:]

I

113TH CONGRESS
2D SESSION

H. R. 4299

To amend the Controlled Substances Act with respect to drug scheduling recommendations by the Secretary of Health and Human Services, and with respect to registration of manufacturers and distributors seeking to conduct clinical testing.

IN THE HOUSE OF REPRESENTATIVES

MARCH 26, 2014

Mr. PITTS (for himself and Mr. PALLONE) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend the Controlled Substances Act with respect to drug scheduling recommendations by the Secretary of Health and Human Services, and with respect to registration of manufacturers and distributors seeking to conduct clinical testing.

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 "Improving Regulatory Transparency for New Medical Therapies Act".

SEC. 2. SCHEDULING OF SUBSTANCES INCLUDED IN NEW FDA-APPROVED DRUGS.

Section 201 of the Controlled Substances Act (21 U.S.C. 811) is amended by inserting after subsection (h) the following:

"(i) Within 45 days of receiving a recommendation from the Secretary to add a drug or substance that has never been marketed in the United States to a schedule under this title, the Attorney General shall, without regard to the findings required by subsection (a) of this section or section 202(b), issue an interim final rule, under the exception for good cause described in subparagraph (B) of section 553(b) of title 5, United States Code, placing the drug or substance into the schedule recommended by the Secretary. The interim final rule shall be made immediately effective under section 553(d)(3) of title 5, United States Code.".

SEC. 3. ENHANCING NEW DRUG DEVELOPMENT.

Section 302 of the Controlled Substances Act (21 U.S.C. 822) is amended by inserting after subsection (g) the following:

"(h)(1) A person who submits an application for registration to manufacture or distribute a controlled substance in accordance with this section may indicate on the registration application that the substance will be used only in connection with clinical trials of a drug in accord-

ance with section 505(i) of the Federal Food, Drug, and Cosmetic Act.

"(2) When an application for registration to manufacture or distribute a controlled substance includes an indication that the controlled substance will be used only in connection with clinical trials of a drug in accordance with section 505(i) of the Federal Food, Drug, and Cosmetic Act, the Attorney General shall—

"(A) make a final decision on the application for registration within 180 days; or

"(B) provide notice to the applicant in writing of—

"(i) the outstanding issues that must be resolved in order to reach a final decision on the application; and

"(ii) the estimated date on which a final decision on the application will be made.".

○

Mr. PITTS. This committee has taken steps to provide more transparency and consistency in the drug approval process through the Prescription Drug User Fee Program and a commitment to review goals imbedded in the PDUFA agreements. However, drugs that contain substances that have not been previously marketed in the United States and that have abuse potential must also be scheduled under the CSA by the DEA before they can begin marketing their product. But under the CSA, there is no deadline for the DEA to make a scheduling decision, and the delays in DEA decisions have increased nearly fivefold since the year 2000. This lack of predictability in the timing of DEA's scheduling decisions leads to unnecessary uncertainty in the drug development process and needless delays in patients' access to new therapies.

H.R. 4299 simply requires the DEA to issue an interim final rule 45 days after it receives FDA's scheduling recommendation for a new drug, allowing patients access to new therapies 45 days after FDA approval. DEA would retain its authority to subsequently transfer the drug between schedules under the Section 201 of the CSA.

This bill also establishes a timeline for DEA to grant approval of manufacturers' applications to register controlled substances not yet approved by FDA to be used in clinical trials, allowing companies to properly plan clinical trial schedules for prospective new therapies. This provision will get products to the market faster because innovators will be able to get clinical trials under way in a timely and predictable way, which is critical to drug developers and patients alike.

H.R. 4299 requires that if the DEA has not made a final decision on whether to approve a registration application for products in the investigational new drug, IND, phase within 180 days of submission of the application, then the DEA shall provide notice to the applicant on the outstanding issues that must be resolved in order to reach a final decision and an estimated date on which a final decision on the registration application will be made.

Such a solution does not force the DEA to make a particular decision but will provide transparency to the process so companies can better plan when regulatory decisions will be made.

I would like to thank all of our witnesses for being here today. I look forward to having a constructive discussion on these legislative proposals. These bills touch on very important issues for this committee, and they offer and excellent starting point for finding solutions.

[The prepared statement of Mr. Pitts follows:]

PREPARED STATEMENT OF HON. JOSEPH R. PITTS

Today's legislative hearing focuses on three bills designed to improve the predictability and transparency in Drug Enforcement Administration (DEA) and Food and Drug Administration (FDA) regulation:

• H.R. 4069, the Ensuring Patient Access and Effective Drug Enforcement Act, introduced by Reps. Marino and Blackburn, will facilitate greater collaboration between industry stakeholders and regulators in an effort to combat our Nation's prescription drug abuse epidemic;

• H.R. 4250, the Sunscreen Innovation Act, introduced by Reps. Whitfield and Dingell, seeks to expedite the FDA's approval process for active ingredients in sunscreens that have long been approved for use in places like Europe, Canada, and

other countries to ensure that U.S. consumers have access to the safest, most effective sunscreens available; and

• H.R. 4299, the Improving Regulatory Transparency for New Medical Therapies Act, which Ranking Member Pallone and I introduced.

Mr. Pallone and I introduced H.R. 4299 seeks to improve the transparency and consistency of DEA's scheduling of new FDA-approved drugs under the Controlled Substances Act (CSA), and its registration process for manufacturing controlled substances for use in clinical trials. Ultimately, this will allow new and innovative treatments to get to patients who desperately need them faster.

It now takes, on average, well over a billion dollars and 14 years from the time a drug is discovered to the time of approval. This committee has taken steps to provide more transparency and consistency in the drug approval process through the Prescription Drug User Fee program and a commitment to review goals embedded in the PDUFA agreements.

However, drugs that contain substances that have not been previously marketed in the United States and that have abuse potential must also be scheduled under the CSA by the DEA before they can begin marketing their product.

But, under the CSA, there is no deadline for the DEA to make a scheduling decision, and the delays in DEA decisions have increased nearly five-fold since 2000.

This lack of predictability in the timing of DEA scheduling decisions leads to unnecessary uncertainty in the drug development process and needless delays in patients' access to new therapies.

H.R. 4299 simply requires DEA to issue an Interim Final Rule 45 days after it receives FDA's scheduling recommendation for a new drug, allowing patients access to new therapies 45 days after FDA approval.

The DEA would retain its authority to subsequently transfer the drug between schedules under the Section 201 of the CSA.

This bill also establishes a timeline for DEA to grant approval of manufacturers' applications to register controlled substances, not yet approved by FDA, to be used in clinical trials, allowing companies to properly plan clinical trial schedules for prospective new therapies.

This provision will get products to the market faster because innovators will be able to get clinical trials underway in a timely and predictable way; which is critical to drug developers and patients alike.

H.R. 4299 requires that if the DEA has not made a final decision on whether to approve a registration application for products in the investigational new drug (IND) phase within 180 days of submission of the application, then the DEA shall provide notice to the applicant on the outstanding issues that must be resolved in order to reach a final decision, and, an estimated date on which a final decision on the registration application will be made.

Such a solution does not force the DEA to make a particular decision but will provide transparency to the process so companies can better plan when regulatory decisions will be made.

I would like to thank all of our witnesses for being here today, and I look forward to having a constructive discussion on these legislative proposals. These bills touch on very important issues for this committee and they offer an excellent starting point for finding solutions.

Thank you.

Mr. PITTS. I yield back the balance of my time and, at this point, recognize the ranking member, Mr. Pallone, 5 minutes for an opening statement.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you, Chairman Pitts.

Today's important hearing will examine a number of bills that aim to provide predictability and transparency for medicines and other products.

This committee has an important balancing act it must play. As prescription drug abuse threatens the safety and health of too many people in this country, we must find ways to combat this growing public health epidemic. At the same time as we examine

different policies to address this issue, we must also ensure patient access to necessary medications. We all agree that the Food and Drug Administration, the FDA, and the Drug Enforcement Agency, the DEA, have critical missions.

FDA ensures that innovative medicines and other products are safe and effective, while the DEA safeguards our communities from illegal and diverted drugs. Once the FDA approves a drug, the DEA's role is to utilize the scheduling process under the Controlled Substances Act, which helps them to keep the medicine in the hands of those who need them and away from criminals and abusers who aim to break the law or, in some unfortunate cases, abuse these drugs.

While both agencies typically work independently, it is important that their authorities and actions work in a complimentary way. There is no question that DEA has an important role in combatting drug abuse, but there must be some recognition by DEA of the legitimate therapies that improve the public health.

One of the bills under consideration today is one that I am proud to sponsor with Chairman Pitts. H.R. 4299, the Improving Regulatory Transparency For New Medical Therapies Act, aims to improve the DEA's scheduling process for new FDA approved drugs under the Controlled Substances Act and the registration process for the use of controlled substances in clinical trials. In recent years, this committee has worked successfully to improve review of new medications. Without weakening FDA oversight, we have given manufacturers and patient groups a more predictable process allowing patients to get timely access to the latest innovation therapies available.

But unfortunately, when a medicine has abuse potential, the DEA's authorities under the Controlled Substances Act are hindering this progress. Specifically the draft bill would require DEA to make a final determination 45 days after receiving FDA's scheduling recommendation for a new drug. Additionally, it would generate more transparency in the application process for clinical trials by requiring the DEA make a final determination within 180 days or provide the applicant with details about what outstanding issues remain unresolved. I hope we can better understand today what is happening at the DEA and find ways to address it.

In addition today, we will examine H.R. 4069, the Ensuring Patient Access and Effective Drug Enforcement Act, introduced by Representatives Blackburn and Marino. The bill aims to improve and better coordinate enforcement efforts within the drug supply chain regarding prescription drug diversion and abuse. It also aims to curtail unnecessary supply chain disruptions that may be affecting patient access to needed medications.

And lastly, we will hear from our witnesses about H.R. 4250, the Sunscreen Innovation Act, introduced by Representatives Whitfield and Dingell. Skin cancer is the most common cancer in the U.S., and one in five Americans will develop skin cancer in their lifetime. Research has shown that sunscreen helps reduce the risk of skin cancer and is essential to protecting the public. However, to date, the FDA has not approved a new sunscreen ingredient in nearly two decades. This is a real issue that needs to be addressed, and I am hopeful we can all work together to establish a process that

promotes the timely review of sunscreen ingredients while ensuring consumer safety and product efficacy.

So I want to thank all of our witnesses here today.

Dr. Woodcock, I don't know, is this the second time in 2 weeks? And I look forward to your comments.

I would like to yield the remainder of my time to Mr. Dingell, who is the lead sponsor, Democratic sponsor, of H.R. 4205.

OPENING STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. DINGELL. Mr. Chairman, I thank the gentleman, and I thank you and commend you for this hearing.

I am particularly grateful to the gentleman from New Jersey for his courtesy to me. I ask unanimous consent that my remarks be extended in the record.

And I would like to address H.R. 4250 and particularly with my concerns as they might exist with regard to Food and Drug. There is no reason why a piece of legislation like this is necessary after 10 years, and why it is that the Congress of the United States has not received the counsel of Food and Drug, that they have had need of legislation of this kind to address a serious problem like skin cancer. This is a great shame indeed. It is the kind of thing that causes distress on the part of the public, puts the public at risk, and puts them at risk of a particularly deadly form of cancer, which is one of the most frequently achieved levels of cancer and kinds of cancer in our society.

Food and Drug did not come up here to talk to us about it. We think that this is legislation, which was crafted somewhat with and somewhat without the assistance of the Food and Drug Administration, but it would have been so much better had Food and Drug come up here with the legislation earlier on.

I want to thank you for holding this hearing, Mr. Chairman.

And I want to particularly thank my good friend Mr. Whitfield for his leadership and responsibility in this matter. I hope that we are going to have supportive testimony from Food and Drug and that the Food and Drug Administration will not let this kind of thing happen again.

Thank you, Mr. Chairman.

Mr. PITTS. The Chair thanks the gentleman.

I now recognize the chairman of the full committee, Mr. Upton, for an opening statement.

OPENING STATEMENT OF HON. FRED UPTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. UPTON. Thank you, Mr. Chairman.

Today the subcommittee will hear testimony on what I think will be three bipartisan bills that address important problems facing the Nation. First, Chairman Pitts and Ranking Member Pallone are collaborating on H.R. 4299, the Improving Regulatory Transparency for New Medical Therapies Act. Their bill would provide more certainty among the Drug Enforcement Administration's review of scheduling decisions for new drug products.

Second, Vice Chair of the Committee Marsha Blackburn is working with Representative Marino on H.R. 4069, the Ensuring Patient Access and Effective Drug Enforcement Act. This bill establishes a collaborative and coordinated approach to the prescription drug abuse crisis that certainly is plaguing our local communities across the country. And finally, we are going to be discussing H.R. 4250, which is cosponsored by Ed Whitfield and Mr. Dingell. Everyone does seem to agree that the current system for approving sunscreen ingredients is broken. It is long overdue that we find a solution to the current backlog of sunscreen ingredients pending at the FDA, and this bill does it. I want to commend my colleagues for working together to develop these legislative solutions. We have had a strong record of bipartisan success this Congress in our work to improve public health, and these bills further that effort.

[The prepared statement of Mr. Upton follows:]

PREPARED STATEMENT OF HON. FRED UPTON

Today the subcommittee will hear testimony on three bills that address important problems facing our country.

First, Chairman Pitts and Ranking Member Pallone are collaborating on H.R. 4299, the "Improving Regulatory Transparency for New Medical Therapies Act." Their bill would provide more certainty around the Drug Enforcement Administration's review of scheduling decisions for new drug products.

Second, Marsha Blackburn, vice chair of the committee, is working with Representative Marino on H.R. 4069, the "Ensuring Patient Access and Effective Drug Enforcement Act." The bill would help establish a collaborative and coordinated approach to the prescription drug abuse crisis that is plaguing our local communities across the country.

Finally, today we will discuss H.R. 4250, which is co-sponsored by Ed Whitfield and John Dingell. Everyone seems to agree that the current system for approving sunscreen ingredients is broken. This bill would help provide a solution to the current backlog of sunscreen ingredients pending at the FDA.

I want to commend my colleagues for working together to develop these legislative solutions. We look forward to working in a bipartisan manner to perfect them so we can move them swiftly through the legislative process.

We have had a strong record of bipartisan success this Congress in our work to improve public health, and these bills further our efforts.

Thank you for holding this hearing.

Mr. UPTON. And I yield the balance of my time to Ms. Blackburn.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Mrs. BLACKBURN. I thank the chairman for yielding, and Mr. Pitts for the hearing.

And, yes, I have worked with Congressman Marino; 4069 is a piece of legislation that we have put some effort into to come up with the Ensuring Patient Access and Effective Drug Enforcement Act. And there is a necessity to clarify a couple of definitions and provide some certainty and some consistency. We will talk more about that.

And Mr. Chairman, I would like to submit my full statement to the record.

Mr. PITTS. Without objection.

Mrs. BLACKBURN. And also three letters of support for our legislation, one from FedEx, another National Association of Chain

Drug stores, and then also the Alliance to Prevent Abuse of Medications.

Mr. PITTS. Without objection, so ordered.

[The information follows:]

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FedEx Corporation

April 7, 2014

The Honorable Fred Upton
Chairman, House Energy and
Commerce Committee
2125 Rayburn Office Building
Washington, DC 20515

The Honorable Henry Waxman
Ranking Member, House Energy and
Commerce Committee
2322A Rayburn Office Building
Washington, DC 20515

The Honorable Tom Marino
410 Cannon House Building
Washington, DC 20515

The Honorable Marsha Blackburn
217 Cannon House Building
Washington, DC 20515

Dear Chairman Upton, Ranking Member Waxman, and Representatives Blackburn and Marino,

FedEx urges passage of the Ensuring Patient Access and Effective Drug Enforcement Act of 2014. This bill will foster important collaboration among government regulators, private industry, and patient groups to combat prescription drug abuse, and protect against disruptions in the pharmaceutical supply chain that can impede access to life-saving medicines.

With our broad portfolio of transportation, e-commerce and business services and through the work of our 300,000 team members worldwide, FedEx supports all points of the pharmaceutical supply chain. FedEx delivers medications to Americans who need prescription drugs to treat and cure illnesses and prolong and improve the quality of their lives. While all consumers benefit from the convenience and cost savings associated with direct-to-patient pharmaceutical deliveries, the greatest beneficiaries are the elderly, the disabled, the chronically ill, and those who live in remote parts of the United States. The Ensuring Patient Access Act will improve enforcement efforts while ensuring that nation's most vulnerable patients receive vitally needed medicines.

The bill's creation of a Prescription Drug Abuse Working Group bringing together law enforcement, supply chain stakeholders, policy experts, and patient groups is laudable. Working collaboratively, with the specific duties and powers set forth in the bill, this group can identify practical and effective measures to curb diversion and the inappropriate use of prescription medications.

We commend Representatives Blackburn and Marino for sponsoring this legislation and stand ready to support your efforts to move H.R. 4069 to passage.

Sincerely,

Gina F. Adams
Corporate Vice President, Government Affairs, FedEx Corporation

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Statement

Of

The National Association of Chain Drug Stores

For

U.S. House of Representatives
Committee on Energy and Commerce
Subcommittee on Health

Hearing on:

"Improving Predictability and Transparency in DEA and FDA Regulation"

April 7, 2014
3:00 p.m.
2123 Rayburn House Office Building

National Association of Chain Drug Stores (NACDS)
1776 Wilson Blvd, Suite 200
Arlington, VA 22209
703-549-3001
www.nacds.org

The National Association of Chain Drug Stores (NACDS) thanks Chairman Pitts, Ranking Member Pallone, and Members of the Subcommittee on Health for the opportunity to share our perspectives on "Improving Predictability and Transparency in DEA and FDA Regulation." Together, DEA and FDA are responsible for approving and regulating prescription medications that may be subject to diversion and abuse. NACDS and the chain pharmacy industry are committed to partnering with federal and state agencies, law enforcement personnel, policymakers, and others to work on viable strategies to prevent prescription drug diversion and abuse. Our members are engaged daily in activities aimed at preventing drug diversion and abuse.

NACDS represents traditional drug stores and supermarkets and mass merchants with pharmacies. Chains operate more than 40,000 pharmacies, and NACDS' 125 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3.8 million individuals, including 175,000 pharmacists. They fill over 2.7 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 800 supplier partners and nearly 40 international members representing 13 countries. For more information, visit www.NACDS.org.

Background

First enacted in 1970, the federal Controlled Substances Act (CSA) regulates the manufacture, importation, possession, use, and distribution of prescription drugs that have a potential for diversion, addiction, and abuse and are collectively known as "controlled substances." The CSA creates a closed system of distribution for controlled substances; DEA often refers to this as "cradle-to-grave" control over controlled substances. DEA has implemented a very tight and comprehensive regulatory regime pursuant to the CSA. States have followed this lead and have implemented similar, sometimes duplicative regimes. This matrix of regulation has created a multi-layered system of checks and balances to protect Americans from the dangers of prescription

drug abuse. Pharmacists and other pharmacy personnel are all trained to understand and comply with this complex regulatory matrix.

Chain Pharmacy Initiatives

To comply with DEA's "cradle to grave" regulatory regime, chain pharmacies have created a variety of loss prevention and internal security systems that are in place from member prescription drug distribution centers right down to the point of dispensing to the patient. Our members undertake initiatives to ensure that prescription drugs are accounted for in every step along the way. Some of those initiatives could include conducting background checks before hiring personnel who have access to prescription drugs, training about controlled substance laws and regulations within 30 days of hire, maintaining electronic inventories of controlled substances, and conducting random audits. Our members work closely with law enforcement to see that perpetrators of crimes relating to controlled substances are brought to justice.

Specifically, at the pharmacy level, examples of the member initiatives include training pharmacy personnel on how to handle suspect prescription drug orders, and exception reporting, in which exceptionally large or unusual orders of controlled substances will trigger an internal investigation. Chain pharmacies also may maintain perpetual inventories of controlled substances that are randomly audited by internal security personnel. Pursuant to DEA and state regulations, pharmacy and chain distribution centers are required to be highly secured with physical barriers, heavy duty safes, secure cages, and complex alarm systems. Some pharmacy chains also utilize cameras and closed-circuit television surveillance to ensure compliance with policies and procedures. Some pharmacies require employees to read and sign "codes of conduct," which commits them to compliance. Some member pharmacies will conduct drug testing, including random, for cause, and pre-employment testing.

In addition to developing, implementing, and maintaining the requisite policies and procedures, our members support numerous other initiatives to mitigate and reduce

prescription drug abuse. Chain pharmacies participate in state-controlled substance prescription drug monitoring programs. NACDS and our member-companies support policies that work to prevent illegitimate Internet drug sellers from selling or offering to sell drugs to U.S. consumers in violation of federal and state laws. We also support efforts to provide patients with means for disposal of their unwanted medications in ways that are authorized by law enforcement.

The Role of FDA

Seven years ago, Congress passed the Food and Drug Administration Amendments Act of 2007 (FDAAA), which provided FDA the authority to impose risk management plans on prescription drugs, known as Risk Evaluation and Mitigation Strategies (REMS). A REMS will be imposed if FDA finds that a REMS is necessary to ensure that the benefits of a drug product outweigh the risks of the drug product. Among the numerous REMS that FDA has implemented is a REMS for long-acting and extended release opioid products ("LA/ER opioid drugs"). These are pain relieving medications that have an elevated potential for abuse. The central component of this "Opioid REMS" is an education program for prescribers (e.g., physicians, nurse practitioners, physician assistants) so that LA/ER opioid drugs can be prescribed and used safely. NACDS agrees that prescribers should be properly educated about the risks and benefits of prescription drugs, including those that have elevated abuse potential like LA/ER opioid drugs. It is critical that all prescribers understand the nature of addiction and abuse before issuing prescriptions for these medications. NACDS supports FDA's Opioid REMS.

In addition, FDA recently implemented a REMS for another class of drugs with elevated abuse potential: transmucosal immediate-release fentanyl (TIRF) products. NACDS and other industry stakeholders have worked closely with FDA over the past few years to design and implement this REMS. We are appreciative of this collaborative effort spearheaded by FDA. If this REMS proves successful, we are hopeful that it could serve as a model for future REMS for products similar to TIRF products.

As we pursue solutions to the problem of prescription drug abuse, it is critical that we do not place undue burdens on legitimate patients who require prescription medications. As FDA has recognized through the REMS program, the risks of medications must be mitigated relative to their benefits. However, we cannot mitigate risks to the point that legitimate patients cannot receive medications' benefits.

The Role of DEA and Improving DEA Transparency

DEA holds the primary authority to implement and enforce the CSA. NACDS and our members vigorously support the mission and efforts of DEA. We seek to work with DEA and other regulatory and law enforcement bodies to curb prescription drug abuse and mitigate drug diversion.

DEA regulations provide that physicians and other prescribers are responsible for ensuring that prescriptions for controlled substances are issued for legitimate medical purposes within the prescribers' usual course of professional practice. According to DEA regulations, the responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility also rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment is not a prescription within the meaning and intent of section 309 of the CSA (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, is subject to the penalties provided for violations of the CSA.

Community pharmacists are front-line healthcare providers and are one of the most accessible members of a healthcare team. As such, the CSA requires pharmacists to take on diverse and sometimes conflicting roles. On the one hand, pharmacists have a strong ethical duty to serve the medical needs of their patients in providing neighborhood care. On the other hand, community pharmacists are also required to be evaluators of the

legitimate medical use of controlled substances.[1] As briefly mentioned above, the CSA requires that a pharmacist, prior to dispensing any controlled substance, make the following determinations—whether the prescription complies with all legal and regulatory requirements, and whether the prescription has been issued for a "legitimate medical purpose" "by a prescriber acting in the usual course of his or her practice."[2] The former obligation is called "corresponding responsibility," and if the two elements are not met, the prescription is not valid. DEA interprets a pharmacist's corresponding responsibility "as prohibiting a pharmacist from filling a prescription for a controlled substance when he either 'knows or has reason to know that the prescription was not written for a legitimate medical purpose.'"[3]

Pharmacies fully understand that controlled substances are subject to abuse by a minority of individuals who improperly obtain controlled substance prescriptions from physicians and other prescribers. Pharmacies strive to treat medical conditions and ease patients' pain while simultaneously guarding against the abuse of controlled substances. The key is to guard against abuse while still achieving our primary goal of assisting patients who need pharmacy services.

DEA's enforcement activities include conducting inspections of the entities that are subject to its regulatory oversight. Although such enforcement activities are essential to its mission, DEA has been criticized for an alleged lack of transparency in its inspection and other enforcement actions, and even inconsistency among the actions of its numerous field offices. Such opaqueness and inconsistency impose challenges on the compliance efforts of DEA registrants.

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[1] In order for a prescription for a controlled substance to be valid, federal law (21 C.F.R § 1306.04(a)) requires that the prescription be issued for a legitimate medical purpose by a prescriber acting in the usual course of his or her practice. The rule places a ***corresponding responsibility*** upon the dispensing pharmacist to establish the validity of the prescription by ensuring the prescription is written for a legitimate medical purpose.

[2] 21 C.F.R. 1306.04(a).

[3] *East Main Street Pharmacy*, 75 FR 66149, 66163 (Oct. 27, 2010).

To help address the problems of DEA opaqueness and inconsistency, we support efforts to promote accountability and transparency with respect to DEA's inspection and enforcement programs. In fact, the following recommendations drawn from FDA transparency and oversight and enforcement initiatives could serve as a model for DEA:

1. Development of a Comprehensive DEA Investigation Program, Corresponding Inspector Manual & Compliance Policy Guides: Specifically, DEA would set forth guidance for its oversight of regulated facilities inspections that provide clear and firm direction. A common set of standards for industry sectors to comply with, and for DEA inspectors to apply in their inspections would provide an essential foundation for effective oversight.

2. Accountability & Consistency among Field Offices: DEA would ensure the uniformity and effectiveness of its inspection program and oversight over field offices. DEA would provide public training for inspectors, and develop an audit process to ensure that inspections are carried out consistently across field offices.

3. Transparency & Communication - DEA Inspection Observations: DEA would provide substantive and timely feedback to inspected regulated facilities regarding agency observations and facility compliance. Specifically, DEA would provide regulated facilities with substantive written feedback upon completion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the CSA and implementing regulations. Without receiving such information, it is difficult, if not impossible, for regulated facilities to implement requisite facility and process improvements and take corrective actions where necessary.

4. Public Disclosure - Oversight of Inspections: An important mechanism of accountability is public disclosure of information. Disclosure of final inspection reports of regulated facilities would provide the public with a rationale for DEA enforcement actions and the industry with transparency into agency decision-

making, allowing them to make more informed actions to enhance facility compliance.

5. Ombudsman Office: An ombudsman office would address complaints and assist in resolving disputes between companies and DEA regarding interactions with the Agency on inspections and compliance issues.

We believe these recommendations would greatly increase predictability and transparency in DEA regulation. The adoption of such recommendations would greatly enhance the compliance efforts of DEA registrants, thus leading to more effective DEA regulation and oversight. Enhanced compliance efforts by DEA registrants and more effective DEA regulation and oversight would have highly beneficial impacts on efforts to combat prescription drug diversion and abuse.

A related challenge for pharmacies is whether the DEA registration number of a prescriber is valid and/or valid for the class of medication that has been prescribed. We support efforts to enhance the verification of prescriber data provided by DEA. It would be most helpful if DEA could provide reliable, consistent, and clear data that serves as the ultimate source for the status of a prescriber. Ideally, this database would include information about the status of the prescriber's license from the state issuing authority, such as the state medical board. Moreover, we request that there be a mechanism for DEA to provide clear guidelines on the expiration of prescribers' DEA registrations. This is currently a protracted process and it can be unclear to pharmacy personnel whether a lapsed prescriber registration (such as due to a late renewal) is still valid or, in fact, expired and invalid.

Better Focusing Resources

In the recent past, it is our understanding that DEA has been taking a harder look at the problem of prescription drug abuse in the U.S. DEA has placed increased scrutiny on both wholesale distributors and pharmacies. Since the mid-2000's, DEA has taken action

against wholesale distributors that it deems are inappropriately distributing controlled substances to pharmacies, including shutting down a number of their wholesale distribution centers. More recently, DEA has focused its attention on chain pharmacies, shutting down such chain pharmacy distribution centers that it deems are distributing controlled substances inappropriately, as well as shutting down a number of chain pharmacies that it believes are dispensing medications to patients inappropriately.

Additionally, we are hearing that DEA and other enforcement actions may be imposing arbitrary limits on the distribution and dispensing of prescription pain medications, causing problems with patients' ability to access much needed prescription pain medications. Different groups are pointing fingers at each other as the source of the problems of prescription drug abuse and for legitimate patients having difficulty accessing their prescription pain medications. Pointing fingers of blame is not a helpful exercise and usually causes more harm than good, especially when lives are at stake. NACDS and chain pharmacies avoid assigning blame for the complex prescription drug abuse issues that we all need to address.

Since NACDS and our members are focusing our energies on real, workable solutions that will address the problem of prescription drug abuse while also ensuring that legitimate patients are able to receive their prescription pain medications, we are pleased to support H.R. 4069, the "Ensuring Patient Access and Effective Drug Enforcement Act of 2013." By establishing the "Combating Prescription Drug Abuse Working Group," this legislation would better focus government resources on solving the problems of prescription drug abuse and ensuring that legitimate patients are not harmed.

We believe that bringing together stakeholders to address the problems associated with prescription drug abuse in this manner would provide better solutions than have been developed to date. Improved collaboration and coordination among federal agencies and other stakeholders would benefit all, including the patient, whose legitimate access to medication must be preserved in order for any potential solution to be successful.

NACDS is committed to efforts to curb prescription drug abuse and ensure patient access to prescription medications. We know that for some patients, access to necessary prescription drugs to control their chronic pain may be limited due to efforts to thwart prescription drug abuse. Even in the news media, we see coverage about the effects of prescription drug abuse, but the patient access challenges are conspicuously missing. However, the pharmacy trade publication, *Drug Store News*, has created a microsite on its website to raise awareness about patients living with chronic pain. The site focuses on the challenges that real patients face if unable to access prescription pain medications due to laws or regulations designed to curb prescription drug abuse. In collaboration with the U.S. Pain Foundation, *Drug Store News* conducted a series of interviews, including an audio segment with a patient who has been living with chronic pain for 20 years. In addition, profiles of four patients living with chronic pain are included on the microsite.

Electronic Prescribing and Prescription Monitoring Programs

Since DEA issued regulations to allow for the electronic prescribing of controlled substance (EPCS) prescription medications, NACDS has aggressively pursued state legislation and regulations to allow all controlled substances to be prescribed electronically. We believe that EPCS will mitigate forgeries associated with written and oral prescriptions, and provide a deterrent effect for prescribers. Most importantly, EPCS holds promise to create a robust database of real-time information that could be used by industry stakeholders and enforcement officials that may assist with the proactive identification of drug abuse. Now that most states allow EPCS, we urge the states to require that all controlled substance prescriptions be issued electronically.

On a parallel track, NACDS and chain pharmacies support controlled substance prescription drug monitoring programs to help combat prescription drug abuse. Currently, 48 states have operational monitoring programs and one more is in the stages of program implementation. Recognizing the important role these programs have in helping to prevent drug abuse and diversion, chain pharmacies actively support these programs.

Pharmacies submit information on the controlled substances they dispense on a weekly or daily basis depending on the particular state's program requirements. This information includes data on the patient, prescribed drug dosage and quantity, and the prescriber. This information allows the state to conduct confidential reviews to determine any patterns of potential abuse or diversion.

These monitoring programs offer many benefits to aid in identifying, deterring, or preventing drug diversion and abuse. They encourage appropriate intervention to determine if a person may have a drug addiction so that treatment may be facilitated. The programs also provide public information on trends in drug abuse and diversion.

NACDS and chain pharmacies support these programs as one of many strategies to help curb prescription drug abuse and diversion. We support these programs and believe they have greater potential. To this end, we have developed a number of recommendations to improve them. Since prescriber access to the information in prescription monitoring programs can be challenging to obtain (and, in some states, is not even permitted under a particular state's laws,) we support initiatives to facilitate and mandate prescriber use of the program data. These programs contain a wealth of data that could assist prescribers in making determinations about whether to issue a prescription for an addictive medication.

All pharmacies and relevant pharmacy personnel should have access to prescription monitoring program data, both at the corporate and the retail pharmacy level. Pharmacy access to this data helps inform whether a prescription has been issued for a legitimate medical purpose. Certain tasks with respect to accessing the data should be allowed to be delegated to supportive personnel, such as pharmacy technicians. To streamline access for pharmacists and other pharmacy personnel, prescription drug monitoring data should be integrated into pharmacy management systems as part of the prescription claims adjudication process.

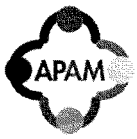
Unfortunately, many state programs are not connected with each other. Connected state prescription monitoring programs would allow prescribers to access patient data from other states which is critically important in any metropolitan area that extends across state lines. Consequently, we support efforts to standardize and interconnect all states' prescription drug monitoring programs.

Law Enforcement-Authorized Programs for Return and Disposal of Unwanted Prescription Drugs

Another important strategy to curb drug diversion and abuse is to provide consumers with appropriate means to return unwanted prescription drugs for disposal. Finding a workable law enforcement-authorized means for consumer disposal of unused and expired drug products is critical to reducing drug abuse. While varying policy options have been proposed, NACDS supports the following principles for proper return and disposal of consumers' unwanted medications. These include protecting patient health and safety by maintaining a physical separation between pharmacies and locations that take back consumers' unwanted drugs. For example, drug take-back events sponsored by DEA provide for such separation and avoid the potential for returned medications to re-enter the drug distribution supply chain. In addition, we support policies where consumers have a reliable and readily available means to return their unwanted medications, such as mail-back envelope programs that are sanctioned by law enforcement or the DEA. The state of Maine operates a DEA-authorized drug mail-back program, funded through federal grants, where consumers are provided with pre-paid, mail-back envelopes distributed at pharmacies and other locations, to mail in their unwanted medications. In addition, at various locations across the U.S., law enforcement partners with pharmacies to provide drug take-back events to give consumers means to return their unwanted medications. These programs help prevent teens and others from accessing and using prescription drugs in dangerous and potentially deadly ways. We have commented on DEA's proposed regulations to allow consumers to properly dispose of unused, unwanted prescription drugs, and look forward to DEA's final rule.

Conclusion

NACDS thanks the Subcommittee for consideration of our comments. We look forward to working with policy makers and stakeholders on these important issues.



Alliance to Prevent the Abuse of Medicines

April 7, 2014

The Honorable Tom Marino
U.S. House of Representatives
410 Cannon House Office Building
Washington, DC 20515

The Honorable Marsha Blackburn
U.S. House of Representatives
217 Cannon House Office Building
Washington, DC 20515

Dear Congressman Marino and Congresswoman Blackburn:

On behalf of the Alliance to Prevent the Abuse of Medicines, we would like to express support for the Ensuring Patient Access and Effective Drug Enforcement Act of 2014 (H.R. 4069). We appreciate your leadership and commitment to bring greater clarity to the requirements for the safe and secure distribution and dispensing of controlled substances to combat the inappropriate use of prescription medicines.

This legislation will clarify key terminology in the Controlled Substances Act to give registrants a better understanding of their responsibilities under the law. Similar to the way drug manufacturers interact with the Food and Drug Administration, this bill will allow DEA-registered companies to submit corrective action plans to address agency concerns, creating a more robust and transparent process to address drug diversion. This will hopefully curtail unnecessary supply chain disruptions that affect patient access to needed medications. In addition, the creation of a Prescription Drug Abuse Working Group will encourage meaningful dialogue and coordination between supply chain stakeholders and federal regulators.

By way of background, the Alliance to Prevent the Abuse of Medicines is a non-profit partnership of key stakeholders in the prescription drug supply chain, including manufacturers, distributors, pharmacy benefit managers, pharmacies, and physicians, that have joined together to develop and offer policy solutions aimed at addressing the prescription drug abuse epidemic. The mission of the Alliance is to raise awareness of the issue of prescription drug abuse, partner with legislators to craft achievable solutions, and serve as a resource for policymakers. As the only industry-led coalition focused on this issue that includes representation across the domestic pharmaceutical supply chain, the Alliance brings a comprehensive perspective to addressing the prescription drug abuse epidemic.

The members of the Alliance believe that the diversion and abuse of prescription drugs is a national, public health crisis that must be confronted and addressed through a collaborative effort by all stakeholders via a multi-faceted approach. We believe H.R. 4069 is one component to reducing diversion and abuse. We appreciate your leadership on this important issue.

Sincerely,

The Alliance to Prevent the Abuse of Medicines

cc: The Honorable Fred Upton
Chairman, House Energy and Commerce Committee

The Honorable Joe Pitts
Chairman, House Energy and Commerce Committee Subcommittee on Health

The Honorable Henry A. Waxman
Ranking Member, House Energy and Commerce Committee

The Honorable Frank Pallone, Jr.
Ranking Member, House Energy and Commerce Committee Subcommittee on Health

Mrs. BLACKBURN. And I appreciate that so much.

Congressman Marino and I are working to clarify the two phrases, "consistent with public health and safety," and how that corresponds to substantial relationship to preventing diversion and abuse of controlled substances, and further define "imminent danger" by providing clarification and harmonizing the CSA with other statutes using the imminent danger standard, such as the Federal Mines Safety and Health Act. And these definitions do matter. We all realize that.

We are also interested in moving forward with the prescription drug abuse working group, which would give Government, public policy, and industry the ability to collaborate and provide recommendations to Congress on initiatives to reduce prescription drug diversion and abuse.

This is an issue that has grown to epidemic proportions in our country, and we had about 27,000 unintentional drug overdose deaths which occurred in the U.S. during 2007 and a number that has increased fivefold since 1990.

[The prepared statement of Mrs. Blackburn follows:]

PREPARED STATEMENT OF HON. MARSHA BLACKBURN

Prescription drug abuse is an epidemic that is killing tens of thousands of Americans each year.

According to the Centers for Disease Control and Prevention (CDC), approximately 27,000 unintentional drug overdose deaths occurred in the United States during 2007—a number that has increased five-fold since 1990.

This is a problem that's greatly in need of a solution. However, simply acknowledging the epidemic of prescription drug abuse isn't enough.

There needs to be a clear distinction between the legitimate pharmaceutical supply chain that directly serves patients and the criminals who are diverting and selling illegal drugs. Supply chain stakeholders need further guidance on how to collaborate more effectively with law enforcement. Stated simply, their obligation to prevent diversion is only achievable if the DEA and other regulators will work with them to get it done.

I believe these stakeholders—physicians, pharmacies, and distributors who want to do the right thing—stand ready to work with law enforcement in combating prescription drug abuse.

That's why I worked with my colleague Congressman Tom Marino in crafting, H.R. 4069, the Ensuring Patient Access and Effective Drug Enforcement Act of 2014.

Our legislation clarifies two definitions within the Controlled Substances Act (CSA) which is essential to providing a clear path forward for enforcement agencies.

We specify that the phrase "consistent with the public health and safety" corresponds to a "substantial relationship to .preventing diversion and abuse of controlled substances."

We also further define "imminent danger" by providing clarification and harmonizing the CSA with other statutes using the "imminent danger" standard such as the Federal Mine Safety and Health Act.

Why do definitions matter? Because Congress—this subcommittee—has a responsibility to make sure the law is crystal clear for both DEA and legitimate businesses who want to understand what the rules are so they can do the right thing. Our job is to make sure they're on the same page.

We also expect industry to step up and do more to minimize the risk of diversion. To protect the integrity of the distribution system, we require criminal background checks and drug testing for employees of distributors who have access to controlled substances. I should note that we are continuing to work with the interested parties to make sure that provision is narrowly crafted to achieve the right policy objective.

Lastly, we establish a Prescription Drug Abuse Working Group which will give Government, public policy and industry the ability to collaborate and provide recommendations to Congress on initiatives to reduce prescription drug diversion and abuse.

I've said many times since I took the lead on this issue over 2 years ago that on this one, the tragic prescription drug abuse epidemic in America, we are all in this together. And that's where Congressman Marino and I are coming from with this bill. A bill which already has the support of three former United States Attorneys now in Congress, including Mr. Marino.

I thank Chairman Pitts for holding this hearing this afternoon, and I look forward to working with my colleagues and our witnesses today on bringing an effective solution to this growing epidemic. I yield back.

Mrs. BLACKBURN. At this time, I yield the balance of my time to Mr. Whitfield.

OPENING STATEMENT OF HON. ED WHITFIELD, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF KENTUCKY

Mr. WHITFIELD. Thank you very much.

FDA has not expanded its approval list of sunscreen ingredients since 1999, even though many innovative products have been used safely for years abroad. In fact, there are eight pending applications, all of which have been used in other parts of the world. Some of them have been under the process of being scrutinized for 12 years.

That is why we have introduced the Sunscreen Innovation Act, Mr. Dingell and others, and we look forward to working with FDA because we need to pass legislation to make sure that this process is speeded up in some way, and I yield the balance of the time to the gentleman from Texas, Mr. Burgess.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. I thank the gentleman for yielding the time.

Glad to have both the FDA and the DEA here today. Time is short. Let me confine my observations to the Drug Enforcement Administration. I am hearing that manufacturers and distributors are having a difficult time working with your agency. They say the relationship is not collaborative. It is one where intimidation and lack of communication is all too common. I am willing to work with anyone to close loopholes to target bad actors and even propose policies that might raise the ire of those in my party, but I will not sit by while patients cannot access lawfully prescribed medication. No doctor, no wholesaler, no pharmacist, should live in fear that in their attempt to alleviate human suffering, they are likely to be put out of business.

I understand your mission, but I want to know that you have a strong voice for patients, for providers, and I want you to know the effect that you have. It is necessary to enter conversations on everything from the scheduling of certain drugs to prescribing drug abuse with an interactive perspective.

No one should stand down in the face of bullying, aggressive and narrow-minded tactics.

Thank you, Mr. Chairman. I will now yield back the balance of my time.

Mr. PITTS. The Chair thanks the gentleman.

I will now recognize the ranking member, Mr. Waxman, for 5 minutes of opening statement.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you, Chairman Pitts, for holding this hearing today.

Today's hearing focuses on three bills, all addressing important issues. Mr. Marino and Mrs. Blackburn's bill, H.R. 4069, makes changes to the Controlled Substances Act that will help drug distributors and others work with the DEA to keep controlled substance prescription drugs out of the hands of drug abusers. It also will help them avoid inappropriately limiting legitimate access to these same drugs by patients who need them. Achieving that balance is a difficult challenge. I will be interested to learn DEA's views on the bill.

Mr. Pitts and Mr. Pallone's bill, H.R. 4299, would speed up DEA decisions on scheduling new FDA approved drugs containing controlled substances so they could get to patients more quickly. It also would speed up the DEA registration process, allowing the manufacture and distribution of controlled substances for use only in clinical trials. It is aiming to address a problem faced by those with epilepsy and other patients, the delay in getting a new FDA approved controlled substance medication to patients in need. I think their bill could make a significant contribution to solving this problem, and I applaud them for introducing it.

DEA's mission and focus is combatting drug abuse. I applaud its work in that area. At the same time, we need to find a way for new FDA-approved controlled substance medicines to get to patients who need them more quickly, and I hope DEA shares that goal and will work with the committee to achieve it.

Mr. Whitfield and Mr. Dingell's bill, H.R. 4250, aims to speed up FDA's regulatory decisions on sunscreens that have been marketed in other countries for at least 5 years. Sunscreens are an important tool in lowering the risk of skin cancer. Skin cancer is the most common cancer in the United States, and its incidence continues to grow. Melanoma, the deadliest kind, kills over 9,000 Americans a year. One way to prevent skin cancer is to minimize exposure to UV rays.

I have had a long interest in this issue. I have been working with Chairman Upton to protect teenagers from the dangers of sun lamps. Getting better sunscreens to market and increasing sunscreen use is another critical element in the fight against skin cancer. We need a regulatory system that enables safe and effective sunscreens to make it to the market in a reasonable amount of time. Under our current system, sunscreen applications have been languishing for 5 to 10 years. I don't think anyone could call that a reasonable amount of time.

Mr. Whitfield and Mr. Dingell, working with the PASS Coalition, have made a good faith effort to come up with a bill that would help FDA reach decisions in a timely fashion on such sunscreen applications. I strongly support those efforts. However, I do have concerns with a number of elements of the bill, most notably the bill effectively cedes FDA's jurisdiction to an advisory committee. If the advisory committee recommends approval, the approval goes into effect, unless FDA rejects it within 45 days, and even then, the

burden is on FDA to justify its decision not to accept the recommendation. I think this would be a bad precedent.

I applaud the bill's sponsors and the PASS Coalition for working on this issue and developing a bill for us to consider. That alone is a step forward. I share the goal of having an FDA review process that enables safe and effective sunscreens to get to market as quickly as possible. I recognize that the current system does not achieve that goal. I hope FDA will commit to work with the committee and with the coalition and other stakeholders to reach that goal.

I look forward to the hearing today and, while I may not be here all of the time, to reviewing the testimony from our witnesses.

Thank you, Mr. Chairman. I would be happy to yield my time if anybody seeks it. If not, I yield it back.

Mr. PITTS. The Chair thanks the gentleman.

That concludes the opening statements. All members' written opening statements will be submitted for the record.

We have two panels before us today. On our first panel we have Dr. Janet Woodcock, Director, Center for Drug Evaluation and Research of the U.S. Food and Drug Administration.

Thank you again for coming to the subcommittee.

And Mr. Joseph Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

Your written testimony will be made part of the record. You will be each given 5 minutes to summarize. Thank you for coming today.

And Dr. Woodcock, you are recognized for 5 minutes for your opening statement.

STATEMENTS OF JANET WOODCOCK, DIRECTOR, CENTER FOR DRUG EVALUATION AND RESEARCH, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND JOSEPH T. RANNAZZISI, DEPUTY ASSISTANT ADMINISTRATOR, OFFICE OF DIVERSION CONTROL, DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE

STATEMENT OF JANET WOODCOCK

Ms. WOODCOCK. Thank you and good afternoon.

I am Janet Woodcock, Director of the Center for Drug Evaluation and Research at FDA, and thank you for the opportunity to discuss important issues concerning sunscreen products.

Now, as you know, manufacturers must have an approved new drug or abbreviated new drug application before they can market a drug in the United States, unless they have a drug that complies with an over-the-counter monograph. The monograph is a regulation that describes the conditions OTC drugs must meet. This allows these monograph products to be offered in many different configurations to the public without filing different applications. And this has been a very successful program. There are over 100,000 products out there, OTC products out there, it is estimated, that are monograph products. And most sunscreens are marketed in the U.S. under the sunscreen monograph.

Now, the FDA must conclude that an ingredient is generally recognized as safe and effective for the condition of use if it is going to be put into a monograph. But the real world conditions of use and what is scientifically considered safe and effective can change over time. And by over time, I mean over decades of time. And in the 1970s, when examination of sunscreens began in the OTC drug review, they were used primarily on a seasonal basis to prevent sunburn. That is what sunscreens were thought to be for back in the day. And the Sunscreen Advisory Panel thought people would be exposed to these sunscreen active ingredients in modest amounts and for short intermittent time periods. And also the ingredients weren't thought to get below the skin, so systemic exposure to these drugs was not a concern. This was before we had all the transdermal skin products that we have now—for hypertension and so forth—that are delivered through the skin. The advisory panel safety evaluation focused on ensuring that sunscreen products caused minimal skin irritation and sensitivity and then, on their efficacy, just that they prevented sunburn.

Today people are urged to apply sunscreen in generous amounts and to reapply it frequently and to use it year round, resulting in exposure to the products that is massively greater than what was contemplated originally in the monograph. In addition, sunscreens are applied all over babies and children repeatedly as well to prevent them from the deleterious effects of the sun.

There is increasing evidence, though, that some sunscreen ingredients are absorbed through the skin, and that leads to systemic exposures that are chronic, that have not previously been understood or anticipated. This shift in sunscreen use, together with advances in scientific understanding and our own safety evaluation methods have raised questions about what is needed to assure sunscreen safety.

FDA has undertaken major actions on important sunscreen issues in the last several years. We have not been inactive. In 2011, we published a regulation that updated efficacy testing and sunscreen labels. This put on what people are used to now the broad spectrum claim that we urge people to use to protect against various types of UV, and also it put information in the label about preventing skin cancer and about decreasing skin aging, so important information about the use of these sunscreens.

We also issued a proposed rule with a maximum SPF value of 50 plus for all sunscreen monograph products, and we put an advance notice of proposed rulemaking about additional information on the safety and effectiveness of various dosage forms, like sprays, that raise new concerns about flammability, for example, and inhalation.

We have also been evaluating these Time and Extent Applications to add eight new ingredients to the sunscreen monograph. This process, established in 2002, provides a potential pathway for newer active ingredients. We recently sent sponsors letters on two of these applications, giving them feedback and noting that their record is insufficient to establish that they are safe for OTC sunscreen use.

We will be holding a public meeting later this year to further clarify our thinking about safety testing for all OTC sunscreen

products. And given the expansion of sunscreen use and scientific advances since the OTC evaluation began, our evaluation must include potential endocrine or other effects from systemic absorption.

Now this process has taken too long. I agree with that, and we really recognize the entire OTC monograph process is outdated, and about 2 weeks ago, we had a public hearing to discuss ways we might be able to modernize the process.

In closing, the OTC monograph process that had historically been so successful is no longer really serving the needs of consumers, industry or the FDA. We have embarked on consideration of how to revise it to work in the current environment, and the problem with sunscreens is really a microcosm of the larger issues we have with the OTC monograph process. Thank you.

[The prepared statement of Ms. Woodcock follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

TESTIMONY OF

U.S. FOOD AND DRUG ADMINISTRATION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

JANET WOODCOCK, M.D.

DIRECTOR, CENTER FOR DRUG EVALUATION AND RESEARCH

BEFORE THE

SUBCOMMITTEE ON HEALTH

COMMITTEE ON ENERGY AND COMMERCE

U.S. HOUSE OF REPRESENTATIVES

"Improving Predictability and Transparency in DEA and FDA Regulation"

APRIL 7, 2014

FOR RELEASE ONLY UPON DELIVERY

INTRODUCTION

Mr. Chairman, Ranking Member Pallone, and Members of the Subcommittee, I am Dr. Janet Woodcock, Director of the Center for Drug Evaluation and Research at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). Thank you for the opportunity to be here today to discuss the important issues concerning sunscreen ingredients, over-the-counter (OTC) drug monographs, and the Time and Extent Application (TEA) process.

Background

The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires FDA to review and approve a new drug application (NDA) or abbreviated new drug application (ANDA) for all new drugs before they can be marketed in the United States. To avoid "new drug" status as defined in the FD&C Act, a drug must be generally recognized as safe and effective (GRASE) and also must have been marketed to a material extent and for a material time under the conditions described in its labeling (the material time-and-extent standard), 21 U.S.C. 321(p).

An OTC drug monograph is an FDA regulation that describes the conditions, including specified active ingredients, that various categories of OTC drugs (such as sunscreens) must meet to be determined GRASE and not misbranded. The monograph process is intended to create a pathway for FDA to review and identify OTC drug ingredients that are GRASE. Products using these ingredients can reach the market without using the NDA process. However, the process of establishing an OTC drug monograph requires multiple stages of notice-and-comment rulemaking, and can be both lengthy and complex. A drug product that complies with an

applicable OTC monograph and the general requirements for OTC drugs can be marketed without an NDA or ANDA. FDA's GRASE determinations must be supported by publicly available data that satisfy the requirements and evidentiary standards specified in FDA's OTC drug regulations.

The TEA process, established by regulations finalized in 2002 (21 CFR 330.14(g)), expanded the scope of the OTC Drug Review. This process provides a potential pathway to OTC monograph status for newer active ingredients and other conditions; primarily, those with no U.S. marketing history. The TEA process enables sponsors to establish that a condition satisfies the threshold eligibility requirement of a "material time and extent" of OTC marketing, based on historic marketing data other than the date of U.S. market entry (TEA eligibility requirements). Active ingredients and other conditions that satisfy the TEA eligibility requirements are subject to the same GRASE standard and evidentiary requirements that apply to other active ingredients and conditions under the OTC monograph process. Like the OTC monograph process, the TEA process requires multi-step, notice-and-comment rulemaking procedures, before a new ingredient is officially included in an OTC drug monograph.

To elaborate, the TEA process begins with the submission of a TEA application containing data documenting the OTC marketing history of the active ingredient or other condition(s) for which monograph consideration is sought. FDA reviews the application and determines whether the sponsor's marketing data establish a material time and extent of OTC marketing, as set forth in the TEA eligibility requirements. If not, the application is denied. If the marketing data satisfy the TEA eligibility criteria, FDA publishes a *Federal Register* notice announcing that the active ingredient or other condition is being considered for OTC monograph status and calling for

submissions of safety and efficacy data. If FDA's review of the submitted data (together with any other data from the published scientific literature) supports a tentative GRASE determination, the Agency will publish a proposed rule to include the active ingredient or other condition in the appropriate OTC monograph. If the evidentiary record does not support a tentative GRASE determination, the regulations provide for FDA to issue "feedback" letters to data submitters and the public docket, in which the Agency details its evaluation of the available data and may identify remaining data gaps and invite further data submissions. If additional data are not forthcoming or do not adequately support GRASE status, FDA will publish a proposed rule declaring that the active ingredient or other condition may be marketed only under an approved NDA or ANDA. If the supplemented record supports GRASE status, FDA will issue a proposed rule adding the active ingredient to the OTC monograph. In each of the cases, where FDA publishes a proposed rule, this will be followed by a public comment period, review of comments, and issuance of a final rule.

Current Scientific Considerations

Human exposure to sunscreens has increased significantly since the 1970s, when the examination of sunscreens in the OTC Drug Review began. Back then, sunscreens were used primarily on a seasonal basis to prevent sunburn. Accordingly, when evaluating the safety of sunscreen drug products, the OTC sunscreen advisory panel anticipated that consumers would be exposed to sunscreen active ingredients in modest amounts and for short, intermittent time periods. Sunscreen ingredients also were not thought to penetrate beyond the surface of the skin, so that potential systemic exposure to sunscreen active ingredients was not a concern.
As a result, the advisory panel's safety evaluation focused primarily on ensuring that sunscreen products caused minimal skin irritation and sensitivity.

Today, sunscreens are used on a routine basis by a large percentage of the population, with labeling that instructs consumers to apply sunscreens in generous amounts and to reapply, often resulting in an extent and duration of exposure to sunscreen ingredients that is orders of magnitude greater than it was in the 1970s, both for individual consumers and for the public at large. There is also increasing evidence that some sunscreen ingredients can be absorbed through the skin, leading to systemic exposures to these agents, not previously anticipated. The shift in sunscreen use, together with advances in scientific understanding and in safety evaluation methods during the same period, have given rise to new questions about what information is necessary and available to support general recognition of safety and effectiveness for sunscreens.

In order for FDA to propose to amend the OTC sunscreen monograph to include a new active ingredient as GRASE, we must also make an initial determination, based on appropriate scientific evidence, that any sunscreen product that could be formulated using the new active ingredient in the concentrations, permitted combinations, or other applicable limitations specified in the monograph, would be GRASE for use under the conditions prescribed, recommended, or suggested in its labeling. In other words, inclusion of a new ingredient in the monograph requires more than a general assessment of the ingredient, followed by adding it to the list of ingredients in the monograph. In some cases, it may require amending the monograph, not only in terms of specifying the concentration of the allowed active ingredient, but also to lay out any other limitations on its use that are needed for its safe and effective use as well as new labeling that would apply to products that included the ingredient.

FDA has been actively examining the important scientific questions for the sunscreen ingredients currently proposed in TEAs, and significant efforts have resulted in FDA recently sending letters to sponsors providing feedback on safety and efficacy data submitted in support of TEA ingredients. These letters are publicly available in the docket, in accordance with the TEA regulation. The letters that have been issued for the TEA ingredients amiloxate and diethylhexyl butamido triazone describe FDA's review of the scientific record for these sunscreen active ingredients (consisting of material submitted by the TEA sponsors and others, and information identified by FDA from the medical literature), and provide initial determinations that the record is insufficient to establish that either ingredient is GRASE for OTC sunscreen use. As described in these letters, given the expansion of sunscreen use and scientific advances since the OTC sunscreen evaluation began, our safety evaluation of these ingredients must consider, not only short term concerns (such as skin sensitivity), but also long-term concerns (such as the results of systemic exposure), about which little scientific data has been provided.

FDA's efforts on the remaining six TEA sunscreen ingredients are actively continuing, and we expect to reach our initial determinations soon. Unfortunately, we cannot say anything further on this topic until we issue our initial determinations. FDA will be holding a public meeting to discuss the information provided in the TEA letters and provide an opportunity to further clarify FDA's thinking about the data required to support a GRASE determination for sunscreens. Another public hearing relevant to the sunscreens and the TEA process was held last week (on March 25 and 26, 2014) to discuss the need to modernize the OTC monograph system in general. Our discussions about modernizing the overall OTC process will continue. However, given the public health benefits of sunscreen use, we are committed to finding ways to facilitate the marketing of additional OTC sunscreen active ingredients independent of

discussion about the overall OTC process, but must do so with appropriate assurances of both their safety and effectiveness.

While evaluating the safety and effectiveness of potential new sunscreen active ingredients has been an important task for FDA, it is not the only major effort regarding sunscreens that FDA has undertaken in the last several years. In 2011, we took several regulatory actions on a number of important sunscreen issues. First, we finalized rules that updated the efficacy testing requirements and related labeling, which applies to sunscreens currently available in the U.S.[1] This final rule prescribes new, improved labeling, including updated Drug Facts labeling. The final rule also establishes two effectiveness tests, one that must be done to support the sun protection factor (SPF) of the product, and another if a product claims to be broad spectrum (protecting against both UVA and UVB).

We issued a proposed rule proposing a maximum labeled SPF value of "50+" for all monograph sunscreen products. We also issued an advance notice of proposed rulemaking (ANPR) to seek additional information on the safety and effectiveness of sunscreens formulated as sprays and to address additional questions related to other specific dosage forms of sunscreens. Subsequent rulemaking activity is needed for each of these topics, and FDA has dedicated resources to ensure diligent follow-up.

[1] The new requirements, and several proposed changes to regulations, are discussed in four regulatory documents that include a final rule, proposed rule, an ANPR, and draft guidance for industry. Links to each of these documents are included below:

-Final Rule, Labeling and Effectiveness Testing, *http://www.gpo.gov/fdsys/pkg/FR-2011-06-17/pdf/2011-14766.pdf*
-Proposed Rule, Revised Effectiveness Determination, *http://www.gpo.gov/fdsys/pkg/FR-2011-06-17/pdf/2011-14769.pdf*
-ANPR, Dosage Forms for Sunscreens, *http://www.gpo.gov/fdsys/pkg/FR-2011-06-17/pdf/2011-14767.pdf*
-Draft guidance for industry, Enforcement Policy – OTC Sunscreen Drug Products Marketed Without an Approved Application,
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM259001.pdf

CONCLUSION

FDA agrees that the review process for TEA submissions has taken too long. However, it is important to note that we have taken important steps to ensure the safety and effectiveness of all sunscreen products, and we are working diligently to complete the pending TEA proceedings. We can work with the Committee to improve the timeliness and predictability of the TEA process while ensuring that any changes maintain the integrity of the review process.

I am happy to answer any questions you may have.

Mr. PITTS. The Chair thanks the gentlelady.

I now recognize Mr. Rannazzisi for 5 minutes for an opening statement.

STATEMENT OF JOSEPH T. RANNAZZISI

Mr. RANNAZZISI. Thank you, sir.

Chairman Pitts, Ranking Member Pallone, distinguished members of the subcommittee, on behalf of Administrator Michele Leonhart and the men and women of the Drug Enforcement Agency, thank you for the opportunity to discuss today the drug scheduling process and the registration and verification suspension process.

First, the DEA was not given the opportunity to comment when legislation that was pending before the subcommittee was drafted. The Department and the administration has not taken a position on the legislation. Therefore, I must emphasize that I am unable to discuss with you the specific details of the legislation.

The Controlled Substances Act provides the DEA with the authority to administratively control substances with abuse potential. As fully explored in my written testimony, generally, the complexity and length of time to complete the scheduling process depends on many variables. There are two important points I will emphasize.

With respect to newly approved medicines, the DEA initiates the scheduling process when it receives a recommendation from HHS. The DEA might receive the recommendation before or after the approval for marketing. One recent example I will share involves two similar medications that are indicated for epilepsy. The DEA completed the scheduling process in about the same time, 10 and 11 months from the time we received the recommendation. However, in one instance, we received the recommendation 5 months before the drug was marketed—was approved for marketing. In the other instance, we received it 4 months after it was approved for marketing. The result was that one drug was controlled 6 months after market approval, and the other drug was controlled 14 months after market approval. The experience here is that the sooner DEA receives the recommendation to control, the closer to market approval a drug can be scheduled.

The next point also concerns timing. Patent holders of recently approved medicines have paid fees to expedite their products through the market approval process, but that is not the process when it comes to scheduling. Like most Federal law enforcement agencies, DEA must prioritize resources to meet the threats and to accomplish the mission. Any perceived delays to control newly approved drugs in the past 3 years must be viewed as part of a bigger picture.

In the 13 years from 1997 to 2010, the DEA controlled nine new pharmaceutical drugs and temporarily controlled four substances to avoid an imminent hazard to public safety, but in the last 3 years, DEA has controlled four new pharmaceutical drugs and 28 different synthetic drugs to avoid imminent hazard to public safety. To be sure, the additional responsibility to control 28 different synthetic drugs had an effect on the time to control new pharmaceuticals.

In 2010, designer drugs exploded in the retail market, resulting in serious injury and death across America. Faced with the responsibility to get these drugs off the retail shelves, the DEA had no choice but to control these substances as quickly as possible. The DEA acted to stop the imminent hazard these drugs caused, which in turn required significant resources.

Another use of DEA's administrative authorities to stop an imminent threat is the authority to immediately suspend a DEA registration. As a law enforcement agency with a regulatory function, the DEA has the authority to revoke a registration and also immediately suspend a registration that poses an imminent danger. In addition to revocation and immediate suspension, there are other nonpunitive actions available to DEA, including a letter of admonition or an informal hearing.

From 2007 to 2013, the DEA issued approximately 5,500 letters of admonition and held approximately 118 informal hearings. This fiscal year to date, DEA issued less than 20 orders to show cause and immediate suspensions combined. When the DEA issues a show cause order, the registrant is afforded the opportunity to present his case at a formal hearing in front of a neutral fact finder before any action may be taken. An immediate suspension is authorized during the pendency of the show cause proceeding and is effective immediately. Immediate suspensions are by law reserved for those entities that are an imminent danger to public health and safety.

The DEA's administrative enforcement authorities are important tools in DEA's arsenal to ensure compliance, deter and prevent diversion, and ensure that every registration is within the public interest. Without these administrative tools, civil and criminal sanctions would increase, and it would be tremendously more difficult to protect the public health and safety from the diversion of pharmaceutically controlled substances.

In closing, I would like to comment on other testimony that the subcommittee will hear today. Some of the witnesses may assume to advocate on behalf of DEA, representing that they believe new legislation will help DEA. I encourage you to look beyond the self-interested statements of witnesses who are here to lobby you to protect their paying clients, present and future, from administrative sanction.

The DEA has a responsibility to maintain the closed system of distribution established by the Controlled Substances Act. As such, the DEA's sole interest is protecting the public from harm. That is what the administrative and regulatory process is for. That is what we do best: Keeping industry in compliance and protecting the public health and safety.

I appreciate the invitation to appear today and look forward to your questions. Thank you.

[The prepared statement of Mr. Rannazzisi follows:]

Department of Justice

STATEMENT OF

JOSEPH T. RANNAZZISI
DEPUTY ASSISTANT ADMINISTRATOR
OFFICE OF DIVERSION CONTROL
DRUG ENFORCEMENT ADMINISTRATION

BEFORE THE

SUBCOMMITTEE ON HEALTH
COMMITTEE ON ENERGY AND COMMERCE
U.S. HOUSE OF REPRESENTATIVES

FOR A HEARING ENTITLED

"IMPROVING PREDICTABILITY AND TRANSPARENCY IN DEA AND FDA REGULATION"

PRESENTED ON

APRIL 7, 2014

STATEMENT OF
DEPUTY ASSISTANT ADMINISTRATOR JOSEPH T. RANNAZZISI
OFFICE OF DIVERSION CONTROL
DRUG ENFORCEMENT ADMINISTRATION
BEFORE THE HOUSE ENERGY AND COMMERCE SUBCOMMITTEE ON HEALTH
APRIL 7, 2014

Chairman Pitts, Ranking Member Pallone, and distinguished Members of the Committee, on behalf of the men and women of the Drug Enforcement Administration (DEA), I am honored to have the opportunity to appear before you today to provide testimony concerning the Drug Enforcement Administration's efforts to enforce the Controlled Substances Act (CSA) utilizing our administrative authorities.

The Closed System of Distribution and the Registration Requirement

The CSA was designed to halt "the widespread diversion of [controlled substances] out of legitimate channels into the illegal market." H.R. Rep. No. 91-1444, 1979 U.S.C.C.A.N. at 4572. Recognizing the need for great scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, Congress established an independent and distinct framework under the CSA that creates a closed system of distribution for all controlled substances. See H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566; 116 Cong. Rec. 977-78 (Comments of Sen. Dodd, Jan. 23, 1970) ("[I]t cannot be overemphasized that the ...[CSA] is designed to crack down hard on the narcotics pusher and the illegal diverters of pep pills and goof balls."). As such, the CSA requires the DEA to establish and maintain a system that strictly controls and monitors the flow of controlled substances in the United States, from the point of importation and manufacture, to distribution, dispensing, and finally, disposal. This is the "closed system of distribution." This framework requires that all those who handle controlled substances (e.g., importers, exporters, manufacturers, distributors, healthcare professionals, pharmacies, and researchers) are registered to do so if their registration is consistent with the public interest, in order to ensure that all controlled substance transactions are legitimate and can be accounted for.

When the DEA was established in 1973, the DEA regulated 480,000 registrants. Today, the DEA regulates more than 1.5 million registrants. As participants in the closed system of distribution, every registrant plays an important part in maintaining the closed system by complying with the CSA and its implementing regulations. Requirements such as recordkeeping, reporting, and physical security are specifically designed to ensure that controlled substances are not diverted to illicit use, and instead are available to meet the legitimate needs of the United States. Other important requirements include the proviso that a practitioner may only dispense (i.e., prescribe or administer) a pharmaceutical controlled substance for a legitimate medical

purpose while acting in the usual course of professional practice. There is also a requirement that all registrants and applicants for registration must "provide effective controls and procedures to guard against theft and diversion of controlled substances." 21 C.F.R. § 1301.71(a). In fact, failure to maintain effective controls against diversion is a factor that shall be considered when determining whether a manufacturer or distributor's registration is in the public interest. 21 U.S.C. § 823(a), (b), (d), (e). Distributors must also "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 CFR § 1301.74(b). Finally, certain transactions involving pharmaceutical controlled substances must be reported to the DEA, such as thefts and losses. 21 CFR §§ 1301.74(c), 1301.76(b).

Consequences of Breaching the Closed System of Distribution

Diversion can occur when registrants fail to adhere to their responsibilities under the CSA and its implementing regulations. For example, failing to follow appropriate physical security requirements can leave controlled substances susceptible to diversion. Distributors that blindly sell pharmaceutical controlled substances to rogue pharmacies, and practitioners who issue prescriptions without a legitimate medical purpose are diverting. Diversion fuels abuse.

The problem of prescription drug abuse has increased exponentially in the last 15 years due to a combination of excessive prescribing, drug availability through friends and family, Internet trafficking, rogue pain clinics, prescribers who prescribe pharmaceutical controlled substances without a legitimate medical purpose or outside the usual course of professional practice, pharmacies that dispense illegitimate prescriptions, and supply chain wholesalers and manufacturers that fail to provide effective controls and procedures to guard against diversion—all of which fueled illicit access at the expense of public health and safety. According to the 2012 National Survey on Drug Use and Health (NSDUH), 6.8 million people age 12 or older used psychotherapeutic drugs for non-medical reasons during the past month (psychotherapeutic drugs included in this estimate are pain relievers, tranquilizers, stimulants, or sedatives and does not include over-the-counter drugs). This was higher than the number of users reported in 2011 (6.1 million), but similar to the number of users reported between 2005 and 2010. Non-medical use of psychotherapeutic drugs is second only to marijuana use (18.9 million) in terms of popularity. There are more current users of psychotherapeutic drugs for non-medical reasons than current users of cocaine, heroin, or hallucinogens (or some combination thereof).

The consequences of abuse are devastating. Recently, the Centers for Disease Control and Prevention (CDC) reported its analysis revealing that 38,329 people died from a drug overdose in the United States in 2010.[1] Nearly 60 percent of those drug overdose deaths (22,134) involved pharmaceutical drugs. Opioid analgesics, such as oxycodone, hydrocodone, and methadone, were

[1] Drug Overdose in the United States: Fact Sheet. www.cdc.gov/homeandrecreationalsafety/overdose/facts.html (accessed March 18, 2014).

involved in about three of every four pharmaceutical overdose deaths (16,651), confirming the predominant role opioid analgesics play in drug overdose deaths.

Also of concern is that, according to the most recent NSDUH, there were 335,000 current heroin users in 2012, more than double the number in 2007 (161,000). The DEA believes the increased heroin use is driven by many factors, including an increase in the misuse (e.g., using more than medically indicated or using in a manner not medically indicated) and abuse (i.e., using in order to feel the psychoactive effects of the drug) of prescription psychotherapeutic drugs, specifically opioids.

Non-medical prescription opioid use, particularly by teens and young adults, can lead to heroin use. Black-market sales for prescription controlled substances are typically five to ten times their retail value. DEA intelligence reveals the "street" cost of prescription opioids steadily increases with the relative strength of the drug. For example, generally, hydrocodone combination products (a schedule III prescription drug and also the most prescribed drug in the country)[2] can be purchased for as little as $5 to $7 per tablet. Stronger drugs like oxycodone combinations (e.g., Percocet, a schedule II drug) can be purchased for as little as $7 to $10 per tablet. Even stronger prescription drugs are sold for as much as $80.00 per tablet or more in the case of the previous formulation of OxyContin 80 mg, and $30.00 to $40.00 per tablet for 30 mg oxycodone single entity immediate release or the 30 mg oxymorphone extended release. These increasing costs make it difficult, especially for teens and young adults, to purchase in order to support their addiction, particularly when many first obtain these drugs for free from the family medicine cabinet or friends. Some users of prescription opioids turn to heroin, a much cheaper opioid, generally $10 per bag, which provides a similar "high."

Maintaining the Closed System of Distribution

In order to prevent diversion and maintain the closed system of distribution, the DEA is a law enforcement agency with a regulatory function. Although the DEA's investigative techniques and methods remain constant with respect to enforcing the CSA, this unique mission calls for an array of criminal, civil, and administrative authorities. In other words, to maintain the closed system of distribution, the DEA can select from a variety of tools to appropriately deter diversion, ensure compliance, and ensure that every registration is in the public interest, as defined by the CSA. Some of the proactive tools include administrative inspections, pre-

[2] On February 27, 2014, DEA published in the *Federal Register* a Notice of Proposed Rulemaking (NPRM) to move hydrocodone combination products from schedule III to schedule II, as recommended by the Assistant Secretary for Health of the U.S. Department of Health and Human Services and as supported by the DEA's own evaluation of relevant data. This NPRM proposes to impose the regulatory controls and sanctions applicable to schedule II substances on those who handle or propose to handle hydrocodone combination products. The NPRM is available on the DEA's website, www.dea.usdoj.gov. Members of the public are invited to submit comments. Electronic comments must be submitted, or written comments postmarked, by 11:59 p.m. Eastern Time on April 27, 2014.

registration inspections, required reporting, order form requirements, education, and the quota system.

The DEA Diversion Groups concentrate on the regulatory aspects of enforcing the Controlled Substances Act. The DEA has steadily increased the frequency of compliance inspections of specific registrant categories such as manufacturers (including bulk manufacturers); distributors; pharmacies; and practitioners. This focus on oversight enables the DEA to educate registrants and ensure that DEA registrants understand and comply with the CSA and its implementing regulations. The DEA conducts approximately 6,000 regulatory inspections every year to ensure compliance with the law. Each inspection entails close communication between the DEA and the registrant to educate the registrant about proper procedures and to ensure corrective action is taken to comply with the law. These inspections typically result in remediation or continued compliance, and no further action is taken.

To complement the panoply of proactive authorities, the DEA focuses its pharmaceutical investigations where diversion occurs: at the distributor, pharmacy and practitioner level of the supply chain. This includes non-registrants and end users who are involved in large-scale distribution, prescription fraud (prescriptions that were written in the name of a practitioner who did not authorize the dispensing of a controlled substance), and doctor shopping (drug seekers who present various complaints to multiple physicians to procure controlled substances). Many of the investigations that DEA initiates are conducted pursuant to complaints received from other law enforcement agencies, regulatory boards, private citizens, former patients, and health practitioners. In some cases involving health professionals, state regulatory or licensing authorities have already initiated proceedings and have requested DEA's assistance in their investigations.

DEA Tactical Diversion Squads (TDSs) investigate suspected violations of the CSA and other Federal and state statutes pertaining to the diversion of controlled substance pharmaceuticals and listed chemicals. These unique groups combine the skill sets of Special Agents, Diversion Investigators, and a variety of state and local law enforcement officers. They are dedicated solely towards investigating, disrupting, and dismantling those individuals or organizations involved in diversion schemes (e.g., doctor shoppers, prescription forgery rings, and practitioners and pharmacists who knowingly divert controlled substance pharmaceuticals). Between March 2011 and March 2014, the DEA increased the number of operational TDS's from 37 to 66. With the expansion of TDS groups across the U.S., the number of diversion-related criminal cases has increased. These TDS groups have also been able to increase the number of diversion-related Priority Target Organization (PTO) investigations. PTO investigations focus on those criminal organizations or groups that significantly impact local, regional or national areas of the country.

Another important component to maintaining the closed system of distribution is educating registrants on their responsibilities under the CSA and the implementing regulations. The DEA educates the registrant population, including pharmacy personnel, as well as parents, community leaders and law enforcement personnel regarding diversion trends and how to best prevent prescription drug diversion. The DEA Office of Diversion Control routinely makes presentations to the public, educators, community-based organizations, registrants, and their professional organizations, industry organizations, and law enforcement agencies regarding the diversion and non-medical use of pharmaceutical controlled substances.

The DEA, along with state regulatory and law enforcement officials, and in conjunction with the National Association of Boards of Pharmacy, hosts Pharmacy Diversion Awareness Conferences (PDACs) throughout the country; to date, 34 separate PDACs have been held in 16 different states. Each one-day conference is held on a Saturday or a Sunday for the convenience of the pharmacy community. The conference is designed to address the growing problem of diversion of pharmaceutical controlled substances at the retail level. The conference addresses pharmacy robberies and thefts, forged prescriptions, doctor shoppers, and illegitimate prescriptions from rogue practitioners. The objective of this conference is to educate pharmacists, pharmacy technicians, and pharmacy loss prevention personnel on methods to prevent and respond to potential diversion activity.

The DEA also established the Distributor Initiative Program in 2005 to educate registrants on maintaining effective controls against diversion, and monitoring for and reporting suspicious orders. This program was initially designed to educate wholesale distributors who were supplying controlled substances to rogue Internet pharmacies and, more recently, to diverting pain clinics and pharmacies. The goal of this educational program is to increase distributor awareness and vigilance to prevent diversion and cut off the source of supply to these and other schemes. Wholesale distributors are required to design and operate a system that will detect suspicious orders and report those suspicious orders to the DEA. Through the Distributor Initiative Program, the DEA educates distributors about their obligations under the CSA, as well as provides registrants with current trends and "red flags" that might indicate that an order is suspicious, such as the type of drug(s) ordered, orders of unusual size, orders that deviate from a normal pattern, frequency of orders, breadth and type of products ordered, and the location of the customer.

Administrative Enforcement Authority

Once violations of the CSA or its implementing regulations are revealed, the DEA must determine what course of action to take—administrative, civil, and/or criminal—depending on the nature and severity of the violations at hand. The facts and circumstances that support criminal charges related to violations of the CSA will always support an administrative action against a DEA registrant. However, the facts and circumstances that support an administrative action will not

necessarily support criminal action against a registrant. The decision to take administrative, civil, and/or criminal action against a DEA registrant rests with the DEA and the prosecuting U.S. Attorneys.

There are several administrative actions that may be taken against a registrant, including issuing a Letter of Admonition (LOA), holding an Informal Hearing (IH), or issuing an Order to Show Cause (OTSC) that could result in the suspension or revocation of a registration, or denial of an application for registration. The LOA or IH can be used to provide formal notice to a registrant who is not in compliance with the regulations or statutory provisions of the CSA. The LOA and IH provide registrants an opportunity to recognize and acknowledge their infractions, and immediately correct them. From 2007 to 2013, the DEA issued approximately 5,500 LOAs to registrants and held approximately 118 IHs.

Before taking action to deny an application for registration or to revoke a registration, the DEA must serve the applicant or registrant with an OTSC why the registration should not be denied or revoked. The DEA Deputy Assistant Administrator may initiate an OTSC on the basis of any five statutory factors, or a combination thereof: material falsification of an application; a controlled substance-related felony conviction; lack of state authority; commission of acts inconsistent with the public interest; or exclusion from Medicare/Medicaid. The DEA generally reserves OTSC for those situations where registrants fail to comply with the CSA and/or its implementing regulations and repeated or egregious violations occur.

OTSC proceedings are conducted pursuant to the Administrative Procedure Act (APA) before an independent fact finder, the administrative law judge, on a date noted in the OTSC. Registrants have the opportunity to evaluate and test the DEA's evidence, and show they have taken corrective action, and any other mitigating factors, at a formal hearing. Upon the conclusion of the formal hearing, the administrative law judge provides a recommended decision to the Deputy Administrator, who reviews the record of proceedings and subsequently issues a Final Agency Decision.

When the DEA issues an OTSC, the DEA is authorized to simultaneously suspend the registration (by issuing an Immediate Suspension Order (ISO)) in order to immediately stop the harm the registrant is causing, or may cause, during the pendency of the OTSC proceeding. Issuing an ISO is the most severe administrative action the DEA can take, and, by law, is reserved for those entities that the DEA can show are an imminent danger to the public health or safety. This OTSC and ISO authority is used sparingly, compared to the vast number of investigations and inspections the DEA conducts every year. In FY11, the DEA issued more than 65 OTSC and ISO each. For FY14, as of March 28, 2014, the DEA had issued less than 20 OTSC and ISO combined.

It must be emphasized that these administrative "*proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings*" under the CSA or any other law of the United States. 21 U.S.C. § 824(c). Accordingly, civil and/or criminal action may proceed simultaneously with administrative proceedings. It is not uncommon for the DEA's enhanced regulatory oversight and expanded criminal investigative efforts to result in the identification of registrants who fail to adhere to their regulatory responsibilities and, in so doing, also commit acts that are appropriate for civil or criminal sanction. In these instances, the DEA would take administrative action against these registrants, and also refer them for civil or criminal action.

The DEA's administrative enforcement authorities, particularly the administrative sanction of revocation or suspension of registration are important tools in the DEA's arsenal to ensure compliance, deter and prevent diversion, and ensure that every registration is in the public interest. Without these administrative tools, civil and criminal sanctions would increase, and it would be tremendously more difficult to protect the public health and safety from the diversion of pharmaceutical controlled substances. For example, before the DEA could shut down a pill mill, civil or criminal investigation and subsequent action would be necessary. Doctors writing prescriptions for fake ailments at $400 per prescription could continue to deal drugs until civil or criminal sanction could occur. Pending such action, the registrant would be able to continue to push pills out the door as fast as possible.

Administrative Scheduling Authority

Another aspect of the closed system of distribution is the DEA's authority to administratively control substances with abuse potential through rulemaking. These actions impose the regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances on persons who handle (manufacture, distribute, dispense, import, export, engage in research, conduct instructional activities, or possess) or propose to handle the substances administratively controlled.

Proceedings for the issuance of a rule may be initiated by the Administrator of the DEA (pursuant to a delegation of authority from the Attorney General) on her own motion, upon request of the Secretary of the Department of Health and Human Services (HHS), or on the petition of any interested party. The Administrator may add a drug or other substance to a schedule or transfer it between schedules if she finds the drug or other substance has a potential for abuse and makes the findings required by 21 U.S.C. § 812(b) for the schedule in which the drug is to be placed. She may also remove a drug from the schedules if she finds that it does not meet the criteria for placement in any schedule.

Before initiating a rulemaking, the DEA must request from the Secretary of HHS a scientific and medical evaluation, and recommendation as to whether the drug should be controlled

(21 U.S.C. § 811(b)). The CSA in 21 U.S.C. § 811(c) sets out the following eight factors that must be considered when making any findings to control a drug or other substance:

1. Actual or relative potential for abuse.
2. Scientific evidence of its pharmacological effects.
3. State of current scientific knowledge regarding the drug.
4. History and current pattern of abuse.
5. Scope, duration, and significance of abuse.
6. Risk to the public health.
7. Psychic or physiological dependence liability.
8. Whether the substance is an immediate precursor of a substance already controlled.

In making the required evaluation and recommendations, the Secretary must consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of § 811(c), and any scientific or medical considerations involved in paragraphs (1), (4), and (5). The recommendations of the Secretary are binding as to scientific and medical matters, and if HHS recommends that the drug not be controlled, then the DEA may not control it. On the other hand, if HHS recommends that a drug be controlled, or that a drug be controlled in a particular schedule, that recommendation is not determinative. The CSA vests responsibility in the DEA to determine whether the facts and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control, and to make the findings necessary to control a drug in a particular schedule. Accordingly, the DEA is responsible for the final determination as to whether a drug should be scheduled, and as to the schedule in which the drug should be placed.

To fulfill its statutory mandate, the DEA reviews the HHS evaluation in great detail before making the findings necessary to schedule a substance. When the DEA receives the scientific and medical evaluation and scheduling recommendation from HHS, the DEA evaluates the facts provided and all other relevant data to determine whether the evidence warrants control of the substance, and if so, in which schedule to place the substance. Throughout the rulemaking process, the DEA independently considers the eight factors of 21 U.S.C. § 811(c) in order to make the findings required by 21 U.S.C. §§ 811(a) and 812(b).

The DEA is entrusted to ensure that all factors determinative of control and all findings are fully supported and legally defensible. Among other things, this involves reviewing the scientific and medical data provided in the HHS recommendation, verifying the underlying facts, analyses, and scientific literature supporting the HHS recommendation, as well as gathering and reviewing any other related data and/or scientific studies or literature that may exist. The DEA conducts its own eight-factor analysis because the DEA must be prepared to defend the scheduling action in the event an interested person requests an administrative hearing or the rulemaking is otherwise

challenged. The DEA also conducts a survey of the available scientific literature and data to ensure, among things, that information from published sources is current and relevant. Furthermore, the DEA and HHS have access to different data sets—e.g., the DEA collects and maintains sensitive law enforcement data on drug seizures and drug analysis (e.g., databases such as the National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE)), while HHS has unique access to product-specific information contained in a manufacturer's New Drug Application. Even when the DEA and HHS access the same raw data (e.g., poison control center data, hospital emergency room data, and data from the Drug Abuse Warning Network), each agency's analysis may differ based upon the context of the data and/or each agency's experience with the data.

The process of evaluating and determining the abuse and dependence liability of a substance, and evaluating that liability in light of other already scheduled substances, is complex and drug-specific. The level of analysis required to control each drug is unique and a direct comparison to the timing of the scheduling of other substances is not appropriate. Generally, the complexity and length of time for DEA and/or HHS to conduct an analysis depends on many variable factors, including but not limited to: the availability of scientific data and literature; the depth and breadth of the available scientific data and literature; the quality of the available data; the reliability of scientific data and conclusions; whether scientific studies must be conducted to determine abuse liability; whether the drug or substance is a new molecular entity or a drug that is already used in medical treatment. The length of the administrative process also depends on whether an interested person requests an administrative hearing; how many public comments are received in response to the scheduling action; the nature and content of any public comments received; and the extent of any regulatory analysis that may be conducted in support of the administrative action, which depends on many factors including how widely the substance or drug is used throughout the United States, who will be affected by the scheduling action, the financial impact on the affected entities, and the impact on the economy and state, local, and tribal governments.

During the administrative rulemaking process, the DEA may ask HHS to clarify aspects of its evaluation and recommendation or reconsider its scheduling recommendation. For example, the DEA requested HHS to reconsider its scheduling recommendation with respect to hydrocodone, based on DEA's review of the available data.

As noted above, under the CSA, the DEA is required to consider the actual or relative potential for abuse ("abuse liability") of a substance when making a scheduling determination. There is no history of use in the United States of newly developed pharmaceutical drug substances. Accordingly, determining abuse liability is a difficult undertaking requiring comparison to other substances of similar structure and abuse liability.

The CSA specifies in 21 U.S.C. § 812(b) the findings necessary to place a substance in a particular schedule. The level of control that will be required of a substance varies depending on the schedule in which the substance is placed. Accordingly, placement in the appropriate schedule will ensure that necessary controls are in place to detect and prevent diversion of the substance to illicit channels, thereby protecting public health and safety.

The placement factors involve whether the substance has a currently accepted medical use in treatment in the United States, the potential for abuse of the substance relative to substances in other schedules, and the level of physical or psychological dependence (severe, moderate or low) that may result from abuse of the drug. See 21 U.S.C. § 812(b).

In addition to the scientific review and analysis required to administratively schedule a drug or other substance, the DEA also assesses whether a scheduling action will have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act, 5 U.S.C. § 601 et seq. If the DEA determines that a scheduling action will have a significant economic impact on a substantial number of small entities, the DEA prepares an initial regulatory flexibility analysis which generally includes elements such as: a description of the reasons why action by the agency is being considered; a succinct statement of the objectives of, and legal basis for, the proposed rule; a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply; and a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule. Even if the DEA certifies that a scheduling action will not have a significant impact on a significant number of small entities, such certifications would be accompanied by a statement providing the factual basis for the certification. Accordingly, the DEA estimates, reviews, and analyzes data on the potential number of small entities affected by the rule and the potential costs that would be incurred by such entities.

Each scheduling action is unique--each substance is evaluated based upon the available information, and there may be more scientific and abuse liability data available for some substances than for other substances. Nonetheless, in recent years, DEA's administrative scheduling actions have increased as the DEA responsibilities have expanded.

From 1997 to 2010, DEA routinely published NPRMs to control newly approved pharmaceutical substances within six months of receiving the HHS scheduling recommendation. During that time, the DEA temporarily scheduled two substances each in 2002 and 2003 in order to avoid imminent hazard to the public safety pursuant to 21 U.S.C. § 811(h).

In 2011, the DEA began to use its temporary scheduling authority to control numerous emerging "designer drugs" because there was a marked increase in the trafficking and abuse of illicit designer drugs such as synthetic cannabinoids and cathinones which resulted in serious injury and death. These substances have become a significant public safety threat requiring the

DEA to devote a large amount of its resources to compiling the necessary scientific data and information, initiate control actions and communicate the scientific and technical information with other offices within DEA and other Federal agencies. The growing public health threat is evidenced by the expanding need for educational efforts across the country. In 2010, DEA scientific staff provided four presentations on designer drugs; in 2011, they presented seven times; in 2012, they presented 11 times; and as of August 21, 2013, they had already given 10 presentations. This developed expertise has demanded scientific staff testimony in important criminal prosecutions of traffickers of these dangerous synthetic drugs. A relatively recent, growing responsibility, this has stretched the resources of the scientific staff as they conduct the scientific analysis required and provide expert testimony in numerous criminal prosecutions pursuant to the Controlled Substance Analogue Enforcement Act of 1986 (Analogue Act). For example, in 2011, the DEA temporarily scheduled eight synthetic substances and subsequently prepared to permanently control these substances. During this time, the DEA received two scheduling recommendations from HHS for newly approved pharmaceutical substances. Of these two substances, the DEA published one NPRM nine months after receiving the HHS recommendation.

In 2012, the DEA was working towards permanently controlling the eight temporarily controlled designer drugs, and published NPRMs for six of those substances. During that time, the DEA received two more scheduling recommendations from HHS for newly approved pharmaceutical substances and published the pertinent NPRMs within six and eight months of receiving the HHS recommendations. Also in 2012, scientific staff provided expert testimony in ten instances and provided technical support in 18 instances with respect to prosecutions pursuant to the Analogue Act. By the end of August 2013, the DEA had temporarily controlled three more synthetic designer drugs, and the scientific staff had already provided testimony in 32 instances, and were providing technical support (including providing written declarations) in approximately 135 instances, in support of Analogue Act criminal prosecutions.

Conclusion

The primary purpose of the CSA is to protect the health and safety of the public while also ensuring legitimate access to controlled substance pharmaceuticals. The DEA has a responsibility to maintain the closed system of distribution established by the CSA, and it does so through various administrative enforcement measures. While there may be a perception among some registrant categories that the DEA unfairly targets them, the facts belie that view. As demonstrated, of 1.5 million registrants, only a very small fraction are subjected to adverse action pursuant to the DEA's administrative authority.

In recent years, rogue pain clinics, pharmacies that fill illegitimate prescriptions for pain clinic "patients", and the wholesale distributors that supply these pharmacies have caused, and continue

to cause, millions of dosage units of highly addictive controlled substances to be diverted. Consequently, the registrants involved—practitioners, pharmacies, and wholesale distributors that do not comply with the CSA or its implementing regulations—are allowing millions of dosage units of controlled substances to pour into the illicit market, endangering the public health and safety. When warranted, the DEA will take appropriate administrative, civil, or criminal action to prevent the registrant from continuing to divert controlled substances.

Mr. PITTS. The Chair thanks the gentleman.

We will now go to questioning. I will recognize myself for 5 minutes for that purpose.

Dr. Woodcock, with respect to scheduling of controlled substances, would you elaborate on what types of data FDA uses in conducting its analysis for a new molecular entity prior to sending the agency's recommendation to DEA, and what is the purpose of this evaluation? Do the scientists at FDA do everything they can to make this evaluation as comprehensive and accurate as possible?

Ms. WOODCOCK. Certainly. Well, the FDA and our partner, we work with NIDA, are trying to predict, based on what data we have, how abusable, how attractive, a drug may be once it is out on the market for abuse and addiction. We use everything from the structural knowledge of the drug to animal studies, and there are animal studies that can look at whether the animals find the drug attractive, to actual human studies, likability studies, where we ask experienced humans what they think of the effects of the drug, and that is very illuminating.

We put all that information together plus epidemiology on similar and related substances, and basically, we do what is called an eight factor analysis, and we put all those factors together into an analysis.

Mr. PITTS. Thank you.

Mr. Rannazzisi, what is the average time it takes DEA to schedule a new molecular entity after your agency receives FDA's recommendation?

Mr. RANNAZZISI. I don't know what the average time is, but it is very product specific. It depends on when we receive the recommendation. See, in some products, we receive the recommendation way before approval, so we could go ahead and start our eight factor because, like my colleague, we have to do an eight factor as well, and three of the factors are based on DEA findings.

Mr. PITTS. And why does it sometimes take over a year to make this determination?

Mr. RANNAZZISI. Depending on when we receive the recommendation, generally there could be problems. When we get the recommendation, we have to send it back to FDA for a clarification. There might have been something that FDA missed that we want them to look at. Remember, when we take the final scheduling action, and we publish it, there may be a hearing and DEA, not FDA, but DEA has to justify the schedule that the product is being put in. We have to provide the evidence that the drug is properly scheduled. So if the scheduling action is questioned and a hearing is requested, DEA is the one that goes into court and justifies the scheduling. We bring FDA in to provide testimony, but in the end, it is our scheduling action based on 811.

Mr. PITTS. In your opinion, are there instances where the agency has taken too long to schedule a new molecular entity after FDA approval?

Mr. RANNAZZISI. No. In fact, there was a statement I think somebody made with a fivefold increase since 1999. I have no idea where that number came from because you have to look at when we received the actual recommendation. It is not when the drug is

scheduled. We have to go back because, like I said, sometimes we get the recommendation well after the approval has been done, 3 to 4 months, so that is when we start. We cannot start the process until we receive the eight factor from HHS.

Mr. PITTS. Section 201–B of the Control Substances Act, it states that DEA is bound by the medical and scientific recommendations of the FDA. Is that correct?

Mr. RANNAZZISI. That is correct.

Mr. PITTS. And FDA's recommendations are made after a thorough analysis of the potential for abuse and misuse of the drug products, right?

Mr. RANNAZZISI. That is correct.

Mr. PITTS. Now, after a drug product is scheduled and available for marketing, it can be rescheduled. Would you explain how DEA participates in that process and how often has DEA initiated these rescheduling discussions?

Mr. RANNAZZISI. Rescheduling action, most recently we have one pending with hydrocodone. We did a scheduling action on carisoprodol, which we had to go and justify in court. Carisoprodol is a muscle relaxant that was not scheduled. We requested a medical and scientific evaluation from HHS on two or three occasions. We finally got the justification necessary to reschedule it. It was challenged. We went into court. We justified based on evidence, and we prevailed. It just depends on the specific drug that we are dealing with at the time. Hydrocodone is pending. That is still a pending action.

Mr. PITTS. The Chair thanks the gentleman.

My time is expired. I recognize the Ranking Member, Mr. Pallone, for 5 minutes of questions.

Mr. PALLONE. Dr. Woodcock, do you want to respond to what Mr. Rannazzisi said about, you know, when the clock stops, in other words— I mean, when the clock starts, that even after you have approved the drug, it may be like another 4 months or so before its scheduled? He was talking about that.

Ms. WOODCOCK. Well, there are multiple clocks involved here. We are working off the user fee clock that has been agreed to by Congress and so forth, and sometimes there may be additional information that we need for the eight factor that may come in at different times, and so that might prolong that particular determination. At the moment, that doesn't prevent us from approving the drug, so we go ahead and approve the drug, but we are still working on information that we may have received later in the cycle, which might mean a gap between the time the drug is approved, and that is information on safety and efficacy, and the drug, when we can make a recommendation for scheduling.

Mr. PALLONE. I am going to go back to Mr. Rannazzisi. I just want to get a little information on some other aspects of this scheduling process. I know Mr. Pitts has addressed this in some way, so I apologize if some of these questions are repetitive, but your responses are significant as we try to move this bill. What is the percentage of times in which DEA scheduled a new drug into a class different from which FDA recommended?

Mr. RANNAZZISI. I don't know of a time where we have not scheduled the drug outside of the recommendation.

Mr. PALLONE. OK. So there has never been any instance?

Mr. RANNAZZISI. Not that I can remember.

Mr. PALLONE. OK. Can you tell us how long it takes on average for DEA to issue a final scheduling decision starting from the time DEA receives a scheduling recommendation from the FDA?

Mr. RANNAZZISI. Again, I can't tell you on average because different drugs require different time periods. It just depends on the information that came back from the HHS on the eight factor analysis. It depends on when we received that information. It depends on if there needs clarification on any one of the eight factors. It is variable. It depends, especially on new molecular entity, because a new molecular entity, we have to do our research, which we try and do as soon as possible. But, again, it involves when we receive the recommendation.

Mr. DINGELL. Will you yield?

Mr. PALLONE. Sure.

Mr. DINGELL. Will you explain why you have to do your research and why you can't use FDA's research and why you can't get a memorandum of understanding as to how you are going to cooperate?

Mr. RANNAZZISI. Actually, we do have a memorandum of understanding pending. It is being reviewed by both agencies.

Mr. DINGELL. I am not hearing you say that today.

Mr. RANNAZZISI. Well, we have a memorandum of understanding pending, and we are working out the differences in the MOA, but I am pretty confident that we will have that in place very shortly. But in the meantime, again, our scientists are the ones who will be testifying in the hearing when it is challenged.

Mr. PALLONE. I am going to run out of time, so I just want to turn now to the process for registering manufacturers and distributors of controlled substances. What is the statutory deadline for making a decision on an application to become registered as a manufacturer or distributor of a controlled substance, or is there no deadline?

Mr. RANNAZZISI. I think it is within a reasonable time period.

Mr. PALLONE. Within a what you said?

Mr. RANNAZZISI. I think it is a reasonable time period. Once we receive all of the data, we do an investigation of the physical location. We grant the registration. As long as they have the proper, appropriate, State licensing.

Mr. PALLONE. How long does it usually take on average from application of registration?

Mr. RANNAZZISI. Again, it just depends on the entity we are registering.

Mr. PALLONE. Does the DEA look at any application to manufacture or distribute a controlled substance for a clinical trial any differently than an application to manufacture or distribute for commercial use? Because I would imagine that the quantities would be considerably smaller for clinical trials?

Mr. RANNAZZISI. On a clinical trial, a researcher for a clinical trial, they would send in their application with their research protocols. Once we receive the research protocols, we send the research protocols to FDA. FDA and NIDA review the research protocols. They make a determination that the protocols are consistent with

good research. At that point in time, they are approved. They come back to us, and we send diversion investigators on site to review, to ensure that they have the appropriate storage container to lock whatever investigational drug that may be a controlled substance they are using, and we give them the application once they understand what paperwork's involved and security is in place. It is no different than anybody else really, except that the protocols must be approved by HHS.

Mr. PALLONE. My time is expired, Mr. Chairman.

Mr. PITTS. The Chair thanks the gentleman.

I now recognize the vice chairman of the full committee, Mrs. Blackburn, for 5 minutes for questioning.

Mrs. BLACKBURN. Thank you so very much, and I appreciate that both of you are here and have just a couple of questions. I want us to be able to move on so we can get to the second panel.

Continuing along kind of with the line that Mr. Pallone was going, I think that when we look at the DEA and look at what is happening with prescription drugs, you know, you can look at—the laws are very clear when it comes to the illegal drug trade. You know that distribution of heroin or the methamphetamines, you know it is illegal. That type clarity is very helpful in enforcing the law, but when we are talking about the pharmaceutical products, what constitutes legal prescribing and dispensing is not quite as clear.

So let me just ask you if you can list for us what you are doing, articulate what the efforts are that the DEA is engaged in to promulgate some clear standards for the prescribers, for the pharmacies, for the distributors. What is your step by step? You say you have got an MOA. You say that is pending, so give me your tick list.

Mr. RANNAZZISI. Well, let's talk about the prescribers first. I believe that the courts have settled what a prescriber must do. He must issue a prescription, a controlled substance prescription for a legitimate medical purpose in the usual course of professional practice. That was given to us by U.S. v. Moore 1975, and that hasn't changed. It is very obvious. When we go out and talk to physicians groups, we tell them that is their standard. They know that is the standard. If you looked back when we were doing the Internet pharmacy debacle, when doctors weren't seeing patients—they were just writing prescriptions without seeing the patient and having a pharmacy over the Internet fill them—that was not for legitimate medical purpose, not in the usual course of professional practice. There was no established doctor-patient relationship.

Now let's talk about the pharmacists. The pharmacists have a corresponding responsibility to ensure the prescription is valid. We go out and we teach the pharmacists, as does the National Associations of the Boards of Pharmacy and the particular pharmacy boards that the pharmacist sits in, that they have a corresponding responsibility to ensure that the prescription is valid, that it is issued for a legitimate medical purpose in the usual course of professional practice. Pharmacists understand that. There is transparency in the case law. There is transparency in how we do things. We have done prescription drug pharmacy diversion awareness conferences in, I think, 14 States.

Mrs. BLACKBURN. OK. Well, a lot of that we know. We were looking for a little bit of that new information, and I guess it is kind of a Monday attitude sort of day, so let me move on.

Mr. RANNAZZISI. I would like to finish my answer. I guess not.

Mrs. BLACKBURN. What are you doing to help well-intentioned registrants to determine who they can do business with?

Mr. RANNAZZISI. I am sorry? We don't dictate who the registrant does business with.

Mrs. BLACKBURN. OK. I thought maybe you were doing a little bit to help——

Mr. RANNAZZISI. Well, we are, if I can proceed with the wholesalers and distributors, besides having one-on-one contact with the wholesalers and distributors in the distributor initiative, telling them what to look for and what red flags to look for, our yearly conference with the distributors as a whole to talk to them about what red flags, what we are seeing trend-wise and what they need to look for, besides the onsite investigations that we do, the cyclical investigations, to determination compliance and to assist them in complying, besides the fact that they call in and request assistance——

Mrs. BLACKBURN. Let me move on, then, if it is laborious.

Mr. RANNAZZISI. It is not laborious. You asked me to tick off what I do: 16,651 people in 2010 died of opiate overdose, OK, opiate-associated overdose. This is not a game. We are not playing a game.

Mrs. BLACKBURN. Nobody is saying it is a game, sir. We are just trying to craft some legislation.

Mr. RANNAZZISI. Especially in Tennessee. There is 340——

Mrs. BLACKBURN. Your written statement indicates that the DEA has initiated less than 20 administrative cases in the last 6 months. What is behind the significant decline in case initiation, and are you satisfied with the number of cases being initiated?

Mr. RANNAZZISI. Well, we are initiating cases, for sure. Our case numbers have not gone down.

Mrs. BLACKBURN. I think the case numbers have gone down. OK. If DEA has only initiated 20 administrative cases in the last 6 months, what is DEA doing to help registrants identify the prescribers and pharmacies that they should refuse to do business with?

Mr. RANNAZZISI. Ma'am, that is a due process issue. We can't direct a wholesaler or distributor or a pharmacy not to sell to a particular person. They are afforded due process like every other person. So if I told them, "Don't sell to this pharmacy, don't sell to this doctor," then they wouldn't be afforded due process.

Mrs. BLACKBURN. My time has expired. I yield back.

Mr. PITTS. The Chair recognizes the ranking member of the full committee, Mr. Waxman, for 5 minutes of questions.

Mr. WAXMAN. Thank you.

Dr. Woodcock, I think we can all agree that the current process has not been working. Mr. Whitfield and Mr. Dingell have a bill that attempts to fix the problem. Of course, it is rather strange because we have got three different bills under discussion, and I am taking a leap from the last one. While I have concerns about elements of their bill, I share their frustration with the current FDA

process and their desire to fix it. Will you commit to work with the committee, with the PASS Coalition, and other stakeholders, to come up with a process under which new, safe and effective sunscreens can get to market quickly?

Ms. WOODCOCK. Yes.

Mr. WAXMAN. I would like to better understand the current process and how we can help improve it. The central element in H.R. 4250 seems to be giving an FDA advisory committee the ability to make approval decisions, albeit providing FDA with some authority to reject that decision. I have serious concerns about such a model. Can you tell us if there are precedents at FDA for using an advisory committee in this way, what are FDA's views of such an approval, and it does at least appear to have the virtue of speeding up the process?

Ms. WOODCOCK. Well, I believe possibly in the device realm in the past, there were some areas where the panel recommendations were more binding. However, this is not true for pharmaceuticals.

The process problems with the OTC monograph go well beyond sunscreens and related or pertain to the entire monograph process, which has to be done by regulations. The Time and Extent Applications is what we are talking about here for sunscreens, were put in place by us actually in the early 2000s to try to bring more products that seemed to be most appropriate for monographs into the monograph system. However, what happened is that got caught up into the prolonged and torturous history of the sunscreen monograph and all the other monographs that we have to get out under the OTC system.

So, personally, the administration does not have a position on this bill, but I would say that, you know, it is making steps forward, and we need to change some things if we are going to make an efficient process that can respond both to safety problems and get more products into the monograph.

Mr. WAXMAN. What do you think of the idea of an advisory committee making that decision instead of you?

Ms. WOODCOCK. Well, I think that will be very difficult because it is a voluminous amount of data, and one of the problems that we have had in general is having time to go through all these data, find out what is missing, figure out what the gaps are, communicate with the sponsors. It is not a typical type of thing that an AC would do.

Mr. WAXMAN. And do you think if there were such a process, the committee members, I don't know how they would be chosen in particular, how would it affect conflict of interest issues?

Ms. WOODCOCK. Well, like any other advisory committee, we have to do an extensive screening for conflict of interest, and a committee considering this wide range of issues would have to have a very broad representation, all of whom would have to be relatively free of conflict of interest.

Mr. WAXMAN. The bill sets outs mandatory time frames for decisions both by the advisory committee and the FDA and even time frames for applicants to submit new information. I understand the sponsors' interest in moving things along quickly. However, the time frame seems somewhat more ambitious or optimistic than is reasonable.

The advisory committee would have 180 days to make its recommendations after receiving an application. Considering that there are eight outstanding applications, that could be a lot of work to expect the committee to accomplish. It also gives FDA 45 days to agree or disagree with the committee recommendation. Again, that seems rather ambitious, even if the committee were to be making only one recommendation for consideration within that time frame. What are FDA's views on those time frames? What times frames would FDA consider reasonable?

Ms. WOODCOCK. Well, I understand the impetus behind the desire for short time frames, however, I feel it may be self-defeating. If it is not possible to identify all the problems and get to a considered opinion in that time frame, then it would be likely to turn something down rather than turn it loose on the public.

Mr. WAXMAN. And what do you think about the shifting of the burden? It appears the advisory committee decision is presumed to be right, unless FDA can prove it is wrong. That seems like an inappropriate shifting of the burden of proof. Seems like a decision could be reversed simply because the FDA reviewer didn't adequately write down the basis for the decision. What is the FDA's view of the appeals process?

Ms. WOODCOCK. Well, I think this does put a tremendous burden on the FDA. And probably inappropriate—as written currently, difficult or undoable burden on the advisory committees as well. So I am not sure this process would end up with the desired outcome, which is clarity, public standards, knowing what needs to be done, and the most efficient process for getting it done.

Mr. WAXMAN. I thank you for your answers and especially your willingness to work with us. I think that is going to be very important.

Mr. PITTS. Chair thanks the gentleman, now recognize the vice chairman of the subcommittee, Dr. Burgess, 5 minutes for questions.

Mr. BURGESS. Thank you, Mr. Chairman.

Dr. Woodcock, always good to have you back before the committee.

And in fact, let me ask you a question, it is a little bit off topic today. Can you provide the committee with the status of the FDA's guidance on biosimilar naming?

Ms. WOODCOCK. It is still under consideration, it has not been be issued.

Mr. BURGESS. But when is that guidance likely to become final?

Ms. WOODCOCK. I do not know. However, I realize that it is urgent. We certainly hope that that program will get up and running this year.

Mr. BURGESS. Sure. Is there anyone advising, outside of the—anybody in the administration outside of the FDA itself? Is there anyone in the administration who is playing a role in this, giving you suggestions or recommendations with respect to the guidance?

Ms. WOODCOCK. Well, the administration has not come to a conclusion on this topic.

Mr. BURGESS. Who in the administration?

Ms. WOODCOCK. I would have to get back to you on that question.

Mr. BURGESS. I really would like for you to do that. And please expect some follow-up on that, because it looks to me as if the administration may be the impediment. You all are taking the fall for it. But it is far too long, and we actually need that.

Mr. Rannazzisi, you mentioned the memorandum of agreement. And you and Dr. Woodcock, I think, both acknowledge there is a memorandum of agreement that is pending; is that correct?

Mr. RANNAZZISI. Yes, sir.

Mr. BURGESS. You know, I don't know that I was aware of the memorandum of agreement. Is that something, can you make the text of the memorandum available to the subcommittee?

Mr. RANNAZZISI. I don't believe we can. Well, you would have to request that from the Department of Justice because it is actually between the Department of Justice and HHS.

Mr. BURGESS. Mr. Chairman, I would, then, suggest that the subcommittee do request that from the Department of Justice.

What is your time line? What is your expectation of when this will be accomplished?

Mr. RANNAZZISI. There are several components to this MOA, and I think there are just some things regarding proprietary information that needs to be passed, and I think that is what they were working on. The time limit, we hope to have it soon because it will make the process more efficient in scheduling once we get it in place.

Mr. BURGESS. Let me ask you the same question I asked Dr. Woodcock. Is there anyone in the administration that is affecting the timeline of this thing adversely?

Mr. RANNAZZISI. I don't believe so, no. It is——

Mr. BURGESS. But you won't share it with us so we couldn't possibly know that, could we? Since you won't share it with us, I am going to let my imagination run wild. It seems as if we have got someone in the administration that is holding this up, and you won't allow us to see the memorandum.

I would suggest, Mr. Chairman, that that memorandum of agreement be made available to the committee, and allow us to participate before you just visit this upon everyone who is involved in this process.

Mr. RANNAZZISI. Well, the problem is, sir, the memorandum of agreement is not finalized. If I gave you a memorandum of agreement right now, it is not a final agreement.

Mr. BURGESS. Share the draft with us.

Mr. RANNAZZISI. I am going to share something that is not finalized. Really?

Mr. BURGESS. Sure. We could help you. We could inform you. We could direct you. Sometimes the legislative and the administrative branches have worked together historically; Mr. Waxman, Mr. Dingell may be able to give you such a time that that happened, but this administration has not worked well with the legislative branch. Here would be an excellent opportunity to start.

Let me just ask you a question. Because it keeps coming up. We are going to hear from people on the supply side in the second panel.

But, what are you doing to draw the line between prosecuting those who overprescribe and not differentiating between those indi-

viduals who are legitimately trying to help? And bearing in mind the people they are trying to help is a pretty vulnerable population?

Mr. RANNAZZISI. Well, it depends. Again, every case is fact specific. The U.S. Attorney makes a judgment call on how we proceed on the cases based on the evidence that is presented to him or her.

The fact is, is the cases that we bring forward are generally pretty egregious. There is no doctor-patient relationship attached, these pain clinics that are operating in Texas, in Tennessee, and pretty much throughout the country now, there is no medical care for rogue pain clinics. They are operating as a facade to distribute controlled substances. In Florida——

Mr. BURGESS. And yet they continue to operate. So, you know, look, we do have to get a balance here taking care of people——

Mr. RANNAZZISI. Absolutely.

Mr. BURGESS [continuing]. Who really need the help that they are looking to receive. But sometimes it seems that all the DEA cares about is the number of enforcement actions and not real solutions to stop the abuse.

Mr. RANNAZZISI. That is not correct.

Mr. BURGESS. Provide to us data on how that—what you have done to stop the abuse without interfering with the legitimate practice, medicine, pharmacy, and distribution.

Mr. RANNAZZISI. If you would go on our Web site and look at the cases that are posted on our Web site, both on the cases against practitioners and also cases, the administrative cases against registrants, you will see that——

Mr. BURGESS. Well, it would have been great had you been prepared to provide that for us.

Mr. Chairman, let me ask that on this memorandum of agreement that we have been talking about, maybe at least the Department could provide us with the goals of what they are trying to achieve with this. Because, after all, we do have legislation pending before this committee that could be impacted as to what those goals are and how they would affect the practice of medicine pharmacy.

I'll yield back my time.

Mr. RANNAZZISI. May I finish my answer? I was not——

Mr. PITTS. You may finish.

Mr. RANNAZZISI. The administration has a four-pillar strategy, we follow the four-pillar strategy. Education, treatment, enforcement. The three basic tenets that we provide. Now, education, we provide education throughout the supply chain. We make sure that the supply chain, the registrants understand what their obligations are under the act. We provide them with red flags. We provide all of the case law, all of the administrative actions are posted on our Web site. We can direct them to particular circumstances and cases that they are inquiring about. We go out and look at them face to face and explain to them. The distributors we talk to before enforcement action is taken on them and give them an opportunity.

See, the fact is, we are not just enforcement, we are a regulatory organization. We go out to their—on-site and look at their facilities and determine if there is any exploitation within their site that could be cause of diversion, and I don't see where you think we are

just an enforcement agency, because we do so much more than enforcement. Talk to the pharmacists that have been to our classes.

Mr. BURGESS. Mr. Chairman, I will reclaim my time. But the vice chair brought it up.

The clarity and the consistency of these regulations at the level of the distribution are things that we hear about all the time. But let's go on with the hearing, and I will yield back.

Mr. PITTS. Chair thanks the gentlemen.

Now recognize the ranking member emeritus of the full committee, Mr. Dingell, 5 minutes for questions.

Mr. DINGELL. Thank you for your courtesy.

I am reminded today of when I was a very small boy and used to go to my granddad's farm out in Iowa. He had a bunch of chickens, and so to keep the chickens happy and keep them laying, when he would take the hens—rather, take the eggs out from under the hens, he would always put a porcelain doorknob in, and those damn chickens would sit on that porcelain doorknob until hell froze over.

I am reminded very much, Dr. Woodcock, of those happy days in Iowa and the chickens that were sitting there very happily on the bloody doorknob.

Now, we got 2 million Americans developed skin cancer each year. Sixty-one thousand developed melanoma last year, and 9,000 people died. How many of these do you have laying around down there at Food and Drug where you have an application on these? Just if you haven't got it, submit it for the record.

And how long has each one of them been laying around there? And when will you have action taken on each of them? And how long is it going to take to reach action on each of them? And why have you not been able to reach action on any of them as of this particular time?

Because I note, Doctor, that all of them have been approved and are being used in Europe and other places which have food and drug laws that are roughly equal to ours in terms of their safety.

Ms. WOODCOCK. The sunscreens are marketed as cosmetics in Europe.

Mr. DINGELL. Well, you are still sitting on them like a hen on a plastic doorknob, and I just find myself thoroughly dissatisfied. So if you will please submit that for the record, I believe it will be most helpful.

[The information apears at the conclusion of the hearing.]

Mr. DINGELL. Now, skin cancer is an epidemic in the United States. It is a pressing public health issue, is it not?

Ms. WOODCOCK. Yes.

Mr. DINGELL. All right. One of the best ways that we could ensure that the American people have access to the most effective sunscreen ingredients is to see to it that we allow those which are—been proven to be safe by long use in Europe; isn't that so?

So you are just sitting there looking at these things. Food and Drug is doing nothing about it. Very comfortable. You come up here and tell us how concerned we are that we are not doing anything.

So now, Doctor, do you believe that the American people should have the access to the latest safe and effective sunscreens to prevent skin cancer and melanoma?

Ms. WOODCOCK. Yes, I do.

Mr. DINGELL. Rest of Food and Drug agree with that?

Ms. WOODCOCK. Yes.

Mr. DINGELL. Now, Doctor, is it correct that there are eight applications for new sunscreen ingredients that have not received final determination under the time and extent application process at FDA? Yes or no?

Ms. WOODCOCK. Yes.

Mr. DINGELL. Do you believe that time and extent application process has ever worked as intended, yes or no?

Ms. WOODCOCK. No.

Mr. DINGELL. Yes?

Ms. WOODCOCK. No, I don't believe it has worked.

Mr. DINGELL. But you still got eight sitting around and Food and Drug sitting on them like a hen on an egg, right?

Now, do you believe that we need to reform this?

Ms. WOODCOCK. Yes.

Mr. DINGELL. And this is precisely why I have been joined by dear friend Mr. Whitfield to introduce the Sunscreen Innovation Act. The goal of this legislation is to ensure a predictable time frame for the review of new sunscreen ingredients while making sure FDA has the final say on all scientific and safety determinations.

Now, Dr. Woodcock, I know there is a request for technical assistance on the Sunscreen Innovation Act that is still outstanding. Will you commit to working with me on this legislation with a goal of resolve the remaining differences by the end of this month?

Ms. WOODCOCK. I will commit to working with you and with the Congress.

Mr. DINGELL. Well, and I would like to have the requested information that I have sought: How many applications you got sitting around down there? How long have they been there? What is holding up each and every one of them? And the other questions that I asked relative to the delay on them, if you please.

Ms. WOODCOCK. Certainly. There are eight applications for sunscreens to TEA. We have responded to two of those. We hope to respond to the remainder soon.

Mr. DINGELL. But in Europe they are all approved; right?

Ms. WOODCOCK. In Europe, they are marketed as sunscreens, I am not familiar, but I don't believe there is an application process, such as we are discussing here.

Mr. DINGELL. They are selling them, aren't they?

Ms. WOODCOCK. Correct.

Mr. DINGELL. And people are using them, aren't they?

Ms. WOODCOCK. Absolutely.

Mr. DINGELL. Do you have any evidence of them being unsafe or causing any danger or—there are two things that a pharmaceutical has got to be in this country, one, it has got to be safe, and the other, it has got to be effective. Do you have any evidence that any of these doesn't meet those two tests?

Ms. WOODCOCK. Well, that is part of the point of the TEA process, to have people submit to us what the evidence is about the safety in marketing.

Mr. DINGELL. You know the affectionate respect I have for you. But you also know that you are make a bad case today. You just can't defend the fact that these things have been sitting around for 8 to 12 years.

I yield back the balance of my time. Thank you.

Mr. PITTS. Chair thanks the gentleman.

Now recognize the gentleman from Kentucky, Mr. Whitfield, 5 minutes for questions.

Mr. WHITFIELD. Thank you very much.

Dr. Woodcock, you had indicated earlier that FDA had not taken a position on this legislation; is that correct?

Ms. WOODCOCK. That is correct.

Mr. WHITFIELD. And I think you said in your testimony and in response to Mr. Dingell's questions and others, you do agree that the TEA process is not working very well as it relates to sunscreens; correct?

Ms. WOODCOCK. Generally, I believe the monograph process is no longer functioning the way it was intended, and the TEA process is simply a route to get into the monograph process.

Mr. WHITFIELD. Do you consider the TEA process working?

Ms. WOODCOCK. I think if it were coupled with a more functional monograph process, it could work, yes.

Mr. WHITFIELD. Well, how difficult is it to get a more functional monograph process?

Ms. WOODCOCK. Well, as I said, we had a public meeting 2 weeks ago, and we had few really substantive suggestions there, except we should work harder.

Mr. WHITFIELD. Yes. Well, we all agree on that. But that is why, you know, at least we have a product here, a piece of legislation. Because there is genuine concern and everyone agrees that there is genuine concern.

Ms. WOODCOCK. I share the concern.

Mr. WHITFIELD. And when you have these eight applications, earliest of which was submitted in 2002, and you have only responded to two of them in 12 years, you know, something is not working.

Ms. WOODCOCK. That is a problem.

Mr. WHITFIELD. So Mr. Waxman, now, he pointed out that he was concerned about this advisory committee, and yet you have indicated in your testimony that in nonprescription drugs or in medical devices, you do have an advisory committee that makes recommendation, and, of course, we are talking about over-the-counter here, we are not even talking about prescription drugs, this is over the counter; and the medical devices, I mean, the artificial knee joints are placed in bodies, and that is recommended by advisory committee.

So are you genuinely opposed to the advisory committee part of this legislation and the process that we have set out in this bill?

Ms. WOODCOCK. I am not sure that the process you have set out will be functional. I mean, the problem with the current process is not functioning correctly, and I am worried that— I think that there are some good steps here, and we can build on this. And perhaps get something that will really work for everyone.

But, you know, if you press people too hard on matters of safety where you are exposing much of the population of the United States to something, you know, you need to give them the appropriate time and tools.

Mr. WHITFIELD. Well, I think you know, I hope that you——

Mr. DINGELL. Will the gentleman yield?

Mr. WHITFIELD. I would be happy to yield.

Mr. DINGELL. Is 12 years too much pressing? Is 8 years too much pressing? I don't find it so.

And I thank the gentleman for yielding.

Mr. WHITFIELD. Well, I mean, I agree, I mean, I think we all agree this is ridiculous. Twelve years.

Ms. WOODCOCK. We all agree. I am not defending the fact that it has taken that long. There are a variety of factors, but that is not appropriate and this process is not working.

Mr. WHITFIELD. And these ingredients are being used elsewhere. But, the commitment that I am asking for from you and others at FDA is to work with us in a sincere way to improve this process for the health and welfare of the American people. Because we know that skin cancer is the most prevalent cancer out there.

So you will make that commitment to me and we can work——

Ms. WOODCOCK. Yes, we would be delighted to work with you, although we would like to reform the whole process of the monographs. Because the sunscreens are just a microcosm, as I said, of a process of has encountered tremendous problems.

Mr. WHITFIELD. Well we are focused on sunscreens because of the prevalence of skin cancer.

And in concluding, I know my time hasn't quite expired yet, but I would like to submit for the record, Mr. Chairman, a letter of support from the American Academy of Dermatology Association.

Mr. PITTS. Without objection.

[The information follows:]

April 4, 2014

The Honorable Joe Pitts
Chairman
Subcommittee on Health
Committee on Energy & Commerce
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Frank Pallone, Jr.
Ranking Member
Subcommittee on Health
Committee on Energy & Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Pitts and Ranking Member Pallone:

The American Academy of Dermatology Association (Academy), which represents more than 13,000 dermatologists nationwide, commends you for holding a hearing on (H.R. 4250/ S.2141), the Sunscreen Innovation Act, which seeks to ensure that sunscreen ingredients are reviewed by the U.S. Food and Drug Administration (FDA) within a predictable timeframe. We applaud you for raising awareness of this issue and look forward to working with you and the FDA to ensure that sunscreen products are thoroughly reviewed in a predictable timeframe.

Skin cancer is the most common cancer in the United States and one in five Americans will develop skin cancer in their lifetime. Research has shown that sunscreen helps reduce the risk of skin cancer and is essential to protecting the public from UV radiation. Skin cancer prevention is a top public health priority and we are committed to working with you and others in Congress to reduce the risk of skin cancer and promote safe sun behavior.

While we recognize and applaud the FDA's progress in finalizing the sunscreen labeling and testing requirements, there has long been a need for more timely review of sunscreen products, a fact of which our dermatologist members are acutely aware. A more timely review process has the potential to reduce Americans' risk for skin cancer by ensuring that they have access to the safest, most effective sunscreens available. We urge the Congress and the FDA to work together to establish a process that promotes the timely review of sunscreen ingredients, while ensuring consumer safety and product efficacy.

We appreciate your continued leadership on this issue and look forward to working with you in the fight against skin cancer. The Academy would like to serve as a resource to you and your subcommittee as you continue to address these important issues. If you have any questions or if we can provide any additional information, please contact Niva Haynes, the Academy's Manager, Congressional Policy, at nhaynes@aad.org or (202) 712-2608.

Sincerely,

Brett Coldiron MD

Brett M. Coldiron, MD, FAAD
President, American Academy of Dermatology Association

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Mr. WHITFIELD. And with that, I would yield back the balance of my time.

Mr. PITTS. Chair thanks the gentleman.

And I now recognize the gentleman from Texas, Mr. Green, 5 minutes for questions.

Mr. GREEN. Thank you, Mr. Chairman.

Thank you and both our Ranking Member Pallone for having this hearing, and our witnesses for taking the time.

First, Dr. Woodcock, I learned just recently that the FDA advisory committee voted last week to recommend that the FDA approve two new antibiotics. These drugs were approved based on the GAIN Act that we passed, this committee passed last Congress, and I know they were in the development stage and before GAIN was enacted and their approval was welcome news. And of course we didn't get everything we wanted to out of the Senate, so we have a real bipartisan bill called Adapt that we are working with FDA on now. But I appreciate that.

Mr. Rannazzisi, the FDA is vital to meeting the growing challenges our country faces, including reducing prescription drug abuse, one of our fastest growing public health threats. I commend the FDA for meeting the public safety threats head-on and appreciate it. Because I have seen those same clinics in my area, and frankly, we have a pretty aggressive U.S. Attorney sometimes that gets involved in them. So I am glad of that.

However, the FDA, as it tackles its mandate in a number of fronts, it is critical that patients who desperately need these medicines have access without undue delay, particularly those with limited potential for abuse or addiction. In 2011, I sent a letter to FDA after learning it takes an average of 5 to 6 months for the DEA—I sent a letter to DEA—5 or 6 months for DEA to schedule a medicine, notwithstanding the drug's classification or potential for diversion. Since then, we have learned that the delays have not shortened and may actually have increased.

I am concerned over the substantial and growing length of time between when the FDA approves a new molecular entity and provides a scheduling recommendation and when the DEA schedules the drug. According to testimony from Dr. Fountain of the Epilepsy Foundation and University of Virginia School of Medicine, the average time between FDA approval and the DEA's final scheduling increased from an average of 49.3 days in the 1990s to an average now of 237.6 days. These delays can result in lack of patient's access to potentially life-saving therapies. Also, a lack of transparency of the DEA scheduling process provides disincentives to companies developing these therapies.

Mr. Rannazzisi, specifically what is the sequence of the internal actions at DEA from a receipt of recommendation by the FDA to the DEA's Federal Register publication?

Mr. RANNAZZISI. When we receive the recommendation, our pharmacists, our pharmacologists begin the process of drafting the eight factor. They look at all the information that has been presented by FDA, and then all the information that they have procured over the last however long when they know the drug is coming. That is a lot of scientific data. They look at all the abuse data, if there is any abuse data.

Remember, there is transparency in the system. It is called the Administrative Procedures Act. The APA is our guidance on how we get drugs into the scheduling process.

We provide a period of public comment after we do the notice. We have to look at every one of those comments. At that point in time, the public may request a hearing from an administrative law judge.

So the process is very transparent. It just takes time because it is a science. The scientific method takes time, and our scientists, just like the FDA scientists, have to ensure that we have the justification to prevail in court.

Mr. GREEN. Well, but it is still is the average increase from the late 1990s to today was from 49 days to 237 days.

Mr. RANNAZZISI. I don't know where that is coming from.

Mr. GREEN. OK, we will get it to you. We will get the numbers there. Because if that is the issue, then somewhere along the way, whether you are not giving some kind of courtesy to what the FDA scientists did and, I expect—you know, I want FDA to do it. But I also know that they expect——

What is your opinion of the shortest time that might plausibly achieve to accomplish this process from start to finish? Is there an average time that the DEA aims for?

Mr. RANNAZZISI. I don't believe there is. Because it depends on—if it is a new molecular entity, that is going to take longer than an established drug that is in a different, you know, a combination of formulations. A drug that we know, a drug that we have done very significant research on.

Mr. GREEN. Well, I know Congress and the FDA is taking steps to improve the transparency and consistency of the regulatory process for new drugs, to provide patients access for these new therapies in a timely manner. The lack of predictability, though, and timing of the DEA scheduling decisions, at least on certainty and drug development, and the process and some delays.

Delays in patient access to new therapies should be addressed in a manner that doesn't threaten public health or weaken the DEA's ability to ensure public safety. But somewhere along the way, we need to make the system work faster than we are seeing.

And I know I am out of time, Mr. Chairman. Thank you.

Mr. PITTS. Chair thanks the gentleman.

Now recognize the gentlelady from North Carolina, Mrs. Ellmers, 5 minutes for questions.

Mrs. ELLMERS. Thank you, Mr. Chairman.

Dr. Woodcock, and thank you to our panel for being here today.

I do have questions about the sunscreen. I think that we have gone over that pretty well here in committee, and as a nurse prior to coming to Congress, obviously, this is an issue that we are all very concerned about, with skin cancer. And I guess what I would like to hear from you, is, please, can you just tell our committee that you are committed to improving upon this issue? I mean, obviously the time has been too long.

Ms. WOODCOCK. It has been too long. As I said a number of months ago when I appeared before this committee, I think I am almost as frustrated as the manufacturers and some of you all

about this issue. So I do commit to improving it. We have already taken steps to speed up this process and move it along.

Mrs. ELLMERS. OK. Moving along to some of the issues having to do with Ensuring Patient Access and Effective Drug Enforcement Act of 2013.

There again, a very important issue. This is one that I think many of us, you know, we understand the drug abuse issue, we understand the deaths that have occurred as a result, and we need to be proactive on this issue.

One of the solutions that has been put forward that holds promise is the development of abuse-resistant prescription drug products. Such formulations make it harder for individuals to break down prescription drugs for abuse purposes. Obviously, that would be the actual drug itself.

And I would just like to thank you for the work that you have been doing, and I do want a clarification. My understanding is that there is some progress being made right now, that the agency is contracting with some of the academic and research institutions, utilizing research grant funding through the Generic Drug User Fee Act, to study this evaluation of abuse-deterrent formulations. Is this correct?

Ms. WOODCOCK. I can't comment on the funding. But the research is correct, yes.

And we are trying to develop a framework so that as—we don't want to approve abuse-deterrent formulations that then disincentivize people from developing better ones. We have approved one, and it has some abuse-deterrent properties. However, we need to get much better than that. So what we need to do is kind of establish both the—you know, the carrot and the stick incentives, and we are doing research in our own laboratories as well as elsewhere.

Mrs. ELLMERS. Will the FDA in its guidance provide flexibility and encourage manufacturers to pursue alternative methods and approaches to develop meaningful abuse-deterrent technologies rather than a single development path such that the innovation and advancement in science are effective harness—I mean, are there incentives that are being put forward?

Ms. WOODCOCK. Absolutely. That is part of the strategy, is to have multiple different abuse-deterrent mechanisms so that if one might be overcome—Mr. Rannazzisi and I were talking earlier that criminals are always sort of one step ahead of you.

Mrs. ELLMERS. Sure.

Ms. WOODCOCK. So we need to keep encouraging that innovation.

Mrs. ELLMERS. Thank you, Dr. Woodcock.

And, Mr. Rannazzisi, I think we have—there is a lot of discussion of clarity and process on how things are moving forward. You know, we are hearing repeatedly that registrants are very concerned about the lack of clarity. However, you have outlined that this is something that the DEA is working on. And you say that you, and I am going to quote you, that you give the opportunity for the registrants to come forward, that there is plenty of opportunity for them.

Is there a process for appeal of a decision by the DEA? And can you describe that, if a registrant is found to have been revoked, their DEA ability to produce suspended or revoked?

Mr. RANNAZZISI. I believe they could take it to district court.

Mrs. ELLMERS. You believe or you——

Mr. RANNAZZISI. They could take it to the district court.

Mrs. ELLMERS. OK, when we are talking about the hearing process, I know my colleague across the aisle, Mr. Green, was referring to some of the hearing procedures, and there seems to be a lot of discrepancy on timing of how long a hearing would take. Can you tell us what the average time is? I know my colleague had said that he had heard of a time frame, and there again, I don't know exactly the number. But you basically said you weren't sure where that number came from. Can you tell us?

Mr. RANNAZZISI. I don't believe that was for a hearing; I believe that was for—I think that was for scheduling. The timeframe it takes for scheduling action.

Mrs. ELLMERS. To schedule?

Mr. RANNAZZISI. Yes.

Mrs. ELLMERS. OK.

Mr. RANNAZZISI. For a hearing, again, it depends on if it is an immediate suspension order with an order to show cause or just a plain, ordinary——

Mrs. ELLMERS. So to that point, how long would you say that it does take a hearing to be scheduled? And then I know my time is——

Mr. RANNAZZISI. When we do an immediate suspension order with an order to show cause, the date of the hearing is on the order to show cause, and I believe if it is within 30 days.

Mrs. ELLMERS. OK. Within 30 days. Thank you so much.

My time has expired.

Mr. PITTS. Chair thanks the gentlelady.

Now recognize the gentleman from Florida, Mr. Bilirakis, for 5 minutes for questions.

Mr. BILIRAKIS. Thank you, Mr. Chairman. I appreciate it very much.

And again, thank you for your testimony. Thank the panel.

Mr. Rannazzisi, numerous seniors in my district are complaining. They call my office on a regular basis because they can't get their pain medications, and the pharmacists have stated that DEA is placing arbitrary and vague quotas on wholesalers and pharmacies.

I also hear that DEA is telling pharmacists not to fill prescriptions that raise red flags, but has given no guidance about these red flags. I want to give you an opportunity to respond.

But considering DEA's mission to ensure an adequate, uninterrupted supply of controlled medications for patients' needs, what is DEA doing to address the impacts on patients that these confusing policies are causing?

And I know we have touched on this earlier. But if you could elaborate, I would appreciate it.

Mr. RANNAZZISI. To start, actually, last year we were down in Florida, and we trained, I think, 1,400 pharmacists on what their role is as far as corresponding responsibility and how they review prescriptions. And we talked about the red flags, and we are trying

to do that in every State. The fact is that we do not want patients to go without their medication, true pain patients that need their medication. We don't want that. But there is no quota——

Mr. BILIRAKIS. Tell me what you are doing about it? Because, I mean, we get calls on a regular basis.

Mr. RANNAZZISI. There are no quotas set by DEA concerning how much downstream drug goes from the wholesalers to the pharmacies. The wholesalers are required to report suspicious orders. They should know their customers, they should do due diligence. But they have certain things that they must do to reconcile an order before it is sent downstream. The pharmacies that are ordering those drugs, again, have a corresponding responsibility to ensure that the prescriptions they are filling are legitimate, are valid, are for legitimate medical purpose.

That is exactly what happened in Sanford. In Sanford, Florida, those two pharmacies that were stripped of their registration, they were not doing any corresponding responsibility, and there are wholesalers that were sending drugs to them, were not doing their due diligence.

And they were filling hundreds of thousands of tablets per year. And most of those prescriptions were not for legitimate medical purpose. They were also filling prescriptions for doctors that didn't have a valid DEA registration.

See, the problem is, is corresponding responsibility has a quite a few different components to it. And this has been in place for 40-plus years.

Mr. BILIRAKIS. Let me go on to the next one. Thank you for that answer.

Does DEA meet the chronic pain patients groups and others to ensure—do they meet with chronic pain patients groups and others to ensure that agencies understand the need and concerns of patients? And yes or no, and please elaborate.

Mr. RANNAZZISI. If we were asked to meet with a pain patient group, yes, we would.

Mr. BILIRAKIS. How often are you asked?

Mr. RANNAZZISI. We meet with treatment groups, for instance, American Association of Opiate—AATOD. AATOD. We meet with them. We meet with physicians' groups. We meet with pharmacy groups. Specific patient groups when they request.

Mr. BILIRAKIS. What is discussed during those meetings? Give me an example.

Mr. RANNAZZISI. We meet with—for instance, AATOD, we give them a trend analysis of what is going on in drug diversions, what drugs are being used. Then we ask them, what are you seeing?

It is the same thing with community groups. We go into the communities all the time. In fact, I am doing a community function with doctors, pharmacists, and community leaders in Weymouth, Massachusetts, next month.

Mr. BILIRAKIS. Thank you very much for the answer.

Dr. Woodcock, Zohydro is a new extended-release opioid approved for the market by FDA but without any requirement for abuse deterrents. I find this disturbing because FDA has taken a number of steps to make sure opioid drugs would have these deterrents.

FDA has even blocked generics from entering the market because they lacked abuse-deterrent properties.

Some brand name drug makers have changed their drug to include abuse deterrents, saying their previous versions were unsafe. 28 State attorneys general sent a letter to FDA asking to reconsider the position on Zohydro. Your own advisory council did not favor approving this drug, from what I understand.

The drug company's own literature says an adult could overdose on two capsules, a child could die from swallowing just one, an addict can easily crush it and receive a dangerous and potentially lethal high.

Why would you approve a drug with 5 times as much hydrocodone as Vicodin with no abuse-deterrent properties?

Ms. WOODCOCK. Well, first of all, there is only one drug that we have approved, and it is on the market, it is a high-potency opioid that has abuse-deterrent properties. All other opioids on the market do not have abuse-deterrent properties——

Mr. BILIRAKIS. But why was that drug approved?

Ms. WOODCOCK. Pardon me?

Mr. BILIRAKIS. Why was that drug approved?

Ms. WOODCOCK. Zohydro?

Mr. BILIRAKIS. Yes.

Ms. WOODCOCK. All right. Zohydro is a single ingredient, high-potency opioid. You can't take—you said Vicodin. You can't take a lot of those if you have severe pain because it has acetaminophen in it, and it will be toxic to your liver, and acetaminophen is a very big cause of liver failure, OK, and liver transplants. Because people are getting too much acetaminophen. So we need high-potency opioids for people who have severe pain.

Mr. BILIRAKIS. But why wouldn't we make sure that it has abuse deterrent prior to approval?

Ms. WOODCOCK. Abuse deterrence is really in its infancy, unfortunately. We have approved one product with abuse-deterrent properties. Those are quite limited, abuse-deterrent properties. I don't want to talk about that further. But they are present, OK. But we have a long way to go, and almost all the opioids on the market do not have abuse-deterrent properties.

Mr. BILIRAKIS. OK. Thank you very much.

I yield back the balance of my time.

Mr. PITTS. Chair thanks the gentleman.

Now recognize the gentleman from Virginia Mr. Griffith for 5 minutes for questions.

Mr. GRIFFITH. Let me pick up on some of what my colleague was just talking about. Because a number of people are having difficulty, particularly at their pharmacies, based on some of the new rules or regulations that have come out.

In fact, I was standing in my local pharmacy waiting to get some drugs for my son a couple of months back, and there was a lady there getting some medication for her mother, and a local judge get something medication for his wife, who just had surgery, and the pharmacist, while I was standing there, had to inform both of them that they had used their allotment under the DEA's new regulations of those particular types of drugs, and they would have to come back next week.

Now, wasn't a problem for the judge. He was coming in, you know, a little early so that he didn't have that pressure, and that she would have the medication she needed.

But for the lady who was getting drug for her mom, it was very stressful. She said, my mother needs this medication. I promised them I would look into it.

What do I tell them? I mean what are we doing to make sure that these folks are heard from and that the drugs are available when there is a valid prescription for a valid patient who presents that to a pharmacist?

Mr. RANNAZZISI. We talk to the pharmacists about this. The pharmacists are being told by their distributors that DEA is setting up a quota. There is no quota, there has never been a quota when it comes to distributors. I defy anybody to show me where there is a quota.

The fact is, we ask the distributors to know their customers and ensure that the drugs they are sending downstream are you know, if it is a suspicious order, that it is reconciled before it is sent. But there has never been a quota to, going downstream from wholesaler to pharmacy. The pharmacists are reporting this. That is what they are being told, but we are not telling them that.

Mr. GRIFFITH. Well, can you figure out why it is that has happened? I mean, are you all making the distributors worry about it? So that if this particular pharmacy deals mostly, not exclusively, obviously, but mostly with older patients, because it has been there in one form or another on Main Street in Salem, Virginia, for about a hundred years, and so a lot of their folks are people that have been in the community for a long time. Some of them are fourth generation, et cetera. But some of them are also older, which means you are going to have, probably, more of those prescriptions.

I think maybe that you all need to talk with the distributors again make sure that if it, you know, is a long-term situation, that drugstore may be a little higher than the CVS down the street just because they have been there forever. So their population by definition is going to be an older population.

Mr. RANNAZZISI. And I understand that, and DEA does not want anybody to go without their medication, if they are a legitimate patient. But the problem is I have no control to tell a distributor to distribute to a pharmacy.

And the fact is that, if they just complied with the act and complied with the regulations, there wouldn't be a problem.

Mr. GRIFFITH. Well, clearly, there is confusion somewhere. And I hope you will work with us to get that resolved.

Let me move to another subject now, involves the DEA, and also may involve pain medication. Most people are unaware of this, and let me state right up front, I do not support recreational use of marijuana. But, believe it or not, Virginia has the oldest medical marijuana law on the books. It was passed in 1979. Either with the hope that the DEA was going to come around and say these are certain legitimate uses, or in the hopes of encouraging the DEA to do that. But it was passed in 1979. It's 182251.1. And right now, it—as I think is the proper way to deal with medicinal marijuana, it requires a valid prescription from a valid physician, and then it has to be taken to the pharmacist to be filled.

Virginia set the construct up, and they did it just for cancer and glaucoma. Because in 1979, that is all the evidence would have justified. So they were trying to work within the construct of the Federal law and the DEA. Needless to say, no doctor in his right mind or her right mind is going to prescribe it, because that would get them in all kinds of trouble with the DEA.

But when is the DEA going to take a look at medicinal marijuana? Forget the crazy laws, as I sometimes call them, that California has passed and some other States that make it open. But a law that would allow the legitimate use of marijuana, smoked marijuana as well, not just the pill form, for purposes of relieving people on any number of areas, but particularly on cancer and glaucoma. Because we know that has been—that science has been out there for decades.

Mr. RANNAZZISI. Well, I think I will answer it and then I am sure my colleague would love to answer it as well——

We have a—maybe not.

We have a——

Mr. GRIFFITH. Our impediment is the DEA won't allow it.

Mr. RANNAZZISI. Well, a petition process where a person could petition the Government to schedule, reschedule, or move through the schedules any drug.

Now, in the case of marijuana, there are several factors. But one is it is based on approval as a medicine, and FDA has looked at this twice now, I believe, and the science is not there. There is no scientific evidence that shows that smoked marijuana is beneficial as a medicine.

Mr. GRIFFITH. Well, and let me say, because my time is running out. I haven't ever used marijuana recreationally or otherwise. But I will tell you that I have numerous constituents who feel that it has been of assistance to them, and I tell a story when I go out and talk to people.

Decades ago, I went to—I knew somebody who was having a problem with cancer, and the story was told to me at the time by some of his friends that the doctors put on his chart "Nobody goes in this room from 11:00 to 12:00, and then bring his food at 12:00." Because the doctors recognized that that would give him some relief.

He was trying to stay alive as long as he could so he could see his 2-year-old child a few more days. Every day he could get was important. I am telling that story in a high school group, what I call my high school town halls. This kid raises his hand up, and I thought it was going to be some question about, what about recreational use? And he says to me, "They did that for my daddy too." And I was in a different part of my district, and my district is about 4 hours long; there are no way they could have been anyway close, plus the kid was way too young. It wasn't the same deal. So we have got doctors out there who are recognizing it.

Further, I would submit there is a Washington Post article that says that it is difficult to get permission to even do the scientific studies because of the DEA.

So I ask you to work on that, because that is a serious issue, and the American people support it for legitimate use, not abuse. Not recreational, but for legitimate use.

I yield back.

Mr. PITTS. Chair thanks the gentleman.

Now recognize the gentleman from New Jersey, Mr. Lance, 5 minutes for questions.

Mr. LANCE. Thank you, Mr. Chairman.

Good afternoon to you both.

I don't want to beat a dead horse. I agree with Congresswoman Ellmers on the issue of the sunscreen, and I hope quick action can be taken, and I would personally benefit. I am in a situation where the sun is poison to me. And I presume that—I like going to the dermatologist about as much as I assume you like hearing us bark at you this afternoon, and I want to work with you so that we might bring these European components to market here in a safe and effective way, Dr. Woodcock.

On a completely different issue. I would like to ask you a couple questions about special protocol assessments. It is my understanding that Congress intended that these agreements should be binding on both parties except when a substantial scientific issue has come to light, after an agreement has been reached and testing has begun.

Dr. Woodcock, could you explain to the committee what type of scientific evidence would be so substantial as to cause the FDA to rescind a special protocol assessment for a drug that was otherwise safe and which had met all of its end points?

Ms. WOODCOCK. Certainly. Well, in some cases, for example, we would learn for a class of drugs that there was a new safety problem, and say for the nonsteroidal, anti-inflammatory agents, we learned, as you recall with Vioxx and others, that they caused cardiovascular events, myocardial infarction or so, and if we had said, you don't have to study that in depth in the premarket assessment, and then subsequently we learned that that whole class of drugs caused that problem, we would be remiss in approving that drug unless that safety problem had been addressed.

OK. Now, similarly on the efficacy side, the special protocol assessment has at what end points, how you study the drug and what end points you use, and often we use surrogate end points of different kinds or intermediate clinical end points or whatever.

And if we find that, in the interim, there is evidence that comes to light that that end point may no longer be valid and actually predict what we are looking for, then we might say we cannot any longer for any applicant rely upon that end point because its validity has been brought into question.

However, I would say that out of—we have entered into almost a thousand agreements since 2007. And we have only rescinded 10 over that whole time.

Mr. LANCE. As a matter of public policy, I do think the FDA should be accountable for continued diligence in identifying issues that bear on the continued enforceability of an SPA agreement, and then notifying the sponsor of such issues within a reasonable period of time after the FDA has become aware of a new situation. Is my understanding correct as to how that system works?

Ms. WOODCOCK. I am not sure it is a system. But I totally agree with you that is what we should do.

Mr. LANCE. Thank you. I hope to work with you in a more extended way on this issue, and I appreciate your attention to the matter.

And, Mr. Chairman, I yield back a minute and 20 seconds.

Mr. PITTS. Chair thanks the gentleman.

Now recognize the gentleman from Pennsylvania, Dr. Murphy, 5 minutes for questions.

Mr. MURPHY. Thank you, Mr. Chairman. I yield my time to you.

Mr. PITTS. All right. Thank you.

Mr. Rannazzisi, with respect to scheduling, is it your understanding that you cannot speak to, at the very least, the goals of the MOA that DEA and FDA are trying to achieve?

Mr. RANNAZZISI. The MOA will give us the opportunity to share information, both proprietary and information pertaining to our different databases, on just about anything in the process. Not only scheduling, but other things as well, and that is something that has never been in place before. So that memorandum of understanding, will give us the opportunity to move information back and forth under agreement of how it should be maintained.

Mr. PITTS. Dr. Woodcock, is that your understanding?

Ms. WOODCOCK. Absolutely. And I would like to add that I think it will be extremely beneficial in some—we work closely with DEA, but we are not able to share certain information, which impedes, say, in the premarket realm, us working as closely as we would like.

Mr. PITTS. Thank you.

Will you both commit to working with the committee to provide this information, as much information as possible, by the end of the week to ensure that we can consider your efforts as we work on our legislation?

Ms. Woodcock?

Ms. WOODCOCK. Yes, as much information as possible, certainly.

Mr. PITTS. Mr. Rannazzisi?

Mr. RANNAZZISI. I would agree with that.

Mr. PITTS. Well, that concludes the questions.

Mrs. ELLMERS. Mr. Chairman, do you mind if——

Mr. PITTS. I yield to Ms. Ellmers.

Mrs. ELLMERS. Mr. Rannazzisi, I just have one question that just is burning in my mind. As we have had these discussions on the process that the DEA is taking, I guess I just don't understand why we are not going after the bad actors, those physicians who are the ones who are writing the prescriptions to those patients. We know they are out there. What is the DEA doing about the physicians who—because, look, I am in the medical community. I know it exists. And I know that I have known doctors who have abused this system. Where is the progress there?

Mr. RANNAZZISI. Absolutely. Well, when we started initially with the Internet, we went after the physicians, the physicians that were prescribing over the Internet.

But the problem evolved. As soon as Congress passed Ryan Haight, they immediately started opening rogue pain clinics. It closed down the Internet, and rogue pain clinics flourished. First in Florida, then in Georgia, Tennessee, Missouri, Kentucky——

Mrs. ELLMERS. OK, to that point, and I understand. Because—you are pointing out a—we kind of went on an explosion. But, you know, we all live in small—I live in a very small community. I live in a small community where I know this is happening.

Mr. RANNAZZISI. Yes.

Mrs. ELLMERS. What is the DEA doing in those communities where you know they exist?

Mr. RANNAZZISI. We have right now 66 task forces, State, local, and Federal task forces, that are working with HHS, OIG, and FBI and other agencies, and we go after these doctors.

But the problem is, there are so many bad clinics right now. We are kind of overwhelmed, just as the States are. If you look at what is happening in Georgia, there are a lot of bad actors out there. And we are doing our best to keep up with them.

As it spreads, as it spreads, for instance, in Texas, we are just—you are overwhelmed by the numbers. And these are not clinics that provide medical care. These are things that distributing——

Mrs. ELLMERS. Pain. And to that point, and then we will finish here so that we can move on. But, you know I do believe there is value in making an example of a physician, a physician's office that repeatedly abuses the system and continues to be that cycle.

Because, unfortunately, what we have learned is that those who are in the community and they are drug seeking and drug shopping, they network very well. They know who the physicians are that will write those prescriptions, and I would just imagine that, you know, maybe even just taking a step backward and just looking at it in a more singular level, especially in some of our rural communities, that that might go a long way.

Mr. RANNAZZISI. That is exactly why the administrative—the immediate suspension order is so important. Because I could stop the hemorrhaging by issuing the immediate suspension order, and, quite frankly, the burden is a lot less than charging the bad actor with a crime. Not that he won't be charged. But if I want to stop the hemorrhaging, I use the immediate suspension order to stop him from doing it. Then working with the State backtrack, and hit him with a criminal charge.

So, yes, it happens, but it takes time. All of these cases take time. It is not distributing heroin or LSD. Those are illegal per se. It is distributing a legal substance illegally.

Mrs. ELLMERS. Well, thank you, sir.

And thank you to the chairman for allowing me to use the remainder of his time.

Mr. PITTS. All right. Chair thanks the members.

Mr. Pallone has a U.C. request.

Mr. PALLONE. Thank you, Mr. Chairman, I have to just ask unanimous consent to submit into the record a comment letter on H.R. 4069 from the Drug Policy Alliance. I believe you have it.

Mr. PITTS. Without objection, so ordered.

[The information follows:]

April 7, 2014

The Honorable Joe Pitts
United States House of Representatives
Chairman, Subcommittee on Health
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Frank Pallone, Jr.
United States House of Representatives
Ranking Member, Subcommittee on Health
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Pitts and Ranking Member Pallone:

The Drug Policy Alliance is the nation's leading organization advancing alternatives to current drug policy that are grounded in science, compassion, health and human rights. Since 2000, the Drug Policy Alliance has promoted reforms that reduce harms both from drugs and ineffective drug policies. A major focus of our efforts is the advancement of policies at both the federal and state level that can help reduce fatalities from drug overdose. Overdose is now the number one cause of injury-related death in the United States, having surpassed injury-related deaths due to motor vehicle collisions. The sense of urgency around this public health crisis has never been greater.

The Drug Policy Alliance is writing in regards to the "Ensuring Patient Access and Effective Drug Enforcement Act," H.R. 4069, which is the subject of a hearing today by the Subcommittee on Health. Although the Drug Policy Alliance is encouraged that the Subcommittee on Health is taking action to address prescription drug misuse, which is a major risk factor for overdose, we are concerned that H.R. 4069, as currently drafted, misses an important opportunity to directly address and help abate the overdose crisis.

H.R. 4069 establishes a working group of expert stakeholders to examine prescription drug abuse. This "Prescription Drug Abuse Working Group" is assigned the duty of studying issues pertaining to the diversion of prescription medications from the industry supply chain and non-medical use of these medications. This working group is also tasked with issuing a report to Congress that contains specific recommendations to prevent or reduce prescription medication diversion and abuse for the Food and Drug Administration, Drug Enforcement Administration and other federal and state agencies.

The mission of this working group has potential to put forth important recommendations on ways to reduce harms from prescription medication diversion and abuse. We urge Members of the Health Subcommittee to incorporate overdose mortality and prevention into the mission of this working group. There is no greater consequence of prescription drug abuse than the loss of life to an overdose.

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We are the Drug Policy Alliance.

Despite the scale of the overdose crisis across the United States today there is little coordination among federal and state agencies to reduce overdose fatalities. The "Prescription Drug Abuse Working Group" should be empowered to examine the effectiveness of existing Federal and community overdose prevention initiatives and make recommendations for reducing overdose mortality in its report to Congress.

The Drug Policy Alliance wishes to bring to the attention of Members of the Health Subcommittee relevant portions of H.R. 4169, the Stop Overdose Stat (S.O.S.) Act, which has been referred to this Subcommittee. In particular, section five of H.R. 4169 would create a task force similar in membership and scope to the "Prescription Drug Abuse Working Group" proposed in H.R. 4069 but for the purpose of developing a plan to reduce overdose fatalities. H.R. 4169 specifically directs the task force to develop a plan to reduce overdose deaths and issue a report to Congress that includes recommendations for improving and expanding overdose prevention programming.

In addition, section six of H.R. 4169 identifies several areas where research is needed that we urge Members of the Health Subcommittee to adopt as duties of the "Prescription Drug Abuse Working Group" authorized by H.R. 4069, should the Health Subcommittee proceed to legislative markup of H.R. 4069. These research areas include:

- Examination of circumstances that contribute to drug overdose and identification of drugs associated with fatal overdose; and
- Evaluation of existing overdose prevention methods; and
- Examination of scientific research concerning the effectiveness of overdose prevention programs; including how to effectively implement and sustain such programs

In addition, the Drug Policy Alliance encourages Members of the Health Subcommittee to incorporate into the "Prescription Drug Abuse Working Group" stakeholders identified in section five of H.R. 4169.

Given the scale of the overdose crisis and the lack of a robust and coordinated federal response, duties of the "Prescription Drug Abuse Working Group" should be expanded to consider the above objectives. Doing so could help mitigate the threat that overdose continues to pose to public health and safety and advance the goal of saving as many lives as possible. Thank you for considering our comments.

Sincerely,

Bill Piper
Director, Office of National Affairs

Mr. PITTS. That concludes the questions of the members here at this point. We will send follow-up questions to you. We ask that you please respond as soon as possible.

And the subcommittee will take a 5-minute recess as we set up for the second panel. Subcommittee is in recess.

[Recess.]

Mr. PITTS. We will ask the witnesses to please take their seats. On our second panel today we have five witnesses, Dr. Nathan Fountain, Chair, Medical Advisory Board, Epilepsy Foundation; Mr. John Gray, President and CEO Healthcare Distribution Management Association; thirdly, Mr. D. Linden Barber, Partner and Director, DEA Compliance Operations, Quarles and Brady; fourthly, Ms. Wendy Selig, President and CEO of the Melanoma Research Alliance; and Mr. Scott Faber, Vice President of Governmental Affairs, the Environmental Working Group.

Thank you all for coming. Your written testimony will be made part of the record. You will each be given 5 minutes to summarize.

And, Dr. Fountain, we will start with you. You are recognized for 5 minutes.

STATEMENTS OF NATHAN B. FOUNTAIN, CHAIR, PROFESSIONAL ADVISORY BOARD, EPILEPSY FOUNDATION OF AMERICA; JOHN M. GRAY, PRESIDENT AND CHIEF EXECUTIVE OFFICER, HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION; D. LINDEN BARBER, PARTNER AND DIRECTOR, DEA COMPLIANCE AND LITIGATION PRACTICE, QUARLES & BRADY, LLP; WENDY K.D. SELIG, PRESIDENT AND CHIEF EXECUTIVE OFFICER, MELANOMA RESEARCH ALLIANCE; SCOTT FABER, SENIOR VICE PRESIDENT FOR GOVERNMENT AFFAIRS, ENVIRONMENTAL WORKING GROUP

STATEMENT OF NATHAN B. FOUNTAIN

Mr. FOUNTAIN. Thank you.

Thank you, Chairman Pitts and Ranking Member Pallone, for allowing the Epilepsy Foundation to provide comments to H.R. 4299 today.

I am a neurologist at the University of Virginia and also director of the comprehensive epilepsy program there. But I am reporting the Epilepsy Foundation today—representing the Epilepsy Foundation today as the chair of the professional advisory board. The Epilepsy Foundation is the largest patient advocacy group in the United States for epilepsy, indeed, in the world.

And the two facts to start with, at least before our earlier discussion, I thought were sort of not in dispute, was first that DEA has progressively taken longer to schedule drugs after approval by the FDA. So the information that was quoted earlier is that in a referenced publication that we can provide if it is not in my written comments, is that between the years 1997 and 1999, the average drug approval by DEA, so the time to scheduling, was 49 days, so about a month and a half. In the period between 2009 and 2013, that increased to 237 days, or about 8 and a half months. So from 1 and a half months all the way to 8 and a half months.

This second point that I think is at least clear to me is that DEA has always agreed with FDA's recommendations for scheduling, at least according to the same published analysis I referred to before. I think we heard that as well.

The epilepsy community is so sensitive to this issue because anti-epileptic drugs, or anti-seizure medications, the medications that people with epilepsy have to take each day, have progressively been more frequently scheduled by the DEA. If you went back to older drugs for epilepsy, they weren't an issue. But newer drugs, because of various reasons, are now scheduled by the DEA.

So the most recently approved seizure medication was approved by the FDA on October 22, 2012 and received scheduling and approval for marketing by DEA on January 2, 2014, an astounding 14 months later, according to FDA news. And I think if I understood their comments, that was even 11 months after it arrived at the DEA from FDA. So I think probably by any measure a very long time.

Some brief background information about epilepsy illustrates why this delay is so important to Americans. Epilepsy is any condition that predisposes to spontaneous, recurrent seizures. You can imagine it happens by many different insults to the brain, such as a stroke or head trauma. But in fact it most often is caused by some microscopic change in the brain or some genetic predisposition to seizures in people who are otherwise perfectly fine and perfectly normal.

Seizures are an electrical storm of the brain. The kind of seizure that people are most familiar with is a generalized tonic-clonic or grand mal seizure, when someone stiffens up, falls to the ground, and jerks rhythmically all over for a few minutes. They are then unconscious for a little while and, over the course of about an hour, return back to normal.

But the electrical storm of the brain can start in just one spot. Seizures can arise focally in just one area, and the most common focal area they arise is in the temporal lobe. The temporal lobe, behind your temple here, controls consciousness and awareness, and during temporal lobe seizures, people don't fall down and jerk all over, but instead stare off, unaware of what is going on around them.

They are awake, but they are confused and don't know what is going on, and that means that they may continue to do behaviors they are doing but they don't do it correctly. So, for example, if they are ironing, they may continue to iron, but unfortunately they may pick up the hot side of the iron, and iron with that, burning their hand. If they are cooking with boiling water, they may put their hand, immerse it into the boiling water to pick something up because they are confused about what they are doing. If they are chopping something, they continue to chop and chop their own fingers. So it can a very dramatic and difficult thing for people with this kind of seizure, which is the most common type.

But the greatest risk from epilepsy is death. Death from sudden unexpected death in epilepsy, or SUDEP, S–U–D–E–P, sudden unexpected death in epilepsy, in which patients die for no apparent reason. They are typically found dead in bed, sometimes associated with a seizure, the same seizure they have had ten, hundreds,

thousands of times before. But for whatever reason in this particular seizure, they don't awaken and they die. SUDEP.

Matthew is an engineering student at a Virginia university—I am from Virginia—with intractable epilepsy. He had seizures in his sleep that happened several times a week. Typically they weren't such a substantial problem because as far as he knew, he didn't have them. They just occurred in his sleep, but eventually, they started to occur during the day. When they started to occur during the day, you can imagine all different ways its disrupted his life. Besides the risk of injury, there are more common ways in which you can imagine if you have seizures that you can't drive, difficulty working and so forth.

He was an otherwise very personable, pleasant young man. I have an 18-year-old son who is at the University of Virginia, a freshman. Could have about been my son, could have been your son, could have been your daughter. And as his seizures persisted, we tried more and more medications to treat them. Eventually, for those situations we consider surgery. It is a several month long evaluation to localize exactly where the seizure is coming from in the brain; if that is a safe spot to remove, then removing that spot. But unfortunately a couple of months into his evaluation, I got an email message I received too many times in which the subject line is "sad news." And whenever that happens, my heart just sinks because I know what is coming next. So, on opening the email, it says, from my nurse, "Matthew's mother called today. He was found dead in bed. He went to bed last night perfectly fine, but he didn't come down for breakfast, I went to check. He was dead."

So you can imagine there is no more devastating thing that could happen to you. What could possibly be more devastating? Most of us would rather cut off our arm than lose a child. Right? And, of course, it doesn't just happen to children and young adults. It happens to everyone with epilepsy. So the question is, how common is this? What is the scope of the problem? Is he just one guy in my thousands of patients with epilepsy? No. I am afraid not.

Take a step back for the scope of the whole problem. Epilepsy is common. About 1 in 26 people have epilepsy at some time in their life. Earlier today there were 96 people in this room. That means three or four of them had epilepsy. Some of they had it as a child. They outgrew it. It went away. Some of them haven't gotten it yet because its highest incidence is in the very young and in the elderly, as you can imagine. But that is pretty common. About 3 million Americans have epilepsy today. That is quite a lot of Americans. And about a third of these people have seizures that are not controlled with available medications. That means they persist in having seizures, despite our best efforts, like Matthew.

I follow about 2,000 people with epilepsy in my clinic per year, and I get this message about twice per year. So I now have accumulated about 50, actually 52 people with epilepsy who have died, mostly in this manner. It is not a small problem. It is a huge problem and as a general sense affecting almost 3 million Americans; in a specific sense, the risk of death for those people with intractable epilepsy, at least a million.

Now, we started Matthew's evaluation when the last drug I mentioned had been approved by the FDA but was awaiting scheduling at the DEA. That is when he died.

Mr. PITTS. Could you please summarize, Doctor——

Mr. FOUNTAIN. One last sentence. So I can't tell that you that Matthew would be alive if he had this drug available, but he certainly might be, as would other patients with epilepsy who desperately need these kind of treatments that have been found safe and effective by the FDA. Thank you.

Mr. PITTS. Thank you.

[The prepared statement of Mr. Fountain follows:]

Nathan B. Fountain, M.D.

Chair, Professional Advisory Board

Epilepsy Foundation of America

Testimony – Committee on Energy and Commerce

Subcommittee on Health

Monday, April 7, 2014

Thank you, Chairman Pitts and Ranking Member Pallone for allowing me to testify on behalf of the more than 2.8 million Americans living with epilepsy and their families. Specifically, as Chair of the Epilepsy Foundation's Professional Advisory Board, I am here to support a legislative initiative that I know is important to this committee – the *Improving Regulatory Transparency for New Medical Therapies Act'* (H.R. 4299). The Epilepsy Foundation is extremely grateful for the leadership of the Chairman and Ranking Member in introducing what we believe is not only important, but a reasonable legislative solution that we hope will garner many supporters as it moves towards passage.

The Epilepsy Foundation is the leading national voluntary health organization that speaks on behalf of more than 2.8 million Americans with epilepsy. The Foundation fosters the well-being of children and adults affected by seizures through research programs, educational activities, advocacy, and direct services. I am pleased to serve as chair of our medical advisors and as a practicing epileptologist. I would like to share information about epilepsy with this committee, so that you might better understand why our organization is steadfast in our support for H.R.

4299 and why we think this is a reasonable and workable solution to current delays for our patients.

Epilepsy is a medical condition that produces seizures affecting a variety of mental and physical functions; it is also called a *seizure disorder.* A person is considered to have epilepsy if they have two or more seizures.[1] Epilepsy is a family of more than 40 syndromes[2] including Dravet syndrome, hypothalmamic hamartomas (HH), and Lennox-Gastaut syndrome (LGS). Dravet syndrome, also known as Severe Myoclonic Epilepsy of Infancy, is a rare and catastrophic form of intractable epilepsy that begins in infancy and includes developmental declines and a higher incidence of sudden unexplained death in epilepsy (SUDEP).[3] HH are benign tumors or lesions in or around the hypothalamus. They can be difficult to diagnose and treat and can lead to daily seizures, developmental delays, and/or precocious puberty.[4] LGS is a debilitating form of childhood-onset epilepsy that is characterized by multiple seizure types, cognitive impairment, and an abnormal EEG.[5]

Epilepsy affects more than 2.8 million Americans[6] and 65 million people worldwide.[7] This condition will develop in approximately one out of 26 people at some point in their lives [8] making it the fourth most common neurological disorder in the United States after Alzheimer's

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[1] Kobau R, Price P. Knowledge of epilepsy and familiarity with this disorder in the U.S. population: Results from the 2002 HealthStyles survey. *Epilepsia*. 2003;44(11):1449–1454.

[2] National Institute of Neurological Disorders and Stroke. Web site, http://www.ninds.nih.gov/

[3] Dravet Syndrome Foundation. Web site, www.dravetfoudnation.org

[4] Hope for Hypothalamic Hamartomas. Web site, www.hopeforhh.org

[5] LGS Foundation. Web sitewww.lgsfoundation.org

[6] Projection based on Begley CE, et al. The cost of epilepsy in the United States: An estimate from population-based clinical and survey data. *Epilepsia*. 2000;41(3):342–351 and U.S. Census Bureau 2010 population estimate of 308,000,000.

[7] Annual Report 2003: Global Campaign Against Epilepsy, p. 2. Published by World Health Organization, International Bureau for Epilepsy and International League Against Epilepsy.

[8] M.J. England et al. / Epilepsy & Behavior 25 (2012) 266–276. Web site, http://iom.edu/~/media/Files/Report%20Files/2012/Epilepsy/epilepsyEBarticleFinal.pdf

disease, stroke, and migraines.[9] This year 200,000 people in the U.S. will be diagnosed with epilepsy[10], with the very young and the very old being the most affected. Currently, 326,000 children under the age of fifteen have epilepsy, and more than 90,000 of them have severe seizures that cannot be adequately treated.[11] Meanwhile, as the baby boomer generation approaches retirement age the number of cases in the elderly population is beginning to soar, with more than 570,000 adults age 65 and above living with epilepsy in the United States.[12] Epilepsy imposes an annual economic burden of $19.2 billion[13] on this nation in associated health care costs and losses in employment, wages, and productivity. Along with the financial costs, epilepsy and its treatment may impact someone's quality of life with side effects such as pain, depression, anxiety, reduced vitality, and insufficient sleep or rest.[14] Depression is significantly linked to epilepsy with more than a third of all people with epilepsy affected by the mood disorder, and people with a history of depression are 3 to 7 times more likely to develop epilepsy than the average person.[15] These side effects are compounded when it is considered that many people with epilepsy live with significant co-morbidities. Research has shown that 25.4 percent of people with autism have epilepsy, as well as 13 percent of those with cerebral palsy, 13.6 percent of those with Down syndrome, and 25.5 percent of those with mental retardation live with epilepsy. The percentage increases when you look at those who have both cerebral palsy and mental retardation, with 40 percent living with epilepsy.[16]

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[9] Hauser A. Epidemiology of seizures and epilepsy in the elderly. In: Rowan A, Ramsay R, eds. Seizures and epilepsy in the elderly. Boston:Butterworth-Heinemann, 1997:7–18.

[10] See note 6 above

[11] See note 6 above

[12] See note 6 above

[13] Begley, op.cit. Reported cost of $12.5 billion for prevalent cases in 1995 is converted here to 2014 dollar value using Bureau of Labor Statistics automated online constant dollars conversion calculator.

[14] From Centers for Disease Control and Prevention. Health-related quality of life among persons with epilepsy. *JAMA*, 2001;285(7):878.

[15] Kanner AM. Depression and epilepsy: A new perspective on two closely related disorders. *Epilepsy Currents*. 2006;6(5):141-46.

[16] McDermott S, Moran R. Prevalence of epilepsy in adults with mental retardation and related disabilities in primary care. *American Journal of Mental Retardation*. 2005;10(1):48-56

Those living with epilepsy also face serious barriers to proper care and first aid. A lack of knowledge about proper seizure first aid exposes affected individuals to injury from unnecessary restraint and from objects needlessly forced into their mouths.[17] Besides poor first aid, those living with epilepsy are also forced to live with uncontrollable epilepsy for an exceptionally long period of time when an effective treatment may be available. On average, it is 14 years between the onset of epilepsy and surgical intervention for seizures that are uncontrollable through medication. American physicians may be unaware of the safety and efficacy of epilepsy surgery, making it among the most underused of proven, effective therapeutic interventions in the field of medicine.[18]

Access to new therapies is particularly important for the 20 to 30 percent of people living with epilepsy who experience intractable or uncontrolled seizures or have significant adverse effects to medication. Patients who have drug resistant epilepsy, defined as a failure to achieve seizure freedom after adequate trials of two tolerated, appropriately chosen and used anti-epilepsy drug schedules (whether as monotherapies or in combination), can develop brain damage or experience other life-threatening effects. As Director of the epilepsy program at the University of Virginia School of Medicine, I am very familiar with the impact of epilepsy for those who have found seizure control, and those patients who are still searching for the hope that a new treatment may offer.

Sudden Unexpected Death in Epilepsy, known as SUDEP, encompasses non-traumatic, non-drowning related deaths in people with epilepsy that may or may not be associated with a recent

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[17] Repeated surveys by the Epilepsy Foundation, the previously cited CDC report, and numerous other surveys have documented the low level of public knowledge about seizures and epilepsy, including persistent misconceptions about seizure first aid.

[18] Engel,JR Jr. A greater role for surgical treatment of epilepsy: Why and when? *Epilepsy Currents*. 2003;3(2):37–40.

seizure, but are not due to prolonged seizures.[19] In definite SUDEP, an autopsy reveals no evidence of an anatomical or toxicological cause of death.[20] As noted in the 2012 Institute of Medicine report, *Epilepsy Across the Spectrum*[21], not only do people with epilepsy succumb to sudden death at a rate over 20 times higher than the general population[22], but SUDEP is also the leading cause of epilepsy-related death.[23] It accounts for the deaths of 40% of people with severe epilepsy and 4% of those with all types of epilepsy.[24] Among people with both cognitive impairments and refractory epilepsy, the cumulative risk of SUDEP can exceed 10%.[25] While much more research is needed into the causes and prevention of SUDEP, the strongest evidence suggests that the occurrence of seizures increases the risk.[26]

The Epilepsy Foundation's SUDEP Institute was established to increase awareness, prevent Sudden Unexpected Death in Epilepsy (SUDEP) through research, and support people confronting the fear and loss of a loved one. The SUDEP Institute carries out SUDEP education and awareness programs for people touched by epilepsy and medical professionals, drives and supports research into the causes of and ways to prevent SUDEP, offers a support network providing counseling, community, and resources for individuals and families affected by

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[19] Nashef, L., E. L. So, P. Ryvlin, and T. Tomson. 2012. Unifying the definitions of sudden unexpected death in epilepsy. *Epilepsia* 53(2):227-233.

[20] Ibid.

[21] National Academies, Institute of Medicine, *Highlights from Epilepsy Across the Spectrum: Promoting Health and Understanding* ***A Focus on Mortality and Sudden Unexpected Death in Epilepsy, 2012. Accessed at: http://www.iom.edu/~/media/Files/Report%20Files/2012/Epilepsy/IOM%20Report%20Highlights%20for%20PAME%20Conference.pdf***

[22] Ficker DE, So EL, Shen WK, et al. "Population-based study of the incidence of sudden unexplained death in epilepsy." Neurology 1998;51:1270-1274.

[23] Tomson, T., L. Nashef, and P. Ryvlin. 2008. Sudden unexpected death in epilepsy: Current knowledge and future directions. *Lancet Neurology* 7(11):1021-1031.

[24] Tellez-Zenteno JF, Ronquillo LH, Weibe S. "Sudden unexpected death in epilepsy: Evidence-based analysis of incidence and risk factors." Epilepsy Research 2005;65(1-2):101-115.

[25] Sillanpää, M., and S. Shinnar. 2010. Long-term mortality in childhood-onset epilepsy. *New England Journal of Medicine* 363(26):2522-2529. Sillanpää, M., S. Lastunen, H. Helenius,

[26] Hesdorffer, D. C., T. Tomson, E. Benn, J. W. Sander, L. Nilsson, Y. Langan, T. S. Walczak, E. Beghi, M. J. Brodie, and W. A. Hauser. 2012. Do antiepileptic drugs or generalized tonic-clonic seizure frequency increase SUDEP risk? A combined analysis. *Epilepsia* 53(2):249-252.

SUDEP, and works together with many epilepsy organizations to find the answers to SUDEP and help families with epilepsy. Since the risk for SUDEP is higher in people with recurring seizures, our mission includes improving pathways to new treatments that can bring seizure control to more patients. Delays in access to these potential therapies are clearly against the patients' interest for those with treatment needs and ultimately result in loss of life.

As you can see, a delay in treatment that may control an individual's seizures is not just a mere convenience or a better side effect profile. Seizures inflict potential damage to the brain and this can be especially concerning for children in developmental stages of life. Seizures can increase risk of injury, and ultimately, as shared, can lead to death for some individuals. As I hope you can understand, the concerns from our community about access to new or better treatments is meaningful and important.

When a new treatment receives approval from the Food and Drug Administration the epilepsy community is filled with hope. This hope can be short lived when consumers learn that the product will not reach them or their loved one due to a delay at the Drug Enforcement Administration (DEA). It is further troubling as a patient advocacy organization that we cannot offer a clear explanation of why this delay occurs since DEA review has never changed the drug schedule recommendation; nor can we offer a timeline or explanation of why there is no timeline. Patients, parents, families wait and we have no answer other than a bureaucratic process. It does not instill faith in our government and undermines the value that patients and their families place on the FDA approval process.

The process to schedule a new molecular entity lacks transparency and timelines, and involves many parties including the FDA, the National Institute on Drug Abuse (NIDA), the Assistant Secretary of Health (ASH) in the Department of Health and Human Services (HHS), as well as DEA. Without apparent cause or justification, the time period between initial drug approval by FDA and final scheduling by DEA has been increasing over the years. Between 1997-1999 and 2009-2013, **the average time between FDA approval and DEA's final scheduling increased from an average of 49.3 days to an average of 237.6 days, an almost five-fold increase.**

While the FDA human drug review process is largely transparent, with predictable timelines, the DEA has no set timeline or transparency requirements to make scheduling determinations. Unfortunately, as DEA's unpredictable and often lengthy review occurs, patients are denied access to important medicines that can improve, and in some cases save, their lives.

Recently, the Epilepsy Foundation merged with the Epilepsy Therapy Project to create a unified organization driving education, awareness, support, and new therapies for people and families living with epilepsy. This merger brings together the mission and assets of both organizations, including www.epilepsy.com, the leading portal for people, caregivers, and professionals dealing with epilepsy; 47 affiliated Epilepsy Foundations around the country dedicated to providing free programs and services to people living with epilepsy and their loved ones; a track record of identifying and supporting important new science, translational research programs, and the most promising new therapies; and the Epilepsy Pipeline Conference, a leading global forum organized in partnership with the Epilepsy Study Consortium that showcases the most exciting new drugs, devices, and therapies.

Innovation is critical for the Epilepsy Foundation both for patients continuing to live with uncontrolled seizures and those who have more seizure freedom but would like to have fewer side effects from medications. Our focus on innovation, research, and new treatments, devices, and technologies for people with epilepsy is another reason why the DEA delay concerns the Epilepsy Foundation. Due to the unpredictable delay caused by the DEA, companies cannot accurately predict the amount of time they will have left on their patent once the drug goes to market, or the amount of time for which they will have data exclusivity. They cannot accurately predict or plan for their product reaching consumers and physicians. This is a disincentive to innovation in an already challenging area of neurological development.

This bill is a simple solution to the problem and will ensure that drugs will not sit around waiting to be scheduled and patients won't be forced to wait on potentially life-changing drugs. HR 4299 will allow more innovative treatments to reach the market and give a clear timeline for drug availability from FDA through DEA.

The Epilepsy Foundation sees no public health reason for these delays; especially after full safety and efficacy reviews and thorough abuse potential analysis by the FDA. We urge all Members to consider full support of the Chair and Ranking Member's proposal. New products that would benefit from this change would continue to have DEA oversight. We would further argue that epilepsy treatments are not the cause for prescription drug abuse programs, or the public health concern overall. Predictable and timely access to new therapies would be a phenomenal accomplishment for epilepsy patients and all Americans suffering from conditions like Epilepsy.. I thank the Committee for its time and attention today.

Mr. PITTS. Mr. Gray, you are recognized for 5 minutes for your summary.

STATEMENT OF JOHN M. GRAY

Mr. GRAY. Good afternoon, and to members of the Energy Subcommittee on Health, Ranking Member Pallone and Chairman Pitts, I am John Gray, President and CEO of the Healthcare Distribution Management Association. I want to thank you for the opportunity to come here to talk about Representatives Blackburn and Marino, the Ensuring Patient Access and Drug Enforcement Act of 2014, H.R. 4069.

HDMA is the national association representing America's primary pharmaceutical distributors, the vital link we say between manufacturers, pharmacies and health care providers. Our industries' prime mission is to operate the safest and most secure supply chain in the world. As part of the mission, the pharmaceutical distribution industry is committed to addressing the serious national epidemic of prescription drug abuse. Drug abuse and diversion as we have heard here today is a complex, challenging problem calling for a collaborative effort on the part of doctors, pharmacists, distributors, manufacturers and importantly State and Federal authorities.

HDMA members are committed to working proactively with the DEA, local law enforcement and other regulatory agencies, to investigate potential cases of diversion and implement protocols to monitor and report suspicious orders.

The supply chain is a complex one depending on numerous core components working closely with one another to ensure patients receive the medicines they need and to prevent the diversion to individuals who would abuse the drugs. It is sometimes difficult to find the balance between proactive and anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications.

We hope this legislation will address the need for balance and encourage some cooperation and collaboration between prescribers, dispensers, distributors, manufacturers, regulators and the like, while making sure that the legitimate patient population continues to get what they require for medication. All HDMA members take seriously this obligation to fill only legitimate and appropriate orders for controlled substances.

However, in many instances, our members struggle with applying the Controlled Substances Act and it is accompanying regulations to the specific situation when balancing the need for preventing the diversion at the pharmacy or the doctor's office and ensuring that the legitimate patient needs are addressed. This is one of the reasons why HDMA supports 4069, the legislation's timely and thoughtful approach to addressing the prescription drug epidemic. And we believe it will foster, again, better collaboration, communication and transparency between the industry stakeholders and the regulators, especially the DEA. Our members appreciate the importance of DEA's law enforcement activities, confronting, disrupting, and dismantling illegal drug trafficking. However, establishing a collaborative working relationship between DEA and our members will serve as a more effective way to curb

the diversion of legal medicines. We feel this legislation will improve the interaction with DEA as they engage in their regulatory duties to prevent the diversion of these substances. The several key components, the bill clarifies the regulatory environment by defining terms that will facilitate greater compliance with and consistent enforcement of the Controlled Substances Act. Another key provision is the bill establishes a corrective action for plan registrants working with the DEA. This concept first raised by Representative Blackburn during a hearing on drug abuse here 2 years ago, is intended to mirror the way the FDA interacts with and regulates pharmaceutical manufacturers.

The bill will allow DEA-registered companies to submit corrective plans, to address and mitigate any of the agency's concerns, we hope and we believe creating a more robust, transparent, time-sensitive approach to addressing diversion. Preventing this diversion and abuse requires a clear understanding of the regulations consistent with the CSA and prompt communication between supply chain members and the regulators. The provision ensures that law enforcement registrants will collaborate to achieve these aims.

Finally, the bill establishes a prescription drug abuse working group to encourage meaningful dialogue and coordination between the supply chain stakeholders, law enforcement, patient advocacy groups, as well as State and Federal regulators. Ultimately, the working group will provide guidance to Congress on the most effective strategies to curb this prescription drug abuse.

HDMA has long been working to improve the collaboration among industry stakeholders. We recently joined the Alliance to Prevent the Abuse of Medicines. The alliance is in the process of developing a platform of policy recommendations to address numerous aspects of the drug abuse diversion problem, and that alliance does support 4069.

We recognize there isn't a one-size-fits-all solution to this problem. There never is. But we believe pharmaceutical distributors, along with our other supply chain partners, are committed to a more coordinated and transparent approach, balancing between addressing enforcement, public health and treatment efforts. We are neither seeking to restrict DEA's authority nor increase the regulatory burden on registrants. What we are seeking is clarity, consistency to ensure that the public health needs are adequately addressed in a balanced, collaborative and effective manner. In the end, we share the same goal, ensure patient access, sufficient, safe and secure supply chain of medicines for the necessary therapies while keeping these drugs out of hands of individuals who will abuse them. The anti-diversion efforts need to strike a balance between the need to reduce abuse and diversion while avoiding disruptions to legitimate patients.

Thank you again for this opportunity to participate in the hearing, and I hope this overview was valuable to the committee. Thank you, Mr. Chairman.

[The prepared statement of Mr. Gray follows:]

Statement from
John M. Gray, President and CEO
Healthcare Distribution Management Association

For the U.S. House of Representatives
Energy and Commerce Committee
Subcommittee on Health

April 7, 2014

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Good afternoon Chairman Pitts, Ranking Member Pallone and Members of the Energy and Commerce Subcommittee on Health. I am John Gray, President and CEO of the Healthcare Distribution Management Association (HDMA). Thank you for the opportunity to discuss with the Subcommittee important legislation introduced by Representatives Blackburn and Marino, the Ensuring Patient Access and Effective Drug Enforcement Act of 2014 (H.R. 4069).

HDMA is the national association representing America's primary pharmaceutical distributors – the vital link between manufacturers, pharmacies and healthcare providers. Our industry's primary mission is to operate the safest and most secure and efficient supply chain in the world. As part of this mission, the pharmaceutical distribution industry is committed to addressing the serious national epidemic of prescription drug abuse. Drug abuse and diversion is a complex and challenging problem that calls for a collaborative effort on the part of doctors, pharmacists, distributors, manufacturers and state and federal authorities.

HDMA's members are committed to working proactively with Drug Enforcement Administration (DEA), local law enforcement and other regulatory agencies to investigate potential cases of diversion and implement protocols to monitor and report suspicious orders.

The healthcare supply chain is a complex system that depends on numerous core components working closely with one another to ensure that patients receive the medicines they need and to prevent diversion to individuals who would abuse these drugs. Physicians see patients and prescribe necessary medicines. Pharmacists receive and dispense prescriptions to the patients. Distributors are tasked with ensuring that pharmacies have the necessary medicines they need to fill legitimate prescriptions. It is sometimes difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications. We hope this legislation will address that need for balance

and encourage cooperation and collaboration between prescribers, dispensers, distributors, manufacturers and regulators, while making sure that legitimate patients continue to receive the medications they require.

All HDMA distributor members take very seriously their obligation to fill only legitimate and appropriate orders for controlled substances. However, in many instances our members struggle with applying the Controlled Substances Act and its accompanying regulations to their specific situation when balancing the need for preventing diversion and ensuring that legitimate patient needs are addressed.

This is one of the reasons why HDMA supports H.R. 4069. This legislation is a timely and thoughtful approach to addressing the prescription drug abuse epidemic. We believe it will foster greater collaboration, communication and transparency between industry stakeholders and regulators, especially the DEA.

HDMA members appreciate the importance of DEA's law enforcement activities in confronting, disrupting and dismantling illegal drug trafficking. However, establishing a collaborative working relationship between DEA and our members will serve as a more effective way to curb diversion of legal medicines. We feel this legislation will improve interaction with the DEA as they engage in their regulatory responsibilities to prevent diversion of controlled substances.

There are several key components of the legislation that I will briefly describe.

This bill brings clarity to the regulatory environment by defining key terms that will facilitate greater compliance with and consistent enforcement of the Controlled Substances Act.

This bill also establishes a corrective action plan for registrants working with DEA. This concept, first raised by Representative Blackburn during a hearing on drug abuse two years ago,

is intended to mirror the way FDA interacts with and regulates pharmaceutical manufacturers. This bill will allow DEA-registered companies to submit corrective action plans to address and mitigate any Agency concerns, creating a more robust, transparent and time sensitive approach to addressing drug diversion. Preventing diversion and drug abuse requires clear understanding of regulations, consistent application of the Controlled Substances Act, and prompt communication between supply chain members and regulators. This provision ensures that law enforcement and registrants will collaborate to achieve these aims.

Finally, the bill will establish a Prescription Drug Abuse Working Group to encourage meaningful dialogue and coordination between supply chain stakeholders, law enforcement, patient advocacy groups, as well as state and federal regulators. Ultimately, this Working Group will provide guidance to Congress on the most effective strategies to curb prescription drug abuse.

HDMA has long been working to improve collaboration among industry stakeholders on this issue. We recently joined the Alliance to Prevent the Abuse of Medicines to bring forth a comprehensive perspective to addressing this problem. The Alliance is comprised of organizations from across the pharmaceutical supply chain, including the American Medical Association, Teva, Cardinal Health, CVS Caremark and Prime Therapeutics. The Alliance is in the process of developing a platform of policy recommendations to address various aspects of drug abuse and diversion and supports H.R. 4069.

There is no one-size-fits-all solution to this problem, but pharmaceutical distributors, along with their supply chain partners, are committed to a more coordinated and transparent approach that provides necessary balance when addressing enforcement, public health and treatment efforts. We are neither seeking to restrict DEA's authority nor increase the regulatory

burden on registrants. What we are seeking is clarity and consistency to ensure that public health needs are adequately addressed in a balanced, collaborative and effective manner. The complexity of this public health challenge will require the entire healthcare supply chain to work together in close partnership with state and federal entities to effectively stem the tide of prescription drug abuse and minimize the potential for unintended consequences.

In the end, we all share the same goal: to ensure patient access to a sufficient, safe and secure supply of medicines for necessary therapies while keeping these drugs out of the hands of individuals who will abuse them. Anti-diversion efforts need to balance the need to reduce abuse and diversion while avoiding disruptions for legitimate patients.

I thank you again for the invitation to participate in this hearing and hope this overview was valuable as the subcommittee evaluates H.R. 4069.

Mr. PITTS. The Chair thanks the gentleman and now recognizes Mr. Barber 5 minutes for an opening statement.

STATEMENT OF D. LINDEN BARBER

Mr. BARBER. Good afternoon, Chairman Pitts, Ranking Member Pallone, and members of the subcommittee. Thank you for the opportunity to testify.

My name is Linden Barber, Partner at Quarles & Brady. I am a former associate chief counsel at DEA. H.R. 4069 provides much needed clarity in the Controlled Substances Act, and that clarity will foster compliance, communication and collaboration, which is essential to preventing prescription drug abuse and ensuring that patients have access to controlled medications.

History tells us why clarity is important. In 2006, DEA stopped issuing immediate suspensions for 8 months because a Federal court ruled that the way DEA issued suspensions was unconstitutional. During that critical time, Internet pharmacies were fueling prescription drug abuse with millions of pills, and the agency issued zero immediate suspensions. That is Exhibit A for why clarity in the law is so important. The CSA allows DEA to immediately suspend a registration based on imminent danger to the public health, but the act does not currently define "imminent danger." This lack of clarity and DEA's inconsistent approach to immediate suspensions has led to judicial intervention. Defining imminent danger will protect DEA's ability to issue immediate suspensions.

In 1974, a year after DEA was created, a pharmacy successfully challenged DEA's immediate suspension order because the alleged danger was one single incident that occurred more than 7 months before the suspension, far from an imminent danger. More recently, the 2006 case I mentioned echoed that same theme, and last year, the DC Circuit Court of Appeals raised pointed concerns about the DEA's apparent lack of a standard in applying the imminent danger definition or lack thereof when issuing suspensions. History is sending a message. In the absence of clarity in the law, courts will intervene, and they will curtail DEA's powers.

After the 2006 adverse decision, I became the associate chief counsel at DEA and was charged with fixing the immediate suspension process for the agency. As part of that, the agency took a disciplined approach to applying the imminent danger standard, an approach that is consistent with the definition of imminent danger in H.R. 4069. Using that approach, we issued a record number of immediate suspensions in 2007 and 2008. I am confident that defining imminent danger the way this bill does will not impede DEA's ability to issue immediate suspensions.

The lack of clarity in DEA's inconsistency has unintended but devastating consequences for the public. Why would a pharmacist tell DEA about a doctor's bad prescribing habits if DEA was going to use that to suspend the pharmacy's registration, even though the pharmacy was no longer filling those prescriptions? This is not a hypothetical. The agency has issued suspensions for conduct that it knew was no longer occurring. Registrants get this message: Don't tell DEA about a bad prescriber who is the real source of diversion because DEA might take action against you.

Clarity in the law will remove that fear and foster communication that helps DEA identify truly bad actors. Clarity also promotes access to controlled medications for patients. Without clarity, registrants often act to reduce the perceived risk of regulatory action. A pharmacist refuses to fill legitimate prescriptions for narcotics simply because dispensing a high volume of narcotics brings the attention of the agency and the supplier on the pharmacy.

No one wants cancer patients or wounded veterans or those with chronic pain to go without their pain medication, but restricting access is an unintended consequence of a regulatory environment that lacks clarity.

The corrective action plan section of the bill also promotes communication with the agency by assuring registrants that the agency will consider remedial actions they have taken. It is important to note that the remedial action section and corrective action plan does not apply to immediate suspensions for the reasons I discussed in my written testimony.

Nearly a decade ago, DEA crippled elicit Internet pharmacy schemes. We issued a record number of administrative actions, collected record-setting civil penalties, but prescription drug abuse continued to rise. All along, DEA was working tirelessly to protect the public, and all along, the vast majority of registrants were looking for ways to cooperate with the agency.

Members of the subcommittee, how can these efforts of the agency and industry be harnessed to effectively address medications for patients and to prevent diversion? The answer is with clarity. Clarity will produce compliance, communication and collaboration, and that collaboration will produce real results in preventing the prescription of diversion drugs and their abuse.

[The prepared statement of Mr. Barber follows:]

Statement from
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Quarles & Brady, LLP

For the U.S. House of Representatives
Energy and Commerce Committee
Subcommittee on Health

April 7, 2014

Good afternoon Chairman Pitts, Ranking Member Pallone, and Members of the Energy and Commerce Subcommittee on Health. My name is Linden Barber, Partner in the law firm of Quarles & Brady and the former Associate Chief Counsel for Diversion Litigation at the Drug Enforcement Administration. Thank you for the opportunity to appear before the Subcommittee to discuss the important issue of preventing the diversion of pharmaceutical controlled substances into illicit channels while ensuring access to these helpful medications for patients with legitimate medical needs. The Ensuring Patient Access and Effective Drug Enforcement Act of 2014 (H.R. 4069) introduced by Representatives Blackburn and Marino is a piece of legislation that will enhance the prevention of diversion of controlled substances while mitigating the unintended consequence of restricting the supply of these helpful medications to patients with legitimate medical needs.

My interest in this issue stems from nearly twelve years of service at the Drug Enforcement Administration during a period of escalating prescription drug abuse. Since leaving the DEA for private practice in late 2011, I have advised many registrants within the pharmaceutical supply chain about DEA compliance issues and have found that members of

industry are keenly interested in working with the DEA to solve the enormous problem of prescription drug abuse.

My interest in this issue is also personal. Like many Americans, I know and love people who have suffered the harms of prescription drug abuse. I also know and love people whose lives and health are better because of the availability of controlled medications.

It is vitally important that steps taken to ensure patient access to controlled medications do not undermine the ability of the DEA to protect the public health from the devastating ills caused by the abuse and misuse of controlled substances. The Ensuring Patient Access and Effective Drug Enforcement Act of 2014 is an Act that addresses both issues by providing clarity in the law and by encouraging collaboration between regulators, law enforcement, health care providers, and the pharmaceutical supply chain.

By providing definitions for two key terms in the Controlled Substances Act, Congress will bring clarity to the regulatory environment. I will focus my comments on defining the term "imminent danger." By defining "imminent danger," Congress can provide clarity that is beneficial to DEA and to the registrants the Agency regulates. How does defining "imminent danger" benefit DEA? The Controlled Substances Act permits DEA to immediately suspend the registration of a registrant whose conduct

poses an imminent danger to public health or safety. Unlike other federal statutes, such as the Mine Safety Act, the Controlled Substances Act does not define imminent danger. In the absence of clarity from Congress, the Agency will determine what constitutes an imminent danger on a case-by-case basis. And when a registrant challenges DEA's use of its immediate suspension power, it is ultimately courts that will determine what constitutes an imminent danger. History is instructive, and there is a long history of judicial challenges to the Agency's use of immediate suspensions. Forty years ago, a registrant successfully challenged an immediate suspension because the conduct that DEA alleged created the danger was not imminent, but was more than seven months old.

More recently, a legal challenge to the Agency's immediate suspension power thwarted the Agency's ability to address illicit Internet pharmacy schemes. In 2005, three pharmacies in Colorado successfully challenged the immediate suspension orders issued by DEA. In early 2006, the U.S. District Court for the District of Columbia ruled that the manner in which DEA processed immediate suspensions deprived the registrants of Due Process. Although the ruling in that case was based on the extraordinary length of time that the registrants had to wait for a hearing, the pharmacy registrants also claimed that the conduct that DEA alleged

created a danger had ceased more than a month before DEA issued the suspensions. Having dissolved the suspensions on Due Process grounds, the court did not need to address the troubling allegation that the conduct at issue ceased well before issuance of the immediate suspension orders.

Because of the court's ruling, the DEA and the Department of Justice imposed a hiatus on issuing immediate suspension orders until the immediate suspension process could be restructured to address the Due Process issue that led to the adverse decision from the court. Several months after that decision, I became the Associate Chief Counsel for Diversion Litigation at DEA and was charged with revamping the immediate suspension process. For more than six months, in the height of the illegal Internet pharmacy schemes that fueled prescription drug abuse, the Agency was effectively stripped of its power to issue immediate suspension orders. Although we fixed the immediate suspension process and, I am proud to say, issued a record number of immediate suspensions in 2007 and 2008, the Agency did not issue immediate suspension orders for more than six months in 2006, during which time millions of dosage units of controlled substances were distributed through illicit Internet pharmacy schemes that could have been dismantled by immediate suspension orders. As a practitioner in this area of the law and an

observer of the courts, I am very concerned that in the absence of legislative clarity about the meaning of "imminent danger," courts will intervene and curtail the Agency's powers in a way that will prevent the Agency from being able to effectively address true imminent dangers. Based on more recent challenges to DEA's suspension authority and some troubling and pointed questions about the imminent danger standard raised by the DC Circuit Court of Appeals in 2012, it is, in my opinion, likely that courts will step in to ensure the fair application of the imminent danger requirement in the absence of a clear legal standard that is consistently applied by DEA. Indeed, many of my colleagues believe that the 2012 case would have resulted in a narrowing of DEA's authority if the Agency had not settled its dispute with the registrant. As a supporter of DEA's mission, I urge this Committee to take legislative action that clarifies the meaning of imminent danger.

The definition of imminent danger in the Ensuring Patient Access and Effective Drug Enforcement Act of 2014 is a common sense standard and is similar to the standard that that Agency used for issuing immediate suspensions employed in the immediate aftermath of the adverse court decision in 2006 previously discussed. Using such a standard the DEA issued a record number of immediate suspensions in 2007 and 2008.

Based on that history, I am confident that the definition of imminent danger in the Ensuring Patient Access and Effective Drug Enforcement Act of 2014 will not inhibit DEA's ability to take swift action to address conduct that poses an imminent danger to the public.

However, the Agency appears to have moved away from using a consistent standard when making a finding that a registrant's conduct poses an imminent danger. In doing so, the Agency invites judicial intervention which could severely limit its powers. The definition of imminent danger in the bill is consistent the plain and ordinary meaning of the term, the definition of that term in other federal statutes, and the case law that has developed around that term. The clarity of this bill, and the Agency's consistent application of the standard articulated in this bill, will substantially strengthen the Agency's position in the face of legal challenges to its suspension powers.

Clarity in the law also benefits DEA registrants. Clarity fosters compliance and collaboration with DEA. Conversely, the current lack of clarity fosters confusion and fear. A pharmacist that decides he or she will no longer fill prescriptions issued by a physician because of concerns about their legitimacy is unlikely to communicate that decision to DEA if the pharmacist is concerned that the Agency will use that information to

immediately suspend the pharmacy's DEA registration because the pharmacy previously filled prescriptions issued by the physician. The DEA has issued immediate suspensions in such contexts. While the Agency surely has a right to address past conduct through normal administrative channels, issuing an immediate suspension for conduct that has stopped is not only contrary to the plain meaning of imminent, it is counter-productive and discourages communication with the Agency.

Many times I have heard my former colleagues at DEA say that enforcement alone will not solve the problem of prescription drug abuse. That is why it so important to provide clarity about the meaning of "imminent danger." The definition found in the Ensuring Patient Access and Effective Drug Enforcement Act of 2014 is precisely the clarity that will encourage registrants to communicate with DEA, turning registrants into a force multiplier that will help DEA identify those registrants who truly require the swift response of an immediate suspension.

Fostering communication and collaboration between registrants and DEA would be further enhanced by the corrective action plan section of the Ensuring Patient Access and Effective Drug Enforcement Act of 2014. A registrant who knows that the Agency will consider corrective action before deciding to revoke or suspend the registrant's registration is more likely to

communicate with DEA. Addressing the problem of prescription drug abuse requires registrants throughout the supply chain to bring concerns about other registrants to DEA's attention. A distributor who grows concerned about a pharmacy's dispensing practices after several months of supplying the pharmacy needs the assurance that DEA will consider any corrective action taken by that distributor in order to encourage the distributor to communicate its concerns to DEA.

As a supporter of DEA's power to issue immediate suspensions, it is important to note the interplay, or lack thereof, between the corrective action plan provision in the bill and the Agency's power to issue immediate suspensions. Foundational to this discussion is the identification of the two types of suspensions in Controlled Substances Act. There is a post-adjudication sanction that includes suspension or revocation, and there is the pre-adjudication suspension (i.e., an immediate suspension) based on a finding of imminent danger. The corrective action plan section of the Ensuring Patient Access and Effective Drug Enforcement Act of 2014 is placed within a subsection of the statute that indicates its application is limited to the context of post-adjudication revocations or suspensions. In other words, DEA would not have to provide a registrant whose conduct poses an imminent danger to the public health an opportunity to submit a

corrective plan prior to issuing an immediate suspension order. This is clear not only from the subsection in which the corrective action plan language is located, but also from standard statutory interpretation. Requiring DEA to give a registrant who poses an imminent danger to public health an opportunity to submit a corrective action plan would eviscerate the clear intent of the statute that empowers DEA to issue immediate suspensions to abate an imminent danger.

Finally, legislative clarity will foster a regulatory environment that will promote access to controlled medications for patients in need. When registrants are uncertain about the regulatory environment, many will take actions to reduce the perceived risk of regulatory action. A pharmacist may refuse to fill prescriptions for narcotics intended to treat chronic pain, not because the pharmacist believes the prescriptions are illegitimate, but simply because dispensing a high volume of narcotics brings scrutiny from suppliers and from the DEA. Similarly, members of the supply chain may refuse to service a pharmacy that dispenses a large volume of narcotics. No one intends for cancer patients, wounded veterans, and those suffering with intractable pain from chronic conditions to have difficulty obtaining pain medication. But this has been an unintended consequence brought about by a chain of actions and reactions that are produced by a lack of clarity in

the law. While some of accounts of the lack of access to drugs may be overstated, the mounting anecdotal evidence that individuals with legitimate medical needs are being refused controlled medications is disturbing. In the absence of clarity in the law, this trend is likely to continue because registrants will continue to take action to limit supply to avoid the perceived threat of administrative action.

It has been nearly a decade since the team of dedicated investigators and lawyers I worked with at DEA used the Agency's administrative power to cripple dozens of illicit Internet pharmacy schemes. Convinced that we would be more effective by expanding our actions to pursue the supply chain, I developed the legal framework to pursue actions against distributors that supplied those Internet pharmacies. We initiated a record number of administrative actions; the Government collected record-setting civil penalties in conjunction with those actions. But prescription drug abuse continued to rise. Action by DEA alone was not and is not enough to address the problem. Now, as then, DEA's actions are fueled by a desire to protect the public. Now, as then, the overwhelming majority of registrants are working diligently to prevent the diversion of controlled substances while ensuring that legitimate patients have access to needed

medications. But how can we channel these efforts to achieve maximum effectiveness?

Prescription drug abuse is a complex problem that no single legislative or regulatory action will fix. Likewise, access to medications for legitimate patients will not be guaranteed by any single piece of legislation. But the clarity provided by the Ensuring Patient Access and Effective Drug Enforcement Act of 2014 is consistent with the findings Congress made when it enacted the Controlled Substances Act -- controlled substance are beneficial in meeting the medical needs of many Americans, but the abuse and misuse of those substances are detrimental to the public health. The clarity in this bill will create a regulatory environment in which DEA and those registrants who are committed to compliance can make meaningful strides to reduce prescription drug abuse while improving access to medication for patients in need. Clarity will foster compliance. Clarity will enhance communication. Clarity will create collaboration and collaboration will address root problems, not just symptoms.

Thank you for inviting me to appear before you. I trust that these insights gleaned from more than a decade of zealously representing DEA and more than two years of assisting registrants with DEA compliance will be of help to you.

Mr. PITTS. The Chair thanks the gentleman.

I now recognize Ms. Selig, 5 minutes for an opening statement.

STATEMENT OF WENDY K.D. SELIG

Ms. SELIG. Thank you, Mr. Chairman, good afternoon, Ranking Member Pallone and members of the subcommittee. My name is Wendy Selig, and I am the President and CEO of the Melanoma Research Alliance, known as MRA. Thank you again for inviting me to testify today on behalf of my colleagues in the Public Access to Sunscreens Coalition, known as the PASS Coalition, in support of H.R. 4250.

The PASS Coalition is a multistakeholder group that advocates for a regulatory pathway for new, safe and effective sunscreen ingredients. The goal of the coalition is to work collaboratively to establish a transparent and predictable process for premarket review of sunscreen components. MRA is a unique non-profit organization whose mission is to end suffering and death due to melanoma by collaborating with all stakeholders to accelerate powerful research, advance cures for all patients, and prevent more melanoma. We are the leading private funder of melanoma research, having awarded more than $51 million in cutting-edge scientific projects around the world.

Mr. Chairman, as has been discussed here this afternoon, skin cancer is the most common form of cancer diagnosed in the United States, with more new cases of skin cancer than breast, prostate, lung, and colon cancer combined every year. Melanoma, which is the deadliest of the skin cancers as a result of its ability to move quickly and to spread to distant organs in the body, is rising dramatically across demographic groups.

Each year, more than 76,000 Americans are diagnosed with melanoma, one every 8 minutes, and more than 9,400 Americans die, one every hour. So, in the time that we have been sitting here, we have lost several melanoma patients.

We have made real strides on the treatment front, as four new drugs have been approved for use by the sickest of these patients. We commend the FDA and especially Drs. Woodcock and Pazdur and their colleagues for their work in this area, including landmark efforts in immune therapy, biomarket-driven targeted therapies, combination therapies, and breakthrough therapy designation to speed review processes. These new drugs are saving lives, and their approval and use are paving the way for continued investment and innovations that will bring about even more dramatic progress.

Still we know that more effective options for patients are urgently needed. Everyone is at risk for developing melanoma. One of the risk factors, as we have been discussing today, for all skin cancer and specifically for melanoma is exposure to UV radiation. In fact, one blistering sunburn that happens during childhood can double a person's lifetime chance of developing this deadly skin cancer. We take every opportunity to urge people to protect themselves and their loved ones by reducing exposure to UV from the sun, from tanning beds, and to examine their skin and watch for changes and see a dermatologist regularly, especially if they notice a change.

A central message is that people should use effective sunscreen protection all year round. As you know, FDA is responsible for ensuring the safety and effectiveness of all drugs, including evaluating medical claims related to sunscreens and sunscreen ingredients. The 2002 TEA process envisioned a 90 to 180 day evaluation process. Yet as we have been discussing today, FDA as not completed the review of any new sunscreen component under TEA or its preexisting OTC process since the 1990s. I think everyone agrees the current sunscreen premarket review process needs to be reformed.

It is important that I point out that the sunscreens Americans use today can be effective for those who use them correctly. However, the latest products developed and used around the world can offer important steps forward and should be made available in the U.S. if found to be safe and effective. Finding innovative ways to make these products more effective and user-friendly can help ensure more people are using them properly and to maximum effect. Unfortunately, given the history of stalled reviews under the FDA's current process, there is a strong disincentive for investment in this kind of sunscreen innovation for the U.S. market.

The Sunscreen Innovation Act would codify a time frame for review and provide FDA with the authority to make a final scientific decision on the application instead of going through the cumbersome and delayed rulemaking process. While keeping the existing process whereby FDA makes an ultimate eligibility determination, the act says an existing advisory committee of experts will review the safety and advocacy data. It ensures that all submissions are reviewed within a predictable time frame. Enactment of this legislation would be a victory for everyone, for the FDA, for manufacturers, and, most importantly, the American people. Mr. Chairman and members of this subcommittee, I commend you for holding this hearing and to Mr. Whitfield and Mr. Dingell for taking the lead on this bill.

May is Melanoma Awareness Month, just a few weeks from now. As the weather improves and people are once again making plans for outdoor activities, MRA and the PASS Coalition look forward to working collaboratively with you and the FDA to enact the Sunscreen Innovation Act this year, and we hope perhaps we can see progress on that in Melanoma Awareness Month.

Thank you, and I'd be happy to answer any questions.

[The prepared statement of Ms. Selig follows:]

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Testimony of Wendy K.D. Selig
President & CEO, Melanoma Research Alliance
On behalf of
The Public Access to SunScreens (PASS) Coalition
House Committee on Energy and Commerce
Subcommittee on Health
April 7, 2014

Good afternoon. Mr. Chairman, Ranking Member Pallone, and members of the Subcommittee, my name is Wendy Selig. I am President and CEO of the Melanoma Research Alliance (MRA). Thank you for inviting me to testify today on behalf of the Public Access to SunScreens Coalition (PASS Coalition) in support of HR 4250, the Sunscreen Innovation Act, bipartisan legislation co-sponsored by Congressmen Whitfield and Dingell.

The PASS Coalition is a multi-stakeholder group formed to advocate for a regulatory pathway to market for new, safe and effective sunscreen ingredients. Specifically, the purpose of the Coalition is to address a breakdown in the current process for consideration by the Food & Drug Administration (FDA) of pending Time and Extent Applications (TEAs) for over-the-counter (OTC) sunscreen ingredients. The goal of the PASS Coalition is to work collaboratively with all stakeholders, including the FDA, the White House, Congress, health providers, consumer organizations, and sunscreen manufacturers to establish a transparent and predictable process for pre-market review of sunscreen components.

MRA is a unique non-profit organization whose mission is to end suffering and death due to melanoma by collaborating with all stakeholders to accelerate powerful research, advance cures for all patients, and prevent more melanomas. Our organization, founded by Debra and Leon Black in 2007 under the auspices of the Milken Institute, is the leading private funder of melanoma research, having awarded more than $51 million in cutting edge research around the world. MRA is proud to be an active member of the PASS Coalition.

The Public Health Problem

Mr. Chairman, skin cancer has become a public health crisis in the United States. Today, skin cancer is the most common form of cancer diagnosed in the U.S. Each year there are more new cases of skin cancer -- including melanoma -- than the combined incidence of breast cancer, prostate cancer, lung cancer and colon cancer. Melanoma, which is the deadliest of the skin cancers as a result of its ability to move quickly and spread to distant organs in the body, is rising dramatically across demographics.

In the United States each year, more than 76,000 Americans are diagnosed with melanoma - one every eight minutes - and more than 9,400 Americans die of melanoma - one every hour. Despite recent tremendous advancements in treatment science, the melanoma death rate for patients with metastatic disease has remained static over the past 30 years, and the incidence of this deadly disease continues to rise at alarming rates.

MRA's mission is to accelerate the progress of science and innovation with the ultimate goal of defeating this deadly disease. And we have made real strides on the treatment front – especially in the last several years where four new drugs have been approved for use by the sickest of melanoma patients. We commend the FDA for its work in this area, including landmark efforts to evaluate and approve new modalities of treatment in immunotherapy, companion diagnostics for biomarker-driven targeted therapies, combination therapies, and activating the new Breakthrough Therapy designation to speed review processes. We see the agency as a vital partner in our fight against melanoma. These drugs are saving lives, while their approval and use are paving the way for continued investment by our academic and industry partners in innovation that will bring about continued dramatic progress.

Still, we know that more effective options for prevention, diagnosis, prognosis, and treatment of melanoma are urgently needed.

That's why I'm here today. Everyone is at risk for developing melanoma, regardless of demographics. One of the risk factors for skin cancer, and specifically melanoma, is exposure to UV radiation. In fact, one blistering sunburn during childhood can double an individual's chance of developing melanoma later in life. We know that people can reduce their risk of suffering and dying from this disease by limiting their exposure to dangerous UV. Along with others in the field, we take every opportunity to urge people to protect themselves and their loved ones by reducing their exposure to UV (from the sun and tanning beds), to examine their skin and watch for changes, and to see a dermatologist regularly, especially if they notice a change. **A central component of our message to the public is that people should use effective sunscreen protection all year round.**

As an organization that is committed to the best science and accelerating innovation, MRA has become increasingly concerned that the current regulatory environment in the U.S. is a barrier to enhanced innovation in the area of bringing the most effective products forward to the public.

As you know Mr. Chairman, FDA is responsible for ensuring the safety and effectiveness of all drugs. FDA's authority over drugs includes medical claims related to sunscreens and sunscreen ingredients. FDA estimated that it would take 90-180 days to evaluate TEA applications and approve approximate 30 new OTC products each year under the TEA process. Despite a number of sunscreen applications pending FDA review and approval -- some that were filed over 10 years ago -- FDA has not completed the review of, or approved, any new sunscreen component under its existing OTC process since the 1990s. As a result, U.S. consumers have not had the benefit of accessing the most cutting edge science and innovation in this field.

I'd like to reiterate my earlier point, Mr. Chairman, about treatments for melanoma. The FDA has recently approved several new drugs for melanoma patients. Unfortunately, while the FDA

is moving forward with timely review and approvals for cutting edge products to treat patients with melanoma -- and we all commend the agency for doing so -- it hasn't fully reviewed or approved any of the latest products that have been designed to *prevent* melanoma and skin cancer in the first place. Mr. Chairman, we can do better.

It's clear the current sunscreen pre-market review process needs to be reformed to ensure timely review and to add transparency and predictability. The general public agrees. A U.S. National poll conducted in 2013 found that 86 percent of Americans support reforms that ensure the United States has access to the latest sunscreen technology.

It is important to point out that the sunscreens Americans use today can be effective for those who use them correctly, which includes sufficient application and re-application, as well as year-round. However, the latest products developed and used around the world, some of which remain pending at FDA for over 10 years, offer important steps forward in the science of broad spectrum coverage, the length of efficacy of active ingredients and sensorial attributes. These should be made available in the U.S. if found to be safe and effective. Picture this scenario as a point of comparison -- imagine if melanoma patients in the United States were told that although new scientific advances in treatment of melanoma are being made available in the rest of the world, in the U.S. they could only have access to treatments available more than a decade ago. It is hard to imagine that we would accept that situation, yet this is precisely where we are today when it comes to sunscreen regulation.

Among the innovations that the companies have been making in sunscreen filters and products are new ways of expanding the broad spectrum efficacy, taking into account improvements in scientific understanding of the different wavelengths of UV rays and the dangers they pose to our skin. Additionally, companies have been working to address issues of consumer preference and sensorial attributes (products that feel less heavy or sticky when applied correctly to the skin.) This is important as people may not use a product as directed for maximum efficacy if that product is uncomfortable to apply. As those of us with children know all too well when our kids squirm when we approach with a tube of sunscreen, finding innovative ways to make these products more user friendly can help improve the rate at which people are using them properly and to maximum effect. Unfortunately, given the history of stalled reviews under the FDA's current process, there is a strong disincentive for companies to invest in sunscreen innovation in the U.S. market.

FDA's Regulatory Approval Approach

Let me provide some background information on the FDA review process for these products. In 1972, FDA began reviewing OTC products already on the market not covered by a New Drug Application (NDA). FDA established review panels to evaluate OTC drugs on the market pre-1972 by category and began developing monographs for each category of drug product. If an OTC drug meets the criteria established in a monograph, it is considered "generally recognized as safe and effective," or GRASE, and does not need independent premarket approval. The existing OTC drug monographs are codified in regulation. Although several versions of a final monograph for sunscreen products have been developed, a final monograph has not been implemented.

In January 2002, FDA published a final rule establishing the TEA process to consider new applications for OTC products that were not covered by existing OTC monographs and to allow for changes to the monographs to include new products or creation of new monographs. The final rulemaking stated that FDA "will strive to complete TEA evaluations in 90-180 days." Sunscreen ingredients were put in the category of products to be reviewed under this process.

The criteria for a product to be eligible for the TEA process are:

- It must be marketed for OTC purchase by consumers; and
- It must have been marketed for use as an OTC product for a minimum of 5 continuous years in the same country and in sufficient quantity.

FDA interpreted 5 continuous years of "use" as either in the US or in a foreign country.

The TEA Process

The TEA application process follows the following timeline:

- **Application.** A sponsor submits an application with a description of the OTC drug component and its basic chemical make-up, a list of all the countries in which the OTC drug component has been marketed, the duration of marketing, and detailed information about how the OTC drug component has been marketed.
- **Notice of Eligibility.** If FDA considers the drug eligible for consideration in the OTC monograph system, it publishes a Notice of Eligibility in the Federal Register and accepts public comment on the application.
- **Public Comment.** The sponsor and other interested parties can submit public comments, including additional data to support or challenge safety and effectiveness.
- **Determination.** FDA makes a determination regarding whether the OTC drug component is GRASE.
- **Rulemaking.** If an application is determined to be GRASE, FDA publishes a proposed rulemaking to either add the OTC drug component to an existing OTC monograph or create a new monograph. After a public comment period, FDA publishes a final rule and the OTC drug component may be marketed in the U.S. according to the terms of the final rule.

Unfortunately, a final rule approving a TEA application has never been issued for any new OTC drug component, including for sunscreen. Some sunscreen applications have been pending since the TEA process was established in 2002. And remember, to be eligible for the TEA program, these products had to have been marketed for at least 5 years prior to eligibility. Therefore, some of the pending sunscreen products were developed in the 1990s and have been used all over the world since then; however, FDA has not completed a review or approved any of these products in the United States.

Imagine our lives if we were living with 1990s technology. Cell phones would still be the size of a briefcase, iPods would not exist, and air bags would still be an optional feature on luxury cars.

Below is a list of the current -- and still pending -- sunscreen ingredient applications:

Pending Sunscreen Ingredient Time and Extent Applications			
Ingredient	Date of Submission	Eligibility Determination	Docket
Amiloxate	8/14/2002	7/11/2003	FDA-2003-N-0196
Enzacamene	8/21/2002	7/11/2003	FDA-2003-N-0196
Octyl Triazone	8/21/2002	7/11/2003	FDA-2003-N-0196
Bemotrizinol	4/11/2005	12/5/2005	FDA-2005-N-0453
Bisoctrizole	4/11/2005	12/5/2005	FDA-2005-N-0453
Iscotrizinol	9/16/2005	7/26/2006	FDA-2006-O-0314
Ecamsule	9/18/2007	9/12/2008	FDA-2008-N-0474
Drometrizole Trisiloxane	1/21/2009	6/2/2010	FDA-2003-N-0196

A Proposal for Reform

The PASS Coalition supports the Sunscreen Innovation Act. This bipartisan/bicameral proposal will improve the TEA process to expedite the approval of applications for components of OTC sunscreen products. While maintaining the basic structure and eligibility standards of the current review process, the Act provides transparency and predictability.

The Act streamlines the TEA process by codifying a timeframe for review and providing FDA with the authority to make a final scientific decision on the application instead of through rulemaking. It ensures that all submissions are reviewed within a predictable timeframe by requiring that the current sunscreen backlog be reviewed within 8 months and new submissions be reviewed within 11 months.

While keeping the existing process whereby FDA makes an eligibility determination, the Act says an existing Advisory Committee of experts, the Nonprescription Drugs Advisory Committee (NDAC), will review the safety and efficacy data. Under the Act, NDAC will make a recommendation to FDA regarding whether the product is safe and effective. But importantly, this is only a recommendation. FDA remains the final arbiter about whether a product is approved for marketing in the United States. FDA has the authority to review every product before it goes to market.

The Act also requires FDA to submit a report regarding the progress of the new review and approval process to Congress 12 months following passage of the bill and every two years thereafter.

The legislation is a pragmatic way of alleviating the current backlog of sunscreen ingredients and streamlining the TEA process for all sunscreen ingredients. Its enactment would be a victory for all parties -- FDA would be administering a process that ensures safe and effective products reach the market as soon as possible; manufacturers would know that their product application would receive a timely review and would be incentivized to invest in innovation to prevent more

melanomas; and most importantly, Americans could get access to the most innovative sunscreen products.

Mr. Chairman, and members of the Subcommittee, I commend you for your leadership in holding this hearing today. May is Melanoma Awareness Month. As the weather improves and people are once again making plans for outdoor activities, MRA and the PASS Coalition strongly urge you to support and enact the Sunscreen Innovation Act. Doing so will bring overdue and needed reforms to the FDA review process and provide a commonsense approach to empowering Americans to reduce their risk for melanoma by providing a responsible path for new, effective products to reach the American consumer.

The PASS Coalition looks forward to working collaboratively with Congress and FDA to further improve the Sunscreen Innovation Act and ensure it is signed by the President this year.

Thank you. I'd be happy to answer any questions you might have.

Mr. PITTS. The Chair thanks the gentlelady.

And I now recognize Mr. Faber, 5 minutes for an opening statement.

STATEMENT OF SCOTT FABER

Mr. FABER. Thank you, Mr. Chairman, members of the committee. EWG strongly supports the goals of the Sunscreen Innovation Act, and we look forward to working with the committee to expedite the review of sunscreen ingredients.

I don't think I need to spend any time describing why skin cancer is a public health crisis or how FDA has not had the incentives to quickly review and approve sunscreen ingredients that have been used in Europe, Australia and other countries. So let me just take a few minutes to describe some of the truly modest improvements that we would propose to this act that we think would ultimately make it a more workable piece of legislation.

So, first, and Mr. Dingell referred to this, we believe that to be eligible for expedited review, that a sunscreen ingredient should have been used for 5 years in a country with a competent regulatory system or, as Mr. Dingell put it, roughly equal to ours. As currently drafted the Sunscreen Innovation Act would allow expedited review for an ingredient that has been used in any one country for 5 years. It doesn't distinguish between any one country and other countries that may have similar review systems to the U.S. review systems.

Second, ingredients that are subject to expedited review should have been used as sunscreen ingredients, not as cosmetic ingredients or ingredients in dietary supplements, and one provision of the bill does suggest that those ingredients, ingredients that have been used for this purposes, could be eligible for this expedited review of sunscreen ingredients in the U.S.

Third, and perhaps most importantly, I think it is very important that the panel that does review these ingredients that have been used in the EU and Australia and elsewhere has the technical competency to review potential health risks posed by sunscreen ingredients as Dr. Woodcock said, that might result from repeated long-term exposures. And while the Nonprescription Drugs Advisory Committee has many experts, they may not have the expertise to quickly and thoroughly review all of the potential health effects that might result from the sorts of ingredients that we are requiring for review.

Fourth, and we have heard a little bit about this already. We think that Congress should set deadlines but workable deadlines for FDA and this advisory committee. For example, the current draft, under the current draft, the expert panel would be required to review all of the eight pending Time and Extent Applications that FDA within 180 days, which seems like a herculean task. So while we think deadlines are important, in light of the long history of delay, deadlines are essential, we think those deadlines need to be workable and, again, that the advisory panel that reviews these ingredients has the technical competency to really do a thorough evaluation.

Similarly, we think the FDA should have more than 45 days to respond to a recommendation by the advisory panel envisioned by the Sunscreen Innovation Act.

Fifth, we think that ultimately, although there is an important role here to be played by a panel of experts, that ultimately, FDA should make the final determination of ingredient safety and that supervisors who are reviewing CDER staff decisions should have the power to ask for more information, either from FDA staff or from the panel, not simply to decide whether or not the ingredient should be intercommerce or not.

Sixth, we believe that applicants seeking expedited review should provide both published and unpublished data regarding the safety and efficacy of sunscreen ingredients, and that data should be shared with the public. Obviously, the current bill does envision a role for the public, and we appreciate that. I think we just need to be clear about precisely what we are asking companies to provide, if they are going to receive expedited review and how much of that is available to the public.

And then, lastly, we think it is critically important that FDA be required to finalize a proposal to restrict the use of SPF claims greater than 50. Other countries have taken steps, including Australia and Japan and others, to restrict SPF claims greater than 50. But we do think that FDA should be given more time than is envisioned in the current bill to assess the inhalation risks and other risks posed by aerosol sprays. FDA has started to look at this question. It has only begun in the last few years. It is a critically important health question. We think they should be given the time to do a thorough and a fair assessment.

Let me just simply close by saying that we applaud Congressman Whitfield and Mr. Dingell for your leadership. We share the goals of the Sunscreen Innovation Act. We look forward to working with you to give FDA the help it needs to quickly review and approve these promising ingredients. Thank you.

[The prepared statement of Mr. Faber follows:]

Testimony of Scott Faber

Senior Vice President for Government Affairs
Environmental Working Group

Before the

Subcommittee on Health

of the

House Committee on Energy and Commerce

on

H.R. 4250, the Sunscreen Innovation Act

April 7, 2014

Thank you for the opportunity to testify. My name is Scott Faber and I am the Senior Vice President for Government Affairs at EWG.

EWG welcomes the opportunity to testify on H.R. 4250, the Sunscreen Innovation Act. We share the goals of Representatives Whitfield and Dingell, and we look forward to working with the Committee to accelerate FDA's review and approval of sunscreen ingredients that may help reduce the troubling rise in skin cancer rates.

EWG has been recognized since 1993 as the nation's leading environmental health organization. Since 2007, EWG has published an annual sunscreen guide that rates the safety and efficacy of sunscreens, lotions, lip products and makeups that advertise sun

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protection. We have also repeatedly urged the FDA to strengthen and finalize regulations governing the safety, effectiveness and labeling of OTC sunscreen products.

Simply put, skin cancer is a public health crisis. Every year, more and more Americans are diagnosed with it. More than 2 million of us develop skin cancer each year, including the most dangerous form, melanoma. In 2009, more than 61,000 people developed melanoma, and more than 9,000 died as a result.[1]

Over the past 35 years, the rate of new melanoma cases has tripled – from 7.89 per 100,000 in 1975 to 23.57 in 2010.[2] The melanoma death rate for white American men, the highest risk group, has increased from 2.64 to 4.10 deaths per 100,000. Since 2000, the rates of new melanoma cases for both men and women have been climbing by 1.9 percent per year,[3] including an especially troubling increase among teenagers.[4]

Sunlight produces two kinds of ultraviolet rays that can damage the skin and lead to skin cancer: ultraviolet A, which can penetrate the skin, and ultraviolet B, which does not penetrate the skin but is still harmful and is the primary cause of sunburn.[5] Although wearing protective clothing and avoiding intense sunlight are the best strategies for minimizing the risk of skin cancer, sunscreens that provide balanced UVA and UVB protection may reduce long term skin damage and aid in lowering the risk of skin cancer.

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[1]http://www.cdc.gov/cancer/skin/statistics/trends.htm
[2]http://seer.cancer.gov/csr/1975_2010/
[3]http://www.cdc.gov/cancer/skin/statistics/trends.htm
[4]http://www.ewg.org/2013sunscreen/skin-cancer-on-the-rise/
[5]http://www.cdc.gov/cancer/skin/statistics/trends.htm

Currently, however, sunscreens marketed in the United States have limited formulation options, and most products provide inadequate protection from UVA rays. That's largely because the FDA has failed to review and approve promising sunscreen ingredients that have been sold for years in Europe, Australia and other countries.

European sunscreen manufacturers can choose from 27 approved sunscreen chemicals, including seven that were expressly designed to filter UVA radiation. By contrast, US manufacturers can choose from only 17 chemicals, including just three that screen UVA rays.[6] The most common is avobenzone, which the FDA approved in 1972. Applications for approval of several promising chemicals that are photo-stable, offer stronger UVA protection, and are already in use in the EU and Australia – including Tinosorb S, Tinosorb M and Mexoryl SX – have been languishing at the FDA since 2005 and 2007, respectively.

To date, the FDA does not have a mechanism to quickly and efficiently review the safety of new active sunscreen ingredients. In 2002, the agency finalized rules for adding chemicals to its sunscreen monograph through a Time and Extent Application, with the intent of completing evaluations within 90 to 180 days.[7] Since then, however, not a single active ingredient has been approved through this process. Of eight chemicals currently under review, six have been under review for more than eight years. While it is imperative that FDA collects adequate health and safety information on new ingredients, long delays in evaluating this information are a detriment to public health.

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[6]http://www.ewg.org/2013sunscreen/europes-better-sunscreens/
[7]http://www.gpo.gov/fdsys/pkg/FR-2002-01-23/pdf/02-1457.pdf

The FDA has also failed to finalize its overall regulations governing sunscreens. In 1978, the agency announced its intention to develop a regulatory monograph governing the safety, effectiveness and labeling of OTC sunscreen products.[8] However, it took the FDA 15 years to develop a draft of its sunscreen monograph.[9] It has since issued a few regulations, but nearly four decades after the original announcement it has yet to finalize the monograph to ensure the safety and effectiveness of sunscreens.[10]

Furthermore, the FDA's recent rules fail to provide consumers with adequate protection. Almost all sunscreens marketed in the U.S. meet the new FDA rules for "broad spectrum" protection – suggesting that they offer adequate protection from both UVA and UVB rays – even though half of these products would likely not be sold in the EU under its stricter guidelines. What's more, the FDA has not restricted the use of Vitamin A as an inactive ingredient in sunscreens, even though it has been shown to hasten the development of skin tumors and lesions on sun-exposed skin,[11] or to consider the toxicity of oxybenzone, a common chemical in sunscreens that triggers allergic reactions and may disrupt the hormone system.[12]

In light of the seriousness of America's skin cancer crisis and the long history of delay, we believe that Congress should act to accelerate the review of sunscreen ingredients and

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[8] 43 Fed. Reg. 38,206 (Aug. 25, 1978)
[9] 58 Fed. Reg. 28,194 (May 12, 1993)
[10] 76 Fed. Reg. 35,620 (June 17, 2011)
[11] Although the NTP found in 2012 that both retinylpalmitate and retinoic acid speed up the development of cancerous lesions and tumors on UV-treated animals, the FDA has refused to take action.
[12] Studies of several sunscreen chemicals indicate they may mimic hormones or disrupt the hormone system (Krause 2012, Schlumpf 2001, 2004b, 2008). Some research suggests that oxybenzone, 4-MBC, and octinoxate are toxic to reproductive systems or interfere with normal development. See http://www.ewg.org/2013sunscreen/the-trouble-with-sunscreen-chemicals/

require the FDA to finalize its sunscreen monograph. While we support the goals of the Sunscreen Innovation Act, we hope the Committee will address the following considerations:

- **Competent Regulatory Authority** – The Sunscreen Innovation Act would grant expedited review to sunscreen ingredients that have been in commerce for five years in another nation. However, H.R. 4250 does not address whether that nation must have a competent regulatory program capable of adequately assessing the safety and efficacy of sunscreen ingredients.

- **Use as Sunscreen Ingredient** – Because the use patterns of cosmetics and dietary supplements are different from use patterns of sunscreen, we believe that any ingredient assessment by the FDA or an expert panel should be based specifically upon its use as a sunscreen ingredient, not as a cosmetic or dietary supplement ingredient, as proposed in Sec 2 © (2) of H.R. 4250.

- **Role of Expert Panel** – The Sunscreen Innovation Act would require the FDA's Nonprescription Drug Advisory Committee to review the safety and efficacy of sunscreen ingredients, including pending Time and Extent Applications and other ingredients FDA deems eligible for review. The NDAC is a 14-member Advisory Committee with broad representation that meets quarterly. EWG is concerned that the NDAC may not have the technical competency to review potential risks posed by sunscreen ingredients, including long-term risks posed by chemicals that

disrupt the endocrine system or cause severe allergic reactions. We look forward to working with the Committee to ensure that sunscreen ingredients are reviewed by an advisory panel composed of qualified experts.

- **Deadlines** – Although EWG shares the frustration of Reps. Whitfield and Dingell, we are troubled by the short deadlines contemplated by H.R. 4250. In particular, we are concerned about the ability of the NDAC to properly review all the ingredients subject to Time and Extent Applications within 180 days. Currently, there are eight Time and Extent applications pending at the FDA, and each of these chemicals poses unique safety and efficacy questions.[13] Furthermore, we believe that 45 days is insufficient time for the FDA to respond to an NDAC recommendation and do not believe that the FDA's failure to act should result in the approval of an ingredient.

- **Role of the FDA** – As noted above, EWG believes the final determination of ingredient safety and efficacy should be made by the FDA. However, we are concerned that Sec. 4(2)(D) limits the ability of the Center for Drug Enforcement and Research (CDER) to seek further review by FDA staff, the NDAC or other experts. As currently drafted, H.R. 4250 would only allow CDER to approve an ingredient when FDA staff has failed to "provide reasonable and sufficient support" for a decision to disregard an NDAC recommendation. In essence, this provision would give the "supervisor" only one choice: to approve an ingredient.

[13]Three ingredients -- Tinosorb S, Tinosorb M and Mexoryl SX – likely pose little or no risk to public health and should receive expedited review.

- **Availability of Data** – EWG is pleased the Sunscreen Innovation Act anticipates public involvement in NDAC and FDA reviews of ingredients. To better understand the safety and efficacy of sunscreen ingredients, we believe that applicants should be required to conduct a literature review and to submit both published and *unpublished* data about toxicity and use, so that the FDA, experts and consumers can fully assess the benefits and risks. We also look forward to working with the Committee to clarify when application information would be treated as confidential or trade secret.

- **Labeling** – Because of their unproven health benefits and because consumers are easily misled by "Sun Protection Factor" ratings, EWG strongly supports proposals to restrict the use of SPF claims greater than 50. While consumers may believe a sunscreen with an SPF of 30 provides twice the level of protection of a sunscreen with an SPF of 15, the reality is that this doubling of the SPF simply increases the ability of the sunscreen to filter UVB rays from 93 percent to 97 percent. A further increase to SPF 50 only blocks out 98 percent of UVB rays. Claims beyond SPF 50 are misleading and should be prohibited – a step already taken by many U.S. trading partners.[14] The FDA should be allowed to set an expedited and reasonable timeline for this review.

[14]In addition, the SPF value does not reflect the product's ability to filter out UVA rays. Studies suggest that high-SPF users are exposed to more UV rays because of the false sense of security created by misleading claims.

- **Aerosol Testing** – We are concerned that Section 3(1) of H.R. 4250 would require an FDA determination of the safety of sunscreens sold as an aerosol – which may pose serious inhalation risks – before adequate reviews have been completed. The FDA began to review the safety and efficacy of aerosol sprays in 2011 and should be granted more than 180 days to complete this important work.

EWG applauds Reps. Whitfield and Dingell for their efforts to accelerate review of the safety and efficacy of sunscreen ingredients and we look forward to working with the Committee to enact legislation that helps reduce the risk of skin cancer.

Mr. PITTS. Chair thanks the gentleman.

That concludes the opening statements.

We will now go to questioning. I will recognize myself 5 minutes for that purpose.

Dr. Fountain, can you please describe the impact DEA delays have on patients suffering from epilepsy?

Mr. FOUNTAIN. Well, in addition to the impact we talked about before, of the risk of death during the whole time seizures are active, there is a much wider and more difficult perspective. So about 3 million Americans have epilepsy and about 1 million of them, so almost a million Americans, have intractable epilepsy, meaning they continue to have seizures despite our best efforts. So for all of those people, having a delay in treatment can be life-threatening, as we talked about. And that affects a relatively few people in a very important way. There is also a huge effect on everyone else. Because for the remainder of people, they need new drugs available soon because they are waiting for a new drug to control their seizures.

Epilepsy is difficult in many ways, but one of the ways is that, although we now have almost 20 drugs available for the treatment of epilepsy, we still have this group of people that continue to have seizures despite our best efforts. But as each new drug is approved, we are able to control more and more people with epilepsy. And if you are in that group that is controlled, then waiting for that drug is a longer time that exposes you to the problems of epilepsy.

Mr. PITTS. Thank you.

Mr. Barber, do you believe DEA adequately factor legitimate patient access into its registration and scheduling time frames as well as its enforcement decisions?

Mr. BARBER. Mr. Chairman, I will first address the issue of scheduling, particularly with regard to new molecular entities. The studies that are done by HHS are binding on DEA when it comes to the medical and scientific factors, and so the delay time in studying a new molecular entity is curious because there is no law enforcement data for a molecule that has not previously existed. So looking for issues of real diversion and law enforcement activity around a new molecular entity seem like they should be very brief because the entity has not previously existed.

I believe that DEA does care about patient access. I am not sure that they necessarily take into account the unintended consequences of the significant delays that come with new molecular entities when scheduling.

With respect to enforcement activity, certainly, Mr. Chairman, I do believe and as a long-time DEA employee—I have been gone for 2½ years—I believe the agency cares about patient access. But, again, it is the unintended consequences. Mr. Rannazzisi testified previously and knowing him, he is a pharmacist, he does care about patient access. I am just not convinced that the way the agency handles enforcement activities contemplates all of the unintended consequences in the supply chain.

Mr. PITTS. Mr. Gray, do you have anything to add on this front?

Mr. GRAY. I believe his assessment is correct. I think they have a legitimate goal.

I think, as you said, Mr. Rannazzisi is a pharmacist himself. But it is the law of unintended consequences when you apply what I would call enforcement tactics for illegal drugs to the legal market. And what happens is what has happened in the case of our members is without specific guidance and detail as far as how they are to interpret suspicious orders, then our members are forced into situations where they make decisions to terminate relationships with pharmacies, thereby immediately limiting that pharmacy's ability to get certain Schedule II drugs.

Mr. PITTS. Would either of you comment on how a more collaborative relationship between supply chain, stakeholders, and the DEA, would help in our effort to address prescription drug abuse and diversion?

Mr. BARBER. Certainly, Mr. Chairman.

I will point to a historical example that really brings this to light. There was a significant problem with methadone overdose deaths related to the 40-milligram methadone diskette. And without any regulation, without any new law, DEA called manufacturers and distributors in and asked them to voluntarily not sell the 40-milligram methadone diskette, except for narcotic treatment programs, not to sell it for dispensing for pain. And the manufacturers and distributors responded and voluntarily did that, and it reduced the overdose deaths related to 40-milligram diskettes, so collaboration absolutely actually addresses the real problem of prescription drug abuse.

Mr. PITTS. Ms. Selig, Mr. Faber, Dr. Woodcock committed to working with the committee to improve the timelines and predictability of the Time and Extent Application, TEA, process is a it relates to new sunscreen ingredients. Do you think the TEA process provides an efficient mechanism by which these types of products can get to consumers in the U.S., and what else can be done?

Ms. SELIG. Thank you, Mr. Chairman. I appreciate Dr. Woodcock's statement, and we look forward to continuing to work with FDA. That said, I think that we have heard repeatedly from FDA, and our own assessment is we need your help here in Congress, and that is why we support this legislation, that the current regulatory process that the TEA system and the OTC system for sunscreens is based on has really been broken. And in order to not only clear out the backlog that exists with those eight applications that are pending, but to encourage innovation and to bring the most cutting-edge innovation to American consumers, we need your help with this legislation.

Mr. PITTS. Mr. Faber, do you want to add anything?

Mr. FABER. I will just had that this process has been in place since 2002, and FDA has been unable to review and improve even one sunscreen ingredient, and that six of the eight ingredients that have sought applications, have filed applications, have languished at FDA for more than 8 years. So I think, clearly, as we have all heard today, that this process is not working for consumers or for manufacturers.

I do think, with all due respect to Dr. Woodcock, that we should not have to wait for a reformation of the sense of the monograph process for FDA and with the help of an advisory panel to review and approve some of these very promising ingredients.

Mr. PITTS. The Chair thanks the gentleman. My time is expired.

The Chair now recognizes Mr. Green 5 minutes for questions.

Mr. GREEN. Thank you, Mr. Chairman.

Dr. Fountain, can you describe what your organization's communication with DEA is like, and how do you think it could be improved?

Mr. FOUNTAIN. Our communication has been limited to more or less the issue at hand because of the seemingly desperate situation that I mentioned before about how long it has taken to have the most recently approved, FDA approved drug scheduled by the DEA. In that case, the communication was sent to DEA and received a response 7 and a half months later, and we don't have—I would have to inquire of the whole organization, but I am not aware of any ongoing dialogue.

Mr. GREEN. And as you know from my questions of the DEA, I have problems with that. I think the DEA needs to be more transparent in dealings with patients, doctors and companies regarding scheduling and registration decisions. I think it needs to have a predictable time frame for making these decisions, and I think the decisions need to be made more quickly, and I hope we can pass our bill to fix it.

Mr. Faber and Ms. Selig, H.R. 4250 could be seen as ceding to FDA decisionmaking authority to an advisory committee, although it does provide the FDA with some authority to reject that decision. As far as I know, this would be unprecedented use of the advisory committee. I would like to get both of your reactions to the description in the bill.

Mr. FABER. As I said earlier, I do think that there needs to be some very modest improvements made to the Sunscreen Innovation Act that would give FDA more time to review the recommendation of a technically competent advisory panel and that the FDA should have the final say regarding the safety and efficacy of a sunscreen ingredient. I think one of the important changes is that there is an appeals process envisioned in this bill where the supervisory staff, CDER staff, could ultimately overrule a staff decision. That supervisor should have the power to ask staff for more information, to ask the panel for more information, and not simply be in the position of having to approve the panel's recommendation.

Mr. GREEN. Would the PASS Coalition be willing to work with the committee and the FDA to improve the legislation to get a bill that would work for all of us?

Ms. SELIG. Absolutely. The coalition has been attempting to work with everybody involved throughout this process and has had multiple conversations and meetings with all stakeholders and will absolutely continue to do that.

I think that the bill as drafted would be a great step forward, and we envision, obviously, and from the perspective of melanoma patients and from the public in terms of our recommendation to the American people about using safe and effective sunscreen and using it properly, we definitely want to make sure that these products are reviewed in an appropriate regulatory environment by the FDA to be both safe and effective.

That said, the current process doesn't work. One reason that we have been told that it has been so difficult is because of the regu-

latory rulemaking process. So I think the proposal that is in the legislation is aimed at trying to get out from under that so that we can move these things forward in an appropriately timely manner and get back to innovating in this country, as opposed to watching the rest of the world have access to more innovation than we are having here. So we absolutely will work with everybody to try to make this bill better, but we definitely want to see the legislation move toward.

Mr. GREEN. Mr. Gray, prescription drug abuse is on the rise and represents significant growing public health threat. Congress and relevant Federal agencies in public and private have responsibilities to address this epidemic and ensure the health and safety of the American people. What in your opinion is the appropriate role of prescription drug distributors in the fight to eliminate and prevent this prescription drug abuse?

Mr. GRAY. Well, my members, we have 34 companies that deliver over 98 percent of the prescription drugs in this country, so we are a logical choice to look at where the drugs are coming through and going to. We have the ability, as we do every day, to monitor the ordering of Schedule II drugs to every pharmacy and clinic in the country. We keep that data. We give it weekly to the DEA. And, in fact, that has been one of the conundrums we face is each distributor submits their data to the DEA. The DEA collects the entire picture but does not share even a redacted version of that entire picture. So one distributor may know what they give to a certain pharmacy, but they don't know the other wholesalers, what they are providing that pharmacy. So it is not a complete picture. The information is there. Our members have the technical capability to create that information. And our goal here is to be able to work collaboratively with DEA as a partner in this problem to say, does your information show what our information is, that this pharmacy is over its limits? Great. Cut that pharmacy off. And unfortunately, that is not the relationship we have today.

Mr. GREEN. Thank you, Mr. Chairman. I am out of time.

Mr. PITTS. Chair thanks the gentleman.

I now recognize the vice chair of the full committee, Mrs. Blackburn, for 5 minutes of questioning.

Mrs. BLACKBURN. Thank you so much, and I want to stay with Mr. Gray and follow on with Mr. Green's questioning, because as Mr. Rannazzisi said several times, DEA doesn't have quotas for the distributors, so it is up to the distributors to basically model how they are going to interact with the pharmacies on this product. So looking at the answer you just gave, is there anything else you would add into how these distributors are modeling their activity on the distribution of these drugs? And then I would like for you to talk for just a second about why this is problematic for our smaller pharmacies.

Mr. GRAY. Well, let's go back on that story line we were just talking about. When our members submit their suspicious orders on a weekly basis, DEA collects that data. They collect data from all wholesalers. Imagine it as a piece of pie. They see the pharmacy as a piece of pie. They will see the 360 degrees of that piece of pie. They see everything going in the door of that pharmacy with respect to Schedule II drugs. The particular distributor, who DEA

may be questioning—and you can correct me if I am wrong on this, Linden—but the DEA sees the whole picture. That particular distributor sees only their slice of the pie. They do not see what other distributors are doing.

Mrs. BLACKBURN. So let me ask you. Would it be helpful then if the DEA were to periodically give a report back to those distributors as to where they are seeing patterns that are troublesome?

And Mr. Barber, you may want to weigh in on this since you basically were involved in taking action.

Mr. GRAY. It would certainly help because I know, in many cases, talking to my members, is that they will approach the regional office of DEA and say, "We have got a pharmacy here, pharmacy X; pharmacy X to us has suddenly seen an increase in ordering. This is out of their normal historical trend. Mr. DEA agent or Ms. DEA agent, should we cut that pharmacy off?"

And the answer most typically back is, "Well, that is a business decision the wholesaler needs to make on their own, and then we will essentially fundamentally let you know if you were wrong after the fact."

So you are right. He was right. There are no quotas, but again, that creates the conundrum and the problem because not having quotas gives DEA the flexibility to take enforcement action I think without any kind of clarity to the wholesalers as to whether or not they are making the right business decision in terminating that pharmacy.

Linden, I don't know if you have a different opinion.

Mr. BARBER. Mrs. Blackburn, I have looked at some of the DEA information that they have provided the industry. One of the things that we hear over and over again from the agency is there is an average number of pills that a pharmacy uses, but a pharmacy that fills 50 prescriptions a day uses a lot less drugs than a pharmacy that fills 500 prescriptions a day, and being above arrange is meaningless because if you have a normal distribution curve, half of your customers are going to be above average, and so it would be very helpful to industry if there was trending and modeling done not just by the industry, but by the agency who has all of the information.

Mrs. BLACKBURN. OK. Mr. Barber, in your testimony, you focused a little bit on the importance of clarity of the law, and are there some specific areas that you think we should highlight in working with the DEA on how they should be more clear with the registrant?

Mr. BARBER. Certainly, and I think your bill takes a great first step in creating the environment that is necessary by clarifying what "imminent danger" means and what "consistent with the public health and safety" means. At an industry conference recently, a DEA official told the industry that it means whatever DEA says it does. That is not really helpful when you are trying to comply with the law. There are other areas where I believe that oversight can be helpful, particularly in the regulatory environment. The agency will talk about things like due diligence by distributors on customers and yet you won't find the term "due diligence" anywhere in DEA's regulation. And so areas like that require clarifica-

tion and notice and comment rule making because it is those types of initiatives that actually will prevent prescription drug abuse.

Mrs. BLACKBURN. Thank you.

I yield back.

Mr. PITTS. Chair thanks the gentlelady.

Now recognizes the ranking member emeritus Mr. Dingell for 5 minutes for questions.

Mr. DINGELL. Mr. Chairman, thank you for your courtesy. These questions are for Ms. Wendy Selig of the Melanoma Research Alliance. They will only require yes or no answers.

Ms. Selig, do you believe that skin cancer is a public health crisis in this country today? Yes or no.

Ms. SELIG. Yes.

Mr. DINGELL. Ms. Selig, is it correct that one American dies of melanoma every hour? Yes or no.

Ms. SELIG. Yes.

Mr. DINGELL. Ms. Selig, is exposure to UV radiation a major risk factor for skin cancer? Yes or no.

Ms. SELIG. Yes.

Mr. DINGELL. Now, Mr. Faber. This is for Mr. Scott Faber. Mr. Faber, your organization has extensive experience in this area. Do you agree that sunscreens which provide balanced UVA and UVB protections help lower the risk of getting skin cancer? Yes or no.

Mr. FABER. Yes, sir.

Mr. DINGELL. Mr. Faber, to confirm, do people in Europe, Canada, and elsewhere, have access to more new innovative sunscreen products than do consumers in the United States? Yes or no.

Mr. FABER. Yes.

Mr. DINGELL. Very quickly, why is that?

Mr. FABER. Because our FDA has failed to provide a process that allows expedited review of promising sunscreen ingredients.

Mr. DINGELL. I have been observing that they are sitting on those regulations like a hen on a porcelain doorknob.

Mr. FABER. Yes, sir.

Mr. DINGELL. Now, Mr. Faber, is it correct that FDA has not acted on applications for several chemicals that offer strong UVA protection but are already in use in the European Union and in Australia? Yes or no.

Mr. FABER. Yes, sir.

Mr. DINGELL. Mr. Faber, do you believe that the American people deserve access to these promising sunscreen technologies as long as they are proven to be safe and effective? Yes or no.

Mr. FABER. Absolutely. Yes, sir.

Mr. DINGELL. Mr. Faber, do you agree that the legislation is needed to improve FDA's review of sunscreen ingredients? Yes or no.

Mr. FABER. Yes, sir.

Mr. DINGELL. Mr. Faber, you have been before this committee on a number of occasions, and I have always appreciated your wisdom and assistance.

Thank you to our panel.

It is clear to me that skin cancer is today a major public health crisis in this country, and legislation is needed to improve FDA's

review of new sunscreen ingredients, which they are sitting most tranquilly by.

The Sunscreen Innovation Act is one way to do so. I look forward to working with all of my colleagues to improve this legislation in whatever bipartisan manner may be necessary so it can be signed into law this year.

I would point out that each hour, there is going to be an American somewhere dying of melanoma and skin cancer, and it does seem that maybe the Congress can assist the Food and Drug to come to a proper conclusion of addressing the concerns that we have about keeping Americans safe and affording them the same privileges and protections that are given in Europe, where there have apparently been no backlash, no problems about the question of safety with regard to these pharmaceuticals.

Ladies and gentlemen of the panel, thank you.

Mr. PITTS. The chair thanks the gentleman.

Now recognize the gentleman from Kentucky, Mr. Whitfield, 5 minutes for questions.

Mr. WHITFIELD. Thank you, and I certainly agree with all the comments made by Mr. Dingell and particularly that relating to the porcelain knob. I like that.

Let me just say this, Mr. Faber, thank you for your testimony and for coming up with some concrete suggestions on ways to improve the legislation, and Ms. Selig, I really do want to thank you and the Melanoma Research Alliance as well as the task group for sort of leading the charge on this issue. I was wondering, had you been aware of the suggestions that Mr. Faber made today before he made them today?

Ms. SELIG. I think recently, yes, and we really appreciate the constructive effort to help everybody come up with a product that Congress can move forward with quickly.

Mr. WHITFIELD. I wish that the PASS group would get together with Mr. Faber's organization and see if we can come up with some improvements, and then maybe both sides of the aisle working together, we can move this legislation. And I know that Dr. Woodcock and others at the FDA have indicated they want to do something, so maybe we can help them make the decision on what should be done. So if you all would do that and get back with us, we would appreciate it.

Mr. FABER. Absolutely.

Mr. WHITFIELD. I yield back now.

Mr. PITTS. The Chair thanks the gentleman.

I now recognize the gentleman from Virginia, Mr. Griffith, 5 minutes for questioning.

Mr. GRIFFITH. Thank you, Mr. Chairman.

Mr. Gray, I am up here trying to problem solve and figure these things out because you may have heard my example earlier when I was standing in my local pharmacy, and they were under the impression, DEA witness testified that that was incorrect, that there is no quota, and you have said that as well, but the distributors have to watch it and be careful, and they don't really know when it is they are going to get in trouble with the DEA.

Mr. GRAY. Correct.

Mr. GRIFFITH. So here is what I have come up with that may be affecting—and I represent a fairly rural district that has a lot of small pharmacies. We have fewer mom-and-pop pharmacies than we used to, but still serve a fairly rural, somewhat suburban, but fairly rural community, and that is that apparently it may be true that at some of the smaller pharmacies, they only use one distributor. Has that been your experience, that maybe some of the small pharmacies use one distributor for their drugs?

Mr. GRAY. You know, I think that will depend upon the where and the when. I mean, I would say, and this is just anecdotal, that is probably true the more rural that it is. More than likely it is one wholesaler involved.

But that being said, there is a growing secondary and tertiary industry. When pharmacy cannot get product, they go into those markets to get that product. So it very well may be that they are actually dealing with other wholesalers that may or may not be reporting data to the DEA. It is very possible.

Mr. GRIFFITH. The concern that I have is that maybe they are being flagged, and the distributor is saying, OK, we can't send you any more because you are getting more than the distributor, you know, next valley over or down the road, depending on the size of the pharmacy. And if you are only using one, that is going to flag. As you said, the DEA gets the whole picture, but each distributor only sees what they are doing.

Mr. GRAY. Correct.

Mr. GRIFFITH. And so they can see a pharmacist perhaps that is using one wholesaler or distributor getting more drugs than some of his contemporaries nearby, but they may be using two distributors, but the first distributor is never going to know that they are getting two sources or three sources versus just the one.

Mr. GRAY. Well, the layer of complexity to that is then it depends upon the demographics of that pharmacy and the patient population because the pharmacy in your district may have historically a number of pain patients. They may be near pain clinics. They may be hospitals or cancer clinics. And so it does vary. This is a difficult target because it does vary by pharmacy, by the location, by the demographics of the pharmacy, by the business model, where it is relative to other health care delivery systems in the area. So it is not as black and white as you might think, and that is where any amount of clarity we can get from the DEA as a wholesaler will be of extraordinary help.

Mr. GRIFFITH. And so that is why you feel that they ought to share some of that information so that you all can get the big picture, too. Not that we want to help the bad guys.

Mr. GRAY. That is right.

Mr. GRIFFITH. And so you think that perhaps the information sharing that is envisioned by 4069 would be a good thing?

Mr. GRAY. I think it would be an excellent thing.

Mr. GRIFFITH. And you think that this might help my pharmacy back home?

Mr. GRAY. I think it would help your pharmacy back home because whatever that wholesaler, whoever it was, made that decision, made it because they know the historical purchasing and delivering with that pharmacy, and they probably saw an uptick de-

pending upon the time of the year or whatever. And the way it is played now, is if there is an uptick, then that is defined in the wholesaler's mind, that is suspicious. And the immediate reaction is if it is suspicious, you must terminate, and then talk with the appropriate people. So the decision always is to terminate first when in doubt.

Mr. GRIFFITH. Now, in this case, they didn't apparently terminate long term. Is that what the normal is, or just say no more for this month, or this cycle?

Mr. GRAY. Well, good point. It should be for a finite set of time. In fact, we submitted a series of questions on two occasions to the DEA in the last 24 months. Do not have answers to those questions. One of them actually addressed that issue. For example, we asked a group of our members, said is 90 days, is 120 days, what is the appropriate amount of time before a wholesaler should reinstitute sales to that? What is the appropriate move on the trend line of the purchase order of that pharmacy to make that decision? Unfortunately, to this date, we have no answers. We have got no guidance from the agency.

Mr. GRIFFITH. It is a difficult answer, and so I certainly don't want to be critical of the DEA trying to control medications that shouldn't be out there on the street and making sure that they are not going to folks who shouldn't have them. At the same time, we want to make sure that the Judge's wife that I mentioned earlier and that this lady whose mother desperately needed that medication are able to get it. So it is a balancing act. I appreciate that, and of course, being a legislator by nature and at heart, having served here not so long, but served a long time in Virginia, I recognize that it is the role of the legislative body to help enact that and move things forward, so I hope that we can get some form of 4069 passed.

And, Mr. Chairman, I yield back.

Mr. PITTS. The Chair thanks the gentleman and also thanks the witnesses for your testimony, for answering our questions. There will be follow-up questions. We will provide those to you in writing. We ask that you please respond as promptly as possible. I will remind members they have 10 business days to submit questions for the record, and that means members should submit their questions by the close of business on Monday, April 21. Very important health and public safety issues raised today. Thank you very much.

Without objection, the subcommittee is adjourned.

[Whereupon, at 5:50 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

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Committee on Energy and Commerce
Subcommittee on Health
Hearing on

"Improving Predictability and Transparency in DEA and FDA Regulation"

Testimony Submitted by the Global Healthy Living Foundation
April 7, 2014

Thank you for the opportunity to submit written testimony for the record of the hearing on "Improving Predictability and Transparency in DEA and FDA Regulation." We applaud the Subcommittee for having today's hearing and bringing attention to the complex issue of prescription drug abuse.

The Global Healthy Living Foundation is a 501(c)(3)non-profit advocacy organization, based in New York, with the mission to improve the quality of life for people with chronic illness. GHLF accomplishes its mission by advocating for improved access to care and by educating the community about the importance of diagnosis, early and innovative medical intervention, long-term lifestyle improvement, and therapeutic compliance. Through our CreakyJoints webpage, we advocate on behalf of more than 60,000 patients living with arthritis who experience severe, chronic pain every day.

Zohydro is a new, FDA-approved time-release opioid for the 115 million people in the US dealing with debilitating pain who need medications likes this to stay productive and attain some measure of quality of life. These people are not abusers, but their access to pain medications for their clinically diagnosed medical conditions is being methodically taken away by frustrated law enforcement officials.

The FDA did its job correctly by approving a treatment based on its safety and efficacy data. Despite what was said, this particular pill isn't any more powerful than others on the market. It appears stronger because its ingredients are released over 12 hours, not four, as with other opioids. So instead of taking two 10mg pills every four hours for a total of 60mg every 12 hours, this pill is 50mg and lasts 12 hours. Any opioid can be abused by taking one or several pills in many different available doses.

Diversion of licit drugs to the street is a very real problem with devastating consequences for our communities. However, restricting legitimate patients' access to needed medications is not the answer. There are many proven, evidence-based options for stemming prescription drug abuse, including one national program authorized by this Committee. The National All Schedules Prescription Electronic Reporting (NASPER) Act, sponsored by Congressman Whitman and Ranking Member Pallone,

established a grant program to assist states with creating prescription drug monitoring programs. Since its passage in 2006, 29 states now have an active prescription drug-monitoring program. These programs allow physicians and pharmacists to check a database before writing a prescription to easily identify an abuser who is doctor shopping for drugs, already received prescriptions for pain management, or has tried to fill multiple prescriptions at several different pharmacies.

GHLF supports the use of prescription drug monitoring programs and urges Congress to reauthorize and fully fund NASPER this year to enable the remaining states to establish monitoring programs and/or enhance the ones they currently have in place.

Another successful tactic at reducing prescription drug abuse is the use of abuse-deterrent formulations of highly addictive drugs. This makes drugs useless when they are crushed or cooked, preventing abusers from getting a lethal super-dose. However, because abuse-deterrent formulations are more expensive, health insurance companies usually won't pay for them. Just as seat-belts were considered too expensive in the 60s, health insurance companies are saying abuse deterrence is too expensive; however GHLF believes they must be the standard of care if we care about our public health. We need to address these reimbursement challenges and create incentives for the development of abuse-deterrent formulations.

As the Committee considers policy solutions for prescription drug abuse, we ask that you also focus on the very real challenges that patients living with chronic pain face day after day. Patients need access to safe and effective medications approved by the FDA and that includes Zohydro. Prescription drug monitoring programs and abuse-deterrent formulations of scheduled drugs provide sufficient options for stemming prescription drug abuse. Let's not force patients to suffer and instead, find a balanced evidenced-based solution to this public health crisis.

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225-2927
Minority (202) 225-3641

April 24, 2014

Dr. Janet Woodcock
Director
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Woodcock:

Thank you for appearing before the Subcommittee on Health on Monday, April 7, 2014, to testify at the hearing entitled "Improving Predictability and Transparency in DEA and FDA Regulation."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

Also attached are Member requests made during the hearing. The format of your responses to these requests should follow the same format as your responses to the additional questions for the record.

To facilitate the printing of the hearing record, please respond to these questions and requests with a transmittal letter by the close of business on Thursday, May 8, 2014. Your responses should be mailed to Sydne Harwick, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to **Sydne.Harwick@mail.house.gov**.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

The Honorable Joseph R. Pitts
Chairman
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

JAN 0 8 2015

Dear Mr. Chairman:

Thank you for providing the Food and Drug Administration (FDA or the Agency) with the opportunity to testify at the April 7, 2014, hearing before the Subcommittee on Health, Committee on Energy and Commerce, entitled "Improving Predictability and Transparency in DEA and FDA Regulation." This letter is a response for the record to questions posed by certain Members of the Committee, which we received on April 24, 2014.

If you have further questions, please let us know.

Sincerely,

[redacted]

Thomas A. Kraus
Associate Commissioner
for Legislation

cc: The Honorable Frank Pallone, Jr.
Ranking Member
Subcommittee on Health

We have restated each Member's questions below in bold, followed by our responses.

The Honorable Michael C. Burgess

1. **Following up from what was asked during the hearing, I would ask that you provide this Committee with the status of FDA's guidance on biosimilars naming.**

   a. **When will this guidance become final?**

FDA is currently considering the appropriate naming convention for biosimilar and interchangeable products. As part of this endeavor, we are carefully reviewing the comments on naming, submitted by stakeholders to FDA's biosimilar draft guidances and public hearing dockets, or that otherwise have been submitted to the Agency. We will take into consideration the comments submitted to FDA as we move forward in developing future policies regarding biosimilar and interchangeable products, including those on naming.

As we are currently considering the appropriate naming convention for products licensed under the Biologics Price Competition and Innovation Act (BPCIA), we cannot comment further at this time. If a draft guidance was issued on this topic, the Agency would adhere to FDA's good guidance practices, which include providing the opportunity for stakeholders to comment before draft guidance is finalized.

   b. **Has anyone in the administration outside of FDA provided the agency with substantive suggestions or recommendations with respect to this guidance? If so, please provide the name of the person or persons who provided those suggestions or recommendations, the substance of those suggestions or recommendations, and any action FDA took in response to those suggestions or recommendations.**

If and when FDA issues a draft guidance on biosimilar naming, it would follow the normal course of review, in accordance with good guidance practices.

2. **Does FDA intend to finalize draft guidance that sets an abuse deterrent formulation standard for innovator products? Will you require all new opioids to meet that standard before making final decisions on the approval of affected generic products? Will you make sure the generic versions of abuse-deterrent drug products show they perform as well on all relevant measures as innovator products?**

FDA has been working internally on the scientific and regulatory issues surrounding development and evaluation of abuse-deterrent generics. On September 30 and October 1, 2013, FDA attended a meeting about the draft guidance for industry: "Abuse Deterrent Opioids – Evaluation and Labeling." The discussion was part of the Abuse Deterrent Formulation Science meeting organized by the Cross-Company Abuse Liability Consortium and facilitated with the aid of the College on Problems of Drug Dependence to provide an open forum to foster discussion about the draft guidance.

The draft guidance explains FDA's current thinking about the studies that should be conducted to demonstrate that a given formulation has abuse-deterrent properties, how those studies will be evaluated by the Agency, and what type of labeling claims may be approved based on the results of those studies. FDA is reviewing the comments submitted to the draft guidance and plans to issue a final guidance after review is complete.

In addition, FDA held a public meeting on October 30-31, 2014, to discuss the development, assessment and regulation of abuse-deterrent formulations of opioid medications.[1]

FDA has not issued guidance on the development and testing of generic versions of drugs with abuse-deterrent properties. However, FDA is actively working on the scientific and regulatory issues surrounding the development and evaluation of abuse-deterrent generics, and we may address this topic in future guidance documents as appropriate.

3. On June 20, 2013, FDA published Draft Guidance on Cyclosporine. This draft guidance contained specific guidance on the design of bioequivalent studies to support abbreviated new drug applications. FDA asked that public comments be submitted by August 19, 2013. When does FDA anticipate providing feedback to stakeholders who commented on this draft guidance and/or when does FDA anticipate issuing final guidance?

As described below, FDA is in the process of reviewing comments on the draft guidance for industry, containing bioequivalence (BE) recommendations for cyclosporine ophthalmic emulsion, to determine whether the Agency needs to revise, finalize, or withdraw the draft guidance. Although that process is not complete, FDA addressed many of the issues raised in the comments in its November 20, 2014, response to a related Citizen Petition.[2]

Under FDA's good guidance practice regulation process (20 CFR 10.115), the intent of a draft guidance is to describe FDA's thinking and scientific recommendations on a particular policy area and to solicit input from the public on those recommendations. A guidance document, once finalized, represents FDA's current thinking on the topic. Typically, FDA announces the availability of a draft guidance in the *Federal Register* (FR) and opens a public docket to collect comments from the public. The draft guidance also states that it "contains nonbinding recommendations." FDA uses this transparent process to communicate with the public, so that all interested parties can participate in the process by submitting comments. FDA carefully considers all comments received as part of the guidance finalization process. Once finalized, guidance documents do not legally bind the public or FDA (21 CFR 10.115(d)). An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

This is the public process FDA is currently using to propose BE recommendations for numerous drug products, including cyclosporine ophthalmic emulsion. The process is explained in a guidance for industry, "Bioequivalence Recommendations for Specific Products" *(http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072872.htm)*, issued on June 11, 2010. This guidance explains that product-specific BE

[1] 79 FR 56810, September 23, 2014, http://www.gpo.gov/fdsys/pkg/FR-2014-09-23/pdf/2014-22514.pdf

[2] http://www.regulations.gov/#!docketDetail;D=FDA-2014-P-0304

recommendations would be made available on FDA's website as a way to develop and disseminate product-specific BE recommendations and to provide an opportunity for the public to comment on them. As part of that process, draft recommendations for different products are posted periodically on FDA's website and announced in the FR. With each FR announcement, the public is encouraged to submit comments within 60 days. FDA considers all comments received and either publishes revised draft recommendations for further comment, finalizes the recommendations, or withdraws the draft recommendations.

On June 20, 2013, FDA published an FR notice announcing the availability of draft guidance for industry containing BE recommendations for cyclosporine ophthalmic emulsion *(http://www.regulations.gov/#!documentDetail;D=FDA-2007-D-0369-0229)*. People wishing to submit comments were instructed to submit them under docket number FDA-2007-D-0369, either online at *www.regulations.gov* or by mail. The comments that were submitted can be found at the above-mentioned website and will be taken into careful consideration as FDA reviews the available science to determine whether to revise, finalize, or withdraw the draft guidance.

On February 28, 2014, Allergan, Inc., submitted a Citizen Petition requesting that, among other actions, FDA refuse to accept or approve any ANDA that references RESTASIS (cyclosporine ophthalmic emulsion) if the ANDA does not include data from one or more appropriately designed comparative clinical trials to demonstrate bioequivalence (Docket No. FDA-2014-P-0304). Many of the issues raised in the petition were issues that had been raised in stakeholders' comments on the draft guidance on cyclosporine ophthalmic emulsion. FDA addressed those issues in its November 20, 2014, response to Allergan's petition (copy enclosed). That response reflects the Agency's careful consideration of the information that stakeholders provided in their comments on the draft guidance.

4. **In FDA's more recent response to the House Energy and Commerce Committee, FDA specifically states that the agency will not be allowing compounding of medications for administration in a doctor's office or other office-use setting. It's my understanding that in a bipartisan and bicameral fashion, when the Drug Quality and Security Act (DQSA) passed, many statements were submitted for the record by Senators and Representatives expressing that it was Congress' intent when passing this legislation to allow the issue of office-use to continue to be overseen by the States. In those statements, Congress made clear that while reinstating 503A, Congress did not intend to grant FDA authority over office-use compounding. Since FDA's most recent communications to the House indicate that FDA believes it has authority over office use compounding and thus discretion to prohibit office use compounding, I would like to know how the agency arrived at that conclusion despite the fact that Congress has taken every measure necessary to clearly inform FDA that congressional intent is otherwise. Where does FDA feel it is given authority over office-use and why does FDA feel it is not required to follow clear congressional intent?**

We believe you are referencing FDA's response for the record to the House Committee on Energy and Commerce, Subcommittee on Health, hearing entitled "Examining Drug

Compounding," delivered to the Committee March, 7, 2014. A copy of FDA's response is attached.

In its response to Congresswoman Blackburn's Question 3 regarding "traditional compounding taking place in an office setting," FDA specifically said the following:

> Since the hearing, the President signed the DQSA. Under the DQSA, hospitals and health care professionals can purchase compounded drugs without a prescription from a compounder that is registered as an outsourcing facility, under section 503B. Section 503A requires, among other things, that, to qualify for the exemptions under section 503A there be a prescription for an identified individual patient. The Agency intends to exercise its authority, as appropriate to protect the public health, against compounded drugs that do not qualify for the exemptions in section 503A or section 503B, and drugs that are adulterated or misbranded or otherwise violate Federal laws.

As noted, section 503A requires that to qualify for the exemptions under section 503A, there must be a prescription for an identified individual patient. FDA stands by the statements in its previous response.

5. **In FDA's most recent Warning Letters, FDA has taken the position that pharmacies inspected over a year ago can be held to manufacturers under the recently passed legislation. FDA has sent these Warning Letters to pharmacies located within the 9th Circuit which originally struck down 503A in its courts. It seems pretty clear that in order to hold these pharmacies to these standards, FDA would have to be retroactively applying the law. Therefore, how is FDA holding these pharmacies to a standard of law found within legislation that had not passed when the pharmacy was inspected? In other words, where does FDA feel it is given authority to retroactively apply a law?**

FDA did not retroactively apply the law. Before enactment of the Drug Quality and Safety Act (DQSA), there were conflicting judicial decisions regarding the applicability of section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. § 353a], which exempts compounded drugs from several key statutory requirements, if certain conditions are met. During this time, the Agency's Compliance Policy Guide 460.200 on Pharmacy Compounding (CPG) (2002) was in effect and applicable in the 9th Circuit. The CPG set forth a non-exhaustive list of factors that FDA considered in determining whether to initiate an enforcement action with respect to the compounding of human drugs. Receipt of valid prescriptions for individually identified patients was relevant for both the CPG and section 503A (see 21 U.S.C. § 353a(a) (providing certain statutory exemptions if, among other things, "the drug product is compounded for an identified individual patient based on the . . . receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient . . . ." and CPG at 2: "FDA recognizes that pharmacists traditionally have extemporaneously compounded and manipulated reasonable quantities of human drugs upon receipt of a valid prescription for an individually identified patient from a licensed practitioner. This traditional activity is not the subject of this guidance."). Although this CPG has been withdrawn in light of new legislation, in its Warning

Letters, FDA applied the law and compliance policy in effect at the time it conducted the inspection and, in appropriate cases, noted that a firm was not entitled to the statutory exemptions described in section 503A of the FD&C Act and did not qualify for the Agency's exercise of enforcement discretion set forth in the CPG at the time of our inspection.

In addition, the Warning Letters informed the recipients of the law that is now in effect going forward as a result of the passage of the Compounding Quality Act (CQA):

> Since FDA inspected your facility, Congress enacted and the President signed into law the Compounding Quality Act (CQA), which amended FDCA section 503A by eliminating the advertising restrictions that had been the basis for conflicting judicial decisions. The CQA otherwise left section 503A intact, and so clarified that the remainder of section 503A, including the requirement of valid prescriptions for individually identified patients, is applicable in every federal judicial circuit. Accordingly, the drugs you compound without valid prescriptions for individually identified patients are not entitled to the exemptions in section 503A. [footnotes omitted][3]

As noted, Congress did not change the part of the law that speaks to the need for a prescription. The Agency intends to continue to exercise its authority, as appropriate, to protect the public health.

6. The Biologics Price Competition and Innovation Act (BPCIA) established a pathway for the approval of generic biologics or biosimilars. What significant actions has FDA taken to implement BPCIA? Have any biosimilar applications been filed with the FDA to date?

FDA continues to develop rigorous scientific standards to ensure that all biosimilar and interchangeable products licensed under the pathway established by the BPCIA will be safe and effective. To date, FDA has held two public hearings and issued six draft guidances related to implementation of the BPCIA. As directed by the BPCIA, FDA successfully developed recommendations for Congress for a user fee program for biosimilar biological products in consultation with companies that intend to make biosimilar products, patient and consumer advocates, health care professionals, and other public stakeholders. The enactment of the Biosimilar User Fee Act of 2012 on July 9, 2012, as part of the FDASIA, authorizes user fees to support the review of marketing applications for biosimilar biological products.

The November 2010 public hearing provided a forum for interested stakeholders to provide input regarding the Agency's implementation of the BPCIA. FDA considered the presentations and public comments submitted to the docket in developing three draft guidances issued in February 2012.[4] FDA held a second public hearing in May 2012 to receive input on these draft guidances

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[3] http://www.fda.gov/iceci/enforcementactions/warningletters/2014/ucm396239.htm

[4] "Scientific Considerations in Demonstrating Biosimilarity to a Reference Product," http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM291128.pdf; "Quality Considerations in Demonstrating Biosimilarity to a Reference Product," http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryInformation/Guidances/UCM291134.pdf; "Q & As regarding Implementation of the BPCI Act of 2009." http://www.fda.gov/downloads/Drugs/GuidanceComplianceregulatoryInformation/Guidances/UCM273001.pdf

and in obtaining public input regarding the Agency's priorities for development of future policies regarding biosimilars. FDA issued a fourth draft guidance in March 2013,[5] a fifth draft guidance in May 2014,[6] and a sixth guidance in August 2014.[7] FDA will take into consideration all comments received as we move forward in finalizing these draft guidance documents and developing future policies regarding biosimilar products and interchangeable products.

FDA listed a number of draft guidances related to biosimilars that are under development on CDER's Guidance Agenda for 2014.[8] The public will be provided with an opportunity to comment on these new draft guidances, when they are published.

In addition, in September 2014, FDA published its first-ever "Purple Book." The "Purple Book" lists biological products, including any biosimilar and interchangeable biological products licensed by FDA under the Public Health Service Act (PHS Act). The Purple Book will also enable a user to see whether a biological product licensed under section 351(k) of the PHS Act has been determined by FDA to be biosimilar to or interchangeable with a reference biological product (an already-licensed FDA biological product). Biosimilar and interchangeable biological products licensed under section 351(k) of the PHS Act will be listed under the reference product to which biosimilarity or interchangeability was demonstrated. Separate lists for those biological products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) will be updated periodically (see *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm*

FDA continues to actively engage with sponsors regarding biosimilar development. This includes holding development-phase meetings and providing written advice for ongoing development programs. FDA continues to meet with sponsors interested in developing biosimilar products. As of November 30, 2014, 51 programs were in the Biosimilar Product Development (BPD) Program involving the development of biosimilar products to 14 different reference products.

FDA has not approved any biosimilar products to date. FDA is prohibited from publicly disclosing the existence of a biological product file before a biologics license application has been approved, unless the existence of the file has been previously publicly disclosed or acknowledged. FDA is aware that an applicant has publicly disclosed that FDA filed its application for a proposed biosimilar to Neupogen (filgrastim), another applicant has publicly disclosed that FDA filed its application for a proposed biosimilar to Remicade (infliximab), and a third applicant publicly disclosed that FDA filed its application for a proposed biosimilar to Neulasta (pegfilgrastim).

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[5] "Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants" *http://www.fda.gov/forindustry/userfees/biosimilaruserfeeactbsufa/ucm311811.htm.*

[6] "Clinical Pharmacology data to support a demonstration of Biosimilarity to a Reference Product," *http://www.fda.gov/Drugs/guidanceComplianceregulatoryInformation/Guidances/ucm290967*

[7] Published August 2014, "Guidance for Industry: Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act (Draft Guidance)" *http://www.fda.gov/Drugs/DevelopmentApprovalProdces/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/default.htm*

[8] *http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm314767.pdf*

The Honorable John D. Dingell

1. **How many sunscreen ingredient applications are currently pending at the FDA and how much time has passed since they were submitted?**

FDA has publicly announced that eight new sunscreen ingredients have satisfied the Time and Extent Application (TEA) eligibility requirements and are being considered for OTC monograph status, and has requested and received submissions of safety and efficacy data for each of these eight ingredients.

FDA received submissions for these eight ingredients between 2002 and 2009.

2. **Why has the FDA not been able to take action on these applications? What is the reason behind the holdup?**

FDA has been actively examining the important scientific questions for the sunscreen ingredients currently proposed in TEAs, and significant efforts have resulted in FDA recently sending six letters to sponsors providing feedback on safety and efficacy data submitted in support of TEA ingredients. These letters are publicly available in the docket, in accordance with the TEA regulation. The letters that have been issued for the TEA ingredients amiloxate, diethylhexyl butamido triazone, octyl triazone, drometrizole trisiloxane, bisoctrizole, and bemotrizinol describe FDA's review of the scientific record for these sunscreen active ingredients (consisting of material submitted by the TEA sponsors and others, and information identified by FDA from the medical literature), and provide initial determinations that the record is insufficient to establish that any of these ingredients are generally recognized as safe and effective (GRASE) for over-the-counter (OTC) sunscreen use. As described in these letters, given the expansion of sunscreen use and scientific advances since the OTC sunscreen evaluation began, our safety evaluation of these ingredients must consider, not only short-term concerns (such as skin sensitivity) but also long-term concerns (such as the results of systemic exposure), about which little scientific data has been provided.

While evaluating the safety and effectiveness of potential new sunscreen active ingredients has been an important task for FDA, it is not the only major effort regarding sunscreens that FDA has undertaken in the last several years. In 2011, we took several regulatory actions on a number of important sunscreen issues. First, we finalized rules that updated the efficacy testing requirements and related labeling, which applies to sunscreens currently available in the United States.[9] This final rule prescribes new, improved labeling, including updated Drug Facts

[9] The new requirements, and several proposed changes to regulations, are discussed in four regulatory documents that include a final rule, proposed rule, an ANPR, and draft guidance for industry. Links to each of these documents are included below:
-Final Rule, Labeling and Effectiveness Testing, *http://www.gpo.gov/fdsys/pkg/FR-2011-06-17/pdf/2011-14766.pdf*
-Proposed Rule, Revised Effectiveness Determination, *http://www.gpo.gov/fdsys/pkg/FR-2011-06-17/pdf/2011-14769.pdf*
-ANPR, Dosage Forms for Sunscreens, *http://www.gpo.gov/fdsys/pkg/FR-2011-06-17/pdf/2011-14767.pdf*
-Draft guidance for industry, Enforcement Policy – OTC Sunscreen Drug Products Marketed Without an Approved Application,
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM259001.pdf

labeling. The final rule also establishes two effectiveness tests, one that must be done to support the sun protection factor (SPF) of the product, and another if a product claims to be broad spectrum (protecting against both UVA and UVB radiation).

We issued a proposed rule proposing a maximum labeled SPF value of "50+" for all monograph sunscreen products. We also issued an advance notice of proposed rulemaking (ANPR) to seek additional information on the safety and effectiveness of sunscreens formulated as sprays and to address additional questions related to other specific dosage forms of sunscreens. Subsequent rulemaking activity is needed for each of these topics, and FDA has dedicated resources to ensure diligent follow-up.

3. When will there be action on these applications?

FDA's efforts on the remaining two TEA sunscreen ingredients are actively continuing, and we expect to issue a proposed sunscreen order for each in accordance with the Sunscreen Innovation Act, P.L. 113-195, signed by the President on November 26, 2014. In addition, FDA held a public meeting on September 4-5, 2014, to discuss the information provided in the TEA letters and to provide an opportunity to further clarify FDA's thinking about the data required to support a GRASE determination for sunscreens.

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
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Majority (202) 225-2927
Minority (202) 225-3641

April 24, 2014

Mr. Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Agency
U.S. Department of Justice
8701 Morrissette Drive
Springfield, VA 22152

Dear Mr. Rannazzisi:

Thank you for appearing before the Subcommittee on Health on Monday, April 7, 2014, to testify at the hearing entitled "Improving Predictability and Transparency in DEA and FDA Regulation."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Thursday, May 8, 2014. Your responses should be mailed to Sydne Harwick, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to **Sydne.Harwick@mail.house.gov**.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachment

U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

MAY 0 1 2015

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Enclosed please find responses to questions for the record arising from the appearance of Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, before the Committee on April 7, 2014, at a hearing entitled "Improving Predictability and Transparency in DEA and FDA Regulation." We hope that this information is of assistance to the Committee.

Please do not hesitate to contact this office if we may be of additional assistance regarding this or any other matter. The Office of Management and Budget has advised us that there is no objection to submission of this letter from the perspective of the Administration's program.

Sincerely,

[redacted]

Peter J. Kadzik
Assistant Attorney General

Enclosure

cc: The Honorable Frank Pallone, Jr.
Ranking Member

Questions for the Record
Deputy Assistant Administrator Joseph T. Rannazzisi
Drug Enforcement Administration
Committee on Energy and Commerce
U.S. House of Representatives
"Improving Predictability and Transparency in DEA and FDA Regulation."
April 7, 2014

Questions Posed by the Honorable Joseph R. Pitts

1. **We have been hearing from pharmacies that their wholesalers are cutting them off for ordering above the "normal" amount. Will you describe your expectations of wholesalers and what guidance has been provided to wholesalers in the last year to help them conduct due diligence on their customers?**

Response:

The U.S. Department of Justice Drug Enforcement Administration (DEA) regulations require non-practitioners such as wholesale distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." (21 C.F.R. § 1301.74(b).) Further, all DEA registrants "shall provide effective controls and procedures to guard against theft and diversion of controlled substances." (21 C.F.R. § 1301.71(a).) One factor relevant to compliance with the security requirements is the "adequacy of the registrant's . . . system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations." (21 C.F.R. § 1301.71(b)(14).)

In recent years, DEA has steadily increased the frequency of compliance inspections of specific categories of registrants, such as manufacturers (including bulk manufacturers), distributors, pharmacies, and certain practitioners. This renewed focus on oversight has enabled DEA to take a more proactive approach to educating registrants and ensuring that they understand and comply with the Controlled Substances Act (CSA) and its implementing regulations. DEA conducts approximately 6,000 regulatory inspections every year to ensure compliance with Federal laws and regulations. Each inspection entails close communication between DEA and the registrant to educate the registrant about proper procedures and to ensure corrective action is taken to comply with the law. These inspections typically result in remediation or continued compliance, and no further action is taken. DEA conducts compliance inspections of registered distributors every two years.

DEA's Distributor Initiative Program was implemented in late 2005 and was designed to educate wholesale distributors that were supplying diversion schemes such as rogue Internet pharmacies and more recently rogue pain clinics and rogue pharmacies. The goal of the

program is to cut off the source of supply to these or other schemes through effective due diligence and monitoring for suspicious orders.

As stated above, wholesale distributors are required to design and operate a system that would disclose suspicious orders to the registrant and report those suspicious orders to DEA. Through the Distributor Initiative Program, DEA provides registrants with information such as "red flags," trending information, and data analysis that they should be aware of prior to distributing controlled substances. Factors that should generally be considered include, but are not limited to: the type of drug(s) ordered (e.g., the breadth and schedule of controlled substances ordered); orders of unusual size; orders that deviate from a normal pattern; frequency of orders, and the percent of controlled and non-controlled substances ordered.

In June 2013, DEA held a two-day Manufacturers/Importers/Exporters Conference, which provided a forum to present Federal laws and regulations that affect the pharmaceutical and chemical manufacturing, importing, and exporting industry and to discuss practices designed to detect and prevent diversion. In addition, topics such as quotas, year-end reporting, Automation of Reports and Consolidated Ordering System (ARCOS) reporting, import/export permits, and import/export declarations were discussed. Approximately 370 people attended, representing over 200 registrants. Currently, there is a Manufacturers/Importers/Exporters Conference tentatively scheduled for September 22-24, 2015.

DEA has also held two Distributor Conferences, most recently on April 15-16, 2015, and previously on October 22, 2013. These conferences provided an overview of federal laws and regulations that affect pharmaceutical and chemical distributors, such as recordkeeping, ARCOS, and suspicious order monitoring.

2. Does DEA conduct an investigation on pharmacy registrants when wholesalers have reported suspicious orders for a particular pharmacy? Can other wholesalers continue to serve that pharmacy?

Response:

Reported suspicious orders are just one factor that is considered amongst many when determining a course of action with respect to registered pharmacies.

Each registered distributor must determine, based on all of the circumstances, whether the fact that one distributor has reported suspicious orders from a particular pharmacy bears on subsequent ordering activity of the particular pharmacy.

3. Does DEA conduct due diligence on an initial application for DEA registration (pharmacy, wholesaler, physician, etc.)? What does that involve?

Response:

DEA's responsibilities with respect to registering entities are outlined in the CSA 21 U.S.C. § 823. Generally, there are five or six factors depending on the type of registration, for example: maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels; compliance with applicable state and local law; prior conviction record of applicant under Federal or state laws relating to the manufacture, distribution, or dispensing of such substances; past experience in the distribution of controlled substances. DEA must consider these factors when determining whether to register a manufacturer, distributor, or practitioner (e.g., a pharmacy or physician). DEA carefully reviews each applicable factor. Before denying an application for registration, DEA is required to provide the applicant with notice and an opportunity to appear before an independent fact-finder to show cause as to why the registration should not be denied.

Questions Posed by the Honorable Michael C. Burgess

4. **I am hearing that DEA actions are causing great difficulties for legitimate patients that are not able to access the medications they need to manage chronic pain. According to DEA's website, "the mission of DEA's Office of Diversion Control is to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate supply for legitimate medical, commercial, and scientific needs."**

   A. **How does DEA ensure that it's regulatory and enforcement actions are not having the unintended consequences of causing harm to legitimate patients?**

Response:

The CSA and its implementing regulations have established a closed system of distribution so that a controlled substance is at all times under the legal authority of an entity registered with DEA, or specifically exempted from registration, until the controlled substance reaches the ultimate user (e.g., patient), or is destroyed. This closed system helps DEA detect and prevent diversion of controlled substances by controlling and monitoring the movement of these substances along the supply chain. DEA routinely works with manufacturers to ensure that an adequate and uninterrupted supply of pharmaceutical controlled substances and listed chemicals is available to meet the legitimate medical, commercial, and scientific needs of the United States. DEA has no authority to direct what a company must manufacture, how much to manufacture, when to introduce such products into the supply chain, or what pharmaceutical controlled substances a pharmacy may legitimately dispense to its patients.

Although DEA is the agency responsible for enforcing the CSA, DEA does not act as the federal equivalent of a state medical board overseeing or regulating the general practice of medicine. DEA has consistently emphasized and supported the prescriptive authority of an individual practitioner under the CSA to administer, dispense, and prescribe controlled substances for the legitimate treatment of pain within acceptable medical standards as outlined in the DEA Statement of Policy published in the Federal Register on September 6, 2006, titled, *Dispensing Controlled Substances for the Treatment of Pain*, 71 Fed. Reg. 52716, and DEA Clarification published on August 26, 2005, titled, *Clarification of Existing Requirements Under the Controlled Substances Act for Prescribing Schedule II Controlled Substances*, 70 Fed. Reg. 50408.

   B. **Does DEA meet with chronic pain patient groups and others to ensure that the agency understands the needs and concerns of patients?**

Response:

DEA routinely responds in writing to inquiries from patients and patient advocacy groups. In the last two years, DEA has adopted a more proactive approach to educating registrants through

holding Pharmacy Diversion Awareness Conferences (PDACs) throughout the country, as discussed later in these responses. DEA has directed resources to these PDACs in order to reach as many registrants as possible. During this timeframe, no chronic pain patient groups or other related groups have requested meetings; however, if such a meeting were to be requested, DEA would consider meeting with the group in order to listen to their concerns.

5. **The Federal Controlled Substances Act (CSA) has been federal law since the early 1970's. Despite decades of DEA enforcement actions, it seems that the drug abuse problem continues unabated, whether the problem is heroin, cocaine, morphine, oxycodone, hydrocodone, etc. Do you not think it is long past due to take a step back and bring together a wide variety of stakeholders to agree upon new solutions to combat drug abuse, as has been proposed by H. R. 4069?**

Response:

DEA conducts a number of outreach initiatives intended to educate registrants on their responsibilities, discuss suspicious order monitoring, and respond to other registrant inquiries. This includes hosting regular conferences with manufacturers, distributors, and pharmacists to discuss their ongoing registrant obligations. DEA also educates parents, community leaders, and law enforcement personnel regarding diversion trends, the scope of the prescription drug diversion problem, and how to best address prescription drug diversion in communities throughout the United States.

Further, the Office of National Drug Control Policy's (ONDCP) Prescription Drug Abuse Prevention Plan expands upon the Administration's *National Drug Control Strategy* and includes action in four major areas to reduce prescription drug abuse: education, monitoring, proper medication disposal, and enforcement. DEA plays an important role in all four of these areas. These outreach initiatives are discussed in greater detail below.

Education

The Department of Justice (the Department) focuses on education as a crucial first step in preventing prescription drug abuse. Through its Demand Reduction Program, DEA delivers educational content via its websites www.GetSmartAboutDrugs.com and www.JustThinkTwice.com. These websites serve as a resource to parents, caregivers, educators, professionals, and teens. DEA also focuses on reducing the demand for illicit drugs, including the abuse of prescription drugs, through its Red Ribbon Week programming, partnerships with other Federal, state, local and non-profit organizations, and numerous publications made available to the general public.

DEA also provides education and guidance to industry professionals such as pharmacists, distributors, and manufacturers by delivering information to registrants, professional associations, and industry organizations on current diversion and abuse trends of pharmaceutical drugs and listed chemicals. DEA also provides information and guidance concerning new and existing programs, policies, legislation, and regulations. DEA's Diversion

Control Program establishes and maintains liaison and working relationships with other Federal agencies, state and local governments, regulated industries, industry organizations, professionals, professional associations, and regulatory boards that interface with DEA regarding diversion matters. In Fiscal Year (FY) 2014, DEA conducted more than 75 public education and outreach events regarding prescription drug abuse. Because of the importance of these activities in addressing prescription drug abuse, the Department has included an Education and Outreach component to DEA's performance measures.

The following reflect the kinds of outreach initiatives undertaken by DEA's Diversion Control Program:

- DEA, along with state regulatory and law enforcement officials, and in conjunction with the National Association of Boards of Pharmacy, hosts Pharmacy Diversion Awareness Conferences (PDACs) throughout the country. Each one-day PDAC is held on Saturday or Sunday for the convenience of the pharmacy community. The conferences are developed and designed to address the growing problem of diversion of pharmaceutical controlled substances at the retail level. Topics addressed include pharmacy robberies and thefts, forged prescriptions, doctor shoppers, and illegitimate prescriptions from rogue practitioners, with the objective of educating pharmacists, pharmacy technicians, and pharmacy loss prevention personnel on methods to prevent and respond to potential diversion activity.

- During FY 2013, DEA hosted 18 PDACs in eight states. Further, DEA hosted 16 PDACs in eight states during FY 2014. As of March 18, 2015, DEA hosted two PDACs in one state in FY 2015. Since DEA began hosting PDACs in 2011, through February 8, 2015, more than 7,841 pharmacy professionals have attended these educational conferences. There are 14 additional proposed PDACs in seven states for FY 2015.

- The Manufacturers/Importers/Exporters Conference held on June 18-19, 2013, provided a forum to present federal laws and regulations that affect the pharmaceutical and chemical manufacturing, importing, and exporting industry and to discuss practices to prevent diversion while minimizing the impact on legitimate commerce. In addition, topics such as quotas, year-end reporting, ARCOS reporting, import/export permits and import/export declarations were discussed. Approximately 370 people attended, representing more than 200 registrants. There is a Manufacturers/Importers/Exporters Conference tentatively scheduled for September 22-24, 2015.

- The Distributor Conference was held on October 22, 2013. This conference provided an overview of federal laws and regulations governing issues that affect pharmaceutical and chemical distributors, such as recordkeeping, ARCOS, and suspicious order reporting. A Distributor Conference was held on April 15-16, 2015.

- The National Conference on Pharmaceutical and Chemical Diversion was held on September 30 through October 1, 2014. This national conference was held to facilitate the exchange of information between DEA and their state and local counterparts who focus on combating the diversion of pharmaceutical controlled substances and regulated

chemicals. Attendees included individuals from state and local agencies who are responsible for regulatory drug or chemical control as well as operational personnel whose investigations target the diversion of licitly manufactured controlled substances and regulated chemicals. Approximately 70 people attended.

- To better assist DEA registrants with their understanding of the CSA and implementing regulations, manuals are drafted and made available to the public. The manuals are not considered legal documents. Readers are instructed to refer to the most current copy of the CSA, the Narcotic Addict Treatment Act of 1974, the Drug Addiction Treatment Act of 2000, the Code of Federal Regulations (C.F.R.), and Federal Register Notices to obtain complete and accurate information. The following manuals are available via DEA website:

    - Chemical Handler's Manual
    - Pharmacist's Manual
    - Practitioner's Manual

Additionally, DEA established the Distributor Initiative Program in August 2005 to educate and inform distributors of their responsibilities under the CSA and its implementing regulations by discussing suspicious order monitoring systems, reviewing sales and purchase data, and discussing national trends involving the abuse and diversion of controlled substances. This program was initially designed to educate wholesale distributors who were supplying controlled substances to rogue Internet pharmacies and, more recently, to diverting pain clinics and pharmacies. The goal of this educational program is to increase distributor awareness and vigilance so that they cut off the source of supply to these and other schemes.

Monitoring

One of the best ways to combat the rising tide of prescription drug abuse is the implementation and use of Prescription Drug Monitoring Programs (PDMPs). PDMPs are typically state-run electronic database systems used by practitioners, pharmacists, medical and pharmacy boards, and law enforcement. These programs are established through state legislation and are tailored to the specific needs of a particular state. PDMPs help prevent and detect the diversion and abuse of pharmaceutical controlled substances, particularly at the retail level where no other automated information collection system exists.[1] However, in many states with operational PDMPs, participation by prescribers and dispensers is voluntary, with utilization rates well below 50%.[2] The Brandeis University Center of Excellence developed a PDMP Management Tool, which recommends calculating the number of in-state prescribers with PDMP accounts as a percentage of the number of in-state prescribers who issued controlled substance prescriptions during the prior year. Based on this calculation, for example, in Florida just 18% of the in-state prescribers who issued more than one controlled substance prescription have registered to use the database (11,408 in-state prescribers signed up for PDMP accounts out of the 62,238 in-

[1] This statement applies to all schedules. However, while many prescription monitoring programs cover all schedules, some programs apply only to controlled substances in Schedule II.
[2] The Brandeis University PDMP Center of Excellence, retrieved 12/18/14 http://www.pdmpexcellence.org/content/mandating-medical-provider-participation-pdmps.

state prescribers who issued controlled substance prescriptions during the prior year).[3] While PDMPs are valuable tools for prescribers, pharmacists, and law enforcement agencies to identify, detect, and prevent prescription drug abuse and diversion, PDMPs do have some limits in their use for detecting diversion at the retail level. For example, the use of PDMPs is limited across state lines because interconnectivity remains a challenge; at the same time, many drug traffickers and other drug seekers willingly travel hundreds of miles to gain easy access to unscrupulous prescribers and dispensers. Also, not everyone who is using/misusing/abusing is being captured by PDMPs, because PDMPs only capture prescriptions for individuals for whom the drug is intended. According to data from the 2013 National Survey on Drug Use and Health, among persons aged 12 or older in 2012-2013 who used pain relievers nonmedically in the past 12 months, 53.0 percent got the drug they used most recently from a friend or relative for free, and 10.6 percent bought the drug from a friend or relative.

The Department continues to support and encourage the development and maintenance of Prescription Drug Monitoring Programs at the state level. Currently, 49 states have an operational PDMP (meaning collecting data from dispensers and reporting information from the database to authorized users). The District of Columbia has enacted legislation enabling the establishment of a PDMP; Missouri has no PDMP. As of June 2014, only 20 states had laws mandating that prescribers and in some cases dispensers enroll with their state's PDMP, and 22 states had laws mandating that prescribers in some cases dispensers use the PDMP in certain circumstances.

The Department has also supported the development of PDMPs through the Harold Rogers Prescription Drug Monitoring grant program, distributing a total of over $87 million from FY 2002 to FY 2014, including $7 million in FY 2014. The purpose of this grant program is to plan, implement, and enhance PDMPs. It focuses on providing help for states that want to establish a PDMP or expand an existing PDMP. In 2012, the Department provided further policy guidance on data sharing efforts among state PDMPs, a critical aspect of the program.

Proper Medication Disposal

Prior to the passage of the Secure and Responsible Drug Disposal Act of 2010, enacted in October 2010 (Pub. L. 111-273) (Disposal Act), the CSA provided no legal means for ultimate users to transfer possession of controlled substance medications to other individuals for disposal. The Disposal Act amends the CSA to authorize ultimate users and Long Term Care Facilities (LTCFs) to deliver controlled substances to another authorized person for the purpose of disposal in accordance with regulations promulgated by DEA.

On September 9, 2014, DEA published in the Federal Register the final rule on the Disposal of Controlled Substances. The final rule became effective on October 9, 2014, and it implements the Disposal Act by establishing requirements that allow authorized registrants to develop secure, ongoing, and responsible methods for ultimate users and LTCFs to dispose of pharmaceutical controlled substances. The final rule expands the options available to collect controlled substances from ultimate users for the purpose of disposal, including: (1) take-back

[3] Electronic-Florida Online Reporting of Controlled Substances Evaluation, 2013-2014 Prescription Drug Monitoring Program Annual Report, published December 1, 2014.

events; (2) mail-back programs; and (3) collection receptacle locations. These regulations contain specific provisions that:

- Recognize the continuing authority of law enforcement agencies to voluntarily conduct take-back events, administer mail-back programs, and maintain collection receptacles;
- Allow authorized manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies to voluntarily administer mail-back programs and maintain collection receptacles; and
- Allow authorized retail pharmacies and hospitals/clinics with an on-site pharmacy to voluntarily maintain collection receptacles at long term care facilities.

In addition, DEA conducted nine Prescription Drug Take-Back Days from September 2010 to September 2014. Each take-back day provided the public with thousands of sites nationwide to turn in their unwanted or expired prescription drugs safely and securely. On September 26, 2014, the most recent National Prescription Drug Take-Back Day, 617,150 pounds (309 tons) of prescription medications were collected from members of the public. As a result of all nine National Prescription Drug Take-Back Days, DEA, in conjunction with its state, local and tribal law enforcement partners, removed a total of just under 4.9 million pounds (2,411 tons) of medications from circulation. Although law enforcement continues to have discretion with respect to take-back events, DEA discontinued this nationwide program because the new final rule on the Disposal of Controlled Substances provides the public with expanded options to safely and responsibly dispose of their unused and unwanted, lawfully-possessed pharmaceutical controlled substances through collection receptacles and mail-back packages. This rule allows for ongoing medication disposal, thereby ridding the home of unused or unwanted drugs that pose a poisoning hazard or can be diverted.

Enforcement

The Department, via DEA's Diversion Control Program, is using all criminal and regulatory tools possible to identify, target, disrupt, and dismantle individuals and organizations responsible for the illicit manufacture and distribution of pharmaceutical controlled substances in violation of the CSA. The deployment of Tactical Diversion Squads (TDSs) is DEA's primary method of criminal law enforcement in the Diversion Control Program. The recent expansion of the TDS program has resulted in 66 operational TDSs throughout the United States, covering 41 states, Puerto Rico, and the District of Columbia. These TDSs incorporate the enforcement, investigative, and regulatory skill sets of DEA Special Agents, Diversion Investigators, other Federal law enforcement, and state and local Task Force Officers. The expansion of the TDS groups has enabled the Diversion Groups to concentrate on the regulatory aspects of the Diversion Control Program.

Several DEA investigations of rogue pain clinics in Southern Florida have resulted in charges against 172 individuals, including 51 doctors and 24 clinic/pharmacy owners, the seizure of approximately 2.5 million dosage units of controlled substances, and approximately $16.6 million in currency, real property, and exotic cars. In addition, approximately 42 doctors and 11 pharmacies lost their DEA registrations. Approximately 192 doctors and 68 pharmacies

voluntarily surrendered their DEA registrations.

In addition to the focus on criminal law enforcement, the Department of Justice also dedicates resources to civil and regulatory matters. DEA is pursuing additional actions when registrants and other entities violate the law. For example, in March 2013, United Parcel Service (UPS) agreed to a $40 million settlement with the Department for payments it received from illicit online pharmacies. This settlement is part of a non-prosecution agreement with the United States Attorney's Office for the Northern District of California (San Francisco) and is the result of a five-year investigation of 12 rogue internet pharmacies. This investigation resulted in 43 convictions, $34 million in seized assets, and forfeiture orders totaling $51 million.

During 2013, DEA, together with the United States Attorneys' Office for the Western District of Oklahoma and the Southern District of Florida, pursued significant regulatory and civil actions in two cases where registrants violated provisions of the CSA. In April 2013, CVS Pharmacy, Inc. executed an $11 million settlement agreement in which it agreed to pay a civil penalty for CSA violations and failure to keep proper records of pharmacy sales. In June 2013, Walgreens Corporation agreed to pay $80 million in civil penalties for actions by their distribution center and six pharmacies in Florida that resulted in the diversion of millions of dosage units of oxycodone, a powerful schedule II painkiller. Their actions helped fuel a prescription drug epidemic in the State of Florida over several years.

While some issues related to prescription drug abuse have worsened in recent years, particularly along the heroin-prescription opiate vector, the Department's continued focus on prescription drug abuse has yielded significant improvements in many areas. For example, the substantial civil penalties and settlements with CVS, Walgreens, and UPS, described above have signaled the serious potential consequences for companies and registrants that fail to recognize the dangers of prescription drug abuse and follow the law regarding controlled substances. Further, the Department and DEA have observed significant changes in Florida, where rogue pain clinics have long been known to operate and have helped fuel the prescription drug abuse epidemic in several other states. According to the Florida Department of Health, the number of pain management clinics in Florida as of December 31, 2013, is 360, down from 635 at the end of 2010. In 2010, 90 of the top 100 oxycodone-purchasing physicians in the country were in Florida, but that number dropped to 13 in 2011. The Department will continue to direct efforts towards the issue of prescription drug abuse, with DEA leading as the Nation's principal enforcer of Federal drug laws and regulations.

6. **How do you response to comments that DEA's actions to stop prescription drug abuse are merely causing an increase in the heroin abuse problem? Why does the DEA not adopt more holistic approaches to drug abuse so that shutting off one source of abuse does not simply lead to another substance being abused? Do you not think this leads to perceptions that all DEA cares about are the numbers of enforcement actions and not about real solutions to stop drug abuse?**

Response:

DEA is dedicated to protecting the public health and safety by enforcing the CSA, regardless of "the numbers of enforcement actions." Enforcing the CSA necessarily entails taking action against persons or corporations that violate the CSA. Enforcement activity is a measure of effectiveness in maintaining the closed system of distribution. As explained in DEA's written statement for the record, the rise in heroin use is due only in part to the rise in prescription drug abuse. As discussed above, ONDCP has established a comprehensive, four-part plan to reduce prescription drug abuse: education, monitoring, proper medication disposal, and enforcement.

7. **Will you explain DEA's efforts to education physicians about the corresponding responsibility of pharmacists under the CSA? If I understand correctly, the CSA requires a pharmacist, prior to dispensing any controlled substance, to determine if the prescription complies with all legal and regulatory requirements, and whether the prescription has been issued for a "legitimate medical purpose" by a prescriber acting in the usual course of his or her practice. Simply put, this means that pharmacists are required to perform due diligence on each controlled substance prescription before dispensing the medication-this may mean calling back the physician to obtain and confirm certain information before the prescription can legally be dispensed. Yet, it seems that some physicians are unaware of this federal requirement-so written guidance and education seems appropriate. Would you agree more agency education can be done?**

Response:

The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. (21 C.F.R. § 1306.04(a).) An order purporting to be a prescription issued not in the usual course of professional treatment is not a prescription within the meaning and intent of the CSA and the person knowingly filling such a purported prescription shall be subject to the penalties provided for violations of the law relating to controlled substances. Please see the response to question 2 for further information regarding DEA's education of registrants.

DEA provides education and guidance to registrants, professional associations, and industry organizations on current diversion and abuse trends of pharmaceutical drugs and listed chemicals, new and existing programs, policies, legislation, and regulations. DEA's Diversion Control Program establishes and maintains liaison and working relationships with other federal agencies, state and local governments, regulated industries, industry organizations,

professionals, professional associations, and regulatory boards that interface with DEA regarding diversion matters. In FY 2013, DEA conducted more than 114 public education and outreach events regarding prescription drug abuse.

8. **The Drug Quality and Security Act of 2013 provides for the registration with the Food and Drug Administration of "outsourcing facilities." These entities are engaged in compounding and distribution of sterile medications in interstate commerce. Sterile medications may contain controlled substances. What plans does the DEA have to require registration of these outsourcing facilities? How will these outsourcing facilities be inspected and reviewed? When will the registration and inspections be conducted? What conversations have been held to date with the FDA to coordinate interagency accountability for appropriate oversight of these outsourcing facilities?**

Response:

Depending on the circumstances, compounding by an "outsourcing facility" under section 503B of the Federal Food, Drug and Cosmetic Act (as added by the Drug Quality and Security Act) may be a "manufacturing" activity under the CSA if the medication contains a controlled substance.[4] If so, the CSA requires that these "outsourcing facilities" be registered with DEA as manufacturers. DEA does not differentiate whether a company is applying because it is an "outsourcing facility" or a traditional manufacturer of controlled substances. If the entity's business activity is manufacturing as defined in the CSA, whether in bulk or dosage units, repackaging/relabeling, or as an "outsourcing facility" under the Drug Quality and Security Act, the entity must apply for a controlled substances registration with DEA as a manufacturer. All manufacturers are subject to the same pre-registration investigation standards.

DEA strives to perform a thorough pre-registration investigation prior to issuing any DEA registration in order to ensure that all registrations are consistent with the applicable standards of the CSA. All applicants applying for a controlled substances registration as a manufacturer with DEA are subject to an onsite inspection by DEA, in which investigators review physical security, recordkeeping, and other operational plans to ensure that issuing a registration would be consistent with the requirements of the CSA. Further, DEA verifies with appropriate state and federal authorities that the entities/individuals have been granted the appropriate authority for their type of business. The timeline for this process varies, as it is dependent upon the complexity of the manufacturer's business operations.

[4] Section 503B(d)(4)(B) of the Drug Quality and Security Act mentions in the definition of outsourcing facility that "an outsourcing facility is not required to be a licensed pharmacy." Retrieved 4/28/15 https://www.congress.gov/113/bills/hr3204/BILLS-113hr3204enr.pdf[].

9. If questions arise during the inspection process, is there a transparent and formal procedure to provide written agency feedback?

Response:

During the pre-registration inspection process, there is an open line of communication between DEA investigators and the applicant. Applicants are given opportunities to provide the investigators with any relevant information pertaining to the statutory factors to be considered when registering a manufacturer. (See 21 U.S.C. § 823(a), (d).) In addition, before DEA could deny a registration as a manufacturer, DEA would be required to provide the applicant with notice and an opportunity to show cause as to why the registration should not be denied, before an independent fact-finder, pursuant to the Administrative Procedure Act. (See 21 U.S.C. § 824(c).)

10. Amidst all of the efforts to curb prescription drug abuse, what are you doing to help ensure that legitimate patients can continue to access their prescription pain medications?

Response:

Please see response to question 4.A, above.

11. DEA has no mandated timeline for approval. Do you believe it is medically ethical to deny access to a drug for over a year after FDA has determined that the product is safe and effective?

Response:

The process of evaluating and determining the abuse and dependence liability of a substance, and evaluating that liability in light of other already scheduled substances, is complex and drug-specific. Accordingly, the level of analysis required to control each drug is unique and a direct comparison to the timing of the scheduling of other substances is not feasible. Generally, the complexity and length of time it takes for DEA to conduct an analysis depends on many variable factors, including, but not limited, to: the availability of scientific data and literature; the depth and breadth of the available scientific data and literature; the quality of the available data; the reliability of scientific data and conclusions; whether scientific studies must be conducted to determine abuse liability; whether the drug or substance is a new molecular entity or a drug that is already used in medical treatment; whether an interested person requests an administrative hearing; how many public comments are received in response to the scheduling action; the nature and content of any public comments received; and the extent of any regulatory analysis that may be conducted in support of the administrative action, which depends on many factors including how widely the substance or drug is used throughout the United States, who will be affected by the scheduling action, the financial impact on the affected entities, and the impact on the economy and state, local, and tribal governments.

Upon receiving from U.S. Department of Health and Human Services (HHS) a scientific and medical evaluation and a scheduling recommendation for a FDA-approved pharmaceutical product, and pursuant to 21 U.S.C. § 811(b) of the CSA, DEA reviews HHS's scientific and medical evaluation and all other relevant data to determine whether the drug meets the criteria to be controlled under the CSA. DEA must prepare its own review via a scheduling review document, and make the findings necessary for control of the drug. These findings determine the most appropriate schedule for the drug involved. In making findings, DEA must ensure that all factors determinative of control and all findings are supported by scientifically and legally defensible positions.

Upon determining that the drug meets the criteria for control under the CSA, DEA drafts a Notice of Proposed Rulemaking (NPRM) for publication in the Federal Register. Following publication of the NPRM in the Federal Register, there will be a comment period during which the public can make comments to the proposed scheduling of the drug. Once the comment period closes, DEA is required to take each comment under consideration when drafting the Final Rule to schedule the drug.

As described above, a comprehensive and thorough review of each proposed scheduling action is required to control the FDA-approved pharmaceutical. Thus, it is very difficult to estimate the typical amount of time required for each step in the process to be completed. However, DEA utilizes all of its available resources fully so that FDA-approved pharmaceuticals with abuse potential are appropriately controlled and thus are available to the U.S. public in an efficient and timely manner.

12. When the FDA approves a product that means the drug has been found to be safe and effective for patients suffering for a particular disease, correct?

Response:

DEA defers to the Department of Health and Human Services regarding the approval of substances for human use.

13. Will 503b OFs be required to be distributors or manufacturers at DEA?

Response:

Where the compounding as contemplated by the Drug Quality and Security Act is a "manufacturing" activity under the CSA, the outsourcing facilities must be registered with DEA as manufacturers. Registered manufacturers may distribute those substances that they manufacture without being separately registered as distributors. Please see the response to question 5 for additional information.

Questions Posed by the Honorable Gus Bilirakis

14. FDA has developed a comprehensive inspection program for each sector it regulates-such as drugs, devices, food, cosmetics. In so doing, FDA has established program inspectional manuals, field guidelines, and industry guidelines.

A. Does DEA have similar public materials to address the inspection process and compliance issues for DEA registrants within the legitimate manufacturing, distribution and dispensing of controlled substances? If not, why not?

Response:

As discussed in Question 5, DEA assists registrants with their understanding of the CSA and implementing regulations by providing manuals. The manuals are not considered legal documents. Readers are instructed to refer to the most current copy of the CSA, the Narcotic Addict Treatment Act of 1974, the Drug Addiction Treatment Act of 2000, the C.F.R., and Federal Register Notices to obtain complete and accurate information. The following manuals are available via the DEA Diversion website (www.DEAdiversion.usdoj.gov): Chemical Handler's Manual, Pharmacist's Manual, and Practitioner's Manual.

Aside from the public materials described above, a large majority of manufacturers and distributors are provided the opportunity to learn of their regulatory obligations during conferences. For example, 20 out of the top 25 manufacturers attended DEA's last Manufacturer/Importer/Exporter Conference and they represent 74.4% of the controlled substances in the market. Furthermore, 16 out of the top 25 distributors attended the last Distributors Conference and they represent 76.72% of controlled substances in the market.

B. How does DEA ensure that its policies across the nation-from region to region and from inspector to inspector-are consistent?

Response:

As a law enforcement agency, DEA conducts its inspections and investigations as determined by many factors, including diversion trends and analysis. While the CSA and implementing regulations apply to all registrants equally, DEA may utilize different methods of investigation, or more frequent inspections, depending on the diversion schemes in certain regions of the country, and the individual circumstances of a particular registrant's suspected diversion activities.

C. Is there a DEA internal quality assurance program?

Response:

DEA provides its investigators with a Diversion Investigator Manual. This manual assists investigators in performing their regulatory duties and ensures uniformity across cyclic investigations. Although this manual provides a general template for regulatory inspections, each inspection may differ based upon the unique circumstances of the registrant, such as the classes of controlled substances handled, volume of business, and other factors. Immediate supervisors and upper management within each DEA Field Office review the investigative reports of all investigators, concurring or not concurring on results as necessary. All investigators must successfully pass the twelve-week Basic Diversion Investigator School prior to entry on duty. Additionally, DEA provides ongoing training for all investigators, including, but not limited to: Regulatory Refresher Courses; Advanced Diversion Investigator Training; Basic and Advanced Interview and Interrogation Training; Diversion Conspiracy and Complex Investigations; Diversion Investigative Training Course; Diversion Financial Techniques; and Prosecuting Diversion Cases. These courses provide investigators with the tools necessary to successfully conduct thorough, uniform, and fair investigations.

D. Has DEA had its inspection process audited by a third party or OIG?

Response:

No.

FRED UPTON, MICHIGAN
CHAIRMAN

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RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
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April 24, 2014

Mr. D. Linden Barber
Partner and Director
DEA Compliance Practice
Quarles & Brady LLP
1700 K Street, N.W., Suite 825
Washington, D.C. 20006

Dear Mr. Barber:

Thank you for appearing before the Subcommittee on Health on Monday, April 7, 2014, to testify at the hearing entitled "Improving Predictability and Transparency in DEA and FDA Regulation."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Thursday, May 8, 2014. Your responses should be mailed to Sydne Harwick, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to **Sydne.Harwick@mail.house.gov**.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachment

Quarles & Brady LLP

[redacted]

May 8, 2014

The Honorable Joseph R. Pitts
U.S. House of Representatives
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515-6115

RE: ***Response to Additional Questions for the Record***

Dear Mr. Chairman:

Thank you for the opportunity to testify before the Subcommittee on Health on April 7, 2014. At your request, I am submitting my responses to the additional questions for the record.

Thank you for your leadership in addressing the important issues of prescription drug abuse and patient access to controlled medications. If I can be of assistance to you, Ranking Member Pallone, or the Subcommittee in addressing these issues, I would be pleased to do so.

Sincerely,

D. Linden Barber

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachment

Additional Questions for the Record

Questions from The Honorable Joseph R. Pitts

1. We have been hearing from pharmacies that their wholesalers are cutting them off for ordering above the "normal" amount. Will you describe your expectations of wholesalers and what guidance has been provided to wholesalers in the last year to help them conduct due diligence on their customers?

Response: DEA held a distributor conference on October 22, 2013. At that conference, DEA gave a presentation stating that the distributor initiative was started to educate the supply chain on "their due diligence responsibilities under the CSA by discussing their Suspicious Order Monitoring System, reviewing their ARCOS data for sales and purchases of controlled substances, and discussing national trends involving the abuse of prescription controlled substances." The presentation also contained slides entitled "Know Your Customers." These slides suggest that ordering a quantity of controlled substances that "far exceeds" the "average purchases" of an "average type registrant" is a "red flag." The slides may be obtained at http://www.deadiversion.usdoj.gov/mtgs/distributor/conf_2013/prevoznik.pdf.

My expectations of a wholesaler are that they comply with the regulations that DEA has promulgated. DEA's regulations require a distributor to know that a customer is registered with DEA prior to distributing controlled substances to that customer. The regulations also require a distributor to design and operate a system to detect suspicious orders and to inform DEA of suspicious orders upon discovery. The concepts of "due diligence" and "know your customer" are not addressed in the regulation or in any formal policy statement of the Agency of which I am aware. However, the requirement to detect suspicious orders implies that a wholesaler must have some knowledge about the customer to determine whether an order is suspicious. What constitutes a suspicious order will vary depending on a wide variety of factors such as the total number of prescriptions filled by a pharmacy, the location, the hours of operation, and the proximity of the pharmacy to prescribers. However, to my knowledge, DEA has not provided guidance to wholesalers on whether the use of such factors is appropriate, and if so, how to use those factors in determining whether an order is suspicious. Without clear guidance, distributors are left in a position to determine whether a particular pharmacy's orders "far exceed" the "average purchases" of an "average type registrant." This ambiguity may be one of the reasons why some wholesalers limit or cut off legitimate pharmacies who order a quantity of controlled substances that is above "normal."

2. Does DEA conduct an investigation on pharmacy registrants when wholesalers have reported suspicious orders for a particular pharmacy? Can other wholesalers continue to serve that pharmacy?

Response: I do not know if the DEA conducts investigations on a pharmacy when a distributor reports the pharmacy's orders as suspicious. DEA employees have stated that reporting suspicious orders are important to the Agency because it helps DEA identify potential diverters. DEA has stated that each distributor must decide whether to do business with a particular customer. There is no regulation or formal policy that indicates a distributor must cease

distributing controlled substances to a pharmacy simply because the distributor has informed the DEA of a suspicious order placed by the pharmacy. DEA has stated that a suspicious order does not necessarily make a customer suspicious. Along those same lines, the fact that one distributor has reported a suspicious order placed by pharmacy or refused to continue doing business with a pharmacy does not preclude other distributors from distributing controlled substances to that pharmacy. However, wholesalers do so at their own risk as history indicates that DEA will use the fact that a wholesaler has cut off a customer as evidence that the new wholesaler should have been wary of taking on that customer.

3. Does DEA conduct due diligence on an initial application for DEA registration (pharmacy, wholesaler, physician, etc.)? What does that involve?

Response: DEA does not generally investigate a pharmacy or physician applicant prior to issuing a registration. However, there are exceptions. If the application reveals a history that requires investigation, the Agency will conduct an investigation. According to DEA personnel, some DEA offices have started conducting inspections on pharmacy applicants in the past 3-4 years. Distributor and wholesaler applicants are inspected. The inspections include review of physical security systems and may include review of operating procedures and policies, discussion of DEA's regulations, and other requirements germane to compliance with the CSA and DEA's regulations.

4. Despite efforts by industry and the government, the prescription drug abuse epidemic continues to increase and it is clear we need to do something different than the track we are on now. Do you have any suggestions as to how industry, DEA, and Congress could better address this epidemic?

Response: Education, compliance, enforcement, treatment, and collaboration all play a role in reducing prescription drug abuse. However, these efforts must be properly focused. Fighting prescription drug abuse requires a different strategy than fighting trafficking of illicit drugs. Trafficking of illicit drugs can be addressed by reducing or eliminating supply. With the most widely abused prescription drugs, supply is already limited by DEA through the quota process in which the Agency establishes the amount of narcotics necessary to meet the legitimate medical, scientific, industrial, and export needs of the United States. Although I was once a proponent of supply reduction through enforcement actions on the supply chain as a means to prevent prescription drug abuse, the continued rise in prescription drug abuse during the decade of enforcement action against suppliers has led me to conclude this strategy has limited effectiveness. The reason the strategy is of limited effect is because conduct leading to diversion and abuse occurs at or after the delivery of the controlled substance to the patient or ultimate user, not at the supply chain level. In some cases, patients receive controlled substances for a legitimate medical purpose but misuse the drugs or sell them to others who abuse the drugs. Prescribers and pharmacists who interact with these individuals are best situated to identify these individuals. Education of prescribers and pharmacists is the best way to address this issue. Additionally, community education on how to identify and intervene with friends or family members who abuse controlled substances is helpful. Treatment for those who abuse controlled substance is also a necessary component of addressing this cause of prescription drug abuse.

In other circumstances, prescribers and pharmacists are deceived by individuals who have no legitimate medical need for controlled substances, but feign conditions that lead to the prescribing and dispensing of controlled substances. Here, education of prescribers and pharmacists is essential. Also, collaboration among regulators, healthcare professionals, and law enforcement to establish best practices for prescribers and pharmacists would be helpful. Compliance with prescribing and dispensing guideline and protocols for detecting individuals who misuse or sell their medications will be effective at addressing this cause of diversion.

Finally, in some circumstances, a prescriber and/or pharmacist is a witting participant in delivering controlled substances for other than a legitimate medical purpose. Enforcement is most effective when aimed at these individuals. Collaboration between DEA and the supply chain to develop protocols and systems to identify ordering patterns of those pharmacies and dispensing physicians who are engaged in illicit conduct will allow suppliers to identify for DEA those prescribers and pharmacies who require investigation and action by DEA. The effectiveness of collaboration hinges on compliance by members of the supply chain. When suppliers fail to comply, enforcement is appropriate. However, it is critical to recognize that enforcement against the supply chain does not address the underlying root and intervening direct cause of diversion and abuse.

An effective strategy to address the problem of prescription drug abuse requires identifying the root cause or causes of the problem. Legislation or oversight by Congress can be a catalyst for bringing stakeholders together to identify the root causes and develop realistic strategies aimed at addressing the root causes of prescription drug abuse. Regulations, policies, enforcement strategies, and industry initiatives could then be focused on the main causes of prescription drug abuse.

5. Does DEA use an escalation of enforcement approach?

Response: Some field offices use an escalation of enforcement approach in some circumstances. However, there is no consistency in this matter. In many instances where escalation of enforcement is not used, the likelihood of diversion is increased. An early admonition or warning by DEA is likely to change the conduct of a registrant in many cases. An admonition or oral warning can be given without the evidence necessary to initiate a suspension or pursue a civil penalty. When the Agency fails to use an escalation of enforcement, the Agency may require substantial time to investigate and initiate a more serious action. However, the opportunity to abate conduct early is missed when the Agency does not use an escalation of enforcement approach.

6. Just because a registrant has stopped its bad conduct does not mean they will not start again. How can DEA address those situations?

Response: DEA has the ability to immediately suspend the registration of a registrant whose conduct poses an imminent danger to public health and safety. There are several notable examples of DEA initiating an administrative action to address past conduct and then learning the registrant was again engage in conduct that threatened the public health. In those cases, even

though an administrative hearing was in progress, the Agency issued an immediate suspension to address the imminent danger to public health and safety.

7. The bill I introduced with Mr. Pallone, H.R. 4299, the "Improving Regulatory Transparency of New Medical Therapies Act" requires the DEA to schedule new molecular entities within in a timely manner. Based on your experience working at the DEA, is this approach a safe and effective way to get patients medications faster?

Response: Based on my review of the DEA's scheduling actions over the past decade, DEA has accepted FDA's scheduling recommendation 100% of the time when scheduling a new molecular entity. Based on that history, requiring DEA to schedule a new molecular entity in a timely manner is highly unlikely to have adverse consequences to public health and safety. In fact, public health is likely to be enhanced by the timely availability of new medicines which have been found by FDA to be safe and effective. Since DEA has authority to initiate action to transfer a substance from one schedule to another, requiring the Agency to schedule a new molecular entity in a relatively short period of time will not impede the Agency's ability to later reschedule that substance if evidence warrants rescheduling. Additionally, scheduling a new molecular entity could be done under an interim final rule that would allow the Agency to examine the pattern, scope, significance and duration of abuse of the substance while the approved drug is on the market. DEA could then make that evidence part of the record and issue a final rule scheduling the substance. Expeditious scheduling of new molecular entities is a safe, effective, and sensible approach that allows patients in need to benefit from the new medicines that have been found by FDA to be safe and effective.

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