

(1) Family Violence Prevention and Services Act (FVPSA) grant funds will be used to provide shelter, supportive services, or prevention services to adult and youth victims of family violence, domestic violence, or dating violence, and their dependents (§ 10408(b)(1)).

(2) Not less than 70 percent of the funds distributed shall be for the primary purpose of providing immediate shelter and supportive services as defined in § 10402(9) and (12) to adult and youth victims of family violence, domestic violence, or dating violence as defined in §§ 10402(2), (3), and (4), and their dependents (§ 10408(b)(2)).

(3) Not less than 25 percent of the funds distributed shall be for the purpose of providing supportive services and prevention services as described in § 10408(b)(1)(B) through (H), to victims of family violence, domestic violence, or dating violence, and their dependents (§ 10408(b)(2)).

(4) Grant funds will not be used as direct payment to any victim of family violence, domestic violence, or dating violence, or to any dependent of such victim (§ 10408(d)(1)).

(5) No income eligibility standard will be imposed on individuals with respect to eligibility for assistance or services supported with funds appropriated to carry out the FVPSA (§ 10406(c)(3)).

(6) No fees will be levied for assistance or services provided with funds appropriated to carry out the FVPSA (§ 10406(c)(3)).

(7) The address or location of any shelter or facility assisted under the FVPSA that otherwise maintains a confidential location will, except with written authorization of the person or persons responsible for the operation of such shelter, not be made public (§ 10406(c)(5)(H)).

(8) Procedures are established to ensure compliance with the provisions of § 10406(c)(5) regarding non-disclosure of confidential or private information (§ 10407(a)(2)(A)).

(9) The applicant or grantee will comply with the conditions set forth in the FVPSA at § 10406(c)(5) and all other FVPSA obligations regarding non-disclosure of confidential or private information. These include, but are not limited to, the following requirements: (A) Grantees shall not disclose any personally identifying information collected in connection with services requested (including services utilized or denied), through grantee's funded activities or reveal personally identifying information without informed, written, reasonably time-limited consent by the person about whom information is sought, whether for the FVPSA-funded activities or any other federal or state program (additional consent requirements have been omitted *but see* § 10406(c)(5)(B)(ii)(I) for further requirements); (B) grantees may not release information compelled by statutory or court order unless adhering to the requirements of § 10406(c)(5)(C); (C) grantees may share non-personally identifying information in the aggregate for the purposes enunciated in § 10406(c)(5)(D)(i) as well as for other purposes found in § 10406(c)(5)(D)(ii) and (iii).

(10) As prescribed by § 10406(c)(2) of the FVPSA, the Tribe will use grant funds in a

manner that avoids prohibited discrimination on the basis of age, disability, sex, race, color, national origin, or, as appropriate, religion.

(11) Funds made available under the FVPSA will be used to supplement and not supplant other federal, state, Tribal and local public funds expended to provide services and activities that promote the objectives of the FVPSA (§ 10406(c)(6)).

(12) Receipt of supportive services under the FVPSA will be voluntary. No condition will be applied for the receipt of emergency shelter (§ 10408(d)(2)).

(13) The Tribe has a law or procedure to bar an abuser from a shared household or a household of the abused person, which may include eviction laws or procedures, where appropriate (§ 10407(a)(2)(H)).

Tribally Designated Official

Tribe or Tribal Organization

Appendix B

LGBTQ (also known as "Two-Spirited")
Accessibility Policy

As the Authorized Organizational Representative (AOR) signing this application on behalf of *[Insert full, formal name of applicant organization]*

I hereby attest and certify that:
The needs of lesbian, gay, bisexual, transgender, and questioning (also known as "Two-Spirited") program participants are taken into consideration in applicant's program design. Applicant considered how its program will be inclusive of and non-stigmatizing toward such participants. If not already in place, awardee and, if applicable, subawardees must establish and publicize policies prohibiting harassment based on race, sexual orientation, gender, gender identity (or expression), religion, and national origin. The submission of an application for this funding opportunity constitutes an assurance that applicants have or will put such policies in place within 12 months of the award. Awardees should ensure that all staff members are trained to prevent and respond to harassment or bullying in all forms during the award period. Programs should be prepared to monitor claims, address them seriously, and document their corrective action(s) so all participants are assured that programs are safe, inclusive, and non-stigmatizing by design and in operation. In addition, any subawardees or subcontractors:

- Have in place or will put into place within 12 months of the award policies prohibiting harassment based on race, sexual orientation, gender, gender identity (or expression), religion, and national origin;
- Will enforce these policies;
- Will ensure that all staff will be trained during the award period on how to prevent and respond to harassment or bullying in all forms, and;
- Have or will have within 12 months of the award, a plan to monitor claims, address them seriously, and document their corrective action(s).

Insert Date of Signature:

Print Name and Title of the AOR:

Signature of AOR:

[End of full FOA]

Authority: The statutory authority for this program is 42 U.S.C. 10401–10414.

Mary M. Wayland,

Senior Grants Policy Specialist, Division of Grants Policy, Office of Administration.

[FR Doc. 2015–05010 Filed 3–4–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0300]

John D. Noonan; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying a request for a hearing submitted by Dr. John D. Noonan (Dr. Noonan), and is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debaring Dr. Noonan for 2 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Dr. Noonan was convicted of a misdemeanor under Federal law for conduct relating to the regulation of a drug product under the FD&C Act and that the type of conduct underlying the conviction undermines the process for the regulation of drugs. In determining the appropriateness and period of Dr. Noonan's debarment, FDA has considered the relevant factors listed in the FD&C Act. Dr. Noonan has failed to file with the Agency information and analyses sufficient to create a basis for a hearing concerning this action.

DATES: The order is effective March 5, 2015.

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Nathan Doty, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–8556.

SUPPLEMENTARY INFORMATION:

I. Background

On August 11, 2009, in the U.S. District Court for the Northern District

of New York, Dr. Noonan, a physician, pled guilty to a misdemeanor under the FD&C Act, namely misbranding a drug in violation of sections 301(k), 502(i)(3) and 303(a)(1) of the FD&C Act (21 U.S.C. 331(k), 352(i)(3), 333(a)(1)) and 18 U.S.C. 2. The basis for this conviction was conduct surrounding his injection of patients seeking treatment with BOTOX/BOTOX Cosmetic (BOTOX) with a product, TRI-toxin, distributed by Toxin Research International, Inc. BOTOX is a biological product derived from Botulinum Toxin Type A that is manufactured by Allergan, Inc., and was approved by FDA for use on humans for the treatment of facial wrinkles in 1991. According to the records of the criminal proceedings, Dr. Noonan's colleague in the same medical practice, The Plastic Surgery Group (TPSG), directed a nurse to obtain 31 vials of TRI-toxin, an unapproved drug product, which was represented by its distributor as "Botulinum Toxin Type A." Dr. Noonan then proceeded to inject approximately 10 patients, who believed they were being injected with BOTOX, with TRI-toxin as a substitute.

Dr. Noonan is subject to debarment based on a finding, under section 306(b)(2)(B)(i)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(i)(I)): (1) That he was convicted of a misdemeanor under Federal law relating to the regulation of a drug product under the FD&C Act and (2) that the type of conduct underlying the conviction undermines the process for the regulation of drugs. By notice to Dr. Noonan dated November 30, 2010, FDA's Office of Regulatory Affairs (ORA) proposed to debar him for 4 years from providing services in any capacity to a person having an approved or pending drug product application.

In a letter dated December 30, 2010, through counsel, Dr. Noonan requested a hearing on the proposal. In his request for a hearing, Dr. Noonan acknowledges his conviction under Federal law, as alleged by FDA. By letter dated January 28, 2011, Dr. Noonan submitted materials and arguments in support of his request. Dr. Noonan acknowledges that he was convicted of a Federal misdemeanor, as found in the proposal to debar, but argues that he should not be debarred for reasons related to the factual basis set forth in the proposal to debar. In particular, with respect to the considerations for determining the appropriateness and period of debarment under section 306(c)(3) of the FD&C Act, he argues that there are genuine and substantial issues of fact for resolution at a hearing, namely factual issues bearing on whether he participated in or even knew of certain

conduct that resulted in his violation of the FD&C Act.

Hearings are granted only if there is a genuine and substantial issue of fact. Hearings will not be granted on issues of policy or law, on mere allegations, denials, or general descriptions of positions and contentions, or on data and information insufficient to justify the factual determination urged or the action requested (see 21 CFR 12.24(b)).

The Chief Scientist has considered Dr. Noonan's arguments, as well as the proposal to debar itself, and concludes that, although Dr. Noonan has failed to raise a genuine and substantial issue of fact requiring a hearing, the appropriate period of debarment is 2 years.

II. Arguments

In support of his hearing request, Dr. Noonan first asserts that he is not subject to debarment under section 306(b)(2)(B)(i)(I) of the FD&C Act. He contends that he pled guilty to a misdemeanor violation of the FD&C Act (see section 303(a)(1)), which is a strict liability offense, and that thus there was no demonstration or admission of criminal intent or knowledge underlying the conviction. Dr. Noonan concludes, therefore, that the conduct underlying his conviction did not undermine the process for the regulation of drugs.

Section 306(b)(2)(B)(i)(I) of the FD&C Act specifically provides for the debarment of individuals convicted of Federal misdemeanors related to the regulation of drug products under the FD&C Act. Given that misdemeanor violations of the FD&C Act themselves are strict liability offenses, it stands to reason that criminal intent is not a critical component to debar an individual under section 306(b)(2)(B)(i)(I). During his criminal proceedings, Dr. Noonan pled guilty to misbranding and causing the misbranding of a drug in violation of sections 301(k), 502(i)(3) and 303(a)(1) of the FD&C Act by offering an unapproved drug, TRI-toxin, for sale as an approved drug product, BOTOX. Dr. Noonan's conduct undermined the process for the regulation of drugs in that it permitted an unapproved drug to be substituted for an approved drug without the knowledge of the patient. As a result, Dr. Noonan is, in fact, subject to debarment under section 306(b)(2)(B)(i)(I) of the FD&C Act.

Dr. Noonan next challenges the manner in which ORA applied the considerations under section 306(c)(3) of the FD&C Act in determining the appropriateness and period of his debarment. In the proposal to debar Dr. Noonan, ORA stated that there are four

applicable considerations under section 306(c)(3) of the FD&C Act: (1) The nature and seriousness of his offense under section 306(c)(3)(A); (2) the nature and extent of management participation in the offense under section 306(c)(3)(B); (3) the nature and extent of voluntary steps taken to mitigate the impact on the public under section 306(c)(3)(C); and (4) prior convictions involving matters within the jurisdiction of FDA under section 306(c)(3)(F). ORA found with respect to Dr. Noonan that the first two considerations weigh in favor of debarment and noted that the third and fourth considerations would be treated as favorable factors for him. In making all of its findings under section 306(c)(3) of the FD&C Act, ORA characterized Dr. Noonan's conduct based on records from his criminal proceedings.

Under section 306(c)(3)(A) of the FD&C Act, in determining the appropriateness and period of debarment, FDA considers "the nature and seriousness of the offense involved." In the proposal to debar, ORA relied on the criminal information to which Dr. Noonan pled guilty to find that the conduct underlying his convictions:

created a risk of injury to consumers due to the use of an unapproved drug, undermined [FDA's] oversight of an approved drug product by representing that [he] used the approved drug while actually substituting an unapproved drug in its place, and seriously undermined the integrity of [FDA's] regulation of drug products.

Under section 306(c)(3)(B) of the FD&C Act, ORA also considered the "nature and extent of [Dr. Noonan's] management participation in the offense" and specifically found that he was a corporate principal who "pleaded guilty to misbranding TRI-toxin" and "participated in the [TPSG's] unlawful conduct of administering [an] unapproved drug on multiple occasions to patients." ORA concluded, therefore, that the nature and seriousness of Noonan's offenses and the nature and extent of management participation were unfavorable factors with respect to him.

Dr. Noonan counters ORA's findings with respect to those two considerations in section 306(c)(3) of the FD&C Act with the following arguments: (1) That he did not admit any criminal intent or intentional wrongdoing when he pled guilty to a misdemeanor offense under the FD&C Act; (2) that, in fact, another physician at TPSG took unilateral action in ordering the TRI-toxin and directing a nurse to substitute it for BOTOX; (3) that the TRI-toxin vials that they used for injecting patients with TRI-toxin

were identical to the vials he used for BOTOX before the substitution; and (4) that since the conviction for the underlying misdemeanor was of an individual, that there was no management participation and that, thus, the nature and extent of management participation is inapplicable as a factor in determining appropriateness and period of debarment. Dr. Noonan concedes that he pled guilty to the misdemeanor offense because he was, in fact, guilty of offering TRI-toxin for sale to their patients as BOTOX. He argues, however, that the criminal records do not establish any intent or knowledge on his part and that thus the conduct underlying his conviction does not warrant debarment in light of the considerations in section 306(c)(3) of the FD&C Act.

As noted previously, ORA relied on the records of Dr. Noonan's criminal proceedings for its findings in the proposal to debar. There is nothing definitive in the criminal records before FDA to contradict Dr. Noonan's assertions with respect to the nature of his involvement in the misdemeanor offense to which he pled guilty. The criminal information to which Dr. Noonan pled guilty alleges that TPSG, as opposed to Dr. Noonan, began ordering TRI-toxin for use in the medical practice, and there are no allegations that Dr. Noonan took part in the ordering process. Indeed, the proposal to debar states that, as claimed by Dr. Noonan, another physician in the practice, William F. DeLuca, Jr., was responsible for authorizing a nurse to substitute TRI-toxin for BOTOX, not Dr. Noonan. At Dr. Noonan's sentencing hearing, at which six other codefendants, including DeLuca, were also sentenced, the presiding judge also made clear that he believed DeLuca was the physician responsible for making the "mistake" that led to the other physician's offenses. In addressing DeLuca, the court stated:

And we're here because of your actions and inactions. As I said, your mistakes were different in kind and degree from those of your colleagues. It was you who brought this drug into the practice, and it was your conduct and your failure to check out either the company or the drug that you were ordering, as you should have done, your negligence in doing that that has brought us here today in the end.

In addressing Dr. Noonan, the court further stated: "There have been disputes on how in the past over who knew what and at what point in time. It is clear from the facts in this case that you had no knowledge that the substance was anything other than

[BOTOX] until your discovery of it in November of 2004."

In short, consistent with the proposal to debar Dr. Noonan for 4 years, the records of his criminal proceedings establish that the misdemeanor convictions for the physicians in TPSG other than DeLuca were not based on any affirmative involvement in ordering the TRI-toxin or substituting the TRI-toxin for BOTOX. Furthermore, in proposing to debar Dr. Noonan for 4 years, ORA did not rely on any findings with respect to Dr. Noonan's intent or knowledge. Rather, citing the records of Dr. Noonan's criminal proceedings, the proposal to debar simply rests on Dr. Noonan's position of authority within TPSG and his conduct in misbranding TRI-toxin by administering it to patients who believed they were receiving BOTOX. As a result, under § 12.24(b), there is no genuine and substantial issue of fact raised by Dr. Noonan's arguments for resolution at a hearing.

As set forth in the proposal to debar and summarized previously, Dr. Noonan pled guilty to a misdemeanor under the FD&C Act for his role in offering a drug under the name of another. Based on the undisputed record before the Agency, the consideration in section 306(c)(3)(A) of the FD&C Act with respect to the nature and seriousness of the offense involved is a favorable factor. As reflected in the records of the criminal proceedings, Dr. Noonan's offense did not rest on any intent or knowledge of wrongdoing on his part, nor may such intent or knowledge be inferred from the circumstances of his offense or the findings in the proposal to debar. Although, as a practicing physician, Dr. Noonan should be expected to take the appropriate steps to avoid administering an unapproved new drug to patients or misrepresenting the drug being administered, his failure to do so over a 10-month period does not warrant considering the nature and seriousness of his offense as an unfavorable factor, relative to the range of conduct that might underlie a Federal misdemeanor conviction.

On the other hand, because of Dr. Noonan's position of authority within TPSG and, thus, presumed ability to prevent the series of events that resulted in the offense underlying his misdemeanor conviction, the nature and extent of management participation in the offense is an unfavorable factor, for the purposes of the consideration under 306(c)(3)(B) of the FD&C Act. Dr. Noonan asserts that there was no management participation, and that, thus, this factor is inapplicable because the underlying conviction was of an individual. However, the criminal

information to which Dr. Noonan pled guilty alleges that TPSG began ordering TRI-toxin for use in the medical practice. It is undisputed that Dr. Noonan is a principal in TPSG, and this is the basis for considering the nature and extent of management participation as a factor in determining the appropriateness and period of debarment. FDA has relied on this factor in other debarment cases where the underlying conviction was of an individual (see 78 FR 68455 (November 14, 2013), 77 FR 27236 (May 9, 2012)).

The limited scope of his direct actions in committing the underlying misdemeanor offense does not mitigate the extent of his management participation, as established during his criminal proceedings and as set out in the proposal to debar. It is true that nothing in the criminal proceedings or the proposal to debar reflects any involvement by him in the decision to order the TRI-toxin and substitute it for BOTOX, and the proposal to debar specifically finds that another physician authorized a nurse to place that order. However, Dr. Noonan, as a principal of TPSG, was responsible for failing to ensure that there were controls and procedures in place to prevent other physicians or a nurse from ordering unapproved drugs for administration to patients. His own admitted inaction on that front warrants treating his management participation as an unfavorable factor.¹

Consistent with the proposal to debar, the record establishes that the medical practice of which Dr. Noonan was a part ultimately took voluntary steps to mitigate the effect on the public health from its unlawful conduct (see section 306(c)(3)(C) of the FD&C Act). Furthermore, it is undisputed that Dr. Noonan had no previous criminal convictions related to matters within the jurisdiction of FDA (see section 306(c)(3)(F) of the FD&C Act). Therefore, these will be treated as favorable factors. In light of the foregoing four considerations, one of which weighs against Dr. Noonan, debarment for 2 years is appropriate.

III. Findings and Order

Therefore, the Chief Scientist, under section 306(b)(2)(B)(i)(I) of the FD&C Act and under authority delegated to him, finds that Dr. Noonan has been convicted of a misdemeanor under Federal law for conduct relating to the development or approval of a drug

¹ See *United States v. Park*, 421 U.S. 658, 673-74 (1975) (holding that a high-level manager within a business entity bears a responsibility to prevent and correct violations of the FD&C Act).

product or otherwise relating to the regulation of a drug product under the FD&C Act and that the conduct underlying the conviction undermines the regulation of drugs. FDA has considered the relevant factors listed in section 306(c)(3) of the FD&C Act and determined that a debarment of 2 years is appropriate.

As a result of the foregoing findings, Dr. Noonan is debarred for 2 years from providing services in any capacity to a person with an approved or pending drug product application under section 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see DATES) (see 21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(iii) and 21 U.S.C. 321(dd)). Any person with an approved, or pending, drug product application, who knowingly uses the services of Dr. Noonan, in any capacity during his period of debarment, will be subject to civil money penalties. If Dr. Noonan, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application he will be subject to civil money penalties. In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. Noonan during his period of debarment.

Any application by Dr. Noonan for termination of debarment under section 306(d) of the FD&C Act should be identified with Docket No. FDA-2010-N-0300 and sent to the Division of Dockets Management (see ADDRESSES). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain documents in the Docket at <http://www.regulations.gov/>.

Dated: February 24, 2015.

Stephen Ostroff,

Director, Office of the Chief Scientist.

[FR Doc. 2015-05042 Filed 3-4-15; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Clinical Outcomes Assessment Development and Implementation: Opportunities and Challenges; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled "Clinical Outcomes Assessment Development and Implementation: Opportunities and Challenges." The purpose of the public workshop is to provide updates on accomplishments, challenges, and ongoing efforts in the use of clinical outcome assessments (COAs), and plan for the future of COA development and utilization in drug development programs, including how to incorporate the patient voice in drug development using well-defined and reliable patient-centered outcome measures. The public workshop will also discuss standards for COA use and collaborative processes for COA development and dissemination.

Date and Time: The public workshop will be held on April 1, 2015, from 8:30 a.m. to 5 p.m. Participants are encouraged to arrive early to ensure time for parking and routine security checks before the workshop.

Location: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, The Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>. Attendees are responsible for their own accommodations.

The public workshop will also be available to be viewed online via Webcast at <https://collaboration.fda.gov/COApublicworkshop2015>. Persons interested in participating by Webcast must register online by March 27, 2015.

Contact Person: Michelle Campbell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6471, Silver Spring,

MD 20993-0002, 240-402-6019, email: COApublicworkshop@fda.hhs.gov.

Registration: Registration is free for the public workshop. Interested parties are encouraged to register early because space is limited to 150 attendees. Workshop space will be filled in order of receipt of registration. Those accepted in to the workshop will receive confirmation. Registration will close after the workshop is filled. Registration at the site is not guaranteed but may be possible on a space available basis on the day of the public workshop beginning at 7:30 a.m. If registration is filled, attendance to the workshop will be available only through the Webcast.

To register, visit <http://www.fda.gov/Drugs/NewsEvents/ucm431040.htm>. For those without Internet access, please call Michelle Campbell (See *Contact Person*) to register.

If you need special accommodations due to a disability, please contact Michelle Campbell (See *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The Center for Drug Evaluation and Research (CDER) reviews COAs, including patient-reported outcome measures, clinician-reported outcome measures, and observer-reported outcome measures, when submitted with an investigational new drug application, a new drug application, or a biologics licensing application. CDER also reviews a COA when submitted for qualification as a drug development tool. Qualification of a COA is a regulatory determination that the COA is well-suited for a specific context of use in drug development. Following a public announcement of the qualification decision by FDA, the COA will be publicly available for use in any appropriate drug development program.

This workshop will focus on current challenges and opportunities in COA development and use, including establishing appropriate standards for use; current efforts to encourage inclusion of well-defined and reliable patient-centered outcome measures in drug development; use of collaborative efforts in developing and utilizing COAs through various partnerships; and future efforts to address challenges and gaps of COA development and use for patient-centered drug development and medical product labeling.

For more information on this public workshop, visit <http://www.fda.gov/Drugs/NewsEvents/ucm431040.htm>.

The Agency encourages patient advocates, health care providers, researchers, regulators, individuals from academia, industry, and other interested persons to attend this public workshop.