



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

EDMUND G. BROWN JR., GOVERNOR

Date: June 8, 2012

To: Enforcement Committee

Subject: Agenda Item 1- PARE Assessment

Attachment 1

Background:

In years past, the National Association of Boards of Pharmacy had an examination that could be used to assess the knowledge and deficiencies in a pharmacist's education and training. This was an assessment that the board would periodically require in disciplinary matters where the skills of the pharmacist were in question. The NABP discontinued this examination several years ago.

In July 2011, representatives of the NABP attended the board meeting to discuss, among other items, a new pharmacist assessment process that could be used to assess a pharmacist's knowledge. This assessment was called the Pharmacist Assessment for Remediation Evaluation (PARE). In July 2011, the PARE was undergoing pilot testing by NABP.

According to the NABP, the PARE is intended for use by boards of pharmacy in "instances when an objective measure is needed to assist in decisions regarding pharmacist practice deficiencies."

At this Meeting:

The NABP recently announced that the pilot has been completed and the PARE is ready for use.

Attachment 1 contains information about the PARE. NABP is unable to attend this enforcement meeting, but hope to be able to attend the July Board Meeting.

The committee will have a chance to review these materials and determine if they wish to have a larger presentation at a future committee or board meeting.

PARE Pilot Complete; Remediation Evaluation to Serve as Support Mechanism for the Boards of Pharmacy

With the Pharmacist Assessment for Remediation EvaluationSM (PARESM) pilot now complete, this multidimensional assessment will soon be made available to all state boards of pharmacy. NABP developed PARE to serve as a contributory factor for the boards in instances when an objective measure is needed to assist in decisions regarding pharmacist practice deficiencies.

Created to empower the boards in cases of remediation or as part of their decision-making process, PARE provides a measure that can be considered when determining conditional pharmacist practice issues and can act as an aid in instances when a board is questioning a pharmacist's adherence to pharmacy practice standards. For example, boards may wish to use the assessment when considering cases such as reinstatement of a pharmacist's license after a brief departure from practice or other conditions related to disciplinary actions.

The Pilot

The intent of the pilot was to obtain feedback regarding the PARE testing experience. During the pilot, PARE was administered to a representative sampling of boards of pharmacy. Each participating board was provided with a detailed

manual that included information on registering, administering, and proctoring the assessment, how the assessment is scored, and other general information. Boards were also provided with a sample handbook for examinees, which contained instructions for PARE registration, sample test questions, and a list of suggested study references.

Pilot participants were also asked to complete a brief survey in order to solicit feedback from stakeholders. These survey results were compiled and used to fine tune the administrative aspects of the assessment process.

The Assessment

PARE will be available for a two-week testing window approximately four times per year. Since the assessment is an Internet-based test, scheduling during the two-week window is left to the discretion of each board of pharmacy; however, if the assessment is scheduled outside of NABP business hours (9 AM - 5 PM Central), the Association will not be able to guarantee that technical support will be available in the unlikely event of a technical issue.

The assessment consists of 210 test items representative of three distinct content domains, which were created by a group of subject matter

experts with input and approval from the NABP Executive Committee. The content domains include:

- Medication Safety and the Practice of Pharmacy (50%)
- Professional Ethics/ Pharmacist Judgment (25%)
- Clinical Pharmacy Practice (25%)

All test questions are stand-alone, four-option multiple choice items and each assessment will be delivered through a special lockdown Web browser that disables all nonessential functions on the examinee's computer for the duration of the assessment. Examinees will be allotted four and one-half hours to complete the assessment.

PARE outcomes will be reported on a number-correct scale. Both an overall composite score as well as individual content domain scores will be reported to the board and the examinee within

seven to 10 business days of the administration.

Registering

Once a board has determined that an individual is required to take the PARE, the board will provide NABP with pertinent information on the individual through the NABP Clearinghouse. The board will then contact the individual to notify him or her to contact NABP to register. Upon contacting NABP, examinees will be asked to verify their personal information and submit payment for the assessment. Each PARE administration costs \$250. After registering, the examinee will contact the board to schedule an assessment date and NABP will work with the board to set up the logistics of the administration.

It is anticipated that PARE will be available to all boards of pharmacy by the end of second quarter 2012. Additional information regarding PARE will be forthcoming. ®

Newly Accredited VIPPS Facility



The following Internet pharmacy was accredited through the NABP Verified Internet Pharmacy Practice SitesSM (VIPPSSM) program:

Kmart Corporation
www.kmart.com

A full listing of the accredited VIPPS pharmacy sites representing more than 12,000 pharmacies is available on the NABP Web site at www.nabp.net. ®



Coming in June!

Pharmacist Assessment for Remediation EvaluationSM

The PARESM is a multidimensional assessment that the boards of pharmacy may use as an auxiliary tool when making decisions regarding pharmacist practice deficiencies that are due to noncompliance with pharmacy practice standards, laws, or regulations, and result in compromises to patient safety.

Created to support the boards, the PARE:

- Provides a measure that can be considered when determining conditional pharmacist practice issues.
- Acts as an aid in instances when a board is evaluating a pharmacist's adherence to pharmacy practice standards.
- Is useful when considering cases such as reinstatement of a pharmacist's license after a brief departure from practice.

Exam Design

Examinees are given 4.5 hours to complete the 210-question, multiple choice assessment. The PARE has three content domains:

- **Medication Safety and the Practice of Pharmacy**
(Area 1 – 50% of questions)
- **Professional Ethics/Pharmacist Judgment**
(Area 2 – 25% of questions)
- **Clinical Pharmacy Practice**
(Area 3 – 25% of questions)



Flexible Administration

The PARE is a Web-based assessment that will be available during two-week periods at four different times throughout the year. During the testing periods, the board of pharmacy can administer and proctor the assessment at the time and place most convenient for them and the pharmacist. There are no tests to collect or score – *it is all done electronically.*

Registration Process

Registering a pharmacist for the PARE is integrated with the submission of disciplinary actions. When submitting a disciplinary action to NABP through the online portal, select the PARE as a requirement of board action from the drop-down menu. After submission, the pharmacist contacts NABP to pay the assessment fees and then board staff may schedule the examination at their convenience.

Visit www.nabp.net/programs today for more information!



National Association of Boards of Pharmacy
1600 Feehanville Drive, Mount Prospect, IL 60056
(P) 847/391-4406 • (F) 847/391-4502 • www.nabp.net

PARESM

Pharmacist Assessment for Remediation Evaluation



Board of Pharmacy Administration Manual



National Association of Boards of Pharmacy®
1600 Feehanville Drive
Mount Prospect, IL 60056

PARE

Board of Pharmacy Administration Manual

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Carmen A. Catizone, MS, RPh, DPh
Executive Director/Secretary

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Assessment Day Schedule

- ✓ Proctor ensures that they are in possession of the exam link and unique test code at least one hour prior to the scheduled start time of the Pharmacist Assessment for Remediation EvaluationSM (PARESM).
- ✓ Examinee reports for the assessment, is checked-in, and is seated.
- ✓ All personal items are properly stored away from the examinee.
- ✓ Instructions are read to the examinee.
- ✓ Scratch paper and pencils are distributed to the examinee.
- ✓ Test code is given to examinee. The assessment begins.
- ✓ When examinee has finished, or the end of the assessment arrives, scratch paper and pencils are collected and examinee is dismissed. A test session report is completed.
- ✓ Scratch paper is destroyed.
- ✓ Test Session Report is mailed or faxed to the PARE contact person at NABP. Any/all irregularities must be noted on the Test Session Report. If no irregularities occurred during the test session, the form may be faxed or an e-mail sent indicating that there were no unusual issues with the test session.

Contact Information

Prior to the day of the assessment, if you have any questions regarding the assessment downloads, administration, report forms, or exam security, please e-mail, call, or fax:

Maria Boyle
Competency Assessment Senior Manager
E-mail: mboyle@nabp.net
Office Telephone: 847/391-4426

Or

Crystal Kaya
Competency Assessment Statistical Analyst
E-mail: ckaya@nabp.net
Office Telephone: 847/391-4557

National Association of Boards of Pharmacy
1600 Feehanville Drive
Mount Prospect, IL 60056
Customer Service: 847/391-4406 (Monday-Friday, 9 AM to 5 PM CST)
Fax: 847/375-1129

PARE Overview

The purpose of the PARE is to provide a multi-dimensional assessment that the boards of pharmacy may use as an auxiliary tool when making decisions regarding pharmacist practice deficiencies that are due to noncompliance with pharmacy practice standards, laws or regulations, and result in compromises to patient safety.

Exam Design

The PARE is a Web-based examination administered on a computer. It contains 210 four-option, multiple-choice questions. Examinees are given a maximum of 4.5 hours to read pre-exam information and to take the assessment. The PARE is comprised of three content domains: Medication Safety and the Practice of Pharmacy (Area 1), Professional Ethics/Pharmacist Judgment (Area 2), and Clinical Pharmacy Practice (Area 3). A list of competency statements per content domain is located in Appendix 1. The assessment content is distributed so that approximately 50% of questions come from Area 1, 25% from Area 2, and 25% from Area 3.

Scoring

To pass the PARE an overall score of 80 as well as a minimum score of 75 in each of the three content areas must be achieved. Scores are calculated as proportion correct and are reported to examinees as Pass/Fail. In the case of a Fail, the score report will include the overall score and the performance in each of the three content areas. NABP will make available the area scores in the case of a PASS at the request of the board of pharmacy.

Within one week of testing, scores will be reported to the examinees and their respective boards. Scores will be conveyed to the boards via posting on a protected FTP site. Login and password information will be provided to each board as needed. Examinees will receive their score from NABP via e-mail.

NABP recommends that outcomes of the PARE be interpreted within context of each examinee's situation and used in conjunction with other information in support of board action.

Administrative Details

How to Register an Individual for the PARE

Boards of pharmacy may register pharmacists to take the PARE through the NABP Clearinghouse for Individuals tab in the Board Portal. When entering disciplinary information for an individual there will be a drop-down menu where boards can indicate whether or not the PARE is required. By selecting the Yes option for the PARE the board is indicating that the individual is required to take the assessment and is now eligible to register. If the board determines at a later time that the PARE must be taken, the individual's disciplinary record may be edited to select the PARE as long as the record is still active.

In addition, NABP will need to know if the pharmacist will be using a personal computer or if the board will supply one so that information on the WebLock can be provided to the individual if necessary. After you have registered an individual to take the PARE through the Clearinghouse, NABP will e-mail you with a request for this information. Once this information has been received the individual will be able to contact NABP to complete registration for the PARE.

To register to take the PARE, examinees will contact NABP Customer Service, who will verify that the individual's information matches what the board provided. The board of pharmacy should direct the pharmacist to contact the NABP Customer Service Department **after** NABP has been provided with the registrant's information. (Examinees may contact Customer Service by calling 847/391-4406 from 9 AM to 5 PM Central time Monday through Friday.)

When registering for the PARE, examinees will need to provide the following information so that it can be verified against what the board supplied through the Clearinghouse record:

1. Examinee's name
2. Examinee's address
3. Phone number
4. Date of birth
5. Social Security number
6. E-mail address
7. Corresponding board of pharmacy

Upon registration, NABP will provide the registrant with a link to the *PARE Examinee Handbook*, which contains details about the processes and procedures on the test day as well as other important information. A link to the WebLock software and instructions for download will also be provided if the individual is using his or her own computer for the assessment. The board will be alerted that the individual has completed the registration process when they receive the test code for the individual. More information on the test code can be found in the General Instructions section of this manual.

Exam Cost

Each administration of the PARE costs \$250 and is payable to NABP. MasterCard, Visa, and American Express are accepted means of payment. Payment confirmation will be e-mailed by NABP.

Scheduling

Because the PARE is a Web-based examination, scheduling will be at the discretion of the board of pharmacy. If the PARE is scheduled outside of NABP's normal business hours (9 AM to 5 PM Central), NABP cannot guarantee that technical support will be available in the unlikely event of a technical issue.

Repeater Policy

If an examinee's score falls below the passing threshold, retaking the PARE is at the discretion of the board of pharmacy.

Testing Windows

The PARE will be available for a two-week testing window approximately four times per calendar year. Dates for the testing windows can be accessed on at www.nabp.net (URL TBD).

Technical Preparations for the PARE

The PARE is administered via computer. It is up to each board of pharmacy to decide if examinees will supply their own laptop for testing or if a board-issued laptop/desk-top computer will be provided. Prior to exam day, NABP will e-mail a link to the exam to the designated board of pharmacy's contact person. This link will be used by the examinee on the day of the assessment.

Technical requirements for the PARE include:

Requirement	Supported
Web Browser	Microsoft Internet Explorer Version 8.0+ With compatibility view disabled
	Mozilla Firefox Version 1.9+
	Google Chrome WebKit Version 531+
	Apple Safari WebKit Version 531+
Adobe Flash Plug-in	Version 9.0.115+
Java Script	1.5+ Must be enabled; automatically included with supported browsers
Cookies	Must be enabled; supported in the above browsers
Screen Resolution	1024 x 768+

During the test session, there must be a continuous power source for the laptop/desk-top and Internet connectivity available (DSL or better).

For security purposes, NABP requires the use of a special WebLock browser. This application locks the computer and prevents the examinee from accessing applications outside of the examination. To ensure seamless delivery of the PARE on assessment day, this browser must be downloaded and installed prior to administration of the exam. Approximately two weeks prior to each scheduled exam, NABP will provide either your office or the examinee with a link to the lockdown browser depending on the computer

that will be used. Instructions for installation and contact information in case of technical issues will be provided along with the link. Installation should take one to two minutes. It is strongly recommended that the WebLock browser be installed at least one day prior to the assessment day to avoid any issues on the day of the PARE. Downloading the browser ahead of time will not impair the functionality of the computer or any of its applications. On the day of administration, the proctor should ensure the WebLock program has been downloaded on the computer designated for the exam and that all programs on the computer have been closed. Furthermore, the WebLock software can be uninstalled after the examination by going through the computer's Add/Remove Programs feature.

Each examinee will be assigned a test code that is unique to them. See the General Instructions section for more information on how this code is used.

FastTEST WebLock Installation and Launch Instructions

Step 1: Install WebLock

8. Before you start, ensure that:
 - a. You have Admin rights for the computer that will be used
 - b. The computer is connected to the Internet
 - c. All other programs running on the computer are closed
 - d. For installing on a Mac, the latest version of Java must be installed on the computer
2. Go to <http://WebLock.fasttestweb.com>

FastTEST Web
Innovative solutions for online testing

Secure Testing with FastTEST WebLock

Follow the steps below to set up the FastTEST WebLock secure browser. If the browser has already been installed on this computer, proceed to Step 2.

Step 1: Install WebLock	Step 2: Launch WebLock
<p>Note: You must have administrator privileges to install FastTEST WebLock.</p> <p>Click here to install the FastTEST WebLock secure browser*</p> <p><small>* Click Run, Install, Next, or Allow when prompted.</small></p>	<p>Note: You must close all other programs before launching FastTEST WebLock.</p> <p>Click here to launch FastTEST WebLock and continue to the testing system*</p> <p><small>* Click Run or Allow when prompted.</small></p>

If there is any problem installing FastTEST WebLock, please contact support@fasttestweb.com.

FastTEST Web v2 5.0
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3. Click on the installation link listed under Step 1: “Click here to install the FastTEST WebLock secure browser” (box on left side of screen).
4. For Windows, clicking this link will download an installer. Run the program and click “Yes” or “Continue” for all prompts. For Mac, you will be directed to a download page that contains instructions for installation. The Mac download requires the use of Java. Users will download an installer

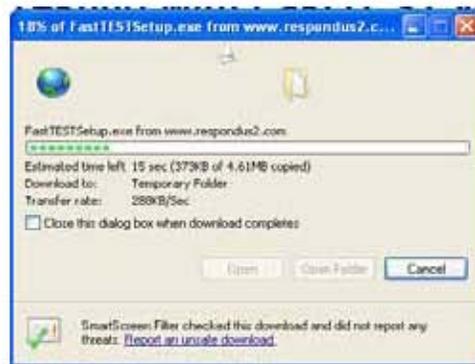
through a Java applet and then run the installer. If the Java applet fails to load, try running in a different browser such as Mozilla Firefox.

Note that Step 1 does not need to be done the moment before the examinee begins taking the test. However, it should be done ahead of time to ensure that the examinee can begin immediately at the scheduled test time.

The following images show the screens from #4 above in a Windows environment. Click “Run” in the first screen.



The setup installer will then download....



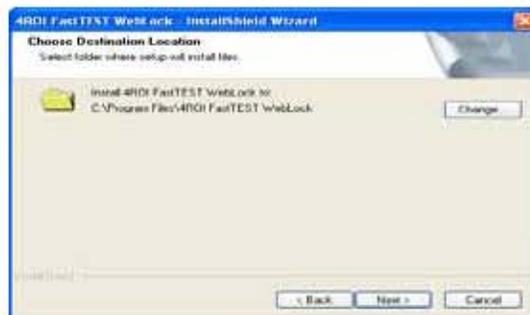
Click “Run” on the next screen.



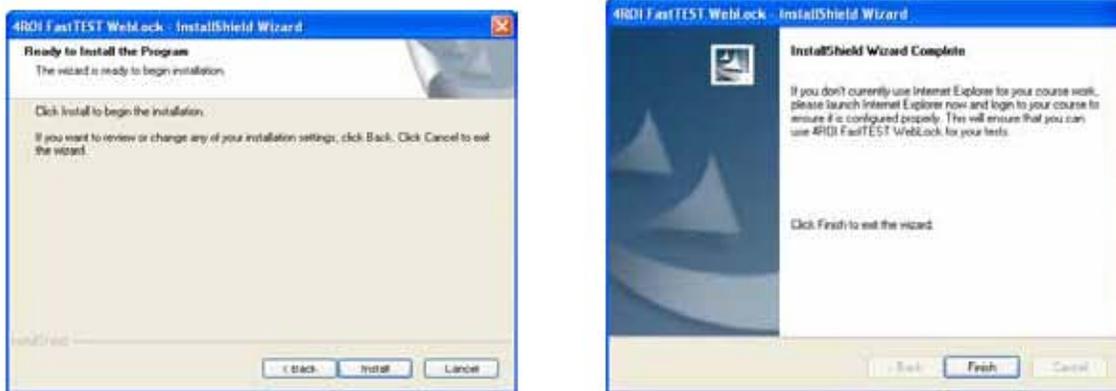
The installer will then open. Click “Next.”



Click “Next” to install to the default folder.



Click “Install” to run the installer. Click “Finish” to close the installer and return the browser.



Step 2: Launch WebLock

1. Before you start, ensure that:
 - b. The computer is connected to the Internet
 - c. All other programs running on the computer are closed
2. Go to: <http://WebLock.fasttestweb.com>
3. Click “Click here to launch FastTEST WebLock and continue to the testing system.” If the screen shown below is displayed, click “Allow.” Prior to launching the exam, you should have closed all other programs, such as Google Desktop and any other auto-start program. If this step was not taken, right click the icon on the toolbar. If WebLock fails to launch after 10-15 seconds, try a different browser such as Mozilla Firefox.



4. The WebLock browser will then open to the examinee login screen as seen on the next page. You can be certain the WebLock browser is running if most of the buttons seen in the computer’s tool tray are gone.
5. In the box labeled “Test Code,” have the examinee enter his or her test code, and then click on “Login.” This procedure will allow the examinee to take the test in a secure setting where he or she is not allowed to run any other programs, visit other Web sites, or access information on the computer.



To Turn Off WebLock

1. Click "Submit Exam" to finish the test.
2. Click "Return to the examinee login page." You can then leave the testing system by clicking "Exit."
3. If the specific computer is only being used for one test and no other test will be given via WebLock, you can uninstall the lockdown browser program. In Windows XP, uninstall via Start -> Control Panel -> Add or Remove Programs. In Windows Vista and Windows 7, it is located at Start -> Control Panel -> Programs and Features.

If the computer loses Internet connection or power during the exam, the exam session can be restarted by launching WebLock again and reentering the test code. No test data will be lost and the exam will restart at the point where connectivity/power was lost.

General Instructions

General Duties of the Proctor

The test proctor's primary responsibilities are to keep the examination code secure, to conduct the assessment according to the instructions put forth in this manual, to guard against cheating or any form of testing irregularity, and to protect the integrity of the test session.

If any special problems or questions arise **prior** to the examination date, please contact the NABP representative listed in the "Contact Information" section on page 5 of this manual.

The proctors should familiarize themselves with:

1. Check-in and admission procedures
2. Distribution, collection, and security of any examination materials, including scratch paper
3. Downloading the required test browser and launch of the exam
4. Continued surveillance of the examination area
5. Completion of the test session and the assessment time reports
6. Contact information for NABP

A proctor should be present in the area at all times during the exam and refrain from conversation or activities that might disturb or distract the examinees. Only examinees and an authorized proctor should be present during the examination.

Receiving Examination Materials

The WebLock program, test code(s) for logging in, and test access information will be e-mailed to the individual designated by the board to receive this information.

Within five business days of each scheduled exam, the board's designated proctor will receive an e-mail from NABP containing test codes for the examinees. Each examinee will be assigned a test code that is unique to them. **It is essential that the test code(s) be kept secure.** On the day of the exam, specific instructions will be read to the examinee by the proctor. At this time, the proctor will provide each examinee with the respective test codes; examinees will use the provided code to log in to the test session.

Materials for the Examination Administration

The following materials are provided by NABP:

1. Administration Manual
2. Test Session Report (TSR) – see Appendix 2

Materials/Items Provided by the Board

1. Designated area in which to take the exam
2. Scratch paper
3. Pencil/pen

Examination Preparation

Examination Proctor Preparation

Prior to admitting and seating the examinee, the proctor should designate a secure place inside or outside the examination room for the storage of all personal belongings such as cell phones, backpacks, purses, briefcases, books, and study notes. **Examinees are not allowed access to personal property during the examination.**

Check-In

The proctor must be in a position to check and recheck the examinees as they enter and leave the room.

Examinees must check-out with the proctor before leaving the testing room.

Admitting and Seating Examinee for the Assessment

The board will notify the examinee of how early he or she may arrive prior to the start time for the PARE.

Admission of Examinee

Upon arrival at the test session, the examinee must provide a valid government-issued photo ID. Acceptable forms of identification include the following non-expired documents:

- ✓ Driver's license
- ✓ Passport
- ✓ State-issued identification card that contains a current photo ID

The proctor will:

1. Verify that the name on the ID matches the name of the examinee scheduled to test.
2. Visually check the picture on the ID against the face of the examinee presenting the identification card. If the person's identity is in question, it is at the proctor's discretion whether or not to admit the examinee.

Once an examinee has been admitted to the test area, he or she may not leave the room unless authorized by a proctor.

Conducting and Supervising the Assessment

WebLock Program Activation Check

Prior to launching the exam, the proctor must ensure that the WebLock browser has been installed and is activated. All programs on the computer must be closed prior to launching the WebLock browser. If programs such as Google Desktop are left running, the WebLock browser will not be properly activated.

Any problems regarding WebLock should be noted in the Test Session Report.

How to Access the PARE

Accessing the PARE is a two-step process: locking down the computer is Step 1; activating the examination is Step 2. Prior to exam day, NABP will e-mail a link to the exam to the designated board of pharmacy's contact person. On the day of the exam, the examinee will open the link in the presence of a proctor. If the WebLock browser has already been installed (highly recommended), then the examinee will be instructed to skip Step 1 and go directly to Step 2. If the WebLock browser was **not** installed prior to the test session, then it will need to be done at the beginning of the test session by clicking on Step 1. Once the initial instructions have been read by the proctor to the examinee, the proctor will direct the examinee to enter the test code and select "Login." The exam will begin immediately.

In order to take the exam, each examinee must agree electronically to the Authorization/Release and Confidentiality Agreement. This Agreement will be available in the *Examinee Handbook* for examinees to review prior to the day of the exam. A copy of the Agreement can be found in Appendix 3 of this manual.

Distributing Materials

At the scheduled examination time, the initial instructions should be read to the examinee and the scratch paper, pencils, and test code distributed. Each examinee will have a unique test code.

Only the examinee may enter the test code to access the exam.

Supervising the Assessment

Detailed instructions to be read to the examinee before and during the assessment are provided on pages 20-22 of this manual.

Examinees may not use resources during the assessment or take written notes (scratch paper) out of the exam session. An on-screen calculator will be available throughout the exam. Use of personal, hand-held calculators is prohibited. There should be nothing on the examinee's desk or workspace other than board-provided scratch paper and pencils. Because no credit will be given for any answers written on the scratch paper, the proctor should emphasize that all answers must be recorded electronically. Upon completion of the test session, all scratch paper must be collected by the test proctor. Examinees may **not** remove scratch paper from the test session.

During the examination, the proctor should be present in the room at all times to guard against possible misconduct.

Cheating or Other Misconduct

Be firm and professional in approaching an examinee that appears to be cheating or trying to cheat. Let the examinee know that you have been watching him or her. Do **not** accuse the examinee of cheating. Suggest that the examinee correct his or her misleading behavior. Make a detailed note of the incident on the TSR and allow the examinee to continue with the examination.

It is extremely important that you write a complete explanation of the incident on the TSR. Provide detail about what you saw, what you did about it, what you said, and what the examinee replied. A copy of this documentation should be retained by the board and a copy sent to NABP.

Suspected misconduct is a delicate issue and must be handled with diplomacy and very close observation. You should document your observations and sign and date the TSR. **Following procedures correctly and documenting exactly what took place makes invalidation of an examinee's examination score more defensible.**

All irregularities should be noted on the TSR and a copy retained for the board's records. The original TSR should be scanned and e-mailed or faxed to NABP attention Maria Boyle or Crystal Kaya. Contact information is located on page 5.

Restroom Visits

The exam cannot be paused for restroom breaks. The exam time continues to run when an examinee is excused to use the restroom. Time lost for restroom breaks cannot be made up at the end of the exam.

If an examinee is excused to go to the restroom during the examination session, the following protocol should be followed:

1. Proctor collects scratch paper prior to the examinee being excused.
2. Proctor ensures the security of the computer while examinee is out of the room.
3. If a laptop is used and if more than one examinee is present at the exam session, the computer screen should be tilted down so that test questions cannot be viewed. If a desktop computer is used, turn the monitor off or tape a piece of paper over the screen.
4. Upon the examinee's return from the restroom, the proctor should return scratch paper to the examinee.

Withdrawing During the Examination

If an examinee needs to withdraw from the examination for any reason, including illness, collect his or her examination materials and apply the following instructions:

1. Ask the examinee if he or she wants the assessment scored.
2. Note on the TSR that the examinee did not complete the exam. Indicate the time, date, reason for the withdrawal, and whether or not the exam is to be scored. The board should retain a copy of this documentation for its records and send a copy to NABP.

Note that it is the board's decision whether or not to allow an examinee to retest.

Examinee Questions

Proctors may not answer any questions regarding individual examination questions.

Collecting Assessment Materials

Before the examinee is dismissed at the close of the examination session, the proctor must make a complete count of the scratch paper provided. The proctor must account for all assessment materials, used and unused. **Under no circumstances is the examinee permitted to keep the scratch paper or to copy any questions from the exam.**

The assessment materials must be guarded so that the examinee does not have access to them as he or she leaves the room. No one may examine the scratch paper after it has been turned in to the proctor.

Since the proctor is solely responsible for the security of the assessment materials, he or she should see that the materials are carefully stored in a secure location under lock and key at the close of each examination session. Examination materials must **never** be left unattended. All scratch paper must be destroyed at the end of the exam.

Detailed Instructions for the Assessment

Good morning/afternoon/evening.

We are about to begin the exam. It is important that you follow along as I read the directions to you. Do not skip ahead as it may impact your exam time.

Please open an Internet browser and go to *WebLock.FastTestWeb.com*. You should see a Web page with the words FastTEST Web at the top. Before we move on, are you able to view this page? At this time, make sure that your computer is plugged in to a continuous power source.

(If the board has already installed the WebLock skip to the next paragraph. If the examinee is using his or her own computer and was supposed to install the WebLock prior to coming to the assessment say:)

On the FastTEST Web page, there are two boxes, labeled Step 1 and Step 2. Have you completed Step 1 to install the WebLock browser? If not, then click the hyperlink under Step 1 and follow the on-screen instructions.

Now click on the link under Step 2, titled “Click here to Launch FastTEST WebLock and continue to the testing system” and follow the on-screen prompts. If you receive an error message, click YES as many times as necessary to resolve the problem.

You should now see a page that says “FastTEST Web Examinee Login” and an empty box titled “Test Code.” I will distribute your individual test code shortly

During the course of the exam, the only items allowed at your seat are your computer, the provided scratch paper, and a writing instrument. You are required to remove all other items and place them with your personal belongings.

There is no scheduled restroom break. If you must leave for the restroom, raise your hand and wait for my instructions. Before leaving your seat, partially lower the top cover of your laptop or turn off your monitor and proceed to the restroom.

You will have 4 and a half hours or 270 minutes to complete the exam. A clock will be located in the upper right corner of your screen to display the time remaining for the exam.

To select an answer, left-click either the bubble or the text that corresponds to the chosen answer. Clicking the item letter alone will not select

the answer. There will be 210 numbered boxes at the top of your screen. Boxes align with the items on the exam. If a question has been answered, the corresponding box will show a slash through it. The item you are currently working on will be shaded in blue, and any unanswered items will be white. Questions may be designated for review by clicking the “review” button, located at the bottom of your screen. This will highlight the item box yellow. You may go back at any time during the exam to review or change your answers.

At the top of your screen is a “Calculator” button. Clicking this button on any screen will make the calculator available to you. Note that to enter a number less than 1, you must first enter a leading zero (Example 0.5). Click the “X” in the right corner of the calculator to close it.

If you finish in less than the allotted time and wish to leave, you may do so. If you want to leave early, please raise your hand so that I can make sure that you have correctly submitted your exam.

Your score on this exam will be result from the questions you answer correctly. There is no penalty for guessing, so it is to your advantage to answer every question.

I will now provide you with your test code. This code enables you to begin the test. You will need to enter your test code into the Test Code box and press the Login button.

(Give the unique test code to the examinee. If there are multiple examinees please approach each one individually.)

After you press the Login button you should see a screen that has 210 item boxes on it. Do you see that screen?

We are now ready to move to the next screen. Please click on the button marked **NEXT**. This will take you to Question Number 1, which is the first of your three demographic questions. We will walk through questions 1 through 4 together. **Do NOT proceed to question Number 5 until you are told to do so.**

The first screen contains the Authorization/Release and Confidentiality Agreement. Please read through this carefully. By clicking the bubble you electronically agree to the terms stated in the agreement. If you do not agree to these terms you may not take the exam. When done, click **NEXT**.

In question Number 2, type your last name.

In question Number 3, type your first name and for question Number 4, your middle initial if you have one. After completing question Number 4 please stop.

Are there any questions?

(Answer any questions.)

You may now proceed to question Number 5. Your 4 and a half hours begin now.

TESTING

At the conclusion of the exam, say:

Your time is up. Please remember that you must leave all scratch paper at your test station.

Thank you for participating in the PARE. You are dismissed.

Any issues/irregularities that arise before, during, or after the exam should be noted in the TSR, which can be found in Appendix 2 of this manual. In the event that there is an issue, this report should be faxed or mailed to NABP. If no issues arise, the proctor should mail or fax the report, or send an e-mail indicating that no irregularities took place.

FastTEST Troubleshooting

Preliminary Troubleshooting

- ✓ Shutting down all other programs before entering WebLock is preferred.
- ✓ Cookies must be enabled.
- ✓ If an error message appears stating “*You must close the following program before starting the browser: (program name here) Do you want 4ROU FastTEST WebLock to attempt to close this program for you?*” click “Yes” as many times as necessary. If problem persists, try using a different Web browser.
- ✓ If an error message appears stating “*4ROI FastTEST WebLock was unexpectedly launched without a custom URL to process. The application will now exit,*” you must launch WebLock through a Web browser with the indicated link, not by directly clicking on the installed program’s icon.

For Mac computers:

- ✓ Firefox is the preferred browser. WebLock is not compatible with Safari.
- ✓ If WebLock browser does not install or launch properly, ensure that the latest version of Java is installed.

Exam Troubleshooting

Force computer to shut down, restart, and log in again using the same log in key if:

- ✓ Pictures do not show up on exam questions
- ✓ Blue slashes do not appear in the boxes at the top of the screen for questions already answered
- ✓ Computer freezes
- ✓ “Submit exam” button does not appear
- ✓ If the refresh button is pushed and blue slashes get cleared out from the already answered questions
- ✓ Any other unique problems occur during the exam

Appendix 1: Content Areas

Area 1 Medication Safety and the Practice of Pharmacy 50% (105 items)

- 1A Safe and Effective Preparation and Dispensing of Medications
 - 1A1- Extemporaneous Compounding/Parenteral/Enteral including Calculations, Sterile Admixture Techniques, USP <797>, Stability and Sterility Testing and Dating, Clean Room Requirements, Infusion Devices and Catheters
 - 1A2- Preparation, Dispensing, Distribution, and Disposal of Medications and Devices including Appropriate Labeling, Storage, Packaging, and Handling
 - 1A3- Distribution Systems Associated with All Types of Practice Settings
 - 1A4- Role of Automation and Technology in Workload Efficiency and Patient Safety
- 1B Prevention of Medication Errors
 - 1B1- Practice Management Tools Needed to Assess and Address Change, Improve Quality, and Optimize Patient Services
 - 1B2 - Identification and Prevention of Medication Errors Within the Dispensing and Distribution System
 - 1B3- Medication Error Reduction Programs
 - 1B4- Medication Safety: Causes of Errors, Strategies for Reducing Errors
- 1C Continuous Quality Improvement

Area 2 Professional Ethics/Pharmacist Judgment 25% (52-53 items)

- 2A Professional Ethics
 - 2A1- Ethical Principles
- 2B Decisions/Actions Affecting Patient Care
 - 2B1- Ethical Issues in Delivery of Patient-Centered Care/Clinical Research
- 2C Code of Ethics, Professional Behavior
 - 2C1- Dealing with Ethical Dilemmas
 - 2C2- Conflicts of Interest
 - 2C3- Ethical Issues in Teamwork

Area 3 Clinical Pharmacy Practice 25% (52-53 items)

- 3A Patient Assessment, Clinical Pharmacology, Therapeutics
 - 3A1-Pharmacotherapy: Selection of Drug Products, Dosing, Routes of Administration, Disease State Management
 - 3A2- Patient Assessment Triage and Referral Skills: Identify and Assess the Patient's Current Health Status, Health Problems, Need for Treatment and/or Referral, and Desired Therapeutic Outcomes
 - 3A3- Diagnostic Tests in the Diagnosis of Various Disease States, Knowledge of the Basis for Common Clinical Laboratory Values and Diagnostic Tests and the Influences of Common Disease States

3A4- Patient Monitoring: Drug Monitoring for Positive and Negative Outcomes, Methods of Outcome Monitoring and Assessment Techniques, Drug Monitoring for Positive/Negative Outcomes in Special-Population Patients, Pharmaceutical Care Plans

3A5- Problem Identification and Resolution (eg, Dosage, Frequency, Dosage Form, Interactions, Adverse Drug Reactions, Indication, Contraindication, Safety, Efficacy, Non-compliance, Abuse)

3B Promotion of Wellness and Public Health

3B1- Disease Prevention and Monitoring

3B2- Infection Control (Pharmacist Intervention, Recommendations)

3B3- Promotion of Wellness (Nutrition, Non-pharmacologic Therapies, Lifestyle)

3C Drug Information

3C1-Fundamentals and Application of Drug Information Skills for the Delivery of Care (Identifying and Using Resources, Accessing References etc)

Appendix 3: Authorization/Release and Confidentiality Agreement

1. I agree to sit for the Pharmacist Assessment for Remediation EvaluationSM (PARESM) and agree to provide to the National Association of Boards of Pharmacy[®] (NABP[®]) my full name, date of birth, and my Social Security number as set forth in the registration process. I authorize NABP to use such information for purposes of confirming my identity, calculating and evaluating my PARE score, and PARE program-related activities including, but not limited to, validity of the PARE and quality assurance. I further authorize NABP to release such identifying information and my PARE score to my Board of pharmacy. NABP will not use such identifying information or my PARE score for commercial or solicitation purposes.
2. Except as permitted herein or in the event that NABP is legally required to disclose the information that I authorize, NABP will keep confidential and will not disclose any of the information that I release and authorize for use pursuant to this authorization and release form (hereinafter "Form"). This paragraph will survive expiration or revocation of this Agreement.
3. I understand and agree that I am expressly prohibited, at all times, from disclosing, reproducing, transmitting, receiving or utilizing without authorization, or making available the PARE including, but not limited to, examination question format, questions, profiles, answers, and scenarios, in whole or in part, in any form and by any means, whether verbal, written, electronic, or mechanical, for any purpose.
4. I understand and agree that if NABP obtains information that I, at any time, disclosed, reproduced, transmitted, received or utilized without authorization, or made available any portion of the PARE in any form to or from individuals, organizations, study groups, or the like, that I forfeit the right to have my examination scored, that NABP has the right to invalidate my examination score, and I understand that NABP may initiate civil, criminal, and/or administrative proceedings against me that may result in civil penalties, criminal punishments, and/or disciplinary action.
5. NABP disclaims all liability and responsibility arising from this Agreement except to the extent that NABP breaches its responsibilities or is negligent in performing under this Agreement and only to the extent that the liability or responsibility is caused by such breach or negligent performance. Further, NABP disclaims all liability and responsibility for all individuals' or entities' use, maintenance, or disclosure of the information described herein after NABP's release of such information in accordance with this Agreement.
6. I understand that I may revoke this Agreement at any time if I sign and send a letter, via certified, registered, or overnight mail with return receipt requested, to the executive director/secretary, National Association of Boards of Pharmacy, 1600 Feehanville Drive, Mount Prospect, IL 60056, or such other address where NABP may be located at the time of sending such letter. Unless I revoke this Agreement as described herein, the Agreement is valid upon the date of my signature and for a period of seven years after the PARE program, and any of its successor programs, cease to exist.



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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

EDMUND G. BROWN JR., GOVERNOR

Date: June 8, 2012

To: Enforcement Committee

Subject: Agenda Item II- Discussion on the Implementation of California's Electronic Pedigree Requirements for Prescription Medication

a. Discussion about the Presence of Counterfeit Avastin and Altuzan in California Physician Offices in California Physician Offices and Clinics

Attachment II a

Since early this year, 58 physician and clinic offices in California have been discovered to have purchased counterfeit Avastin and Altuzan from the supply chain.

Attachment II a contains some of these articles. More recently, counterfeit Adderal has been also discovered, some of the origin has been from Internet sales initially, but there has been concern expressed that the drug could find its way into the US supply chain.

b. Dysfunction in California Supply of Prescription Medication Discovered During Board of Pharmacy Inspections

During inspections of California pharmacies and wholesalers, the board's inspectors are encountering numerous serious violations involving "redispensing" of previously dispensed medication.

During this meeting, a short presentation will be provided on some of photos taken during these inspections.

c. Board of Pharmacy Letters to Federal Representatives and Senators on Elements Needed in any Proposal for Federal Legislation

Attachment II c

At the May board meeting, the board directed that a letter explaining California's e-pedigree requirements be sent to certain federal legislators who are deliberating on a possible federal system for drug chain security. This letter was sent in early May. A copy of the letter sent to Congress Member Waxman is provided in **Attachment II c**.

d. Colloquy from Senators Enzi and Harkin in Support of Retaining Protections in California Law in Future Federal Requirements for Tracking Prescription Medications Through the Pharmaceutical Supply Chain

Attachment II d

Senators Enzi and Harkin released a colloquy on May 22, 2012, supporting California's serialization requirements as elements in a federal supply chain system.

A copy of the colloquy is provided in **Attachment II d**.

e. Presentations and Questions from the Pharmaceutical Supply Chain on their Readiness to Meet California's E-Pedigree Implementation Schedule

Up until late 2008 when California's e-pedigree requirements were amended to delay implementation until at least 2015, the enforcement committee held public discussions with the supply chain to discuss readiness issues. Earlier this year, the committee resumed these discussions.

Interested parties are encouraged to provide information and or presentations to the committee members on implementation issues during this part of the meeting.

f. General Discussion on E-Pedigree

g. Discussion and Possible Action to Develop Regulation Requirements Specifying a Unique Identification Number for Prescription Medication Pursuant to California's E-Pedigree Requirements

Attachment II g

At the May board meeting, the board directed the enforcement committee to reconsider the proposed parameters for a serialized numeric identifier that will be the tracking number for each prescription container. At this time, the committee will have the chance to review the proposed regulation text, which mirrors that developed by the FDA as a guideline.

The current proposed language is provided in **Attachment II g**, along with the FDA "Guidance for Industry Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages."

Meanwhile, staff is working on modifications to the language to share at the meeting. This proposal will be handed out at the meeting.

h. Discussion and Possible Action to Develop "Grandfathering" Provisions for Non-Pedigreed Dangerous Drugs Pursuant to Section 4163.2 of the California Business and Professions Code

Attachment II h

California Business and Professions Code section 4163.2 requires the board to develop conditions for “grandfathering” non-serialized products so that they may remain in California commerce. At the last meeting, the committee reviewed a draft regulation for this purpose.

At the May board meeting, the board asked the committee to reexamine the proposed regulation. In **Attachment II h** is the current draft of this proposed regulation.

At the enforcement committee meeting, staff will share a new draft proposal to accomplish the requirements of section 4163.2 using alternate text.

Section 4163.2 provides that:

4163.2. (a) (1) A manufacturer, wholesaler, or pharmacy lawfully possessing or owning dangerous drugs manufactured or distributed prior to the operative date of the pedigree requirements, specified in Sections 4034 and **4163**, may designate these dangerous drugs as not subject to the pedigree requirements by preparing a written declaration made under penalty of perjury that lists those dangerous drugs.

(2) The written declaration shall include the National Drug Code Directory lot number for each dangerous drug designated. The written declaration shall be submitted to and received by the board no later than 30 days after the operative date of the pedigree requirements. The entity or person submitting the written declaration shall also retain for a period of three years and make available for inspection by the board a copy of each written declaration submitted.

(3) The board may, by regulation, further specify the requirements and procedures for the creation and submission of these written declarations. Information contained in these declarations shall be considered trade secrets and kept confidential by the board.

(b) Any dangerous drugs designated on a written declaration timely created and submitted to the board may be purchased, sold, acquired, returned, or otherwise transferred without meeting the pedigree requirements, if the transfer complies with the other requirements of this chapter.

i. Discussion Concerning Elements for Inference as Provided by California Business and Professions Code section 4163.3

Attachment II i

Scheduled for discussion at the meeting is the topic of inference. Inference would allow a read of a single serialized number on a case or pallet to link with every serialized package within the case or pallet, without having to separately read and confirm the presence of each individual container.

Attachment II i illustrates visually inference from a unit to a case to a pallet.

Inference is required because the numeric identifier that is likely to be affixed to a container will be a 2-D matrix code, which requires a line of sight scan. To access or append the pedigree, a “read” of the number will be needed.

Inference is referenced in Business and Professions Code section 4163.3:

4163.3. (a) It is the intent of the Legislature that participants in the distribution chain for dangerous drugs, including manufacturers, wholesalers, or pharmacies furnishing, administering, or dispensing dangerous drugs, distribute and receive electronic pedigrees, and verify and validate the delivery and receipt of dangerous drugs against those pedigrees at the unit level, in a manner that maintains the integrity of the pedigree system without an unacceptable increase in the risk of diversion or counterfeiting.

(b) To meet this goal, and to facilitate efficiency and safety in the distribution chain, the board shall, by regulation, define the circumstances under which participants in the distribution chain may infer the contents of a case, pallet, or other aggregate of individual units, packages, or containers of dangerous drugs, from a unique identifier associated with the case, pallet, or other aggregate, without opening each case, pallet, or other aggregate or otherwise individually validating each unit.

(c) Manufacturers, wholesalers, and pharmacies opting to employ the use of inference as authorized by the board to comply with the pedigree requirements shall document their processes and procedures in their standard operating procedures (SOPs) and shall make those SOPs available for board review.

(d) SOPs regarding inference shall include a process for statistically sampling the accuracy of information sent with inbound product.

(e) Liability associated with accuracy of product information and pedigree using inference shall be specified in the board's regulations.

FiercePharma Manufacturing

Published on FiercePharma Manufacturing (<http://www.fiercepharmamanufacturing.com>)

FDA commish suggests putting more bite in laws for counterfeiting

June 7, 2012 | By Eric Palmer

FDA Commissioner Margaret Hamburg called on drugmakers to be "accountable for the integrity of their supply chains" to help fight counterfeit drugs, a reference to the need for a track and trace system in the U.S. She also called for stronger penalties for traffickers.

In an interview with *The Financial Times*, Hamburg said, "We need to really strengthen the integrity of the supply chain to really be able to assure safe passage of products through the complex network of packagers and distributors and redistributors and importers."

Her remarks came as the House and Senate will reconcile their separate versions of the bill reauthorizing the FDA to collect user fees to help fund nearly half its 5-year budget. The FDA wants the final law to have a track and trace system with unique identifiers on each drug container and requirements that they be scanned along their distribution route. The industry has agreed to the unifiers but wants only lot scanning.

It also comes after two recent high-profile cases of counterfeits being found in the U.S. Just last week, the FDA sent out an alert that fakes of Teva Pharmaceutical Industries' (STEVA) attention-deficit drug Adderall, were being sold over the Internet. In February, the agency discovered counterfeits of Roche's (SRHHBY) cancer drug Avastin had been sold directly to physician clinics.

Hamburg also called for harsher penalties for those trafficking in fakes, saying that criminals are now viewing drug counterfeiting as a lucrative enterprise with no more threat of jail time than selling fake purses. The FDA reauthorization bill would give drug counterfeiting penalties more punch.

"We need legal authorities to give teeth to our actions," Hamburg said. "We are increasingly concerned that this is becoming an attractive area for bad guys, including organized crime."

The International Journal of Clinical Practice warns that increasing numbers of fakes are getting into legitimate supply chains, and global sales of fake meds doubled from 2005 to 2010, to \$75 billion.

- read the *Financial Times* [interview](#) (reg. req.)

Related Articles:

[Fake Adderall surfaces as Congress turns attention to track and trace](#)

[Fake Avastin case highlights need for supply-chain controls](#)

FiercePharma

Published on FiercePharma (<http://www.fiercepharma.com>)

Fake Avastin case highlights need for supply-chain controls

March 12, 2012 | By Tracy Staton

Global pharma police have few weapons against fly-by-night drug distributors that deal in counterfeits. This is no secret to drugmakers; Pfizer ([\\$PFE](#)), for instance, has a vast security force focused on cracking down on fake versions of its meds, including--perhaps especially--that little blue pill, Viagra. And before phony [Avastin](#) surfaced in the U.S., Roche ([\\$RHHBY](#)) teams tracked fake versions of the company's drugs in the Middle East.

Now, that phony Avastin has cast a spotlight on the pharma supply chain. The fake cancer drug--which contained none of the real thing's active ingredient--had passed through several countries and half a dozen companies before the FDA warned U.S. doctors about it. "The business about counterfeit Avastin really demonstrates how easy it is to be fooled," Sandra Kweder, deputy director of FDA's Office of New Drugs, said, as quoted by *Reuters*.

Complicating matters is distributors and customers themselves ignore red flags--such as markedly discounted prices, as in Avastin's case--which only feeds the counterfeit trade. In other cases, import/export rules prohibit middlemen from opening boxes to inspect their cargo; Switzerland's Hadicon, for instance, blamed such rules for its unwitting participation in the Avastin fraud. Plus, experts say, many counterfeiters are simply good at faking it.

"The perpetrators certainly acted in a highly professional manner and knew that drugs would not be allowed to be opened once smuggled into the delivery chain," Hadicon CEO Klaus-Rainer Toedter told *Reuters*. And one anonymous buyer said the U.S. Avastin distributor was "a good con man" with documentation and licenses that appeared authentic.

What's to be done? Drug-tracking systems have been proposed, and Europe starts requiring unique identifiers on all drug packages beginning in 2016. But even RFID tags can be circumvented, especially if customers are willing to look the other way, *Reuters'* sources said. And drug shortages have healthcare providers casting about for new suppliers, which could aid counterfeiters. Some U.S. lawmakers have proposed harsher penalties for counterfeiters and increased tracking along the supply chain.

- read the *Reuters* [analysis](#)

Related Articles:

[Fake Avastin adds urgency to foreign-drug importation probe](#)

[Phony Avastin vials contained chemicals, but no drugs](#)

[Fake Avastin's path shows tangled global supply chain](#)

FiercePharma Manufacturing

Published on FiercePharma Manufacturing (<http://www.fiercepharmamanufacturing.com>)

Fake Adderall surfaces as Congress turns attention to track and trace

May 31, 2012 | By Eric Palmer

Another counterfeit drug, this time the ADHD drug Adderall, has surfaced in the U.S. even as details of how the FDA and the industry should track drugs to protect against fakes is about to be hashed out by Congress.

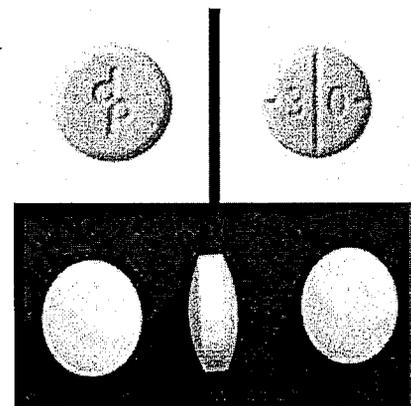
The FDA this week warned that fake versions of the drug have shown up on Internet sites as shortages have made it difficult to get. Made by Teva Pharmaceutical Industries ([\\$TEVA](#)) and other generics companies, the short-acting form of Adderall has been in short supply since last year because of "active pharmaceutical ingredient supply issues," *The Wall Street Journal* reports.

There are concerns about counterfeits sold over the Internet making their way into the legitimate supply chain, and the industry and the FDA are looking at ways to better police the problem. The urgency was raised earlier this year when counterfeit versions of Roche's ([\\$RHHBY](#)) cancer drug [Avastin](#) were sold to more than four dozen physician practices throughout the U.S.

The House and Senate versions of the FDA reauthorization bill include language that would set up more stringent tracking of drugs to help prevent counterfeiting, but the details have yet to be set, *Reuters* reports. The FDA wants a nationwide program that includes and tracks identifiers on individual containers. The plan put up by an industry coalition would put unique serial numbers on individual drug packages but require scanning drugs only in "lots" when they get to distributors. They have argued that to expect individual tracking from truck to warehouse to distributor to pharmacies is unworkable, at least for now.

FDA Commissioner [Margaret Hamburg](#) has made her case to consumers on the FDA blog, writing, "To learn that the cancer drug you were taking to save or prolong your life might be nothing but a counterfeit is unthinkable. We ... need authority to require a robust system to track and trace all drugs throughout the supply chain."

The U.S. is not the only country thinking this way. Europe starts requiring unique identifiers on all drug packages beginning in 2016. The Senate and House reconciliation process will sort out whether the FDA or the industry has the most clout on this issue, but the appearance of more fakes as the



Teva's Adderall (top) can be distinguished from counterfeits (bottom) by its color and insignia--courtesy of the FDA



U.S. Food & Drug Administration



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Another counterfeit cancer medicine found in U.S. - Illegal practice puts patients at risk

Statement Update Issued: April 25, 2012

FDA has issued letters to medical practices in the United States that purchased unapproved cancer medications from Quality Specialty Products (QSP) (also known as Montana Health Care Solutions), and distributed through Volunteer Distribution of Gainesboro, Tennessee that may include counterfeit versions of Altuzan.

Letters to Doctors about Risks of Purchasing Medications from Foreign or Unlicensed Suppliers¹

Statement Update Issued: April 17, 2012

In a related action, FDA has issued letters to medical practices in the United States that purchased unapproved cancer medications that may include counterfeit versions of Altuzan.

Statement Issued: April 3, 2012

The U.S. Food and Drug Administration is alerting healthcare professionals that another cancer drug, originating from a foreign source and purchased by U.S. medical practices, has been determined to be counterfeit. Medical practices that purchase and administer illegal and unapproved foreign medications are putting patients at risk of exposure to drugs that may be fake, contaminated, improperly stored and transported, ineffective, and dangerous. Illegal drugs purchased from foreign sources may not be genuine or meet appropriate quality, safety, and efficacy standards, putting patients at risk and depriving them of proper treatment.



Patients receiving cancer drugs or other drugs not approved by the FDA for the U.S. market may not be receiving needed therapy. Patients are encouraged to discuss any concerns they may have about the source of their medications with their healthcare professional.



FDA lab tests have confirmed that a counterfeit version of Roche's Altuzan 400mg/16ml (bevacizumab), an injectable cancer medication, found in the U.S. contains no active ingredient. Even if the identified drugs were not counterfeit, Altuzan is not approved by FDA for use in the United States (it is an approved drug in Turkey). On February 14, FDA issued an alert about another cancer drug² in U.S. distribution that was purchased from a foreign source and found to be counterfeit.



Medical practices obtained the counterfeit Altuzan and other unapproved products through foreign sources, in particular from Richards Pharma, also known as Richards Services, Warwick Healthcare Solutions, or Ban Dune Marketing Inc (BDMI). Many, if not all, of the products sold and distributed through this distributor have not been approved by the FDA. The agency cannot ensure that the manufacture and handling of these illegal products follows U.S. regulations, nor can FDA ensure that these drugs are safe and effective for their intended uses.

Any medical practice that has obtained unapproved products, in particular from Richards Pharma, Richards Services, Warwick Healthcare Solutions, or Ban Dune Marketing Inc (BDMI), should stop using them and contact the FDA. The products should be retained and securely stored until further notice by the FDA.

Healthcare professionals and patients should report adverse events related to the use of suspect injectable cancer medicines to the FDA's MedWatch Safety Information and Adverse Event Reporting Program either online, by regular mail, by fax, or by phone. Health care professionals and consumers can either:

- Complete and submit the report online: www.fda.gov/MedWatch/report.htm³, or
- Download form⁴ or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

FDA is asking the public to report suspect counterfeit products and other suspect products obtained from Richards Pharma, Richards Services, Warwick Healthcare Solutions, Ban Dune Marketing Inc (BDMI), or other sources:

- Call FDA's Office of Criminal Investigations (OCI) at 800-551-3989, or
- Visit OCI's Web site (www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm)⁵, or
- Email - DrugSupplyChainIntegrity@fda.hhs.gov

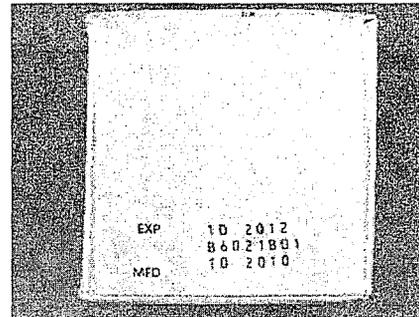
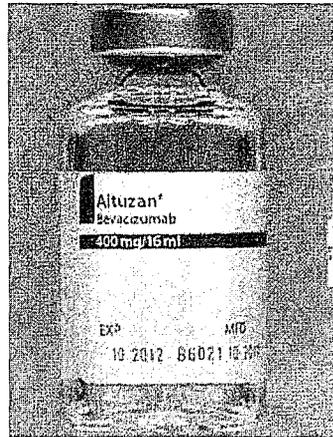
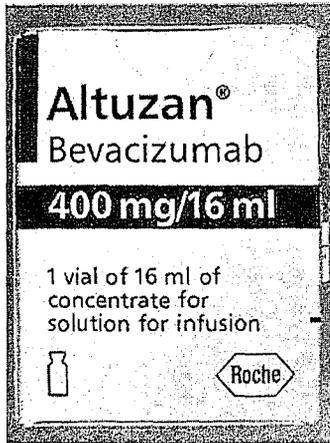


For more information about counterfeit medicine:

<http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/CounterfeitMedicine/default.htm>⁶.

Pictures of the counterfeit version of Altuzan are shown below:

Packaging or vials found in the U.S. that claim to be Roche's Altuzan with lot number B6021 should be considered counterfeit.



Links on this page:

1. [/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm299920.htm](http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm299920.htm)
2. <http://www.fda.gov/Drugs/DrugSafety/ucm291960.htm>
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4. <http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm>
5. <http://www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm>
6. <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/CounterfeitMedicine/default.htm>

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FDA Tracks Fake Avastin to Foreign Supply Distributed in U.S.

By: KERRI WACHTER, Oncology Report Digital Network

02/21/12

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The Food and Drug Administration has tracked counterfeit bevacizumab, the cancer drug marketed as Avastin, to at least one foreign supplier and identified 19 medical practices in the United States that purchased unapproved cancer medicines, possibly including counterfeit bevacizumab.

The FDA said the practices obtained the fake Avastin from Quality Specialty Products (QSP), a foreign supplier also known as Montana Health Care Solutions. QSP products are also distributed by Volunteer Distribution in Gainesboro, Tenn., the agency said.



Courtesy of Genentech

This package of counterfeit Avastin has the letter B in the lot number and a date of manufacture -- neither of which appears on packages of Avastin approved for use in the United States. Also, Genentech is not identified on the label, and the expiry date is written entirely in numerals.

The FDA has requested that medical practices stop using any remaining products purchased from these suppliers "or any other unapproved foreign source," because the agency cannot ensure the safety or efficacy of any of these unapproved products.

"The Agency is very concerned that these products may cause harm to patients because they are unsafe or ineffective. ... These products may be from unknown sources; have unknown ingredients; and may not have been manufactured, transported or stored under proper conditions required by U.S. law, regulations, and standards," the agency said.

Avastin's manufacturers announced Feb. 14 that they learned of the distribution of the counterfeit in the United States. "The counterfeit product is not safe or effective and should not be used. Chemical analyses of the counterfeit vials tested to date have confirmed the product does not contain the active ingredients for Avastin," warned F. Hoffmann-La Roche and Genentech.

Avastin, an injectable medicine used to treat many cancers, is administered to patients in clinics, hospitals, and doctors' offices. The counterfeit version does not contain the monoclonal antibody bevacizumab.

The FDA similarly warned health care professionals and patients about a counterfeit version of Avastin 400mg/16mL, which may have been purchased and used by some medical practices in the United States.

The FDA has since issued letters to 19 U.S. medical practices that purchased unapproved cancer medicines that may include the counterfeit Avastin. It is believed that some product in the United States labeled as Avastin 400 mg/16 mL with the following lot numbers on either the vials or packaging may be counterfeit: B86017, B6011, and B6010.

Importantly, the counterfeit product does not look like authentic Avastin. Authentic Avastin's cartons and vials (approved for use in the United States) have "Genentech" or "Genentech, a member of the Roche Group" printed on the labels. The counterfeit version is labeled as

Avastin, manufactured by Roche, which manufactures Avastin for marketing outside of the United States.

In addition, the lot number on the carton and vial should be six digits with no letters; the expiry date is formatted as a three-letter month and four-digit year (such as, JUL 2014); the date of manufacture is not printed on the carton or vial; and all the text on the vial labels, cartons, and package inserts is in English on products approved for sale in the United States.

The fake Avastin scandal comes at a time when many injectable cancer drugs are in short supply – a situation that "may present an opportunity for unscrupulous individuals to introduce non-FDA approved products into the drug supply," the FDA warned on Jan. 13.



Courtesy of Genentech

These authentic Avastin packages are in English and carry the Genentech name.

At that time, it advised health care providers about the risks of purchasing unapproved injectable cancer medications that are not in short supply from unlicensed sources. The agency named Faslodex (fulvestrant), Neupogen (filgrastim), Rituxan (rituximab) and Herceptin (trastuzumab) – but not Avastin – in [the January warning](#).

"In certain circumstances, the FDA may authorize limited importation of medications that are in short supply. Such medications are imported from approved international sources and distributed in the U.S. through a controlled network, and would not be sold in direct-to-clinic solicitations," the agency advised.

"If the FDA has arranged for limited importation of the foreign version of a medication, information on obtaining that medication will be available on the FDA drug shortages website, often in the form of a 'Dear Healthcare Professional' letter."

Based on information to date, the FDA has determined that none of the unapproved cancer medicines that medical practices are known to have received from Volunteer Distribution are in short supply in the United States. FDA-approved versions of these medicines are available in adequate supply to meet current demand.

Medical practices that have obtained unapproved products from foreign sources, in particular from Volunteer Distribution and/or QSP, should stop using them and contact the FDA. These products should be retained and securely stored.

To report suspect counterfeit products and other suspect unapproved products obtained from Volunteer Distribution or QSP/Montana Health Care Solutions or other sources: Call FDA's [Office of Criminal Investigations](#) (OCI) at 800-551-3989, or visit OCI's website.

For information about this counterfeit medicine, see Roche's [statement](#).

Click [here](#) for more information about counterfeit medicines found in the United States.

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Cancer Patients Fume Over Counterfeit Avastin

By KATIE MOISSE

Feb. 15, 2012—

abcnews.go.com

Fake Version Missing Cancer-Fighting Ingredient, FDA Warns

Cancer patients are furious that a counterfeit version of the drug Avastin has landed in U.S. clinics.

Avastin, which is made by the California-based company Genentech, is used in combination with chemotherapy to treat cancers of the colon, brain, kidneys and lungs. But the counterfeit lacks the tumor-starving ingredient some patients need to survive.

"It's an outrage," said Diane Barraza, 48, who takes Avastin for stage IV colon cancer. "For a company to sell this drug, put it in our blood, it's an outrage."

The U.S. Food and Drug Administration announced Tuesday that 19 clinics in California, Texas and Illinois may have purchased the phony Avastin from Quality Specialty Products, an "unapproved" foreign supplier also known as Montana Health Care Solutions. The counterfeit vials are labeled "Avastin" but indicate "Roche" as the manufacturer. Roche is the parent company of Genentech.

"The counterfeit contains no Avastin, no generic Avastin, no active ingredient whatsoever," Genentech spokesman Ed Lang told ABC News. Lang said the contents of the vials are still under investigation.

For patients like Barraza, a fake cancer drug would be the cruelest con.

"To sit in the chemo chair and watch that stuff drop into my veins," said an emotional Barraza, who lives in Fullerton, Calif., with her 6-year-old daughter. "It's all I've got. And it might just be water?"

Avastin is expensive, costing upwards of \$650 for a small vial. But Montana Health Care Solutions sold the counterfeit vial for \$480, according to one of the clinics -- a cost savings of 25 percent.

"Obviously it makes good business sense to try to get the drug at a reduced cost," said Dr. Jack Jacoub, a medical oncologist at Orange Coast Memorial Medical Center in Fountain Valley, Calif. "But when you start to get drug pricing that's markedly different from that of the standard distributor, it should raise a red flag."

Only four U.S. distributors are authorized to sell Avastin to doctor's offices; another four can sell the drug wholesale to hospitals. Montana Health Care Solutions is not an authorized Avastin distributor. Jacoub, who treats Barraza, said his clinic buys Avastin in bulk from an approved distributor for \$593.20.

Montana Health Care Solutions claimed to be based in Belgrade, Mont. But the company's

recently disconnected phone number has a New Brunswick, Canada, area code. It's unknown whether Montana Health Care Solutions knew the Avastin was counterfeit. They also sold other cancer drugs, including Neulasta and Faslodex, at a significantly discounted price.

The FDA was alerted to the possible counterfeit in December 2011 by the Medicines and Healthcare Products Regulatory Agency in the U.K., according to Genentech's Lang. In a Feb. 10 letter, the agency urged the 19 clinics known to have purchased through unapproved distributors to "retain and secure" any unused drugs. The counterfeit Avastin vials have the lot numbers B86017, B6011, B6010, and the labels are slightly different.

Counterfeit or illegally imported drugs are rare in the U.S. but not unheard of. In 2008, heparin (a blood thinner) imported from China killed 81 Americans.

"Counterfeit drug makers have reached a level of sophistication where the real and fake products look almost identical," said Peter Pitts, president of the Center for Medicine in the Public Interest and former associate commissioner for the FDA. Pitts estimated that counterfeit drugs generated \$75 billion in 2010, a figure expected to grow by 20 percent annually. "It's a low risk, high reward proposition. It's almost a perfect crime -- people aren't getting the drugs they need and they end up dying."

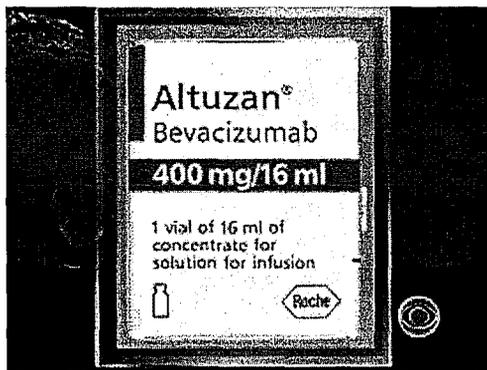
For Barraza, who will have four more Avastin treatments over the next two months, the thought of criminals profiting from her disease is sickening.

"I wish they could understand what it feels like to be a cancer patient, to take a drug and to suffer," she said. "I'd do anything to stay alive, but I need the right medication."

April 4, 2012 7:02 PM

Fake cancer drug surfaces again from overseas

By Armen Keteyian



(CBS News) It is just about the worst kind of fraud you can imagine -- fake cancer drugs, not much more than a vial of water with a drug label on it. CBS News previously reported on this, but it's happened again: A number of clinics received counterfeit vials of cancer drugs. CBS News chief investigative correspondent Armen Keteyian has traced the source overseas.

CBS News' Armen Keteyian looks into the distribution of counterfeit Altuzan from U.K. distributors to the U.S.

(Credit: CBS News)

This week, the Food and Drug Administration alerted healthcare professionals that 120 vials of fake Altuzan -- which contained no active ingredient -- had entered the U.S. from distributors in the U.K. after being purchased from wholesalers in Turkey.

Connie Jung is with the FDA's Office of Drug Security, Integrity and Recalls. "What we're seeing is a pattern of this risky practice of purchasing unapproved drugs from foreign suppliers," she said.

Altuzan has the same active ingredient as the cancer-fighting Avastin, but is sold only in Turkey and not approved for use in the United States.

According to British authorities, 82 of the counterfeit vials were shipped to the U.S. by River East Supplies, located in the U.K. and owned by Canadian businessman Tom Haughton. Haughton is currently under federal investigation for shipping counterfeit Avastin into the U.S., offering Avastin for about \$2,000 a vial -- some \$400 less than the manufacturer's price.

We tracked Haughton down last month in Barbados. He denied any wrongdoing and took a strong stance against counterfeits.

Fake Avastin importer claims he broke no laws
Following the trail of fake Avastin
How fake Avastin from overseas ends up in U.S.

"We're depending on the governments and regulators to make sure these supply chains are indeed safe. I will do everything within my power to ensure this never happens ever again."

The FDA said one distributor of the worthless Altuzan was California-based Ban Dune Marketing. In February, its owner pleaded guilty to distributing "adulterated prescription drugs" used for cancer treatment and not approved by the FDA.

According to the government, it offered big discounts on cancer treatment drugs -- "14 to 60 percent" -- requesting doctors keep its price list confidential.

When contacted by CBS News Wednesday, Tom Haughton had no comment. The FDA, meanwhile, would not tell us how many doctors may have received the fake Altuzan, but said these counterfeit products are potentially dangerous to patients who are relying on these medicines to get better.



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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
EDMUND G. BROWN, JR., GOVERNOR

May 9, 2012

Representative Henry Waxman
2204 Rayburn House Office Building
Washington, DC 20515

RE: SECURING PHARMACEUTICAL DISTRIBUTION INTEGRITY
Comments of the California State Board of Pharmacy
H.R. 3026 – Safeguarding America’s Pharmaceuticals Act of 2011
Securing Pharmaceutical Distribution Integrity Act of 2012 (Senate)

Dear Representative Waxman:

I write on behalf of the California State Board of Pharmacy (Board). We are pleased to have this opportunity to share with you our comments and concerns regarding the development of federal legislation addressing the security of the pharmaceutical distribution supply chain, a topic of considerable interest to this Board. We understand that this legislation is or may soon be included in bills relating to the Prescription Drug User Fee Act (PDUFA) reauthorization that are in motion in the Senate and/or the House of Representatives. We hope that you will consider our comments as you are asked to review, sponsor, or vote on legislation that addresses this topic.

We would first like to thank you for your historical and continued leadership on the topic of pharmaceutical supply chain security, and for your ongoing effort to solicit Board input on the path forward. We appreciate the regular contacts your staff have made with Board staff, and are pleased to have a partner at the federal level who is so supportive of California’s pedigree law(s).

We support the idea of a federal approach. It would be best for supply chain security to be addressed at the federal level by a bill approximating the principles of the California law(s), given the scope of the regulated market. California stepped into this area of regulation out of a perceived need, in the absence of federal standard(s) and in response to acts of counterfeiting and other threats to security that led to the formation of the U.S. FDA Counterfeit Drug Task Force in 2003. But we acknowledge that a federal standard and enforcement would be advantageous. However, we also share your view, expressed during a May 1, 2008 hearing on H.R. 5839, that “federal legislation that seeks to nullify California’s law must provide the same or greater degree of protection, or else preserve California’s ability to proceed with its legislation.”

We believe that H.R. 3026, the “Safeguarding America’s Pharmaceuticals Act of 2011,” as introduced on September 22, 2011, has the potential to establish this kind of robust federal standard. However, we do not believe the same can be said of another proposal under review, known variously as the “Pharmaceutical Traceability Enhancement Code (RxTEC) Act” or the “Securing Pharmaceutical Distribution Integrity Act of 2012.” We are writing to express our concerns about this legislation, that would preempt California’s law and replace it with what we believe is a less robust, and less secure, supply chain infrastructure.

History and Structure of California's Pedigree Law(s)

As you know, California and this Board have taken a leading role in setting standards for securing the prescription drug supply through deployment of our pedigree law(s). Inspired in part by a vision of a universal electronic pedigree/track-and-trace infrastructure laid out in FDA Counterfeit Drug Task Force reports in 2003, 2004, 2005, and 2006, between 2003 and 2008 the Board worked with the California Legislature to enact and amend California law(s) requiring adoption of such an infrastructure. The most recent amendments to the law(s), in 2008, were the outcome of careful and protracted legislative negotiations involving many stakeholders. Our legislative record includes statements of support from many of the most important players in all segments of the industry, reflecting a rough consensus that the California approach is the best way forward. As you are aware, the basic elements of the California approach call for staggered implementation between 2015 and 2017 of a pedigree/track-and-trace infrastructure including:

- An electronic pedigree record showing each change in ownership, from original manufacturer (and/or subsequent repackager), through all drug distributor(s), to final dispenser/furnisher/administerer(s) of the dangerous drug;
- Data that is exchanged in an interoperable electronic system incorporating track and trace infrastructure, based on a unique identifier established at point of manufacture;
- Tracking at the smallest package or immediate container (saleable unit); and
- Data that is passed, certified, and authenticated by all supply chain participants.

In our view, deployment of such an infrastructure promises significant benefits. It was originally designed to prevent or diminish introduction of counterfeit, misbranded, or adulterated drugs into the secure supply chain. It clearly serves this purpose, while also providing tools for investigation and enforcement of any such intrusions, promoting accountability. As has recently been shown by the Avastin example,¹ pharmaceutical counterfeiting remains a real and perhaps growing threat to the security of our drug supply.² As does drug diversion and black market sale of pharmaceuticals, as illustrated by the indictment recently announced by New York Attorney General Schneiderman of a ring distributing black market/diverted HIV medications.³

A universal electronic pedigree/track-and-trace infrastructure also has great potential to address other significant threats to our drug supply. For instance, our experience in California with the Heparin recall(s) in 2008,⁴ and with more recent drug and device recalls, has convinced us there are gaps and deficiencies in our nation's current recall practices. Problems include the sheer number of recalls initiated each year, resulting confusion over whether any recall notice that is received is new or duplicate information, and confusion and debate over the "voluntary" nature of most recalls. As the Heparin example demonstrated, it is unlikely that most recalls result in the desired effect of removing all doses of a drug from the market. Universal electronic pedigree/track-and-trace infrastructure could vastly improve the operation, specificity, reliability and accountability of recall processes. Recalls could be targeted, and their accuracy tracked.

¹ See "Counterfeit Version of Avastin in U.S. Distribution," Statement by the FDA, February 14, 2012, available at <http://www.fda.gov/Drugs/DrugSafety/ucm291960.htm>.

² See also, e.g., Dr. Sanjay Gupta's report on counterfeit prescription drugs for "60 Minutes," aired March 13, 2011.

³ See Press Release, April 4, 2012, available at <http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrests-274-million-black-market-prescription-drug-operation>.

⁴ See, e.g., "Information on Heparin" in Postmarket Drug Safety Information for Patients and Providers, available at <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM112597>.

Likewise, the historical problem of “shrinkage” and loss of inventory control via theft and/or diversion seems to be growing dramatically in scale, as more and more drugs disappear on a daily basis for resale and/or are taken in large cargo thefts or warehouse burglaries.⁵ There is very likely growing involvement by organized crime in theft and resale of pharmaceuticals. The obvious motivators include lesser exposure to criminal penalties and a ready market for resale of those drugs into the supply chain. A universal electronic pedigree/track-and-trace infrastructure could significantly diminish if not eliminate the market for stolen and diverted products, since a stolen or diverted drug would not have the requisite electronic documentation for such resale.

The Board and its staff have several years’ experience developing and then implementing pedigree laws. Further, since 2005 the Board and its staff have engaged in extensive outreach to all segments of the drug supply chain on the California pedigree law, including hosting regular public meetings and workgroups, conducting private meetings with members of all segments of the industry, attending industry conferences, publishing Question and Answer documents on the law and its implementation, and other similar efforts. We have been repeatedly assured through that process that the California pedigree approach to drug security is the “gold standard” among the various approaches outlined to date, either at the federal level or by the various states.

That “gold standard” consists of several basic elements and requirements that make the California drug pedigree law a uniquely comprehensive approach to prescription drug security. The elements of the law that we consider crucial to its purpose include the following:

- The requirement of a “pedigree” record for every prescription drug, initiated by every manufacturer and transmitted and appended through the supply chain, with required data regarding each transaction resulting in a change of ownership of every drug – to be fully effective, we believe the pedigree requirement must be universally applied;
- The record must be created, transferred/received, and maintained, in an electronic form, using secure electronic transactions to enhance the security of the data – in our experience, paper pedigrees are more easily counterfeited and duplicated;
- The pedigree tracks each drug down to its smallest saleable unit, e.g., each bottle in a case of 48 bottles – the only way to effectively track and prevent counterfeits or drug adulteration is by a system that requires individual-unit mass serialization;
- The pedigree uses and is based on a unique identification number affixed to smallest unit packages by the manufacturer, and is created/maintained within an interoperable electronic system using a standardized nonproprietary data format and architecture – reliance on standards and nonproprietary formats discourages data segmentation;
- One pedigree record tracks all changes of ownership of a given prescription drug in a supply chain, including lateral transfers (e.g., wholesaler to wholesaler), downstream transfers (e.g., manufacturer to wholesaler), and upstream transfers (e.g., pharmacy to wholesaler, including returns and recalls) – without one universal record as to all such transactions, there is no reliable audit trail to source counterfeits or adulterations; and
- The pedigree must contain certifications of delivery and receipt, and a certification of the authenticity of the pedigree data from each source/owner of the drug – this assists with traceability, auditability, and accountability of the pedigree record.

⁵ See, e.g., Katherine Eban, “Drug Theft Goes Big,” *Fortune*, March 31, 2011.

In large part, these basic elements arise from and are consistent with the recommendations of the FDA Counterfeit Drug Task Force, first convened by then-FDA Commissioner Mark McClellan in July 2003. In its 2004 Report, the Task Force recommended industry adoption of RFID as the standard track and trace technology, to be used for mass serialization/unique identification (at the unit level) of all drugs in or by 2007, and further recommended industry implementation of a full electronic track and trace/pedigree system by the same date. (2004 Report, pp. 9-15.) In its most recent (2006) Report, the Task Force again noted the desirability and feasibility of a universal e-pedigree system based on package-level RFID serialization, and expressed disappointment that it would not be achieved by 2007. (2006 Report, pp. 7-17). The 2006 Report reinforced the utility of package-level identifiers and tracking (pp. 12-14), and of a universal and uniform requirement that all participants in the distribution chain be required to send or receive pedigrees (pp. 14-16). That Report specifically singled out California as having advanced the pedigree cause (p. 9).

This mention of California in the 2006 Report mirrors a level of support that California has received from the FDA for its law since its enactment, particularly over the last several years, wherein the FDA has repeatedly testified at Board hearings in support of the California law. The Board of Pharmacy has been grateful for this support, and remains very engaged with the FDA.

Because of California's size and share of the market for prescription drugs, the California model for a universal electronic pedigree/track-and-trace infrastructure has been driving industry action for the last several years. All segments of the supply chain appear to be actively preparing for the negotiated 2015-2017 deadlines in California law. We believe in that model, and will be ready to enforce its provisions should it become necessary to do so. We are excited about what it will mean for the supply chain to have full compliance with the infrastructure requirements. We fully expect a more dynamic, secure, and accountable supply chain to be the result.

Pending Federal Legislation

We also know, however, that to be most effective the universal electronic pedigree/track-and-trace infrastructure ought to be deployed and enforced at the federal level.⁶ We are therefore pleased to see that the FDA is making real strides toward this goal. The Final Guidance issued in March 2010 defining the Standardized Numerical Identifier (SNI) that the FDA recommends for serializing drug products in a pedigree/track-and-trace infrastructure is an excellent document, by all reports the result of an industry consensus on this standard.⁷ And it is clear that the FDA has made substantial progress toward defining its preferred "System Attributes" for track-and-trace infrastructure requirements since convening a public workshop on this subject in February 2011.⁸

We are especially pleased to see so many commonalities between the California law and the "System Attributes" distributed by the FDA for discussion at the public workshop, and made public in various fora (including Board meetings) since. We hope that the FDA, and legislation that may result at the federal level in consultation with the Board and the FDA, will continue to look to California for an effective model, one for which the industry is now actively preparing.

⁶ The 2008 amendment(s) to the California pedigree law(s) also contemplated federal action in this arena, providing that any enactment of federal statutes or regulations addressing pedigree or serialization of drugs would render the California law(s) inoperative, and that any provision inconsistent with subsequent FDA rulemaking is likewise void. In other words, California law contains "self-preemption" provisions, even if any eventual federal law does not.

⁷ The Board has taken initial steps to make clear that the SNI should be used for serialization under California's law.

⁸ The Board, through its Executive Officer, was a primary participant in the public workshop in February 2011.

Unfortunately, we feel that the legislative proposal now circulating at the federal level, known variously as the “Pharmaceutical Traceability Enhancement Code (RxTEC) Act” or the “Securing Pharmaceutical Distribution Integrity Act of 2012” (and perhaps also by other names), is not an effective equivalent to the California pedigree law(s). Rather, by its own terms as well as by the operation of the “self-preemption” language in the California law, this proposal would preempt the California pedigree requirements, and replace them with a less robust and ultimately less purposeful federal infrastructure. Therefore, while we are excited to see some action on this subject at the federal level, and while we recognize that in some small ways this proposal makes improvements in existing federal law,⁹ we are writing to convey our concern that this legislation, if enacted as proposed, would provide less immediate supply chain security than California law.

As we understand the various versions of that proposal,¹⁰ our primary concerns relate to the following features of the “RxTEC System” that it envisions creating:¹¹

- **Timing:** The proposal calls for various implementation dates triggered by issuance of final regulations by the Secretary. Even assuming those regulations are issued by the 18-month deadline set forth in the proposal, the “RxTEC System” would not be fully rolled out (i.e., require participation by dispensers) until 6 years after that date. So the earliest date for full implementation would be sometime in 2020, a full three years after the final implementation date of the California law. And given the failure to fully promulgate or implement regulations required under the Prescription Drug Marketing Act (PDMA) in the nearly 25 years since its enactment, it is not difficult to imagine that federal implementation of this law would likewise be further delayed.
- **Non-Utilization of Serialized Numeric Identifiers:** Although the proposal calls for manufacturers (and repackagers) to apply “RxTEC” data carriers that include the SNI to individual saleable units and homogeneous cases, it frankly does not require much to be done with those data carriers or the associated data. For one thing, the proposal requires that tracking routinely take place only at the lot level (a lot could include up to hundreds of thousands of individual units). It is not clear what purpose is served by using an RxTEC data carrier to track at the lot level, since this would be entirely duplicative of the (human-readable) lot numbers that are already printed on individual units. The proposal envisions a significant investment to affix serialized identifiers to individual units and cases without any clear purpose for doing so. And even within this apparent requirement to affix numeric identifiers, there is significant ambiguity, since the proposal also seems to provide numerous exemptions to this requirement in the “Limitations” subdivision that would appear to be transaction-specific (e.g., sales in an emergency), but which arguably provide a broad exemption to all requirements.

⁹ For instance, we acknowledge that this would be the first federal requirement to serialize drug products at the unit level, though as our subsequent comments make clear too little is being done by supply chain participants with those serial numbers to ensure supply chain security. Similarly, we recognize that the proposal(s) aim to tighten up/ make more uniform 3PL, wholesaler, and manufacturer licensing requirements (by states), but again, because California is already a leader in these requirements, in some ways these provisions would actually relax California standards. We do welcome the proposal’s efforts to rein in online pharmacies, and to increase the penalties for drug counterfeiting.

¹⁰ Because several drafts of the proposal have circulated, and additional changes may have been made since the latest copy was shared with us, we will not attempt to tie our comments to particular sections or provisions of the proposal but will instead offer general comments on provisions that appear to be in common among the various drafts or that seem to have been retained in the latest versions of the proposal that were shared with Board staff.

¹¹ We have not attempted to be comprehensive in our comments, and are limiting ourselves to our primary concerns.

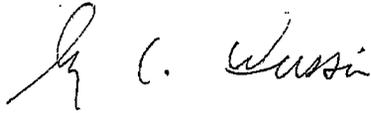
- Specification of 2D Barcode Technology:** The RxTEC proposal also specifies the use of 2D data matrix barcodes as standard data carriers. California has assiduously avoided specification of carrier technology, although at the time its law was originally enacted the author of the bill assumed, as did the FDA, that this data would be coded and read using RFID tags. California has preferred to let the market dictate the means of data transmission, and has sought to avoid interfering with technology innovations that may be developed to respond to the outcomes dictated by California law. While it is true that to this point 2D data matrix barcodes appear (based primarily on cost) to be the preferred carrier being employed by the industry participants who are readying for California compliance, there is still the chance that a further drop in price of RFID technology, or development of some other technology, will result in adoption of some other form of data carrier in addition to or as an alternative to 2D barcodes. There are some obvious disadvantages to 2D barcodes, including most notably that 2D barcodes require line-of-sight scanning (which RFID tags do not). We are hesitant to “freeze” innovation by specifying 2D data matrix barcodes as the default data carriers, even if the Secretary is given latitude to allow other data carrier technologies as supplements. It is difficult to imagine supply chain participants, where the default under the law is a 2D data matrix barcode, ever investing in any other data carrier technologies.
- Lack of Verification/Validation of Product and Data:** As the FDA has repeatedly expressed, the best way to interdict and prevent counterfeits and other sub-standard drugs from reaching patients is to create a “closed system” within which every drug product is tied to a data infrastructure (by its SNI), and is scanned at each point in the distribution chain so that if a product *does not have* a valid SNI, it can be immediately quarantined and its origins investigated. The RxTEC proposal does not envision this kind of universal verification/validation of drug products to the data that is required under California law to accompany physical transfer of the drugs. In fact, the RxTEC proposal does not appear to require that the SNI data carriers will *ever* be scanned by wholesalers, pharmacies, or other downstream participants in the supply chain, and certainly does not envision that any supply chain participants will ever validate the drug product that is received. Again, under these circumstances it is not clear what purpose would be served by affixing an RxTEC data carrier, where the data carrier will never be read. As a practical matter, the RxTEC proposal does not enhance the ability of supply chain participants to *automatically detect and intercept* counterfeits or other suspect products; they will not scan that product and detect anything about its SNI or other identifiers that is suspicious. Under California law, a counterfeiter will have to steal or fabricate enough SNIs to be able to label counterfeit product, but then that product should be intercepted almost immediately, because the illegitimate SNIs would be read by the first buyer and compared to SNIs authorized by the legitimate manufacturer. By contrast, under the RxTEC proposal, there is no opportunity to intercept illegitimate SNIs (assuming the counterfeiter even bothered to apply SNIs).
- Practical Inability to Investigate/Trace “Suspect Product”:** Along the same lines, although the RxTEC proposal says that the Secretary or a state could require one-up, one-down investigation of “suspect product,” without an infrastructure within which a product is being scanned and tracked at each level of distribution, this is not possible to do at the unit level. All investigations and recalls will remain at the lot level.

- **Broad Exemptions from Participation:** As mentioned above, even the reach of the “RxTEC System” requirements is called into significant question by the inclusion of a laundry list of exemptions in the “Limitations” section of the proposal. Particularly curious about many of these exemptions is that while they appear to describe specific *types* of transactions (e.g., intracompany sales, group purchasing transfers, charitable sales, emergency sales, transfers pursuant to mergers, etc.), the exemptions granted to these transactions relate to the entire chapter, and are not transaction-specific. So for a given transaction (e.g., an intracompany sale), it is not clear at what point in time an exemption would be applied. Would any drug product that is ever transferred within a company or a purchasing group be forever exempted from the requirements of this chapter? This is how this list of exemptions appears to read. If so, these exemptions are so broad as to render the legislation’s requirements effectively meaningless.
- **Prohibition on Aggregation:** We also believe that an infrastructure that intends to track drug products at the unit level within an industry that distributes these units in a non-regular aggregate format (e.g., homogeneous and non-homogeneous totes, cases, pallets, etc.), especially one that depends on a non-line-of-sight technology such as a 2D data matrix barcode, must rely on aggregation of product and product data into a hierarchical data structure. For instance, the only way to track individual units within an aggregation (such as a case or pallet), without having to open every case or pallet and individually scan its contents, is to have the individual SNIs for those drug units associated with another data point (e.g., a case or pallet SNI). There are legitimate questions to be explored about whether it is appropriate to *infer* from a “good read” on a case or pallet identifier that the expected contents of that aggregate container are contained within, but it is difficult to imagine a serious data sharing infrastructure for tracking and tracing drug products that does not make at least some use of aggregate structures and data identifiers. Yet the RxTEC proposal not only does not require or encourage aggregation, it specifically prohibits the regulations from doing so. This seems to signal that there is no intention to ever track products at the unit level.
- **Restrictions on State Enforcement:** And finally, we are concerned that if our own law(s) are preempted by the RxTEC proposal, California’s enforcement capacities as to investigations of counterfeits or other suspect products will likely be significantly curtailed. First, the proposal contemplates that even the FDA will only be authorized to “request” RxTEC data from supply chain participants in the event of a recall or as necessary to investigate “suspect product.” But this allowance for investigation of a “suspect product” appears to be circular, since it is not clear how “suspect product” is ever likely to be identified in the absence of FDA (or state) inspection of same, where the supply chain is not routinely validating that product. Also, as mentioned above, it is not clear what data could possibly be transmitted by the supply chain in aid to any such investigation. Second, even this limited authority given to the FDA is available to the states only upon specific delegation from the Secretary. So whereas the Board is now authorized under California law to inspect California wholesalers/pharmacies, and could review maintenance of pedigree data, implementation of the pedigree law, and receipt of serialized, pedigreed drug products as part of its routine inspections, it would not appear to have that same ability if this proposal becomes federal law.

For all of these reasons, we are concerned about the impacts that the RxTEC proposal is likely to have on the security of the supply chain in California, and by extension in the rest of the country, by replacing California's pedigree law with a less robust infrastructure. While we agree in principle that a uniform national standard would be ideal, we would like to see that standard a much closer approximation of the California model than is reflected in the RxTEC proposal. We would encourage something closer to the Bilbray-Matheson model of H.R. 3026. We once again commend you for your leadership on these vital issues of national drug security.

Thank you for your attention to these matters, and for your willingness to hear our input. We look forward to continuing to work together to secure the nation's drug supply. Please feel free to contact the Board at any time if we can be of assistance. The best ways to reach me are on my cell phone, (909) 633-2574, or by email to stanweisser@aol.com.

Sincerely,

A handwritten signature in cursive script, appearing to read "S. C. Weisser".

STANLEY C. WEISSER, R.Ph.
President, California State Board of Pharmacy

Michael B. Enzi

**Colloquy with Sen. Harkin on Downstream Distribution
Security**

**Food and Drug Administration Safety and Innovation Act of
2012**

May 22, 2012

Mr. President, I have been working very hard with Senator Harkin on the underlying bill to reauthorize the Food and Drug Administration user fee program. We have been working together across the aisle for many months and our Committee recently approved this bill by voice vote.

As part of that process, Sen. Harkin and I gave our commitment to Senators Burr and Bennet to work with them on the supply chain amendment they filed to the bill in Committee.

We have been working very hard to reach an agreement on this issue – and we have come a long way. Stakeholders including industry, consumer groups, and the FDA, have been sitting around a table to find a consensus solution. We've made good progress, but we still have work to do.

The language in the Manager's Amendment is a placeholder to show our intent to continue working on this critical, but complex, policy. Currently, the stakeholders do not agree on a policy solution, but feel we could get a solution with continued work.

Further, we do not want this language to preempt state laws that address this policy.

The provision focuses on the "downstream" supply chain, or from the finished product to the pharmacy. Currently, there is no common system for drug manufacturers to serialize their products. Further, different states have different requirements for

wholesalers and other supply chain participants. Stakeholders have been working to solve this problem for over a decade.

California, specifically, has been a leader in enacting regulations on the distribution of drugs. It is important that my colleagues from California are comfortable with the consensus solution that results of this hard work; we do not want to preempt their regulations without their support.

It would be a landmark accomplishment to find a consensus policy to ensure the safety of drug distribution systems in this country, without adding unnecessary burden and costs to rural pharmacists. I intend to continue to work with Senators Bennet and Burr on their proposal, and the language here will allow us to do so as this bill goes to conference.

Chairman Harkin is here to discuss what this language represents, and his views of a path forward with this important policy.

###

SENATOR HARKIN:

Mr. President, for well over a year I have been working with Senator Enzi to craft the FDA Safety and Innovation Act. As part of that effort we have worked closely with Senators Bennet, Burr, Grassley, and Whitehouse to examine and modernize the integrity of our supply chain, to help ensure that drugs and drug ingredients coming into the U.S. are safe for American patients.

The logical next step in this policy is to work to improve the safety of the drug distribution system that gets drugs from manufacturers to the pharmacists and other providers who dispense them to patients. The FDA currently lacks the authority to establish a uniform, comprehensive national system to secure the pharmaceutical distribution supply chain. There is no common system for drug manufacturers to serialize their products, and different states have different requirements for wholesalers and

other supply chain participants. Stakeholders have been working to solve this problem for over a decade.

I applaud the special interest Senators Bennet and Burr have taken in drug distribution security, and appreciate the work they have done to propose policy ideas in this area. Since they filed their drug distribution security amendment with the HELP committee we have been working very hard to reach an agreement on this issue. Manufacturers, distributors, pharmacists, consumer advocates and the FDA have all devoted significant time and effort to helping us find a solution to this policy problem. We have been working cooperatively and in good faith, and have gained a better understanding of the perspective of each of the stakeholders involved. We have come a long way, and are moving closer to consensus. But this is very complicated policy, with a lot of competing priorities and interests, and we still have work to do.

Senator Enzi and I have made a commitment to Senators Bennet and Burr to continue working on this policy. The language in the Manager's Amendment is a placeholder to show our commitment to continuing to work on this critical policy. I firmly believe that we need a uniform, comprehensive approach to ensuring drug distribution security. A patchwork of differing state systems is not only inefficient for supply chain participants, but makes it impossible to develop a comprehensive system to protect patient safety nationwide. I am personally committed to getting this done.

Currently, the stakeholders do not agree on what any drug distribution security system should look like, but are working together cooperatively. With additional time, I think we can find a policy solution that – like the other aspects of the underlying bill – will be bipartisan, consensus policy. The placeholder language included in the manager's package does not represent an

agreement on how drug distribution should work, but it does represent a strong commitment to finding agreement in this area.

Notably, the placeholder language does not pre-empt state law in this area. California has been a particular leader in enacting regulations on the distribution of drugs. While we hope and expect that we will find a consensus policy that my colleagues from California are comfortable with, and that we can make that policy the uniform national standard, we simply are not there yet.

I am proud of the work that we've done to secure the route drug ingredients travel on their way into the United States, and think that securing the drug distribution chain is a critical next step to ensuring patient safety. I agree with Senator Enzi that finding a consensus policy in this area would be a landmark accomplishment, and I am looking forward to continued work to get that done.

Unique Identification Number

Pursuant to Business and Professions Code section 4034, the "unique identification number" established and applied to the smallest package or immediate container by the manufacturer or repackager shall conform to the Standardized Numerical Identifier (SNI) set forth in the Guidance for Industry published by the U.S. Food and Drug Administration (FDA) in March 2010, consisting of a serialized National Drug Code (NDC) identifier (or equivalent product identifier for dangerous drugs for which no NDC has been assigned) combined with a unique numeric or alphanumeric serial number that is no more than twenty (20) digits or characters in length.

Guidance for Industry Standards for Securing the Drug Supply Chain - Standardized Numerical Identification for Prescription Drug Packages

FINAL GUIDANCE

**U.S. Department of Health and Human Services
Food and Drug Administration
Office of the Commissioner (OC)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Office of Regulatory Affairs (ORA)
March 2010**

Guidance for Industry

Standards for Securing the Drug Supply Chain - Standardized Numerical Identification for Prescription Drug Packages

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**U.S. Department of Health and Human Services
Food and Drug Administration
Office of the Commissioner (OC)
Center for Drug Evaluation and Research
Center for Biologics Evaluation and Research
Office of Regulatory Affairs**

March 2010

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Guidance for Industry¹

Standards for Securing the Drug Supply Chain - Standardized Numerical Identification for Prescription Drug Packages

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This guidance is intended to address provisions set forth in Section 505D of the Federal Food, Drug, and Cosmetic Act (the Act) regarding development of standardized numerical identifiers (SNIs) for prescription drug packages. In this guidance, FDA is identifying package-level SNIs, as an initial step in FDA's development and implementation of additional measures to secure the drug supply chain.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

¹ This guidance has been prepared by the Office of the Commissioner (OC), the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Office of Regulatory Affairs (ORA) at the Food and Drug Administration.

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II. BACKGROUND

A. Food and Drug Administration Amendments Act of 2007

On September 27, 2007, the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110-85) was signed into law. Section 913 of this legislation created section 505D of the Federal Food, Drug, and Cosmetic Act, which requires the Secretary of Health and Human Services (the Secretary) to develop standards and identify and validate effective technologies for the purpose of securing the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs. Section 505D directs the Secretary to consult with specific entities to prioritize and develop standards for identification, validation, authentication, and tracking and tracing of prescription drugs. The statute also directs that, no later than 30 months after the date of enactment of FDAAA, the Secretary shall develop an SNI to be applied to a prescription drug at the point of manufacturing and repackaging at the package- or pallet-level, sufficient to facilitate the identification, validation, authentication, and tracking and tracing of the prescription drug. An SNI applied at the point of repackaging is to be linked to the SNI applied at the point of manufacturing and, to the extent practicable, the SNI should be harmonized with international consensus standards for such an identifier. (See Section 505D(b)(2)). The provisions in section 505D(b) of the act complement and build upon FDA's longstanding efforts to further secure the U.S. drug supply. This guidance finalizes the draft guidance of the same title dated January 16, 2009 (74 FR 3054).

B. Scope of this Guidance

This guidance is intended to be the first of several guidances and regulations that FDA may issue to implement section 505D of the Act, and its issuance is intended to assist with the development of standards and systems for identification, validation, authentication, and tracking and tracing of

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prescription drugs.² This guidance defines SNI for package-level identification only. For the purpose of this guidance, FDA considers the prescription drug package to be the smallest unit placed into interstate commerce by the manufacturer or the repackager that is intended by that manufacturer or repackager, as applicable, for individual sale to the pharmacy or other dispenser of the drug product. Evidence that a unit is intended for individual sale, and thus constitutes a separate “package” for purposes of this guidance, would include the package being accompanied by labeling intended to be sufficient to permit its individual distribution. For example, if a manufacturer’s smallest unit of sale package is a container holding six drug-filled syringes, a single SNI would be the package-level identifier for the container holding the six drug-filled syringes; there would be no SNIs for the individual syringes, not intended by the manufacturer for individual sale. If a repackager then breaks that container down and repackages each syringe for individual sale, then the repackager must ensure that appropriate labeling accompanies each individual syringe³ and a new and unique SNI would be the package-level identifier for each new package (e.g., each individual drug-filled syringe). SNIs applied to each new package by the repackager are to be linked back to the manufacturer’s SNI for the container of six drug-filled syringes (505D(b)(2)).

This guidance does not address how to link a repackager SNI to a manufacturer SNI, nor does it address standards for prescription drug SNI at levels other than the package-level including, for example, the case- and pallet-levels. Standards for track and trace, authentication, and validation are also not addressed in this guidance because this guidance only addresses the standardized numerical identifier itself and not implementation or application issues.

² Prescription drugs as defined in section 503(b)(1) of the act.

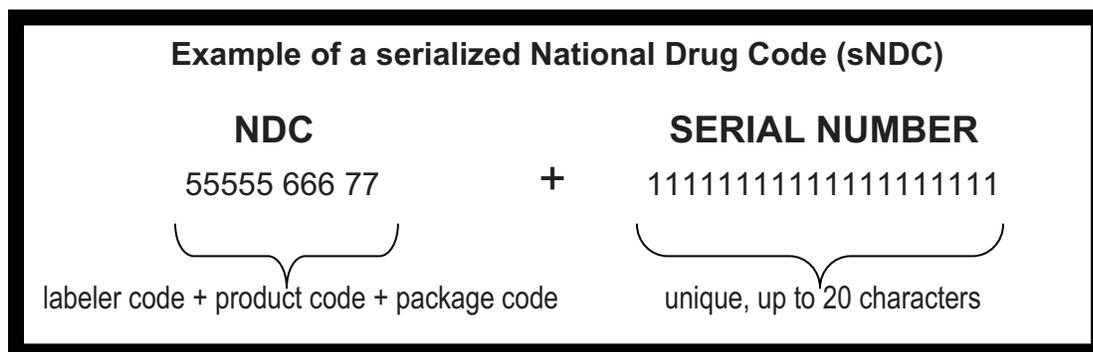
³ See, e.g., Sections 502 (b) and (f).

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III. STANDARDIZED NUMERICAL IDENTIFIERS

A. What should be a package-level SNI for most prescription drugs?

The SNI for most prescription drug packages should be a serialized National Drug Code (sNDC). The sNDC is composed of the National Drug Code (NDC) (as set forth in 21 CFR Part 207) that corresponds to the specific drug product (including the particular package configuration)⁴ combined with a unique serial number, generated by the manufacturer or repackager for each individual package. Serial numbers should be numeric (numbers) or alphanumeric (include letters and/or numbers) and should have no more than 20 characters (letters and/or numbers). An example is shown below with a 10-character NDC.



B. What should be the package-level SNI for certain biological products that do not use NDC numbers?

Some prescription drugs approved under Section 351 of the Public Health Service Act, such as blood and blood components and certain minimally manipulated human cells, tissues, and cellular and tissue-based products (HCT/Ps), do not currently use NDC numbers. Examples of HCT/Ps that do not use NDC numbers include allogeneic placental/umbilical cord blood, peripheral blood progenitor cells, and donor lymphocytes for infusion. Instead, such products

⁴In the case of repackaged drugs, each package type should have an NDC that corresponds to the repacker or private label distributor for whom the drug is repacked and to the new package configuration.

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currently use other recognized standards for identification and labeling, such as ISBT 128, which creates a unique identification number for each product package. See

http://iccbba.org/about_gettoknowisbt128.html, “Guidance for Industry: Recognition and Use of a Standard for Uniform Blood and Blood Component Container Labels,”

(<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/ucm073362.htm>.) The SNI for these products should be the unique identification

number created for each package under these other recognized standards, such as ISBT 128.⁵

C. Does the SNI include expiration date and/or lot or batch number?

Expiration date and/or lot or batch numbers are not part of the recommended SNI. Expiration date and/or lot or batch numbers are already accessible because FDA regulations require the inclusion of this information on the label of each drug product. (See 21 CFR §§ 201.17, 201.18, 211.130, 211.137, 610.60, and 610.61.) In addition, the SNI can be linked to databases containing this and other information. Addition of this information within the SNI will unnecessarily increase the length of, and introduce complexity into, the SNI. However, if a manufacturer or repackager chooses to include expiration date and/or lot or batch number with the SNI, it should ensure that the resulting number still permits users to distinguish and make use of the SNI. For example, expiration date and lot or batch number may be incorporated in accordance with the GS1 standards for use of Global Trade Item Numbers (GTIN)⁶ (discussed below in Section F).

⁵ FDA currently also recognizes Codabar as a standard for blood and blood component container labels. We note that ISBT 128 is becoming the more widely-used industry standard.

⁶ See www.gs1.org -- Healthcare GTIN Allocation Rules (http://www.gs1.org/docs/gsmpr/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf).

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D. Why did FDA select the serialized NDC for package-level SNI for most prescription drugs?

FDA chose the sNDC as the package-level SNI for most prescription drugs because we believe that it serves the needs of the drug supply chain as a means of identifying individual prescription drug packages,⁷ which in turn should facilitate authentication and tracking and tracing of those drugs. Most prescription drug product packages already have an NDC on them. By combining a serial number of up to 20 characters with the NDC, the sNDC should be sufficiently robust to support billions of units of marketed products without duplication of an SNI. This approach will allow manufacturers and repackagers to assign serial numbers to combine with the NDC for unique identification of individual product packages. The SNI can also be linked to databases containing such product attributes as lot or batch number, expiration date, distribution/transaction history information, and other identifiers related to a product. As already noted, defining the SNI is expected to be a first step to facilitate the development of other standards and systems for securing the drug supply chain. Many aspects of the implementation of package-level identification will take shape in the future, as the standards that make use of SNI are developed.

E. Should the SNI be in human- and machine-readable forms?

FDA believes that an SNI generally should be applied to each package in both human-readable and machine-readable forms. However, at this time, FDA is not specifying the means of incorporating the SNI onto the package. The SNIs described in this guidance are compatible with, and flexible for, encoding into a variety of machine-readable forms of data carriers, such as

⁷ As described above, ISBT-128 and Codabar serve the same function for certain biologics that lack NDCs.

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2-dimensional bar codes and radio-frequency identification (RFID),⁸ leaving options open as technologies for securing the supply chain continue to be identified, and standards making use of SNI are developed. A redundant human-readable SNI on the package would provide the ability to identify the package when electronic means are unavailable (e.g., in the event of hardware/software failure). Due to the wide-variety of packaging required to accommodate different products and product integrity needs, FDA also is not specifying a location on the package where an SNI should be placed. If the NDC is already printed on the package in human-readable form, then the serial number could be printed in human-readable form in a non-contiguous manner elsewhere on the product package. Any SNI placed on the package must not obstruct FDA-required labeling information⁹ and should be placed in a manner that allows it to be readily scanned/viewed without damaging the integrity of the packaging or product..

F. Is the SNI that FDA is recommending compatible with international standards?

In addition to facilitating other actions to secure the drug supply chain, adoption of the sNDC as the SNI for most prescription drugs, and of other recognized standards, such as ISBT 128, for certain biological products, satisfies the requirement in 505D(b)(2) that the SNI developed by FDA be harmonized, to the extent practicable, with internationally recognized standards for such an identifier. Specifically, use of an sNDC is compatible with, and may be presented within, a GTIN, which can be serialized using an Application Identifier (AI) (21) to create a serialized GTIN (sGTIN) for use with RFID or for certain barcodes.¹⁰ GTIN is a global standard for item and object identification, established by GS1, a consensus-based, not-for-profit, international

⁸ FDA's enforcement policy with respect to the application of current good manufacturing practices to RFID technology is provided in Compliance Policy Guide (CPG) Section 400.210. See <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074357.htm>. This CPG would apply if an SNI were embedded into an RFID tag.

⁹ See section 502(c) of the Act.

¹⁰ See [www.GS1.org](http://www.gs1.org) -- Healthcare GTIN Allocation Rules (http://www.gs1.org/docs/gsmf/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf).

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standards organization that works with manufacturers, distributors, retailers, and others in the drug supply chain. A GTIN may be used to uniquely identify items at the package level throughout the supply chain. FDA has been an active observer and participant in GS1 standards development related to healthcare and drug products. According to documentation from GS1, the GTIN is used worldwide by twenty-three industry sectors, including healthcare, and has been adopted by sixty-five countries to uniquely identify pharmaceutical products.

Specification of Non-Pedigreed Dangerous Drugs

Pursuant to Business and Professions Code sections 4163.2, 4163.4, and 4163.5, manufacturers, wholesalers, repackagers, and pharmacies may take the following actions to specify dangerous drugs that are not yet subject to the pedigree requirements set forth in sections 4034 and 4163 et seq. Other than as specified below, all dangerous drugs distributed in or through California are subject to the pedigree requirements set forth in those sections.

(a) By no later than December 1, 2014, any manufacturer seeking to limit application of the pedigree requirements to 50 percent of its drugs pursuant to Business and Professions Code section 4163.5 shall submit to the Board a declaration, signed under penalty of perjury by an owner, officer, or employee of the manufacturer with the legal capacity to bind the manufacturer, that specifies the dangerous drugs by name and product package (SKU) type representing 50 percent of its total as of January 1, 2015, as measured pursuant to section 4163.5, subdivision (d), that is ready for implementation of pedigree requirements as of January 1, 2015. The declaration shall identify the measurement from section 4163.5, subdivision (d) used to measure the 50 percent, shall illustrate the calculation(s) used to arrive at the 50 percent figure, shall identify those drugs by name and product package (SKU) type that are in the remaining 50 percent not yet subject to pedigree requirements, and shall specify the technology employed to meet the pedigree requirements, including but not limited to any platform(s), vendor(s), hardware, software, and communication technologies deployed. Any manufacturer submitting a declaration to identify the 50 percent of its drugs that are subject to the pedigree requirements as of January 1, 2015 shall also, by no later than December 1, 2015, submit a declaration, signed under penalty of perjury by an owner, officer, or employee of the manufacturer with the legal capacity to bind the manufacturer, that specifies the remaining 50 percent of its dangerous drugs by name and product package (SKU) type ready for implementation as of January 1, 2016. The declaration shall identify the measurement from section 4163.5, subdivision (d) used to measure the 50 percent, shall illustrate the calculation(s) used to arrive at the 50 percent figure, shall

identify all drugs by name and product package (SKU) type that are ready for implementation, and shall specify the technology employed to meet the pedigree requirements, including but not limited to any platform(s), vendor(s), hardware, software, and communication technologies deployed. The Board or its designee shall have discretion to determine whether any submitted declaration is compliant, and to reject and require re-submission of any non-compliant declaration(s) until fully compliant. Information contained in these declarations shall be considered trade secrets and kept confidential by the Board. Any failure to submit a first or second declaration conforming to these requirements by December 1, 2014 or December 1, 2015, or any failure to submit a fully compliant first or second declaration by January 31, 2015 or January 31, 2016, shall automatically make the entire drug stock of any manufacturer failing to do so subject to the pedigree requirements as of January 1, 2015, and no exemption shall be applied to any drugs owned or distributed by that manufacturer.

(b) By no later than August 1, 2016, any wholesaler or repackager seeking to designate dangerous drugs it possesses, owns, or controls that are not subject to the pedigree requirements pursuant to Business and Professions Code sections 4163.2 and 4163.4, shall submit to the Board a declaration, signed under penalty of perjury by an owner, officer, or employee of the wholesaler or repackager with the legal capacity to bind the wholesaler or repackager, that specifies the dangerous drugs by name and product package (SKU) type in the possession, ownership, or control of the wholesaler or repackager that were acquired prior to July 1, 2016, specifies the means and source of acquisition, and specifies the anticipated means of any subsequent distribution or disposition. The Board or its designee shall have discretion to determine whether any submitted declaration is compliant, and to reject and require re-submission of any non-compliant declaration(s) until fully compliant. Information contained in these declarations shall be considered trade secrets and kept confidential by the Board. Failure to submit a declaration conforming to these requirements by August 1, 2016, or failure to submit a fully compliant declaration by September 31, 2016, shall automatically make the entire drug

stock of any wholesaler or repackager failing to do so subject to the pedigree requirements as of July 1, 2016, and no exemption shall be applied to any drugs owned or distributed by that wholesaler or repackager.

(c) By no later than August 1, 2017, any pharmacy or pharmacy warehouse seeking to designate dangerous drugs it possesses, owns, or controls that are not subject to the pedigree requirements pursuant to Business and Professions Code sections 4163.2 and 4163.4, shall submit to the Board a declaration, signed under penalty of perjury by an owner, officer, or employee of the pharmacy or pharmacy warehouse with the legal capacity to bind the pharmacy or pharmacy warehouse, that specifies the dangerous drugs by name and product package (SKU) type in the possession, ownership, or control of the pharmacy or pharmacy warehouse that were acquired prior to July 1, 2017, specifies the means and source of acquisition, and specifies the anticipated means of any subsequent distribution or disposition. The Board or its designee shall have discretion to determine whether any submitted declaration is compliant, and to reject and require re-submission of any non-compliant declaration(s) until fully compliant. Information contained in these declarations shall be considered trade secrets and kept confidential by the Board. Failure to submit a declaration conforming to these requirements by August 1, 2017, or failure to submit a fully compliant declaration by September 31, 2017, shall automatically make the entire drug stock of any pharmacy or pharmacy warehouse failing to do so subject to the pedigree requirements as of July 1, 2017, and no exemption shall be applied to any drugs owned or distributed by that pharmacy or pharmacy warehouse.

Serialization

