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

STATE BOARD OF PHARMACY
PUBLIC EDUCATION AND COMMUNICATION COMMITTEE
MINUTES

DATE:	April 1, 2014
LOCATION:	Department of Consumer Affairs 1747 N Market Boulevard, 1st Floor Hearing Room Sacramento, CA 95834
COMMITTEE MEMBERS PRESENT:	Ryan Brooks, Chair Lavanza Butler, R.Ph. Ramon Castellblanch, PhD Albert Wong, PharmD Allen Schaad, R.Ph.
COMMITTEE MEMBERS NOT PRESENT:	Shirley Wheat
STAFF PRESENT:	Virginia Herold, Executive Officer Michael Santiago, DCA Staff Counsel Carolyn Klein, Manager II Joyia Emard, Public Information Officer Laura Hendricks, Administrative Analyst

Call to order

Chair Ryan Brooks called the meeting to order at 10:05 a.m.

Chair Brooks conducted a roll call. Committee members Lavanza Butler and Allen Schaad were present.

Dr. Albert Wong arrived at 10:09 a.m. and Dr. Ramon Castellblanch arrived at 10:13 a.m.

1. **FOR INFORMATION: Presentation by Mpack Systems on New Product Design for Pharmacy Prescription Containers**

Mpack Systems presented information on its new design for pharmacy prescription packaging. Presenting were Bill Negrini, president; Bill Hartig, RPh, president of PreScripts and consulting pharmacist; Richard Lee, vice president; all from Mpack Systems.

The Mpack prescription containers are rectangular in shape and fairly flat, leaving a lot of room for information on labels on both sides of the package, presenters said up to 80 percent more room than standard packaging labels. The Mpack cap label makes the containers easy to identify and organize. The containers also mail well and do not open during shipping.

Mpack has a system that prepackages the prescription and preprints the labels and warnings. The system eliminates the risk of the wrong drug being dispensed.

The Mpack system has a bar code and fully supports tracking and tracing. The system outputs a finished prescription in a minute and eliminates will-call.

Mpacks can ship for under $1 and the containers have right angles so they stack well for better storage. They also have blister packaging.

Presenters said the military likes the Mpacks because they can be put in uniform pockets, otherwise the pills have to be removed from their round bottles and put into plastic bags to carry.

Chair Brooks asked why prescription pill bottles are round. Presenters said that it's because "they always have been" and because the bottles are produced in volume and therefore cost less. He said as the Mpack system increases in use, their packages will be produced in larger volume and will become less costly.

Dr. Wong asked about automation. Presenters said their automated system reduces the number of pharmacy employees needed in the pharmacy because of greater use of automation.

Chair Brooks called the system innovative and said he likes the package shape. However, he added that the board is unable to endorse products.

2. FOR DISCUSSION AND POSSIBLE ACTION: <u>Resumption of the Committee's Assessment of California's Patient-Centered Labeling Requirements</u>

The committee was tasked by the board to discuss the following items and other elements relating to patient-centered labels, and bring recommendations back to the board.

- Should Section 1707.5(a)(1)(B) Require Listing of the Manufacturer's Name in the Patient-Centered Clustered Area of the Label When a Generic Drug Is Dispensed?

- Should Changes Be Made to 1707.5(a)(1)(B) regarding the Name of the Drug and Strength of the Drug to Improve Patient Understanding of the Medication?

- When a Generic Drug Is Dispensed, Should the Generic Equivalent Drug Dispensed to a Patient Be Referenced Back to the Brand Name, e.g., Phrased as "Generic for (brand name)_____"?

- Should Purpose or Condition Be a General Requirement for Labels?

- Should the Existing Requirements for "Added Emphasis" in the Patient-Centered Area of the Prescription Label Be Modified?

- Translated Directions for Use Are Available on the Board's Website. Should the Board Require Use of Them to Aid Patients with Limited English Proficiency?

- Should the Board Consider Technology Standards to Enhance the Patient-Centered Requirements?

Chair Brooks asked that no action be taken on any of these items because in the last year and a half the board has worked on the design of the label and has been waiting for feedback to come in before making more changes.

Dr. Castellblanch wanted to know when the committee could do something about these matters because he said there may be some urgency on these issues. Chair Brooks agreed, but said he didn't know what they could do until they got the results from the first go-around. He said the board is going through a process where they are constantly changing the label, so they need feedback from the public and board investigators in the field.

He asked committee members to identify items from the agenda item they wanted to discuss.

Dr. Castellblanch said they'd been discussing translations on the labels for five years and it might be time to do something. He said he would like to have a hearing and testimony from authorities who have done research on the issue of translations on labels. He also wanted to hear from experts.

Executive Officer Virginia Herold stated that surveys on this subject have been shared with the committee several times. She suggested they might want to hear from Mike Wolfe, who is a national expert in label design and conducted research on the translated label directions that are posted on the board website. She said surveys conducted by the board indicate very few people are using those translations.

Dr. Castellblanch asked if the translations were mandated, then would that improve service and outcomes in regards to mortality.

Chair Brooks questioned whether translated labels would affect first responders who may not be able to read translated labels.

Ms. Herold said many of the issues have already been discussed, such as whether English must also be on a translated label and whether only the directions for use should be translated or other label elements as well. She said one of the problems is that translated directions of use require that the directions be standardized in English first. She said the board has standardized usage instructions in English that appear in the regulation's text and are translated in other languages. They are available on the board's website and aren't being used. She said NCPDP has issued a white paper which supports the use of the standardized directions. She added she has presented this to the Medical Board.

Dr. Castellblanch said he could make some suggestions on who could speak at the next meeting. Chair Brooks asked to hear from first responders and pharmacists on translations.

Dr. Wong asked if there is a demand for translations from the public. He wants to know who is responsible if the language translation on a bottle isn't correct. He said he doesn't understand Russian, but if he put Russian on a prescription label then he would be responsible for its accuracy. He said if it becomes mandatory, then he doesn't have the ability to ensure the translation is correct.

Ms. Herold said the board did conduct a survey for a four month period and found that 70 percent of the pharmacies in the state already do provide translations on the label.

Chair Brooks said it might be a solution in search of a problem and he has not heard that there is a demand that would require the board to mandate this service, but there still may be a need. He asked for four or five speakers to present to the full board because the information could have a greater impact.

Ms. Herold said the next board meeting is in April and is when legislation is discussed. Another meeting will be held in July. She said she could bring in the same groups that helped the board before – the NAPB, the Institute of Medicine and researchers that were instrumental in the early stages of the patient-centered label discussions.

Chair Brooks said including "generic for" is another topic that has been discussed, but he did not feel the committee was ready to act on it. He said he wants this item to go back to the full board. He said there is another question as to how long to include a brand name once the patent has expired.

Ms. Herold said she included possible draft language for this in the meeting materials. The draft requires listing the brand name with the generic name for five years after the brand

name drug has gone off patent, but she said that number could be changed. She said that the language would give the pharmacist the professional discretion as to whether to put "generic for" on a container when the generic name essentially becomes the most common name of the drug.

Chair Brooks reiterated that he didn't know if there was an actual need for this or if it was again a solution looking for a problem. Dr. Castellblanch agreed that he did not know what problem they'd be solving.

Ms. Herold stated that at the last meeting it was discussed that people sometimes get a drug where only the name brand appears on the container. When they get a refill they get the generic drug with only the generic name on the label. This can cause confusion. She said there are documented cases where someone gets the new generic drug and takes both drugs because they don't recognize they're the same drug.

Chair Brooks said if the purpose was on the label they would know.

Ms. Herold said purpose on the label is another outstanding issue. She said currently the prescriber starts the process by putting it on the prescription, but it is not required.

Chair Brooks wanted to know if putting purpose on the label would be a HIPAA violation. Legal counsel Michael Santiago said there would be no HIPAA implications or violations because even if the condition or purpose for which the drug was prescribed was on the label and even if it went into more detail then just "for infection" and included the condition or actual diagnosis, so long as the drug was not dispensed to someone who was not authorized – either not the patient or their agent – then there would be no HIPAA violation.

Chair Brooks said if the purpose was on the label then there would be no need for "generic for."

Allen Schaad said the problem is that for a medical condition like blood pressure it is very common for people to need three medications. A prescriber will often prescribe multiple medications for multiple conditions.

Ms. Butler said she's always thought "generic for" should be on the label because if a patient has three medications at home for high blood pressure and they get a generic for one of those, then they overdose. She said "generic for" should be on the label.

Dr. Castellblanch said he now remembers prior discussions that people didn't know the generic and brand were the same drug and this could be a problem. He said two things could happen – they could take double the amount or they could take drugs that would counteract each other.

Ms. Herold said regarding national authorities, the USP states the drug names should be spelled out fully and the generic name spelled out fully with no abbreviations. The model guidelines of the National Association of Boards of Pharmacy do recommend that "generic for" be added when a generic is used.

Chair Brooks asked whether they had determined if that correlates to a reduction of overdoses or misuse. He said he wanted empirical data. Ms. Herold said she was not aware of any.

Dr. Wong asked if he puts Chinese translations of the indication on his patients' labels at their request, then is it a violation of any laws. Ms. Herold said as long as he is meeting all the requirements of what must be on the label, putting purpose translations on the label is permitted because it is an addition, such as adding a photo of the pill on the label or the phone number of the poison control center.

Chair Brooks said the more that is put on the label, the less opportunity a pharmacist has to add information that may be useful to the patient.

Dr. Wong said some of the generic names are so long pharmacists can't get all of it on the label.

Chair Brooks said he'd like to give the process more time to play itself out.

Dr. Castellblanch said staff should conduct research to find evidence to support adding "generic for."

Ms. Herold added a point of information and said the board approved 12-point font at the October meeting as the minimum font size for the patient-centered area of the label. The documents are now at the Office of Administrative Law to be released for the 45-day initial public comment.

Chair Brooks asked for public comment.

Sarah de Guia, from the California Pan-Ethnic Health Network, said it was very important to have a full board hearing on having translations on labels. She said some stakeholders or some of the community groups who worked on these issues should be included.

Ms. De Guia said there are 6-7 million Californians who don't speak English proficiently, which means they can't read their prescription label. She said they rely on family and friends to translate for them. She does not believe that's a good quality standard. She said she's heard of people having problems with their medications because of poor translations and there are people who have to travel far distances to get their translations because one pharmacy will provide it, but another won't. She said there isn't a lot of empirical data available because it is not an area that researchers tend to look at. She said her organization

does have a couple of studies that show that patients' ability to understand their label increases dramatically when it's in their language.

Jonathon Tran, with the Southeast Asia Resource Action Center, said California has the largest resettlement of relocated Southeast Asians in the world. He said there are more than 900,000 here. He said the availability of translations of labels is sporadic and the quality is sporadic and will remain so if the industry is relied upon to regulate itself.

Dr. Castellblanch said he checked in Berkeley and found that translations are sporadic.

3. **FOR INFORMATION: Availability of Options for Prescription Labels for Visually Impaired Patients**

   The board was recently made aware of a new technology to aid visually impaired patients in taking their medications. The information was provided in the meeting materials.

   Ms. Herold said this is another example of issues that some patients have when reading prescription labels.

4. **FOR INFORMATION: Proposal by the Federal Food and Drug Administration on "Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products"**

   The Food and Drug Administration late last year proposed to amend its regulations to revise procedures for generic drug manufacturers who hold a generic drug approval to change the product labeling to reflect certain types of newly acquired information before the FDA's actual review of the labeling change. The proposed rule would direct generic drug manufacturers to distribute revised product labeling that differs in certain respects from the labeling of its reference listed drug previously submitted to the FDA.

   The proposed rule would direct generic manufacturers to update product labeling promptly to reflect certain types of newly acquired information related to drug safety, essentially if information about the brand name counterpart becomes available. The GPhA, which represents the generic industry, does not support this proposal and said that any negative effects associated with a brand name drug should be on the label of the brand name product, not to the generic version their members manufacture.

   Chair Brooks said the board has not taken a position on this item.

   Ms. Herold said she has been asked twice in the past month what the board's position is on this – by CalPERS and the Governor's Office. She said in the past when there's a problem with a drug, it is the brand drug makers' responsibility to inform the public, not the generic drug maker. She said there may be some developing policy on this in the future.

There was no public comment.

5. **FOR INFORMATION: <u>The National Association of Boards of Pharmacy 's Launch of ".pharmacy" to Identify Legitimate Internet Web Sites for Prescription Drugs</u>**

The National Association of Boards of Pharmacy recently received approval from the ICANN Board (which approves the use of top level domains – e.g., controlling those who can use suffixes such as ".com," ".org" or other addresses for web sites) to approve those entities who can use the ".pharmacy" domain. This will enable the NABP to approve who can use .pharmacy as a suffix, thereby enabling them to approve "legitimate" Internet businesses (those who comply with the NABP's standards). Currently 97 percent of the drug outlets operating drug-selling websites are illegitimate according to the NABP.

The meeting materials contained the recent report on ".pharmacy" by the National Association of Boards of Pharmacy.

Dr. Castellblanch asked if this information could be included on the board's website.

Ms. Herold updated the committee on where The National Association of Boards of Pharmacy is in the process. She said ".pharmacy" will legitimize online pharmacies that operate legally and help distinguish those that don't.

6. **FOR INFORMATION: <u>Update on *The Script*</u>**

The Script is scheduled to go into design in April. This edition focuses on new laws for 2014 and disciplinary actions. Staff intends to resume at least bi-annual production of this newsletter from this point forward.

7. **FOR INFORMATION: <u>Review of the Board's Public Service Announcement and Video Developed on Prescription Drug Abuse</u>**

The board has developed public service announcements on prescription drug abuse for both radio and television to inform the public about the prescription drug abuse epidemic and give simple steps that can be taken in the home to keep prescription medications out of the hands of teens. There was a print format and a video format produced.

The committee viewed the 60-second and 30-second prescription drug abuse prevention public service announcement videos.

Ms. Herold credited Public Information Officer Joyia Emard with producing the videos and the PSAs' script.

Chair Brooks said he liked the video very much and said the board needs to do more on this issue. He said prescription drug abuse is an epidemic that is spreading like wildfire through the state's high schools and junior highs.

Dr. Castellblanch asked how the videos would be distributed. Ms. Herold said materials were in the process of being approved that would go on the board's website. She said she'd appreciate board members' assistance in distributing the videos. She also said the videos would be sent to the media.

Dr. Castellblanch said the next Prescription Drug Abuse subcommittee meets in May in San Diego. He said middle-aged people, mostly working people, die from fatal overdoses.

8. FOR INFORMATION: Update on the Board's Consumer Education Materials on Counterfeit Drugs and a Newsletter Article for the Medical Board's Newsletter

A new online brochure on counterfeit drugs is in the design phase and is expected to be completed in April.

An article on patient centered prescription labels was written to appear in the upcoming Medical Board newsletter. It was included in the meeting materials.

9. FOR INFORMATION: Update on Media Activity

The following is a report distributed at the meeting on recent media contacts handled by the office.

DEA investigating CVS

- March 10: David Lazarus, L.A. Times, interviewed Virginia Herold
- March 11: KCRA TV interviewed Virginia Herold
- March 11: FOX 40 TV interviewed Virginia Herold
- March 11: CNN interviewed Virginia Herold
- March 12: Andrew Westrope, Rocklin Placer Herald/Press Tribune, interviewed Virginia Herold

Pharmacist facing suspension/revocation running for council

- March 19: Luke Money, Santa Clarita Daily Signal, interviewed Joyia Emard
- March 19: Perry Smith, KHTS AM Radio, interviewed Joyia Emard

Information request

- March 28: Vik Jolly, Orange County Register

Chair Brooks said the staff has been very busy with the media. He said he wishes the media activity could be more proactive instead of reactive.

10. FOR INFORMATION: <u>Public Outreach Activities Conducted by the Board</u>

Ms. Herold reviewed public outreach conducted by the board.

Ms. Butler said she and Dr. Wong attended the DEA program on prescription drug abuse and stated it was a very informative program.

11. Public Comment for Items Not on the Agenda, Matters for Future Meetings

Dr. Castellblanch said the board's "Ask you pharmacist" posters have too much information on them and the type is too small to read. Chair Brooks said he agreed, but the items on the poster were required by law.

Dr. Castellblanch said patient rights posters are helpful, but he doesn't think the current poster is effective. He would like to find a better way to do it. Chair Brooks agreed. He said there is too much information on it.

Ms. Herold said the video version of the poster breaks the information down into smaller items.

Chair Brooks said he would like pharmacy schools to educate students about prescription drug abuse.

Adjournment: 11:36 a.m.