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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE MEETING SUMMARY

Date: June 27, 2007

Location: State Office Building
Sequoia Conference Room
First Floor, Rooms A and B
2420 Del Paso Road
Sacramento, CA 95834

Board Members Present: Ken Schell, PharmD, Board Member and Chairperson
Susan L. Ravnan, Pharm. D.
Henry Hough, Board Member

Board Member Absent: Andrea Zinder, Board Member

Staff Present: Virginia Herold, Executive Officer
Karen Cates, Assistant Executive Officer
Spencer Walker, DCA Staff Counsel
Anne Sodergren, Legislation and Regulation Manager
Robert Ratcliff, Supervising Inspector
Karen Abbe, Public and Licensee Education Analyst

Call to Order

Chairperson Schell called the meeting to order at 9:41 a.m.

1. Consumer Fact Sheet Series with UCSF's Center for Consumer Self Care

Dr. Schell advised that a history of the fact sheet series was provided in the meeting materials. He stated it was time for the committee to determine what the board's future relationship with UCSF's Center for Consumer Self Care would be, since only nine consumer fact sheets had been completed over the past four years. Additional fact

sheets were drafted during the past year, but could not be approved as presented. Edits and annotated versions of the draft fact sheets were not forthcoming.

Dr. Schell referred to the extensive list of topics for fact sheets included in the meeting materials. He said there were many good topics under the bullets and sub-headings, and the committee was still open to suggestions about new topics to add to the list as well. Dr. Schell noted that the nine approved fact sheets currently posted to the board's Web site contain the previous UCSF Center for Consumer Self Care physical address.

Executive Officer Herold stated that the board had an opportunity with this project to receive professional reviews of consumer outreach materials and get solid information out to the public. UCSF also saw the project as an opportunity for their students to add valuable experience to their resumés. When the board initiated the project with UCSF, the board had recently lost two public outreach staff. Only nine fact sheets have actually been completed since the project was initiated, so the project has not progressed as quickly as hoped.

Ms. Herold further stated that the board considered opening the project to participation with other schools of pharmacy. Two students from UOP showed interest in the project, and Ms. Herold offered to contact USC to see if they would be interested as well. She recommended that the board create some of the fact sheets in the interim, given that UCSF is busy and they are not able to give the project a higher priority. She emphasized that the committee should go ahead with the project and begin drafting some of the fact sheets in-house, and that Ms. Abbe can start that process now. She asked whether the committee members had a preference for some topics that may be more important than others.

Dr. Schell stated that counterfeit medicine is a key concern, but agreed that he and Ms. Herold should sit down and prioritize the list of topics provided. A fact sheet concerning immunizations would be useful during the next couple months, prior to flu season. He further stated that topics that have come up in the media during the last couple months, like direct consumer marketing, would be useful. He wants to avoid stopping and starting work on various topics. Dr. Schell recommended that he and Ms. Herold generate a list, but ultimately, the priorities should be confirmed by the board.

Ms. Herold clarified that generally it is a three to four month process to generate a fact sheet from an idea to the printed mode. If we want to develop a fact sheet for the upcoming flu season, we should start that fact sheet now.

Orriette Quandt from Longs Drugs was in attendance, and she suggested that a fact sheet be developed relating to cold medication for young children under the age of two. She said that the FDA has made comments on the topic.

Dr. Ravnan said she agreed that the topic of pediatrics and over-the-counter products was prominent in the news and would be good subjects for pharmacists as well.

Mr. Hough said that counterfeit drugs are an exploding issue, and he recommended that the board provide a fact sheet on the subject because consumers need to know what medicines they are actually taking.

Dr. Schell agreed that we should be on the fast track to create a fact sheet on the subject of counterfeit drugs and buying drugs on the Internet.

Dr. Ravnan agreed to contact Touro and UOP to determine whether their students would like to be involved in this project. Dr. Schell agreed to contact Loma Linda and UCSD. Ms. Herold agreed to contact Western and USC.

2. Update Report on *The Script*

Dr. Schell stated that the next issue of *The Script* is planned for publication and distribution in July 2007. The focus of the issue will be application of laws, questions and answers about pharmacy practice asked of the board, and new regulation requirements. The issue will also contain an article on pill splitting, aimed at pharmacists.

Dr. Ravnan asked whether the draft fact sheet relating to pill splitting is the article to be included in the next issue of *The Script*.

Ms. Herold clarified that the article in *The Script* contains language geared toward pharmacists, and is not identical to the language in the draft fact sheet in the committee packet that is aimed at consumers.

Dr. Schell said that the July issue was graphically designed by board staffer Victor Perez, and is currently at the State Printing Plant for production and mailing. The Pharmacy Foundation of California agreed to print and mail the July 2007 issue to all California pharmacists.

3. Development of New Consumer Brochures

Dr. Schell stated that the committee is revising the board's public education materials, including the overview brochure about the board.

Mr. Hough said he found an error in arithmetic in the (graphic) layout of the overview brochure in the meeting materials.

Dr. Schell said he saw an error in the layout of the overview brochure as well, relating to the number of board members that are "public" board members. He clarified that the board currently has two vacant positions, so the math in the brochure did not add up.

Ms. Herold noted that DCA converted some of the language we submitted, causing errors and other nonsubstantive changes. Unfortunately, other more substantive changes made by DCA revealed a lack of understanding of what the board does. Ms. Herold recommended that the board thank DCA for the draft layout, but we will use the text that the committee previously approved that was developed by board staff and create our own graphic layout.

Ms. Herold stated that they edited out the core of our text, and missed the mark. It wasn't clear whether they were aiming the brochure at consumers or licensees or both, but it missed both marks. She emphasized that we will ensure the information provided reflects the board's mission.

Mr. Hough said that he agreed with Ms. Herold's recommendation.

Dr. Ravnan said she also found several inaccuracies in the layout provided by DCA. She was uncomfortable with the wording used in the layout because it didn't reflect what the board really does.

Dr. Schell noted that we should also be sure that our own information is accurate. For example, whether the board issues 90,000 licenses or 100,000 licenses. Once the information is correct, the committee can proceed with the brochure, and will not need a recommendation by the full board.

Ms. Herold added that the Communication and Public Education Committee normally doesn't edit text during the meeting, but she saw this meeting as working session.

Dr. Schell, Dr. Ravnan, and Mr. Hough agreed that a revised layout with correct text of the overview brochure should be provided to the board for the July 2007 Board meeting.

Dr. Schell referred to the graphic layout for the board's complaint brochure that was also provided in the meeting materials. He said the photo was not flattering, and was somewhat stereotypical of an elderly woman with a complaint. The image didn't match the title given by DCA (We Want to Hear From You).

Ms. Herold stated that the text for the complaint brochure approved by the committee fit the board's needs better than the converted language provided by DCA. She agreed that the graphic of the woman with the headache was not acceptable, but the other graphics were suitable.

Dr. Schell referred to the draft fact sheet for pill splitting provided in the meeting materials. He said the committee should develop materials on tablet splitting, and that's how this fact sheet came about. He said the draft looks good, and he sees it as one in a series on the topic.

Dr. Schell said that one document for consumers couldn't cover all the issues on the topic, but this first attempt is good. He emphasized that we are charged to provide

information, and we are taking it seriously. He asked for comments from the committee and from the audience.

Dr. Ravnan stated that the fact sheet is a good start, but would suggest some edits to the wording. She provided hand-written edits to the committee for consideration. Dr. Ravnan agreed that the fact sheet should be part of an ongoing series.

Mr. Hough agreed with Dr. Schell and Dr. Ravnan. He said that we've heard from Dr. Phillips several times, whose points are well taken and pretty well covered in this fact sheet.

Dr. Phillips stated that the first time he saw pill splitting was 10 years ago in Kaiser. He said seniors were splitting pills resulting in fragments and "garbage." He emphasized that the term "half" should not be used because it's not accurate. If pills were split in half, he would never have contacted the board. Dr. Phillips said that splitting results in dosages up to 38% off, either too high or too low, and that people split 100 pills, and then work their way down to dust.

Dr. Phillips said that everything he was saying was pertinent to the draft because the word "half" is all over our draft fact sheet. He said the issue is that tablets don't split evenly, and he referred to the lawsuit of a patient who was ordered to split pills and she didn't have a choice. He said it is not voluntary, pills do not split evenly, and this is an abuse of seniors.

Dr. Phillips stated that a judge said this is a matter that belongs "here" and not in the courts, so the courts gave it to "you" because it's wrong and abusive. He further stated that what happens is that the Board of Pharmacy leads the nation, who then leads the world. He stated that comments previously brought to the board were not reflected in the meeting minutes.

Dr. Schell advised Dr. Phillips that he would have to stop him because he invited comments on the fact sheet only. Dr. Phillips then provided Dr. Schell with copies of his hand-written comments to the draft fact sheet.

Paris Piche introduced himself, and said he was running a petition of over-the-counter drugs. He also asked seniors if they were splitting tablets; one gentleman that responded said he got awful sick one time after taking tablets that had been split.

Mr. Hough referred to the last bullet point in the draft fact sheet, and asked for clarification about the term "narrow therapeutic index."

Dr. Schell responded that it refers to the minimum effective dose and maximum effective dose and whether it is a narrow index. He agreed that we should clarify that term in language we give to consumers. He also agreed with Dr. Phillips that we should use the term "fragment" instead of "half."

Supervising Inspector Ratcliffe stated that he liked the fact sheet because it's informative, but he suggested adding a bullet point asking whether the medication is available without splitting.

Dr. Quant suggested that edits were needed to one bullet, "don't split capsules, liquids, or topical medications" because the title of the fact sheet refers only to tablet splitting.

Douglas Hillbloom from Prescription Solutions commented that if a pill is oval, it's the hardest one to cut, and round pills are not as hard to cut. Liquids actually can be split with an eyedropper or measuring cup.

Dr. Schell advised that we should focus on tablets, and a dosage of "one swallow" is poor direction. Capsule reference is good, but omit the liquids and topical medications.

Dr. Schell also recommended that the bullet point referring to enteric-coated tablets be split into two bullet points.

Dr. Schell suggested using the term "talk to prescriber and pharmacist" instead of "prescribing physician."

Ms. Herold emphasized that the board's brochure would advise patients to decline the request to split their medications if they don't want to do this. She further stated that consumers, on their own, might decide to split capsules, since they are splitting tablets.

Dr. Phillips stated that in covering the topic for 10 years, capsules haven't really come up, but it would be good to put it in the fact sheet and leave off liquids and topical medications.

Dr. Schell said that the committee should try to get the fact sheet language down to the lowest effective level. We should focus on the implications of pill splitting, and then consumers should look at the fact sheet and sit down with their providers and ask questions.

Dr. Schell referred to the draft text of the "Prescription Drug Discount Program for Medicare Recipients" brochure. He said it's a federal program, and a political program as well. We still need to help our citizens so they can use the program. He approved of the wording in the draft text and did not see a need for many modifications.

Dr. Quandt asked Ms. Herold if she could verify that the California program is still in effect. She believed that once the federal program was in place, there would no longer be a state program.

Ms. Herold responded that the Senate Rules Committee advised that the program was still in effect, but she would confirm this with the Department of Health Services.

Dr. Hillbloom stated that the actual statute said upon enactment of federal benefits, the state program would not be in existence anymore. He recommended that we look at the statute.

Ms. Herold asked, if a patient was in the donut hole and asked for the Medicare price, would they get it, even in the absence of the law.

Dr. Quandt responded that this law was used significantly. It was well known and well used, and chain pharmacies still give patients the discounts.

4. Update on Committee Projects

a. Activities of the California Health Communication Partnership

There was no update provided pertaining to the California Health Communication Partnership during this committee meeting.

b. Pill Splitting

As noted earlier in the committee meeting, a consumer-friendly fact sheet pertaining to pill splitting is in the works. In addition, an article geared toward pharmacists will be included in the next issue of *The Script*.

c. Public forum on Medicare Part D Plans

There was no update pertaining to the Public Forum on Medicare Part D Plans during this committee meeting.

d. SCR 49 Medication Errors Task Force Report

Dr. Schell stated that we have the full report, and he believes our charge is to help the public understand the information in the report. He suggested that Ms. Abbe draft a fact sheet on the subject of the task force findings because the full report is a tough read. He recommended that we abstract key points, with references back to the full report.

Dr. Quandt stated that one aspect of the report enacted by statute was the requirement that a description of the medication be put on the label. She said this is very important for consumers so they can verify that they have the right medication. She further stated that we should make it better known that that's why the description is on the label.

Ms. Herold stated that the board has a potential new charge from a new bill, and if enacted, it will be a huge undertaking. The board must design a standardized prescription label, and it will probably be done under the Communication and Public

Education Committee. Companies like Target who already provide clear labels will have to change their labels. All prescription container labels provided to California patients will have to conform to the new requirements. She stated that the matter is controversial, and will also affect prescriptions filled by mail order. The board will be setting the standard for the nation. The label will be patient-focused and the patient information will be more prominent.

Dr. Schell asked if there will be flexibility of the label for font size or shape of label.

Ms. Herold responded that the specificity will be left up to the board. However, if the board leaves it too broad, it could result in senior issues, language issues, and problems for people with visual acuity.

Dr. Phillips added that labels for eye drops are among the worst, as the brand name tends to be much larger than the patient information.

Dr. Hillbloom stated that labels on inhalers are bad too, and the board will have to come up with a standardized format.

Ms. Herold responded that the label will also need to reflect the directions for use.

Dr. Hillbloom suggested that a separate card attached with elastic around the neck of a bottle would work.

Ms. Herold responded that the new requirements will affect the container label for all medications dispensed to California patients.

Dr. Schell asked whether there was opposition to the legislation.

Ms. Sodergren responded that the California Retailers Association was opposed to the bill, but has since withdrawn its opposition.

Dr. Schell stated that vials for eye drops may need to be larger to accommodate the new labels, and that possibly a vial within a larger vial would work.

Dr. Quandt stated that if you put a label on an inhaler, the patient will repeatedly handle the inhaler, causing the printed wording on the label to become distorted.

Dr. Ravnan stated instead of going through and bullet pointing some of the findings of the SCR 49 report, the issue of labeling was selected for us.

Dr. Quandt asked whether there will be public meetings held where 85 different proposals about labels will come up, or whether the board will narrow it down.

Ms. Herold responded that the board will conduct a series of meetings in communities, soliciting comments from specific groups. One suggestion was made

that the label could address language barriers by showing a full sun and full moon or it could visually show the pills or use international symbols. She said the board should develop a prototype so we can give people something to react to, instead of allowing wide open grazing on the topic.

Dr. Hillbloom said we might want to incorporate the e-prescribing groups.

Ms. Herold responded that stakeholders will be invited to participate, and the meetings will be held throughout the state. Industry representatives will likely show up wherever we hold a meeting. We will need to hold the meetings in areas with good public access.

Ms. Herold responded that we can hold the meetings at night too because we want full participation.

e. Board of Pharmacy Web Site Redesign

Ms. Herold advised that two board staff are working on the Web site redesign. The Web site will be a resource center, including links for people so they'll know where they report prescription errors. There will also be links to other Web sites, like the Institute for Safe Medication Practices. She further advised that the board's Web site will contain information about pill splitting, and will include articles separated into pro, con, and other.

Mr. Piche stated that pharmacists carry more power than pharmaceutical companies, on the consumer level. They're trusted by consumers more than doctors.

Ms. Herold responded that she will consult with Spencer Walker about language for a disclaimer clarifying that the board is not endorsing pill splitting.

5. Miscellaneous Consumer Issues/Articles in the Media

Dr. Schell advised that the purpose of providing these articles in the meeting materials is to see what's happening in the media. The articles in this packet were across the board, including Wall Street Journal articles about drugs bought abroad, compliance issues, and the FDA. There are also articles regarding herbal remedies. He added that there's a lot of concern about herbal remedies, including nutraceuticals that can contain toxic substances not shown on the label. The committee may consider getting something out to the public stating that substances in herbal remedies may not work as well as expected. The articles in the packet also pertain to the abuse of drugs, which includes prescription drugs, not just illicit drugs.

Mr. Piche stated that over-the-counter drugs are abused as well. He provided a print-out with the heading "72 HOURS FOR BETTER HEALTH" from his Web site

www.grassroots72hours.com. He also provided a petition signed by people who support legislation and education about over-the-counter drugs.

Mr. Piche further stated that youth are abusing cough syrups and other over-the-counter drugs. He said that his 10 year-old grandson was able to buy Nyquil, and those drugs should not be available for children to purchase. Sudafed is another drug that he believes should be put behind the counter. Emergency rooms admit young people due to taking Robatussin.

Mr. Piche said he thinks pharmacists carry a lot weight and are respected. He said Giant Foods does not sell certain products to anyone under 18, so there is some voluntary action. He believes that pharmaceutical companies are killing our children. Kids shouldn't even have the right to buy aspirin; they should tell their parents instead, and their parents can take them to a doctor. He wants the board to talk to pharmacists that work for retail outlets about acting voluntarily to not sell these products to children under 18. He referred to his petition and that he was able to get 800 signatures on the petition in just four days.

Dr. Schell responded that the board can prepare a patient information fact sheet, but if Mr. Piche has this kind of support, he should go to his legislator as well.

Mr. Piche said that he talked to Tom Torlakson's office, but they said he needs 10,000 signatures.

Dr. Schell said that the board appreciates Mr. Piche's input, which helps us prioritize our efforts to protect the public.

Dr. Hillbloom stated that grocery stores give easy access to over-the-counter medicines. They may have three aisles full of over-the-counter medicines, which are not even in a pharmacy.

Ms. Herold suggested to Mr. Piche that he review the meeting materials packet because it includes information from The Partnership for a Drug-Free America. They put out a report dealing with a number of issues including over-the-counter medications. Mr. Piche should consider giving this material to Senator Torlakson.

Dr. Quant stated that Robitussin with dextromethorphan is the problem, not the regular Robitussin. Sometimes parents send their children in to the store to buy the products.

Mr. Piche said that children need to have an open dialogue with their parents. The last question on his survey is "Will you discuss this questionnaire with your parents?" Mr. Piche said he believes this question is the most important on his survey, because we need to know where kids' heads are at, without invading their rights.

Dr. Schell suggested that the committee prioritize development of public outreach materials, and consider a fact sheet on over-the-counter medications. The board wants to ensure that medication is safe and effective.

Dr. Phillips stated that when only one company takes an action, it can affect the rest of the industry.

Ms. Herold agreed that the board should develop public outreach materials on topics including counterfeit drugs, direct-to-consumer marketing, vaccines/flu, and fact sheets for applicants for exams. A revised version of the consumer fact sheet on pill splitting and the overview and complaint brochures should be ready for the next board meeting. Other draft materials will be ready for the next committee meeting.

6. Update on the Board's Public Outreach Activities

An update on the board's public outreach activities was provided in the meeting materials.

Adjournment

Dr. Schell said the next Communication and Public Education Committee meeting will be held in September 2007. There being no additional business, Chairperson Schell adjourned the meeting at 11:28 a.m.