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

Contact Person: Patricia Harris
(916) 445-5014

ENFORCEMENT COMMITTEE MEETING

March 18, 2004
9:30 a.m. – 12:30 p.m.

Hilton Burbank Airport & Convention Center
2500 Hollywood Way
Burbank, CA 91505-1019
(818) 843-600

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Candy Place at telephone number (916) 445-5014, at least 5 working days prior to the meeting.

Opportunities are provided to the public to address the committee on each agenda item. Members of the board who are not on the committee may attend and comment during the meeting.

AGENDA

CALL TO ORDER **9:30 a.m.**

A. Discussion Regarding the Reimportation of Prescription Drugs from Canada
Overview of Pending Legislation

B. Update on the Implementation of Legislation Regarding Wholesalers –
Introduction of SB 1307 (Senator Figueroa)

C. Discussion and Action Regarding Conversion from Paper Invoices to Electronic Billing by Wholesalers for Drug Purchases – B & P Code § 4081, 4105 and 4333

D. Discussion and Action Regarding the Use of Robotic Technology in Hospital and Institutional Pharmacies and the Interpretation of Pharmacy Law that Pharmacist Must Check Each Medication

E. Proposed Revisions to the Public Disclosure Policy – Status of License Verification on Web site

F. Discussion Regarding the Implementation of SB 151 (Chapter 406, Statutes of 2003) – New Requirements for Controlled Substance Prescriptions and the Elimination of the Triplicate

G. Report from the NABP Task Force on Limited Distribution and Shortage of Medications

H. Continuing Education Outreach Efforts on Board of Pharmacy – Overview of Enforcement Program

I. Review of Strategic Plan

J. Adjournment **12:30 p.m.**

Committee materials will be available on the board's website by March 11, 2004

AGENDA ITEM A

State of California **Department of Consumer Affairs**

Memorandum

To: **Enforcement Committee** **Date:** **March 8, 2004**

From: **Patricia F. Harris**
Executive Officer
Board of Pharmacy

Subject: **Importation/Reimportation of Prescription Drugs**

This issue has been a long-standing agenda item for the Enforcement Committee and Board meetings. For this meeting, I have included articles that reflect some recent actions by the FDA, actions by other states, and legislation introduced in California.

The legislation is provided as information since the bills will be on the agenda for the Legislative/Regulation Committee meeting in March and the Board of Pharmacy meeting in April.

Hospital, Planned Parenthood Clinic Did Not Properly Report Death of Wom
Took Mifepristone, CA Health Dept. Says

Daily Reports
THE COMPREHENSIVE SOURCE

Daily Health Policy Report

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Prescription Drugs | McClellan Named as Leader of Federal Study on Prescription Drug Reimportation; Illinois Couple Sues U.S. for Restricting Access to Medications From Abroad
[Feb 26, 2004]

HHS Secretary Tommy Thompson on Wednesday named FDA Commissioner Mark McClellan to lead a committee that will conduct a study on the reimportation of lower-cost, U.S.-manufactured prescription drugs from Canada, the *Wall Street Journal* reports (*Wall Street Journal*, 2/26). The one-year study, required under the new Medicare law (HR 1), will examine whether the United States could safely reimport prescription drugs if the federal government hired additional inspectors, shipments of reimported medications entered through specific ports and the treatments had small electronic tags to trace them as they moved through the U.S. supply chain. The nomination of McClellan to lead the committee "infuriated" reimportation supporters because McClellan has "adamantly opposed any relaxation of the rules barring" the practice, the *New York Times* reports (Pear, *New York Times*, 2/26). Sen. Byron Dorgan (D-N.D.) said, "Dr. McClellan has clearly made up his mind not to allow importation and has done everything in his power to stop it," adding, "It gives new meaning to putting the fox in charge of the chicken house" (*Congressional Quarterly Today*, 2/25). A spokesperson for Sen. John McCain (R-Ariz.) said that the senator "is concerned because Dr. McClellan has already displayed a personal bias" against reimportation. According to Thompson, the committee that will conduct the reimportation study will hear testimony from governors and federal lawmakers on both sides of the issue, the *Times* reports (*New York Times*, 2/26). In addition to McClellan, the committee will include officials from CMS, the Drug Enforcement Administration and the Bureau of Customs (*Congressional Quarterly Today*, 2/25).

Illinois Couple Files Reimportation Lawsuit

An Illinois couple on Wednesday plans to file a class-action lawsuit against HHS, FDA and Thompson in U.S. District Court in Washington, D.C., to challenge a federal law that bars reimportation, *USA Today* reports. The couple, Ray and Gaylee Andrews, both 74, said that they spend $800 to $1,000 per month on prescription drugs (Appleby, *USA Today*, 2/26). The lawsuit alleges that the law restricts "access to medical choices ... in ways that violate the Constitution," Robert Clifford, a Chicago trial attorney who represents the Andrews, said. Clifford added that FDA violates the equal protection clause because the agency does not take legal action against U.S. residents who "drive across the bridge from Detroit to Windsor, Canada" for prescription drugs but threatens to prosecute residents who reimport medications (Connolly, *Washington Post*, 2/26). Illinois Gov. Rod Blagojevich (D), after he learned that the Andrews planned to file the lawsuit, "steered them toward Clifford," a supporter and campaign contributor, the *Chicago Sun-Times* reports (McKinney, *Chicago Sun-Times*, 2/26). Abby Ottenhoff, a spokesperson for Blagojevich, said that although Illinois is not a party to the lawsuit, the state may file a legal brief in support of the plaintiffs (*New York Times*, 2/26). A senior aide for Blagojevich said that if the Andrews win the lawsuit, "FDA must (draft) rules for importation, and Illinois and all the other states that are working for a way to do this will be able to do it. All of the obstacles that have been put in our way will be wiped away" (*Chicago Sun-Times*, 2/26). HHS spokesperson Bill Pierce said that the department cannot comment on the lawsuit (*USA Today*, 2/26).

Wisconsin Governor Announces Web Site Expansion

Wisconsin Gov. Jim Doyle (D) on Wednesday announced that a state prescription drug Web site has expanded to include information on three Canadian pharmacies that residents can use to reimport medications, *USA Today* reports (*USA Today*, 2/26). Last week, Doyle announced plans to expand the Web site to include information similar to that included on a similar Web site operated by Minnesota. Last December, Doyle said that the Wisconsin Web site would help state residents purchase prescription drugs from Canada. However, when the Web site originally launched in January, it did not include links, addresses or phone numbers of Canadian pharmacies. In a statement posted on the Web site, Doyle said, "I would like to provide you with the names of those Web sites, but I can't," adding, "The Bush administration refuses to permit states to help people save money by purchasing medicine from Canada." The Minnesota Web site, which the state launched earlier this month, lists the prices for 829 brand-name and generic medications and phone, mail and e-mail contact information for the two state-approved pharmacies -- Total Care Pharmacy of Calgary and Granville Pharmacy of Vancouver (*Kaiser Daily Health Policy Report*, 2/23). Doyle said that the three Canadian pharmacies on the expanded Wisconsin Web site are "reliable sources of safe medicines," the *Times* reports. Two of the three Canadian pharmacies appear on the Minnesota Web site; the third is CanadaDrug.com of Winnipeg (*New York Times*, 2/26). FDA Associate Commissioner Peter Pitts called the expanded Wisconsin Web site "a well put-together snake oil site," adding, "It's got more legal jargon than you can shake a stick at." Dan Leistikow,

spokesperson for Doyle, said, "It would be nice if the FDA would spend more time helping seniors and less time attacking Republican and Democratic governors." Leistikow said that the Web site "is easy to use, easy to navigate and it will allow people to order drugs from Canadian pharmacies the state has checked out" (*Washington Post*, 2/26). Doyle said that the Bush administration continues to "obstruct, criticize and undermine every effort to lower the price of prescription drugs, instead of working with states to make the process easier" (*New York Times*, 2/26).

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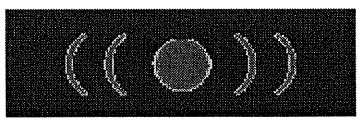

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

February 23, 2004

Via Fax: (312)814-6183

The Honorable Tim Pawlenty
The Governor of Minnesota
Office of the Governor
130 State Capitol
75 Rev. Dr. Martin Luther King Jr. Blvd.
St. Paul, Minnesota 55155

Dear Governor Pawlenty:

Recently Minnesota launched a state-sponsored website called "Minnesota RXConnect." This website provides information on Canadian websites that illegally sell unapproved pharmaceuticals. We strongly believe that this state endorsement of foreign internet "pharmacies" is unsafe, unsound, and ill-considered. We appreciate the need to find safe ways to make affordable prescription drugs available to all Americans, but we urge you to reconsider your action and work with our help on legal, proven ways to provide greater access to more affordable pharmaceuticals that are assured to be safe and effective.

When you recommend to your citizens that they go outside of our regulatory system and enter into a "buyer beware" gray zone, you assist those who put profits before patient health. Your actions also shine a bright light on a path that can (and, indeed, is) used not only by profiteers masquerading as pharmacists, but by outright criminals who do not pause before actively feeding counterfeit drugs into the marketplace.

Your own taskforce has pointed out widespread, significant problems related to illegally purchasing non-FDA approved pharmaceuticals from foreign Internet pharmacies. Even Canadian pharmacies that participate in the Canadian Internet Pharmacy Association, which claims to "self-regulate" safety, were observed engaging in dangerous practices on a single voluntary, pre-announced "visit" by Minnesota State officials who have no regulatory authority over the foreign businesses. Even on these single, preannounced visits, your state officials noted dozens of safety problems, such as:

- One pharmacy had a technician, not a trained pharmacist, enter prescriptions into the pharmacy computer. This practice precluded a trained pharmacist from having an opportunity to catch any prescribing errors. Several pharmacies also used unsupervised technicians, not trained pharmacists, to enter medication orders and to try to clarify questions involving the prescriptions. One pharmacy had its pharmacists check 100 new prescriptions or 300 refill prescriptions per hour, a volume so high that here is no way to assure safety.
- One pharmacy failed to label its products, but instead just shipped the labels unattached

in the same shipping container, even when patients received multiple medications in one shipment.

- Drugs requiring refrigeration were being shipped un-refrigerated with no evidence that the products would remain stable.
- One pharmacy had no policy in place for drug recalls. Representatives of the pharmacy allegedly said that the patient could contact the pharmacy about a recall "if they wished".
- Several pharmacies failed to conduct drug utilization reviews, failed to check patient profiles for allergies, and failed to check new prescriptions to verify their accuracy.
- Several pharmacies dispensed grossly improper amounts of medications, e.g., a 250-count bottle of Lanoxin, which is far larger than is consistent with good prescribing for this medicine.
- One pharmacy re-dispensed medicines that were not labeled and apparently had been previously returned by U.S. Customs and Border Protection.
- One pharmacy technician repeatedly scanned the same prescription bottle when checking an order of six separate bottles, instead of scanning and verifying the accuracy of each of the six bottles in the prescription order.
- Several pharmacies had poor storage practices and poor record keeping, making mishandling of prescriptions more likely.
- Several pharmacies failed to send any patient drug information to patients receiving prescription drugs.
- All of the pharmacies generally allowed customers to fax in their own prescriptions. This not only fails to assure the validity of the prescription; it means that patients can get multiple drug orders from a single prescription, including for more risky drugs.
- Several pharmacies appeared to make unsupervised pharmacy technicians responsible for contacting the American prescriber by telephone if something on the original prescription needed to be clarified. This is a task that a pharmacy technician would not be allowed to perform under Minnesota pharmacy laws and rules, even if pharmacist supervision was present.
- One pharmacy failed to apply child resistant safety caps to any of the prescription drug products shipped to the U.S.
- Only one of the pharmacies visited had a thermometer in their refrigerator to verify that labeled storage requirements were being met for refrigerated products. This is a requirement for all Minnesota pharmacies.
- Most facilities visited did not meet the minimum lighting standard that Minnesota pharmacies would be required to meet. In several of the pharmacies, the lighting was judged to be extremely poor with only half as many "foot candles of illumination" in the work area as are required for safety under Minnesota law.

Many drugs obtained through at least one of the pharmacies were apparently not even of Canadian origin, and many of the drugs were obtained from a difficult-to-follow path of writing and rewriting prescriptions across multiple Canadian provinces. Also disturbing was the statement from one of the pharmacy presidents who allegedly said, "We won't have any problems getting drugs. We have creative ways to get them." Given the clear evidence of questionable sources of these prescription drugs, do you or anyone know what methods are being used and might be used in the future to obtain these drugs, let alone to assure their safety?

Most importantly, a one-time preannounced "visit" to any Internet pharmacy is no substitute for the comprehensive system for assuring the safety of the prescription drugs used by Americans. Regulatory oversight by both federal and state authorities has been proven time and again to be essential to assure the safety and effectiveness of drugs not only in the State of Minnesota, but nationwide. And this is particularly germane today, as you well know by the egregious violations of good pharmacy practices that were prevalent on your single preannounced visit. The fact that your own website admits that you cannot assure the safety of foreign imports is cause for concern. This is very different than the situation here, where the Minnesota Pharmacy Board, backed by FDA and U.S. law enforcement, has the regulatory authority needed to assure the safety of the domestic drug supply.

We are also concerned that you chose not to make public the serious concerns about the safety of international Internet pharmacy practices noted by every provincial pharmacy board in Canada. When we met with you we noted the potential tort liability that a state could be subject to if a citizen purchases an unapproved, illegal drug on your advice, and suffers an injury as a result. Your failure to warn your citizens that you have found substantial deficiencies in these foreign pharmacies may well increase your vulnerability in this area.

There are very good reasons why Health Canada (our counterpart across the border) continues to state that they cannot and will not guarantee the safety of drugs exported across the border through Internet pharmacies. Your continued support and active promotion of Minnesota ConnectRX is unwise and, most urgently, unsafe. At a minimum, your statement that you cannot assure the safety of drugs purchased from these sites seems like a questionable way to limit your own liability if and when Americans who visit these websites fail to get the quality care they deserve, or worse.

Your actions are especially concerning when there are many other safe, legal, and proven ways that the state could pursue with assistance from the Federal government to lower drug costs for Minnesotans. As we noted when we met with you, we and others in the Federal government are ready to work with you to implement these approaches for the people of Minnesota. These approaches include: promoting access to FDA-approved generic drugs, which are proven safe and effective, account for the majority of prescriptions filled in the U.S., and generally cost less than the generic drugs sold in Canada; disease management programs to help educate patients and practioners about low cost ways to meet medical needs; and implementation of the new Medicare Drug Discount Program, which will become effective in June and will enable seniors who lack medical coverage to obtain medicines at reduced prices.

Meanwhile, you should also know that we are working diligently to respond to our mandate from Congress to assess whether and how foreign drugs could be imported while providing assurances of their safety and effectiveness. We intend to consider the public health questions posed by Congress in a way that is fair, public, and evidence-based. Indeed, we will soon begin a series of meetings with the various stakeholders in this important area, so that we can advise the Congress on how and whether to proceed in its deliberations on drug importation. I would be glad to discuss how you can participate in this process if you so desire.

I want to repeat that offer and hope that you are ready to work with us on meaningful, proven, legal approaches to provide broader access to safe and effective drugs for the people of Minnesota. We can do better than simply giving Minnesotans a foreign fax number and wishing them luck.

Sincerely,

/s/

William K. Hubbard
Associate Commissioner for Policy and Planning

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FDA Website Management Staff

Subject: FDA P04-07 -Immediate release: RECENT FDA/U.S. CUSTOMS IMPORT BLITZ EXAMS CONTINUE TO REVEAL POTENTIALLY DANGEROUS ILLEGALLY IMPORTED DRUG SHIPMENTS

January 27, 2004
xxUPDATED WITH REPLAY OPTIONxx
MEDIA ADVISORY
FDA will hold a tele-briefing to discuss the findings of the second series of joint FDA and U.S. Customs and Border Protection (CBP) import blitz examinations.
WHO: Mark B. McClellan, M.D., Ph.D.
Commissioner
John M. Taylor, III, Esq.
Associate Commissioner for Regulatory Affairs
Tom McGinnis, R.Ph.
Director, Pharmacy Affairs
WHEN: TODAY
Tuesday, January 27, 2004
11:00AM-12:00PM ET
CALL-IN: 1-800-779-9313
Passcode: FDA
Leader: Jason Brodsky
REPLAY: AVAILABLE AT 1:00PM TODAY UNTIL 6:00PM ON FRIDAY
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January 27, 2004

RECENT FDA/U.S. CUSTOMS IMPORT BLITZ EXAMS CONTINUE TO REVEAL POTENTIALLY DANGEROUS ILLEGALLY IMPORTED DRUG SHIPMENTS

The Food and Drug Administration (FDA) and the United States Customs and Border Protection (CBP) agency today announced that their second series of import blitz examinations found 1,728 unapproved drugs, including so-called "foreign versions" of FDA-approved drugs, recalled drugs, drugs requiring special storage conditions, drugs requiring close physician monitoring and drugs containing addictive controlled substances.

These findings provide additional evidence of the serious risks posed by the illegal importation of prescription drugs. Unapproved drugs lack assurances of safety, effectiveness, quality and purity. Moreover, FDA cannot assure the safety and efficacy of a drug product the agency has not reviewed and approved and when FDA has not monitored the manufacturing and quality control processes of the facility in which the product was produced.

The blitz examinations were performed in November 2003 at the Buffalo, Dallas, Chicago and Seattle mail facilities and the Memphis and Cincinnati courier hubs. FDA has been examining trends in the illegal importation of unsafe drugs since 2001 when it undertook a blitz examination at the Carson, Calif. mail facility. In September 2003, FDA released the results of a similar study to the one contained in today's announcement, and which had also been conducted in collaboration with CBP at the Miami, New York (JFK), San Francisco and Carson mail facilities in July and August, 2003. The most recent blitz marked the first time that imported drugs entering the U.S. through courier hubs were targeted in addition to those that pass through mail facilities. Each of these studies has shown that the types of products that are imported into the U.S., as well as the countries from which they originate, vary depending upon the

port and facility through which they enter. All of these studies have prompted the same safety concerns about the risks presented by imported drugs. Moreover, the information that FDA has garnered will assist us in doing a better job of quantifying the information obtained as a result of these studies, as well as the risks associated with imported drugs from foreign sources.

FDA and CBP inspectors examined a total of 1,982 parcels that appeared to contain drug products. The majority of the products found in the examined parcels were drugs. The parcels also contained other types of FDA-regulated products, such as dietary supplements and foods, as well as products not regulated by FDA such as pens and notepads.

Parcels were examined irrespective of the country from which they were being exported. Canadian parcels appeared more frequently than parcels from any other country. Of the 1,006 parcels that entered through the mail facilities, FDA determined that approximately 80% of the parcels were exported from Canada, approximately 16% from Mexico, and the remaining 4% were exported from Japan, the Netherlands, Taiwan, Thailand and the United Kingdom.

Commenting on the findings of the recent blitz operations, FDA Commissioner Mark B. McClellan, M.D., Ph.D. said, "We're once again alerting consumers of the risks associated with buying medications from foreign sources outside of the safe, regulated systems of the United States and other nations. Americans deserve access to drugs that are safe, effective and affordable. Compromising safety for price is not in the best interest of the American public."

"During the import blitz, we have examples where our examinations revealed that products were manufactured in countries other than Canada, yet were exported from Canada. For example, at the Dallas, Seattle and Buffalo mail facilities, imported drugs were encountered which were manufactured in Canada, Mexico, Costa Rica, India, Pakistan, New Zealand, Taiwan, Thailand, and a host of other countries. However, in some cases, the drugs that had obviously been manufactured in other countries were exported from Canada," added Commissioner McClellan.

The following examples are typical of the 1,728 unapproved drug products found during the blitzes and illustrate the potential risks they posed to their buyers:

Improperly Labeled Drugs: Many of the drugs did not bear adequate labeling or instructions for proper, safe use. For example, some products contained strictly foreign labeling, many contained duel labeling (in both English and a foreign language) and several contained no labeling whatsoever and were simply loose in plastic baggies or wrapped in tissue paper. Moreover, many of the imported drugs, including those from Canada, were shipped in containers which appeared to be intended for pharmacists without U.S. approved patient labels. This common problem is especially concerning in light of the special risks associated with many of the drugs noted below.

Controlled substances: Ratio-Lenoltec with codeine, codeine, diazepam (Valium), lorazepam (Ativan), Tylenol 3 (containing codeine), and clonazepam are controlled substances that have abuse potential and can be dangerous when consumers take them inappropriately and without a physician's supervision.

Potentially recalled drugs: Serevent Diskus and Flovent Diskus medicines are used in the U.S. and Canada to treat asthma and chronic obstructive pulmonary disease (COPD). Flovent Diskus is approved in the U.S., but is not currently marketed in the U.S. The blitz results indicate that American consumers were sent these drugs from Canada. Shortly after the blitz operations, certain lots of the Canadian versions of these drugs were recalled in Canada. In the U.S., the import of these lots was the

subject of an FDA consumer alert because of concerns that the product's delivery system might not function properly and might deliver too little of the drug - or none at all. Thus, at the time of importation, American consumers had no way of knowing if the Canadian products they were purchasing would subsequently be recalled. However, the FDA-approved product, sold in the U.S. through legitimate marketing channels, did not have the delivery system problem and was not subject to the recall. (A picture of one of the Serevent Diskus products found during the blitz is available online at http://www.fda.gov/bbs/topics/NEWS/photos/ <http://www.fda.gov/bbs/topics/NEWS/photos/>serevent.html

So-called "foreign versions" of FDA approved drugs: The FDA approved versions of many of these products pose safety concerns that require use only under the close supervision of a health care professional. Variations from U.S. standards in potency and purity of unapproved versions may raise additional concerns regarding both safety and efficacy. Examples of these products include:

x APO-Tamox - an unapproved, foreign version of the anti-cancer drug Tamoxifen;

x APO-Warfarin - an unapproved, foreign version of the blood thinner warfarin. The potency of warfarin may vary depending on how it is manufactured, and the drug must be carefully administered and monitored by a health professional in order to prevent serious bleeding problems;

x APO-Carbamazapine - an unapproved, foreign version of the anti-convulsant drug carbamazapine which requires initial screening and monthly monitoring of blood and platelet counts to ensure safe use;

x APO-Allopurinol - an unapproved, foreign version of a drug used in the management of certain types of cancer. Allopurinol, which requires periodic monitoring of kidney function during the first few months of treatment, and

can cause kidney failure with underlying renal disease;

x Alti-azathioprine - an unapproved, foreign version of an immunosupressant drug. This drug can cause severe bone marrow depression and can be associated with an increased risk of infection and cancer development. The FDA approved version of this drug requires regularly scheduled monitoring of blood counts, and

x Human Growth Hormone - This is a widely used drug indicated for a number of conditions in both children and adults. It can have serious side effects (for example, it can unmask or worsen diabetes and cause elevation of pressure in brain) if used inappropriately or in excessive doses.

Drugs requiring risk management and/or restricted distribution programs: For example, Canadian-manufactured isotretinoin, a drug to treat a severe form of acne, was shipped without any assurance that its use would be monitored by a physician. In the U.S., isotretinoin is subject to a stringent risk management plan, under which prescribers are required to screen, educate and monitor patients to avoid certain serious risks, such as birth defects that may occur following the use of the drug. U.S. prescribers are also expected to attest, prior to prescribing isotretinoin, that pregnancy testing has been done to confirm that the patient is not pregnant.

Drugs that require initial screening or periodic monitoring of patients: Initial screening and periodic patient monitoring by a medical professional (for example, monitoring liver function or blood parameters) are recommended in FDA's approved labeling for the following drugs which were found during the blitz operation:

x Casodex is used in the treatment of prostate cancer. A medical

professional must rule out baseline liver disease prior to treatment initiation and should monitor liver function tests periodically during treatment.

x Coumadin and Warfarin are anticoagulants that require initial and periodic monitoring of blood parameters to avoid bleeding problems.

x Clomid is used in the treatment of ovulatory dysfunction. A medical professional must rule out liver, thyroid, and adrenal dysfunction before beginning treatment and should also perform monitoring during treatment to avoid ovarian hyperstimulation.

x Metformin is an oral hypoglycemic that requires regular monitoring of blood parameters and pre-treatment and ongoing assessments of kidney function to reduce the risk of development of lactic acidosis.

x Tamoxifen is a drug for which a medical professional must rule out uterine malignancy prior to, and regularly during, treatment.

x Amitriptyline (Elavil) is an anti-depressant for which cardiovascular disorders must be ruled out prior to treatment.

x Lithium carbonate is an anti-psychotic also used to treat manic depression. Individualized dosing and careful monitoring of serum levels is required for this drug to avoid life-threatening toxicity.

Drugs requiring careful dosing: For example, Synthroid (levothyroxine), Glucophage (metformin), Dilantin (phenytoin), digoxin, theophylline, Coumadin (warfarin) all require individualized titration of the dose prescribed and very careful dosing in order to avoid serious and potentially life-threatening side effects.

Drugs with clinically significant drug-drug interactions: Zocor (simvastatin), imipramine, Viagra (sildenafil citrate) and tramadol can be associated with clinically significant interactions with other drugs the buyer may be taking.

Biologic drugs which should be administered by a healthcare provider and are not licensed by FDA - For example, Influenza Virus Vaccine approved in Canada but not licensed by the FDA was encountered.

Investigational Products: These products should only be shipped pursuant to FDA's IND regulations, which assure that patients who use investigational products are fully informed and are not exposed to unreasonable risks. When these products are shipped through the mail, and used outside of the protections established to protect patients involved in clinical trials of experimental drugs, there is a significant risk that a patient may be harmed. Examples of investigational products found during the blitz examinations include the drug atrasentant labeled as "medical study cancer samples."

In general, FDA and CBP do not have sufficient resources to perform comprehensive examinations of the huge number of parcels brought to the U.S. by mail and commercial couriers. Instead, the FDA intends to continue to cooperate with CBP in conducting more "blitz" exams of individual drug imports. To this end, the FDA will endeavor to:

x use its limited investigatory and regulatory resources more strategically to focus on the foreign sources of illegal, unsafe imported drugs;

x work with commercial shippers and credit institutions to identify shipping patterns of known vendors of unsafe drugs so that it can more accurately target their shipments and sources;

x form partnerships with other federal, state, and international regulatory and law enforcement agencies to combat these illegal imports; and

x educate the public about the dangers of illegally imported drugs.

Additional information about the risks of buying illegally imported drugs is available at http://www.fda.gov/oc/opacom/hottopics/importdrugs/default.htm <http://www.fda.gov>l. Details regarding the first joint FDA/CBP import blitz, which occurred in July-August 2003, are available online at <http://www.fda.gov/bbs/topics/NEWS/2003/NEW00948.html>. Pictures of drugs found during this series of import blitz examinations can be found online at <http://www.fda.gov/bbs/topics/NEWS/2004/NEW01011.html>.

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Affordable Prescription Drug Act of 2004

Assemblymembers Unveil Bill Package to Halt Skyrocketing Drug Prices

Prescription drug costs continue to skyrocket, making life-saving drugs increasingly unaffordable for individuals, employers, local governments and the state. Individuals without health coverage and seniors, who require more medications on average than younger Californians, are especially hard hit. As a result, many Californians are forced to turn to Web sites that offer prescription drugs from Canadian pharmacies at deeply discounted prices. At the same time, even those with health coverage are being squeezed as increases in prescription drug spending lead to higher costs for employers and higher copayments for consumers. Even the state is not immune: taxpayer dollars pay for needed medications through Medi-Cal and other state programs, and costs have increased by as much as 20% per year.

In 2002, United States consumers paid $48.6 billion in out-of-pocket costs for prescription drugs, an increase of 15.3% over the previous year. Over the three prior years, prescription drug spending increased an average of 17.3% each year. On average, United States residents spend $654 on drugs, while a resident in Britain only pays $197, according to a recent *TIME* magazine article. For that reason, news reports estimate that more than a million Americans spent $800 million last year on prescription drugs from Canada, where drugs are, on average, 40% cheaper.

In California, taxpayers spent $2.9 billion for prescription drugs in the Medi-Cal program in 2002-03. That number is expected to rise to $3.8 billion in 2003-04. The California Department of Corrections has seen its prescription drug costs spike by 20% each year and now pays more than $125 million annually. CalPERS spends $700 million a year on prescription drugs.

California needs to take significant steps to remedy a situation that is literally forcing taxpayers to break the law in order to preserve their health and is recklessly driving health care costs up to unprecedented levels. Our approach will accomplish the following:

1. In the short term, we will provide immediate options to help Californians buy more affordable prescription drugs safely.

2. In the long term, we will increase prescription drug buying power in the public and private sectors by bringing public and private purchasers together for volume discounts and aggressive negotiating.

1. IMMEDIATE OPTIONS FOR SAFE, AFFORDABLE PRESCRIPTION DRUGS

AB 1957 (Frommer)
Safe and Affordable Drug Importation from Canada

- Requires the Board of Pharmacy to establish a Web site with two primary purposes:
  - Provide price comparisons between American and Canadian pharmaceutical prices.
  - Provide links to certified Canadian pharmacies.
- Specifies that for a Canadian pharmacy to be certified, it must be licensed in the province in which it is located and meet standards established by the Board for safety, access and affordability._
- Permits the Web site to contain links to the Web sites of health plans and health insurers to enable Californians to get information about their formularies._
- Requires the Department of General Services (DGS) to coordinate a department-by-department review of state drug purchasing to determine which programs may save significant state funds by purchasing from Canadian sources.
- Requires DGS to report findings of review to Legislature and to recommend options, including pilot programs, to facilitate drug importation. Permits DGS to establish pilot programs allowing state agencies to purchase drugs from Canada, after obtaining any necessary federal approvals.

According to IMS Health, a company that tracks prescription drug sales, Americans spent $800 million in 2003 buying prescription drugs from Canada. Many of these purchases are made through the Internet. While properly dispensed drugs from Canada are at least as safe as those sold in the U.S., there is no oversight of these Internet transactions to ensure that California consumers are buying from reputable Canadian pharmacies that engage in safe dispensing practices. At the same time, there is no organized effort underway for state and local governments to take advantage of these lower Canadian drug prices.

While Californians are turning increasingly to Canada, there are still many state residents who are simply forgoing their medications because they are unaffordable. Californians should not be forced to choose between breaking the law or not taking medication they need to be healthy. Consumers must have the resources they need to compare the prices of different medications and pharmacies, whether they be American or Canadian, so they can make the best, most cost-efficient decision possible when buying drugs. In addition, for patients who are opting to buy drugs from Canada, the Legislature needs assurance that these imported drugs are safe.

2. INCREASE PUBLIC AND PRIVATE SECTOR BUYING POWER

Together, the state of California, the employers of California and individuals in the state spend nearly $25 billion every year on prescription drugs. Total drug purchasing in California exceeds total drug spending in Canada. Buying drugs from Canada will help some, but it is not a panacea. California must implement long-term strategies to reduce drug prices.

Leverage Buying Power by Pooling Public and Private Drug Purchasing.

AB 1958 (Frommer)
California Drug Purchasing Pool

- Expands California's purchasing power by authorizing the California Public Employees' Retirement System (CalPERS) to form a purchasing pool for prescription drugs for public and private purchasers.
- Allows other California institutional purchasers of prescription drugs, such as businesses and HMOs, to join the pool and take advantage of the state's purchasing power to achieve lower prices.

One critical tool the state needs is the ability to flex more purchasing power when negotiating drug prices for its agencies. To increase California's purchasing muscle, state agencies should join together, along with HMOs and businesses, to negotiate for lower prices. The existing CalPERS system provides a good starting point for partnership with the private sector because public employees and privately insured individuals obtain drugs from similar systems of retail and mail-order pharmacies.

Better Transparency in Negotiations

AB 1959 (Chu)
Uncloak the Secrecy of State Spending on Prescription Drugs.

- Provides state Legislature oversight of drug contracts entered into by DHS, DGS and CalPERS by authorizing the Chair and Vice-Chair of the Assembly and Senate Health and Budget Committees to review those contracts.

AB 1960 (Pavley)
Improving Transparency within the Drug Purchasing Process

- Pharmacy benefit managers (PBMs) are fiscal intermediaries that specialize in the administration and management of prescription benefit programs for clients such as state governments, HMOs, employers, and union trust funds. Currently, PBMs have no fiduciary duty to their clients, and often do not disclose the true cost of drugs they are providing for their clients or the discounts, kickbacks or rebates they receive from drug manufacturers.
- This bill mandates that PBMs have a fiduciary duty to their clients. Since clients, including state and local governments, are unable to access basic information from PBMs that enable them to determine whether or not they are paying excessive amounts for prescription drugs, this will hold the PBM responsible for passing on savings so taxpayer-funded programs can be assured they are getting the best deal.

Prescription drug prices in this country are set through a complicated process of rebates and other secret special deals that may or may not result in large purchasers, such as the state of California, getting the best price possible. It is imperative that we open up this process, bringing a critical level of transparency to the system to ensure that the Legislature knows that the state and other large purchasers, such as businesses, are getting maximum value for each dollar spent.

Stop the Sale of Physician Prescription Information

AB 262 (Chan)
Restrict Sale of Physician Prescribing Data

- Prohibits sale of a physician's prescribing data, except in limited circumstances, if the physician has placed his or her name on a DO NOT USE list to be set up by the Attorney General.

In 2002, more than 2.7 billion prescriptions were filled in California. For virtually every prescription filled at a pharmacy, drug companies paid the pharmacies to find out the name of each physician prescribing a competitor's product, how often, and in what amounts. Drug companies bought this data without the consent of either the physician or the patient. The data is provided to drug sales reps that are then dispatched to persuade physicians to change drug products.

In addition to compromising the sanctity of the physician-patient relationship, this practice is a significant contributor to the skyrocketing costs of prescription drugs. It is estimated that in California alone drug companies spend almost $2 billion a year in purchasing prescription data and related marketing efforts. AB 262 will restore physician control over their prescribing information by creating a "Do Not Sell" list. Modeled after the telemarketer's "Do Not Call" list, it will prohibit pharmacies from selling physician prescriber information of any physician who has signed up.

Resolutions Calling upon Congress and the U.S. Department of Health and Human Services to Take Action to Lower Drug Costs

AJR 61 (Ridley-Thomas)
Call on Federal Government to Implement Importation Law

- Asks the U.S. Secretary of Health and Human Services to certify that the importation of drugs from Canada is safe and cost-effective, as specified in existing federal law, so that pharmacists can import prescription drugs from Canadian wholesalers.

AJR 62 (Ridley-Thomas)
Call on Federal Government to Repeal Anti-Competitive Drug Pricing Rules

- Asks Congress and the President to repeal a provision of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 that prohibits the federal government from negotiating prices for the new Medicare drug benefit.

The federal government is not doing enough to stop the runaway train of skyrocketing prescription drug prices. Right now, the Secretary of the federal Department of Health and Human Services sits idly on the authority to help Americans buy lower drugs from Canada. Even worse, the new Medicare Prescription Drug, Improvement, and Modernization Act prohibits the federal government from negotiating or otherwise influencing prices for this benefit, which will cost taxpayers and seniors hundreds of billions of dollars. California must urge the federal government to address a crisis that is already forcing over a million Americans to break the law

barring prescription drug importation.

ASSEMBLY BILL No. 1957

Introduced by Assembly Members Frommer, Chu, Pavley, and Ridley-Thomas

February 12, 2004

An act to add Article 25 (commencing with Section 4430) to Chapter 9 of Division 2 of the Business and Professions Code, and to add Sections 14982 and 14983 to the Government Code, relating to prescription drugs, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

AB 1957, as introduced, Frommer. Prescription drugs.

Existing law establishes, within the Department of Consumer Affairs, the California State Board of Pharmacy, which has licensing, regulatory, and disciplinary functions relating to pharmacists, pharmacies, and prescription drugs and devices. Existing law requires the board to impose upon pharmacists and pharmacies fees to fund these functions. The fees are paid into the Pharmacy Board Contingent Fund which is continuously appropriated for the expenses of the board. Existing law provides for the registration and licensure of a nonresident pharmacy and establishes the fee for an out-of-state drug distributor's license and annual renewal issued pursuant to those provisions.

This bill would require the board to establish a Web site on or before July 1, 2005, to facilitate the safe purchase by California residents of prescription drugs at reduced prices. The bill would require the Web site to include price comparisons of prescription drugs, including prices charged by licensed pharmacies in the state and Canadian pharmacies that provide mail order service to the United States that meet certification requirements established under the bill.

Because the bill would result in increased expenditures from funds that are continuously appropriated to the board by requiring the board to establish a Web site and administer the certification of Canadian pharmacies under the bill, the bill would make an appropriation.

Existing law authorizes the Department of General Services to administer a coordinated prescription drug bulk purchasing program under which the department may enter into contracts on a bid or negotiated basis with manufacturers and suppliers of single-source or multisource drugs and obtain from them discounts, rebates, and refunds as permissible under federal law. Existing law requires certain state agencies to participate in the program and authorizes any other state, local, and public agency governmental entity to elect to participate in the program.

This bill would require the department to review state departments and agencies that purchase prescription drugs to determine which state programs may save significant state funds by purchasing from Canadian sources. The bill would require the department to report to the Legislature and recommend options to facilitate prescription drug importation. The bill would authorize the department to establish pilot programs under which purchases of prescription drugs from Canada would be made at reduced prices for purposes of state departments and agencies.

Vote: majority. Appropriation: yes. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Article 25 (commencing with Section 4430) is
2 added to Chapter 9 of Division 2 of the Business and Professions
3 Code, to read:
4
5 Article 25. Prescription Drugs
6
7 4430. (a) The board shall establish a Web site on or before
8 July 1, 2005, that will facilitate the safe purchase by California
9 residents of prescription drugs at reduced prices.
10 (b) (1) The Web site shall include price comparisons of the 50
11 most commonly prescribed brand name prescription drugs,
12 including typical prices charged by licensed pharmacies in the

state and by certified Canadian pharmacies that provide mail order service to the United States.

(2) (A) The Web site shall establish electronic links to certified Canadian pharmacies.

(B) The Web site may establish electronic links to other appropriate Web sites to allow California residents to safely purchase prescription drugs at reduced prices, including links to Web sites of health plans and health insurers regarding their prescription drug formularies.

(c) For purposes of this section, "certified Canadian pharmacy" means a pharmacy that is located in Canada and meets all of the following requirements as determined by the board:

(1) Is licensed by the province in which it is located.

(2) Complies with all of the requirements of a nonresident pharmacy as specified in Section 4112.

(3) Meets the safety, access, and affordability standards established by the board for a certified Canadian pharmacy. These standards established by the board shall require, at a minimum, that only a Canadian pharmacy that complies with all of the following may be certified:

(A) Requires a prescription from a patient's personal physician.

(B) Requires a patient medical history.

(C) Requires a signed patient agreement.

(D) Ships prescriptions in tamper proof original manufacturer containers to individuals in the United States.

(E) Includes a physical address and pharmacy license number on its company Web site.

SEC. 2. Section 14982 is added to the Government Code, to read:

14982. (a) The department shall coordinate a review of state departments and agencies that purchase prescription drugs to determine which state programs may save significant state funds by purchasing from Canadian sources. State departments to be reviewed shall include, but not be limited to, all of the following:

(1) The State Department of Health Services.

(2) The Managed Risk Medical Insurance Board.

(3) The Department of General Services.

(4) The California Public Employees' Retirement System (CalPERS).

(b) The department shall report its findings based on the review required under subdivision (a) to the Legislature and shall recommend options to the Legislature, including conducting pilot programs, to facilitate prescription drug importation. The recommendations shall include a determination of the need to seek any federal approvals or waivers.

SEC. 3. Section 14983 is added to the Government Code, to read:

14983. (a) The department may establish pilot programs under which purchases of prescription drugs from Canada are made at reduced prices for purposes of state departments and agencies.

(b) As a condition of implementing any pilot program under this section, the department shall seek and obtain all appropriate federal waivers and approvals necessary for the implementation of that pilot program.

CORRECTIONS

Heading — Authors.

O

ASSEMBLY BILL No. 1958

Introduced by Assembly Members Frommer, Chu, Pavley, and Ridley-Thomas

February 12, 2004

An act to amend Section 22791.5 of the Government Code, relating to the Public Employees' Medical and Hospital Care Act.

LEGISLATIVE COUNSEL'S DIGEST

AB 1958, as introduced, Frommer. Public Employees' Medical and Hospital Care Act: purchasing consortiums.

The Public Employees' Medical and Hospital Care Act authorizes the Board of Administration of the Public Employees' Retirement System to contract with carriers for health benefits plans and major medical plans for employees and annuitants, and approve other specified plans. Existing law further authorizes the Board of Administration of the Public Employees' Retirement System to enter into a joint purchasing arrangement with private or public entities, if the arrangement satisfies specified conditions.

This bill would authorize the Board of Administration of the Public Employees' Retirement System to establish or enter into pharmaceutical purchasing consortiums with private or public entities, as specified.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 22791.5 of the Government Code is amended to read:

22791.5. *(a)* The board may enter into any joint purchasing arrangement with private or public entities, if the arrangement does all of the following:

~~(a)~~

(1) Benefits persons receiving health coverage under this part.

~~(b)~~

(2) Does not restrict the authority of the board or the state.

~~(c)~~

(3) Does not jeopardize the system's tax status or its governmental plan status.

~~(d)~~

(4) Does not violate federal or state law.

(b) The board is specifically encouraged to take advantage of pooling pharmaceutical purchasing with other public agencies and private entities in order to obtain better prices through larger volume purchasing. The board may establish or enter into a pharmaceutical purchasing consortium with other public agencies or private entities or both to obtain better prices.

CORRECTIONS

Heading — Authors.

O

ASSEMBLY BILL No. 1959

Introduced by Assembly Members Chu, Frommer, Pavley, and Ridley-Thomas

February 12, 2004

An act to amend Section 14977.1 of, and to add Section 22790.1 to, the Government Code, and to amend Section 14105.33 of the Welfare and Institutions Code, relating to health care contracts.

LEGISLATIVE COUNSEL'S DIGEST

AB 1959, as introduced, Chu. Health care.

Existing law authorizes the Department of General Services to enter into contracts on a bid or negotiated basis with manufacturers and suppliers of single-source or multiple source drugs, authorizes the department to obtain from them discounts, rebates, or refunds as permissible under federal law, and provides that those contracts are exempt from competitive bid and other acquisition procedures applicable to the state acquisition of goods and services. Existing law requires the State Department of Mental Health, the Department of Corrections, the Department of the Youth Authority, and the State Department of Developmental Services to participate in the program, and authorizes other state, local, and public agency governmental entities to elect to participate in that contracting program.

Existing law, the Public Employees' Medical and Hospital Care Act, authorizes the Board of Administration of the Public Employees' Retirement System to contract with eligible carriers for health benefits plans for employees and annuitants and major medical plans or approve health benefits plans offered by employee organizations.

Existing law authorizes the State Department of Health Services to enter into contracts with manufacturers of single-source and multiple source drugs, on a bid or nonbid basis, for drugs from each major therapeutic category, and requires the department to maintain a list of those drugs for which contracts have been executed. Existing law also provides that those contracts are exempt from competitive bid and other acquisition procedures applicable to the state acquisition of goods and services.

This bill would authorize the chair and vice chair of specified committees of the Legislature to inspect any of those contracts, and would require the chair and vice chair of those committees to maintain the confidentiality of the contractS or amendments to the contract.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Section 14977.1 of the Government Code is
2 amended to read:
3 14977.1. (a) Notwithstanding any other provision of law, the
4 Department of General Services may enter into exclusive or
5 nonexclusive contracts on a bid or negotiated basis with
6 manufacturers and suppliers of single source or multisource drugs.
7 The department may obtain from those manufacturers and
8 suppliers, discounts, rebates, or refunds based on quantities
9 purchased insofar as permissible under federal law. Contracts
10 entered into pursuant to this chapter may include price discounts,
11 rebates, refunds, or other strategies aimed at managing escalating
12 prescription drug prices.
13 (b) Contracts under this chapter shall be exempt from Chapter
14 2 (commencing with Section 10290) of Part 2 of Division 2 of the
15 Public Contract Code.
16 *Notwithstanding any other provision of law, any contract or*
17 *amendments to the contract subject to this section shall be open to*
18 *inspection by the chair and vice chair of the following legislative*
19 *committees, who shall maintain the confidentiality of the contracts*
20 *and amendments thereto, until the contract or amendments to the*
21 *contract are open to inspection by the public.*
22 *(1) The Assembly Committee on Health.*
23 *(2) The Senate Committee on Health and Human Services.*

1 *(3) The Assembly Committee on Budget.*
2 *(4) The Senate Committee on Budget and Fiscal Review.*
3 SEC. 2. Section 22790.1 is added to the Government Code, to
4 read:
5 22790.1. All contracts entered into by the board for health
6 benefits for employees and annuitants, including prescribed drug
7 benefits, shall be open to inspection by the chair and vice chair of
8 the following legislative committees, who shall maintain the
9 confidentiality of the contracts and amendments thereto, until the
10 contracts or amendments to the contract are open to inspection by
11 the public:
12 (a) The Assembly Committee on Health.
13 (b) The Senate Committee on Health and Human Services.
14 (c) The Assembly Committee on Budget.
15 (d) The Senate Committee on Budget and Fiscal Review.
16 SEC. 3. Section 14105.33 of the Welfare and Institutions
17 Code is amended to read:
18 14105.33. (a) The department may enter into contracts with
19 manufacturers of single-source and multiple-source drugs, on a
20 bid or nonbid basis, for drugs from each major therapeutic
21 category, and shall maintain a list of those drugs for which
22 contracts have been executed.
23 (b) (1) Contracts executed pursuant to this section shall be for
24 the manufacturer's best price, as defined in Section 14105.31,
25 which shall be specified in the contract, and subject to agreed-upon
26 price escalators, as defined in that section. The contracts shall
27 provide for an equalization payment amount, as defined in Section
28 14105.31, to be remitted to the department quarterly. The
29 department shall submit an invoice to each manufacturer for the
30 equalization payment amount, including supporting utilization
31 data from the department's prescription drug paid claims tapes
32 within 30 days of receipt of the Centers for Medicare and Medicaid
33 Services' file of manufacturer rebate information. In lieu of paying
34 the entire invoiced amount, a manufacturer may contest the
35 invoiced amount pursuant to procedures established by the federal
36 Centers for Medicare and Medicaid Services' Medicaid Drug
37 Rebate Program Releases or regulations by mailing a notice, that
38 shall set forth its grounds for contesting the invoiced amount, to
39 the department within 38 days of the department's mailing of the
40 state invoice and supporting utilization data. For purposes of state

accounting practices only, the contested balance shall not be considered an accounts receivable amount until final resolution of the dispute pursuant to procedures established by the federal Centers for Medicare and Medicaid Services' Medicaid Drug Rebate Program Releases or regulations that results in a finding of an underpayment by the manufacturer. Manufacturers may request, and the department shall timely provide, at cost, Medi-Cal provider level drug utilization data, and other Medi-Cal utilization data necessary to resolve a contested department-invoiced rebate amount.

(2) The department shall provide for an annual audit of utilization data used to calculate the equalization amount to verify the accuracy of that data. The findings of the audit shall be documented in a written audit report to be made available to manufacturers within 90 days of receipt of the report from the auditor. Any manufacturer may receive a copy of the audit report upon written request. Contracts between the department and manufacturers shall provide for any equalization payment adjustments determined necessary pursuant to an audit.

(3) Utilization data used to determine an equalization payment amount shall exclude data from both of the following:

(A) Health maintenance organizations, as defined in Section 300e(a) of Title 42 of the United States Code, including those organizations that contract under Section 1396b(m) of Title 42 of the United States Code.

(B) Capitated plans that include a prescription drug benefit in the capitated rate, and that have negotiated contracts for rebates or discounts with manufacturers.

(c) In order that Medi-Cal beneficiaries may have access to a comprehensive range of therapeutic agents, the department shall ensure that there is representation on the list of contract drugs in all major therapeutic categories. Except as provided in subdivision (a) of Section 14105.35, the department shall not be required to contract with all manufacturers who negotiate for a contract in a particular category. The department shall ensure that there is sufficient representation of single-source and multiple-source drugs, as appropriate, in each major therapeutic category.

(d) The department shall select the therapeutic categories to be included on the list of contract drugs, and the order in which it seeks contracts for those categories. The department may establish

different contracting schedules for single-source and multiple-source drugs within a given therapeutic category.

(e) (1) In order to fully implement subdivision (d), the department shall, to the extent necessary, negotiate or renegotiate contracts to ensure there are as many single-source drugs within each therapeutic category or subcategory as the department determines necessary to meet the health needs of the Medi-Cal population. The department may determine in selected therapeutic categories or subcategories that no single-source drugs are necessary because there are currently sufficient multiple-source drugs in the therapeutic category or subcategory on the list of contract drugs to meet the health needs of the Medi-Cal population. However, in no event shall a beneficiary be denied continued use of a drug which is part of a prescribed therapy in effect as of September 2, 1992, until the prescribed therapy is no longer prescribed.

(2) In the development of decisions by the department on the required number of single-source drugs in a therapeutic category or subcategory, and the relative therapeutic merits of each drug in a therapeutic category or subcategory, the department shall consult with the Medi-Cal Contract Drug Advisory Committee. The committee members shall communicate their comments and recommendations to the department within 30 business days of a request for consultation, and shall disclose any associations with pharmaceutical manufacturers or any remuneration from pharmaceutical manufacturers.

(f) In order to achieve maximum cost savings, the Legislature declares that an expedited process for contracts under this section is necessary. Therefore, contracts entered into on a nonbid basis shall be exempt from Chapter 2 (commencing with Section 10290) of Part 2 of Division 2 of the Public Contract Code.

(g) In no event shall a beneficiary be denied continued use of a drug that is part of a prescribed therapy in effect as of September 2, 1992, until the prescribed therapy is no longer prescribed.

(h) Contracts executed pursuant to this section shall be confidential and shall be exempt from disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code). *Notwithstanding any other provision of law, any contract or amendments to the contract subject to this section shall be open to*

inspection by the chair and vice chair of the following legislative committees, who shall maintain the confidentiality of the contracts and amendments thereto, until the contract or amendments to the contract are open to inspection by the public.

(1) The Assembly Committee on Health.

(2) The Senate Committee on Health and Human Services.

(3) The Assembly Committee on Budget.

(4) The Senate Committee on Budget and Fiscal Review.

(i) The department shall provide individual notice to Medi-Cal beneficiaries at least 60 calendar days prior to the effective date of the deletion or suspension of any drug from the list of contract drugs. The notice shall include a description of the beneficiary's right to a fair hearing and shall encourage the beneficiary to consult a physician to determine if an appropriate substitute medication is available from Medi-Cal.

(j) In carrying out the provisions of this section, the department may contract either directly, or through the fiscal intermediary, for pharmacy consultant staff necessary to initially accomplish the treatment authorization request reviews.

(k) (1) Manufacturers shall calculate and pay interest on late or unpaid rebates. The interest shall not apply to any prior period adjustments of unit rebate amounts or department utilization adjustments.

(2) For state rebate payments, manufacturers shall calculate and pay interest on late or unpaid rebates for quarters that begin on or after the effective date of the act that added this subdivision.

(3) Following final resolution of any dispute pursuant to procedures established by the federal Centers for Medicare and Medicaid Services' Medicaid Drug Rebate Program Releases or regulations regarding the amount of a rebate, any underpayment by a manufacturer shall be paid with interest calculated pursuant to subdivisions (m) and (n), and any overpayment, together with interest at the rate calculated pursuant to subdivisions (m) and (n), shall be credited by the department against future rebates due.

(*l*) Interest pursuant to subdivision (k) shall begin accruing 38 calendar days from the date of mailing of the invoice, including supporting utilization data sent to the manufacturer. Interest shall continue to accrue until the date of mailing of the manufacturer's payment.

(m) Except as specified in subdivision (n), interest rates and calculations pursuant to subdivision (k) for medicaid rebates and state rebates shall be identical and shall be determined by the federal Centers for Medicare and Medicaid Services' Medicaid Drug Rebate Program Releases or regulations.

(n) If the date of mailing of a state rebate payment is 69 days or more from the date of mailing of the invoice, including supporting utilization data sent to the manufacturer, the interest rate and calculations pursuant to subdivision (k) shall be as specified in subdivision (m), however the interest rate shall be increased by 10 percentage points. This subdivision shall apply to payments for amounts invoiced for any quarters that begin on or after the effective date of the act that added this subdivision.

(o) If the rebate payment is not received, the department shall send overdue notices to the manufacturer at 38, 68, and 98 days after the date of mailing of the invoice, and supporting utilization data. If the department has not received a rebate payment, including interest, within 180 days of the date of mailing of the invoice, including supporting utilization data, the manufacturer's contract with the department shall be deemed to be in default and the contract may be terminated in accordance with the terms of the contract. For all other manufacturers, if the department has not received a rebate payment, including interest, within 180 days of the date of mailing of the invoice, including supporting utilization data, all of the drug products of those manufacturers shall be made available only through prior authorization effective 270 days after the date of mailing of the invoice, including utilization data sent to manufacturers.

(p) If the manufacturer provides payment or evidence of payment to the department at least 40 days prior to the proposed date the drug is to be made available only through prior authorization pursuant to subdivision (o), the department shall terminate its actions to place the manufacturers' drug products on prior authorization.

(q) The department shall direct the state's fiscal intermediary to remove prior authorization requirements imposed pursuant to subdivision (o) and notify providers within 60 days after payment by the manufacturer of the rebate, including interest. If a contract was in place at the time the manufacturers' drugs were placed on prior authorization, removal of prior authorization requirements

shall be contingent upon good faith negotiations and a signed contract with the department.

(r) A beneficiary may obtain drugs placed on prior authorization pursuant to subdivision (o) if the beneficiary qualifies for continuing care status. To be eligible for continuing care status, a beneficiary must be taking the drug when its manufacturer is placed on prior authorization status. Additionally, the department shall have received a claim for the drug with a date of service that is within 100 days prior to the date the manufacturer was placed on prior authorization.

(s) A beneficiary may remain eligible for continuing care status, provided that a claim is submitted for the drug in question at least every 100 days and the date of service of the claim is within 100 days of the date of service of the last claim submitted for the same drug.

(t) Drugs covered pursuant to Sections 14105.43 and 14133.2 shall not be subject to prior authorization pursuant to subdivision (o), and any other drug may be exempted from prior authorization by the department if the director determines that an essential need exists for that drug, and there are no other drugs currently available without prior authorization that meet that need.

(u) It is the intent of the Legislature in enacting subdivisions (k) to (t), inclusive, that the department and manufacturers shall cooperate and make every effort to resolve rebate payment disputes within 90 days of notification by the manufacturer to the department of a dispute in the calculation of rebate payments.

O

ASSEMBLY BILL No. 1960

Introduced by Assembly Members Pavley and Frommer
(Coauthors: Assembly Members Chu, and Ridley-Thomas)

February 12, 2004

An act to add Article 8 (commencing with Section 4130) to Chapter 9 of Division 2 of the Business and Professions Code, relating to pharmacy benefits management.

LEGISLATIVE COUNSEL'S DIGEST

AB 1960, as introduced, Pavley. Pharmacy benefits management.

Existing law, the Pharmacy Law, creates the California State Board of Pharmacy and makes it responsible for the regulation and licensure of persons engaged in pharmacy practices relating to the furnishing of dangerous drugs, as defined. Under existing law, a violation of the provisions of the Pharmacy Law is a crime.

This bill would define the term "pharmacy benefits management" as negotiating the purchase of dangerous drugs on behalf of specified entities and administering or managing the prescription drug benefit programs of those entities. The bill would also define the term "pharmacy benefits manager" as an entity that performs pharmacy benefits management. The bill would impose on that entity a fiduciary duty to the person employing or contracting with the entity.

Because the bill would specify an additional requirement under the Pharmacy Law, a violation of which would be a crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state.

Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Article 8 (commencing with Section 4130) is
2 added to Chapter 9 of Division 2 of the Business and Professions
3 Code, to read:
4
5 Article 8. Pharmacy Benefits Management
6
7 4130. "Pharmacy benefits management" means negotiating
8 the purchase of dangerous drugs on behalf of an entity that
9 provides health care services, including a health care service plan
10 or a health insurer, or an entity that purchases those services and
11 administering or managing the prescription drug benefit program
12 provided or purchased by those entities. The administration or
13 management of a prescription drug benefit program includes all of
14 the following:
15 (a) Providing mail pharmacy services.
16 (b) Claims processing, managing a retail network, and paying
17 claims to a pharmacy for dangerous drugs dispensed to an enrollee
18 or insured.
19 (c) Rebate contracting and administering the rebates.
20 (d) Therapeutic intervention and generic substitution
21 programs.
22 (e) Disease management programs.
23 4131. A "pharmacy benefits manager" means an entity that
24 performs pharmacy benefits management and includes a person or
25 entity acting for a pharmacy benefits manager in a contractual or
26 employment relationship in the performance of pharmacy benefits
27 management.
28 4132. A pharmacy benefits manager owes a fiduciary duty to
29 the person who contracts with, or employs, the pharmacy benefits
30 manager.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

CORRECTIONS

Heading — Authors.

O

SENATE BILL No. 1144

Introduced by Senator Burton

January 22, 2004

An act to amend Sections 14977.1 and 14981 of the Government Code, relating to public contracts.

LEGISLATIVE COUNSEL'S DIGEST

SB 1144, as introduced, Burton. Public contracts: prescription drugs.

Existing law authorizes the Department of General Services to enter into contracts on a bid or negotiated basis with manufacturers and suppliers of single source or multisource drugs, and authorizes the department to obtain from them discounts, rebates, or refunds as permissible under federal law. Existing law also requires the department, on or before February 1, 2005, to submit a report containing specified information to certain committees of the Legislature regarding the purchase of prescription drugs for government agencies.

This bill would provide that the manufacturers and suppliers of single source or multisource drugs with whom the department is authorized to contract shall include Canadian sources. The bill would also require the report to include estimated costs and savings attributable to the purchase of prescription pharmaceuticals from Canadian sources.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. It is the intent of the Legislature that in enacting
2 this act to authorize the Department of General Services to achieve

the greatest savings for the state and participating government entities through the negotiation of contracts for the purchase of prescription drugs with prescription drug manufacturers, wholesalers, and suppliers.

SEC. 2. Section 14977.1 of the Government Code is amended to read:

14977.1. (a) Notwithstanding any other provision of law, the Department of General Services may enter into exclusive or nonexclusive contracts on a bid or negotiated basis with manufacturers and suppliers of single source or multisource drugs. *These manufacturers and suppliers shall include, but are not limited to, Canadian sources.* The department may obtain from those manufacturers and suppliers, discounts, rebates, or refunds based on quantities purchased insofar as permissible under federal law. Contracts entered into pursuant to this chapter may include price discounts, rebates, refunds, or other strategies aimed at managing escalating prescription drug prices.

(b) Contracts under this chapter shall be exempt from Chapter 2 (commencing with Section 10290) of Part 2 of Division 2 of the Public Contract Code.

SEC. 3. Section 14981 of the Government Code is amended to read:

14981. On or before February 1, 2005, the department shall submit a report to the appropriate policy and fiscal committees of the Legislature on activities that have been or will be undertaken pursuant to this chapter. The report shall include, but not be limited to, all of the following:

(a) The number and a description of contracts entered into with manufacturers and suppliers of drugs pursuant to Section 14977.1, including any discounts, rebates, or refunds obtained.

(b) The number and a description of entities that elect to participate in the coordinated purchasing program pursuant to Section 14977.5.

(c) Other options and strategies that have been or will be implemented pursuant to Sections 14978 and 14980.

(d) Estimated costs and savings attributable to activities that have been or will be undertaken pursuant to this chapter,

1 *including, but not limited to, the purchase of prescription*
2 *pharmaceuticals from Canadian sources.*

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SENATE BILL No. 1149

Introduced by Senator Ortiz

January 26, 2004

An act to add Section 4001.2 to the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 1149, as introduced, Ortiz. Dangerous drugs: foreign suppliers.

Existing law, the Pharmacy Law, establishes the California State Board of Pharmacy and makes it responsible for licensing and regulating pharmacy practices, including the furnishing of dangerous drugs, as defined.

This bill would require the board to collect and publish information concerning suppliers of dangerous drugs that are located and operating outside of the United States that have violated safe shipment, handling, and processing standards.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. The Legislature finds all of the following:
2 (a) Increasing numbers of Californians are purchasing
3 prescription medications from foreign countries, and are
4 purchasing them in many cases through an Internet Web site.
5 (b) Despite this, California consumers currently have few ways
6 of determining the legitimacy of outlets and suppliers of
7 prescription medications in foreign countries, particularly those
8 offering their products through an Internet Web site.

(c) Because of the lack of identification of unsafe suppliers of prescription medications, seniors and other consumers in California are at risk of harm from the shipment of expired, contaminated, outdated, or counterfeit prescription medications.

(d) There is a need to provide consumers with information about fraudulent and unsafe suppliers or outlets of prescription medications whose practices may potentially harm consumers and to assist consumers in making informed choices for obtaining prescription medications for their health care needs.

SEC. 2. Section 4001.2 is added to the Business and Professions Code, to read:

4001.2. (a) The board shall collect and publish information concerning suppliers of dangerous drugs that are located and operating outside of the United States that have been found to have violated recognized standards for the safe shipment, handling, and processing of dangerous drugs.

(b) In carrying out this section, the board may rely on information made available by regulatory and law enforcement bodies, including, but not limited to, the federal Food and Drug Administration, the United States Customs Service, prescription drug regulatory bodies of foreign countries, the Attorney General, the United States Department of Justice, the boards of pharmacy of other states, and the National Association of Boards of Pharmacy.

(c) The board is not required to conduct surveillance activities or its own investigations in order to carry out the requirements of this section, but is authorized to engage in those activities to the extent its resources permit.

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AGENDA ITEM B

State of California **Department of Consumer Affairs**

Memorandum

To: **Enforcement Committee** **Date: March 8, 2004**

From: **Patricia F. Harris**
Executive Officer
Board of Pharmacy

Subject: **Update on the Implementation of Legislation Regarding Wholesalers**

As a recommendation from the Enforcement Committee, the Board of Pharmacy acted at the January board meeting to sponsor legislation to strengthen the regulation of wholesale facilities. Senator Figueroa agreed to author the legislation and introduced SB 1307. In its current format, the bill only contains the licensing provisions that the board approved last October and will be amended to include the additional provisions, which are:

- Pedigrees for all drugs beginning January 1, 2007.
- Prohibition against the wholesaling of prescription drugs by pharmacies
- A $100,000 bond to secure payment of administrative fines and penalties.
- Fines on a per occurrence basis for specified violations (e.g., sale of counterfeit drugs, sale of outdated drugs, failure to preserve records, etc.).
- Definition of "closed pharmacy" as one only serving a distinct patient population and prohibits the owners of a closed pharmacy from owning a wholesale facility.

In addition, Assembly Member Negrete McCloud has introduced AB 2682, which would require the board to adopt regulations governing the wholesale distribution in California consistent with the federal regulations and would require all out-of-state wholesalers selling or distributing prescription drugs into California to be licensed.

Major Policy Initiatives

Proposal to Strengthen the Regulation of Wholesalers to Protect the Integrity of California's Prescription Drug Distribution System

Issue Background

The Food, Drug and Cosmetic Act (FDCA) was passed by Congress to ensure public confidence in our drug distribution system and to require that drugs are both safe and effective. The FDCA requires the Food and Drug Administration (FDA) to regulate drug manufacturers and to approve drugs for sale. This federal law also requires state governments to regulate the drug distribution system by licensing and regulating drug wholesalers. California law assigns this responsibility to the Board of Pharmacy (board). There are approximately 600 wholesalers licensed by the board.

Three large wholesalers account for about 90% of the wholesale drug market (McKesson, AmerisourceBergen, Cardinal Health). These wholesalers comprise the "primary" wholesale market and are distinguished from other wholesalers by their size and status as "authorized distributors" of individual drug manufacturers.

In the simplest situation, a manufacturer sells drugs directly to one of the major wholesalers who then sell the drugs to a hospital or pharmacy. Unfortunately, this simple distribution pattern is not the norm. Typically, there is more than one wholesaler who receives the drugs before they reach the pharmacy. These transactions include transfers between separate facilities owned by major wholesalers and transfers between the major wholesalers and the large drug store chains that have their own wholesale facilities in the company distribution system.

The distribution system is further complicated by the practice of "repackaging." Unlike European countries and Canada, most drugs in the United States are not packaged in a "unit of use" sizes by the drug manufacturers. Instead, many drugs are sold by the manufacturers in large bulk containers and then are repackaged into smaller containers for resale to the pharmacy.

The "normal" distribution channel for drugs is not the straightforward three step (manufacturer to wholesaler to pharmacy) pattern that one intuitively expects.

The distribution system is complicated yet again by the existence of a "secondary" wholesale market. "Secondary" wholesalers are smaller companies (regional down to small family owned companies) that focus their business on selling drugs to other wholesalers and serving smaller niche clients that are not routinely served by the major wholesalers (individual practitioners, small clinics, rural locations, etc.). Secondary wholesalers provide benefits to consumers in a number of ways, including:

1) Purchasing drugs products at discount when a manufacturer or wholesaler offers a reduced price for legitimate reasons.
2) Serving low volume or unusual customers (e.g., selling unusual products used by special populations, smaller physician practices, etc.).
3) Supplying drugs where temporary shortages occur due to unexpected increase in demand or other supply chain disruption.
4) Supplying drugs to remote and hard to serve areas.

Drugs routinely move between both primary and secondary wholesalers and from pharmacies to secondary wholesalers as well. These intermediate steps pose that the greatest opportunities for compromising the integrity of the drug distribution system. The primary threat to system integrity is the introduction of counterfeit products. Counterfeit drugs are most likely to be introduced into a distribution system that involves multiple wholesalers because drugs are largely untraceable unless they are only handled by a major wholesaler who purchases directly from the manufacturer. Without being able to trace a drug back, there is no assurance to the consumer that the drug has been stored and handled appropriately to preserve its potency and safety.

Drug Diversion

In California, one of the primary methods for diverting drugs from legitimate distribution channels is through "closed" pharmacies. These pharmacies fill prescriptions for specific patient populations (commonly skilled nursing and board and care facilities) but do not fill prescriptions for the general population. These pharmacies obtain significantly lower drug prices from manufacturers under "bid contract pricing" for these special populations. These pricing contracts require that the drugs be provided only for the specified patient population. In many diversion cases, the pharmacy does not use these drugs to fill prescriptions for their patients, but instead "diverts" these drugs by selling them to a secondary wholesaler for a profit. These secondary wholesalers can then profitably resell the drugs at below market prices. In over 70% of the board's drug diversion investigations, the non-pharmacist owner(s) of the offending pharmacy also owned a drug wholesaler through which the discounted drugs were sold. Diverted drugs enter a national market and frequently travel circuitous routes leaving California, traveling across country, perhaps several times, going as far as Puerto Rico, before reaching their final destination, which may be back to California. This movement of drugs through numerous facilities with minimal or non-existent records makes the drugs untraceable.

This activity poses a real threat to consumers by creating a vibrant market in sharply discounted drugs of unknown origin. Such a market is an ideal point of entry for counterfeit and adulterated drugs. Currently, there is no method to be sure that the drugs being sold are legitimate. There have been cases where legitimate major wholesalers have unknowingly purchased counterfeit drugs in the secondary market and resold them to pharmacies.

The board has been developing rules designed to strengthen the integrity of the drug distribution system. This effort has been spurred on by the 91 drug diversion investigations completed by the board. These investigations involved the diversion of large quantities of drugs from California pharmacies. These investigations identified the loss of over 100 million doses. In one case, a group of 8 pharmacies were ordering between $400,000 and $4,000,000 worth of drugs per month. However, these pharmacies had no employees and no drug stock when they were inspected by the board. The drugs were routed through a wholesaler also under the control of the pharmacy owner and then disappeared.

Today counterfeit drugs are an unfortunate reality for the California consumer. It is known that some of the Lipitor subject of a recent nationwide recall because it was counterfeit, was repackaged by a California repackager that also held a California wholesale and pharmacy permit.

Pedigrees

The absence of a "pedigree" is a principal challenge in ensuring the integrity of the drug distribution system. A pedigree is a history of all the transactions related to an individual bottle of drugs. Currently, there is no effective means to verify the source and the history of any given

bottle of drugs sitting on a pharmacy shelf. A pedigree requirement would enable wholesalers, pharmacies and regulators to track the movement of any drug from the manufacturer to its final destination. Such a system will make the introduction of counterfeits much more challenging. The wholesale industry (primarily through the efforts of the Healthcare Distribution Management Association or HDMA) is developing an electronic pedigree system that will using radio frequency tags that will make the collection and communication of this information efficient and accurate.

Board of Pharmacy Proposal

The board is sponsoring a legislative proposal in 2004 to substantially decrease the threat of counterfeit drugs and drug diversion. Much of this proposal draws from recently adopted laws in Nevada and Florida and from recent draft revisions to model laws published by the National Association of Boards of Pharmacy. The proposal is designed to address challenges presented by the existing distribution system for prescription drugs. These challenges were also highlighted in a series of 5 articles in *The Washington Post* that appeared last October. The principal elements of the proposed legislation are described as follows:

- Requires licensure of all wholesalers that ship drugs into California.
- Requires pedigrees for all drugs beginning January 1, 2007.
- Generally prohibits the wholesaling of prescription drugs by pharmacies
- Requires wholesalers to obtain a $100,000 bond to secure payment of administrative fines and penalties.
- Permits the board to issue fines on a per occurrence basis for specified violations (e.g., sale of counterfeit drugs, sale of outdated drugs, failure to preserve records, etc.).
- Defines "closed pharmacy" as one only serving a distinct patient population and prohibits the owners of a closed pharmacy from owning a wholesale facility.

SENATE BILL No. 1307

Introduced by Senator Figueroa

February 17, 2004

An act to amend Sections 4160, 4163, 4164, 4165, and 4166 of, to repeal Section 4162 of, and to repeal and add Section 4161 of, the Business and Professions Code, relating to drugs.

LEGISLATIVE COUNSEL'S DIGEST

SB 1307, as introduced, Figueroa. Wholesalers and manufacturers of dangerous drugs and devices.

Existing law, the Pharmacy Law, provides for the licensing and regulation of wholesalers of dangerous drugs or dangerous devices by the Pharmacy Board. Existing law makes the violation of Pharmacy Law a crime. Existing law prohibits a person acting as a wholesaler of dangerous drugs or devices without a license.

This bill would require dangerous drugs or dangerous devices to be acquired from a person authorized by law to possess or furnish them. The bill would exempt a licensed drug manufacturer that only ship drugs of its own manufacture from the provisions governing wholesalers, except for the prohibition against furnishing dangerous drugs or devices to an unauthorized person.

Existing law imposes certain licensing and registration requirements on out-of-state manufacturers and wholesalers doing business in this state, and on their principals.

This bill would delete these requirements. The bill would make a wholesaler located outside the state that ships, mails, or delivers dangerous drugs or dangerous devices into this state a nonresident wholesaler. The bill would require a nonresident wholesaler to meet specified licensing and reporting requirements, to comply with lawful directions and requests for information, to maintain a record in readily

retrievable form of dangerous drugs or dangerous devices sold, traded, or transferred to persons in this state, and to designate an exemptee-in-charge to be responsible for compliance with laws governing wholesalers.

Existing law requires any manufacturer who sells or transfers a dangerous drug or dangerous device into this state or who receives a dangerous drug or dangerous device from a person in this state to, upon request, furnish an authorized officer of the law with all records or other documentation of that sale or transfer. Existing law makes a manufacturer who fails or refuses to comply with that request subject to a citation and a fine, an order of abatement, or both.

This bill would instead apply these provisions to a wholesaler licensed by the board. The bill would delete the provision that makes the failure or refusal to comply with a request subject to a citation and a fine, an order of abatement, or both.

Because a violation of the requirements and prohibitions created by this bill would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 4160 of the Business and Professions
2 Code is amended to read:
3 4160. (a) No person shall act as a wholesaler of any
4 dangerous drug or dangerous device unless he or she has obtained
5 a license from the board. ~~Upon~~
6 *(b) Upon* approval by the board and the payment of the required
7 fee, the board shall issue a license to the applicant.
8 ~~(b) No selling or distribution outlet, located in this state, of any~~
9 ~~out-of-state manufacturer, that has not obtained a license from the~~
10 ~~board, that sells or distributes only the dangerous drugs or the~~
11 ~~dangerous devices of that manufacturer, shall sell or distribute any~~

~~dangerous drug or dangerous device in this state without obtaining a wholesaler's license from the board.~~

(c) A separate license shall be required for each place of business owned or operated by a wholesaler. Each license shall be renewed annually and shall not be transferable.

(d) The board shall not issue or renew a wholesaler license until the wholesaler designates an exemptee-in-charge and notifies the board in writing of the identity and license number of that exemptee. The exemptee-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. Each wholesaler shall designate, and notify the board of, a new exemptee-in-charge within 30 days of the date that the prior exemptee-in-charge ceases to be exemptee-in-charge. A pharmacist may be designated as the exemptee-in-charge.

(e) For purposes of this section, "exemptee-in-charge" means a person granted a certificate of exemption pursuant to Section 4053, or a registered pharmacist, who is the supervisor or manager of the facility.

(f) A drug manufacturer licensed pursuant to Section 111615 of the Health and Safety Code that only ships drugs of its own manufacture is exempt from this section.

SEC. 2. Section 4161 of the Business and Professions Code is repealed.

~~4161. (a) No person shall act as an out-of-state manufacturer or wholesaler of dangerous drugs or dangerous devices doing business in this state who has not obtained an out-of-state dangerous drug or dangerous device distributor's license from the board. Persons not located in this state selling or distributing dangerous drugs or dangerous devices in this state only through a licensed wholesaler are not required to be licensed as an out-of-state manufacturer or wholesaler or have an out-of-state dangerous drug or dangerous device distributor's license.~~

~~(b) Applications for an out-of-state dangerous drug or dangerous device distributor's license shall be made on a form furnished by the board. The board may require any information as the board deems is reasonably necessary to carry out the purposes of the section. The license shall be renewed annually.~~

~~(c) The Legislature, by enacting this section, does not intend a license issued to any out-of-state manufacturer or wholesaler pursuant to this section to change or affect the tax liability imposed~~

~~by Chapter 3 (commencing with Section 23501) of Part 11 of Division 2 of the Revenue and Taxation Code on any out-of-state manufacturer or wholesaler.~~

~~(d) The Legislature, by enacting this section, does not intend a license issued to any out-of-state manufacturer or wholesaler pursuant to this section to serve as any evidence that the out-of-state manufacturer or wholesaler is doing business within this state.~~

SEC. 3. Section 4161 is added to the Business and Professions Code, to read:

4161. (a) A wholesaler located outside this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state shall be considered a nonresident wholesaler for purposes of this chapter.

(b) A nonresident wholesaler shall be licensed by the board.

(c) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler. Each license shall be renewed annually and shall not be transferable.

(d) A nonresident wholesaler shall disclose to the board the names, locations, and titles of each of the following:

(1) Its agent for service of process in this state.

(2) Principal corporate officers, as specified by the board.

(3) General partners, as specified by the board.

(e) A report containing the information in subdivision (d) shall be made within 30 days of any change of office.

(f) A nonresident wholesaler shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board pursuant to this section.

(g) A nonresident wholesaler shall maintain a record of dangerous drugs and dangerous devices sold, traded, or transferred to persons in this state, and the record shall be in a readily retrievable form.

(h) A nonresident wholesaler shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler license in this state shall include a license verification from the licensing authority in the applicant's state of residence.

(i) The board shall not issue or renew a nonresident wholesaler license until the nonresident wholesaler designates an exemptee-in-charge and notifies the board in writing of the identity and license number of the exemptee-in-charge.

(j) The exemptee-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers. Each nonresident wholesaler shall designate and notify the board of a new exemptee-in-charge within 30 days of the date that the prior exemptee-in-charge ceases to be the exemptee-in-charge.

(k) For purposes of this section, "exemptee-in-charge" means a person granted a certificate of exemption pursuant to Section 4053 or a registered pharmacist who is the supervisor or manager of the facility.

(*l*) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

SEC. 4. Section 4162 of the Business and Professions Code is repealed.

~~4162. (a) No person acting as principal or agent for any out-of-state manufacturer, wholesaler, or pharmacy who has not obtained a license from the board, and who sells or distributes dangerous drugs or dangerous devices in this state that are not obtained through a wholesaler who has obtained a license, pursuant to this chapter, or that are not obtained through a selling or distribution outlet of an out-of-state manufacturer that is licensed as a wholesaler, pursuant to this chapter, shall conduct the business of selling or distributing dangerous drugs or dangerous devices within this state without registering with the board.~~

~~(b) Registration of persons under this section shall be made on a form furnished by the board. The board may require any information as the board deems reasonably necessary to carry out the purposes of this section, including, but not limited to, the name and address of the registrant and the name and address of the manufacturer whose dangerous drugs or dangerous devices he or she is selling or distributing.~~

~~(c) The board may deny, revoke, or suspend the person's registration for any violation of this chapter or for any violation of Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code. The board may deny, revoke, or suspend the person's registration if the manufacturer, whose dangerous~~

~~drugs or dangerous devices he or she is selling or distributing, violates any provision of this chapter or any provision of Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code. The registration shall be renewed annually.~~

SEC. 5. Section 4163 of the Business and Professions Code is amended to read:

4163. *(a)* No manufacturer or wholesaler shall furnish any dangerous drugs or dangerous devices to any unauthorized persons.

(b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices.

SEC. 6. Section 4164 of the Business and Professions Code is amended to read:

4164. All wholesalers licensed by the board ~~and all manufacturers who~~ *that* distribute controlled substances, dangerous drugs, or dangerous devices within or into this state shall report to the board all sales of dangerous drugs and controlled substances that are subject to abuse, as determined by the board.

SEC. 7. Section 4165 of the Business and Professions Code is amended to read:

4165. ~~(a)~~ Any ~~manufacturer~~ *wholesaler licensed by the board* who sells or transfers any dangerous drug or dangerous device into this state or who receives, by sale or otherwise, any dangerous drug or dangerous device from any person in this state shall, on request, furnish an authorized officer of the law with all records or other documentation of that sale or transfer.

~~(b) Any manufacturer who fails within a reasonable time, or refuses, to comply with subdivision (a), shall be subject to citation and a fine, an order of abatement, or both, pursuant to Section 125.9 and any regulations adopted by the board, in addition to any other remedy provided by law.~~

SEC. 8. Section 4166 of the Business and Professions Code is amended to read:

4166. (a) Any wholesaler ~~or other distributor~~ that uses the services of any carrier, including, but not limited to, the United States Postal Service or any common carrier, shall be liable for the security and integrity of any dangerous drugs or dangerous devices through that carrier until the drugs or devices are delivered to the transferee at its board-licensed premises.

(b) Nothing in this section is intended to affect the liability of a wholesaler ~~or other distributor~~ for dangerous drugs or dangerous devices after their delivery to the transferee.

SEC. 9. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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Board of Pharmacy
Draft Revisions to Wholesaler Statutes

Add Section 4021.5 to the Business and Professions Code, to read:

4021.5. "Closed Door Pharmacy" means a pharmacy that only serves patients in a skilled nursing or intermediate care facility. A closed door pharmacy may not dispense dangerous drugs or dangerous devices to a person not receiving care in either a skilled nursing or intermediate care facility.

Add Section 4034 to the Business and Professions Code, to read:

4034. "Pedigree" means a document containing information that records each distribution of any given dangerous drug or dangerous device, from sale by a manufacturer, through acquisition and sale by any wholesaler, until final sale to a pharmacy or other person administering or dispensing the drug. A pedigree shall include:

(a) quantity
(b) dosage form and strength
(c) lot numbers
(d) the name, address, signature, and California license number of each licensee possessing the dangerous drugs or dangerous devices
(e) shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug or dangerous device,
(f) a certification that the recipient has authenticated the pedigree papers.
(g) the name, address, California license number, and telephone number for each wholesaler involved in the chain of custody for the dangerous drug or dangerous device.

Add Section 4126.5 to the Business and Professions Code, to read:

4126.5. (a) A pharmacy may only furnish dangerous drugs or dangerous devices as follows:

(1) To the wholesaler or manufacturer from whom the dangerous drugs or dangerous devices were acquired.
(2) To a licensed reverse distributor.
(3) To another pharmacy or wholesaler to alleviate temporary shortages that could result in the denial of healthcare.
(4) To a patient or a provider of health care, other than a pharmacy, authorized to purchase dangerous drugs and dangerous devices.

Amend Section 4160 of the Business and Professions Code, to read:

4160. (a) No person shall act as a wholesaler of any dangerous drug or dangerous device unless he or she has obtained a license from the board.
(b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.
~~(b) No selling or distribution outlet, located in this state, of any out-of-state manufacturer, that has not obtained a license from the board, that sells or distributes only the dangerous drugs or the dangerous devices of that manufacturer, shall sell or distribute any dangerous drug or dangerous device in this state without obtaining a wholesaler's license from the board.~~
(c) A separate license shall be required for each place of business owned or operated by a wholesaler. Each license shall be renewed annually and shall not be transferable.

(d) The board shall not issue or renew a wholesaler license until the wholesaler designates an exemptee-in-charge and notifies the board in writing of the identity and license number of that exemptee. The exemptee-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. Each wholesaler shall designate, and notify the board of, a new exemptee-in-charge within 30 days of the date that the prior exemptee-in-charge ceases to be exemptee-in-charge. A pharmacist may be designated as the exemptee-in-charge.
(e) For purposes of this section, "exemptee-in-charge" means a person granted a certificate of exemption pursuant to Section 4053, or a registered pharmacist, who is the supervisor or manager of the facility.
(f) Notwithstanding any other provision of law, the board shall not issue or renew a wholesaler license if the applicant is a person beneficially interested, as defined in Section 4201, in a closed door pharmacy.
(g) An applicant for a wholesaler license or an applicant for the renewal of a wholesaler license must submit a bond of $100,000 payable to the Pharmacy Board Contingent Fund. A separate bond shall be provided for each location. The purpose of the bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3. The board may make a claim against the bond if the licensee fails to pay a fine within 30 days of the issuance of the fine or costs become final.
(h) A drug manufacturer licensed pursuant to Section 111615 of the Health and Safety Code that only ships drugs of its own manufacture is exempt from this section.

Repeal Section 4161 of the Business and Professions Code:

~~4161. (a) No person shall act as an out-of-state manufacturer or wholesaler of dangerous drugs or dangerous devices doing business in this state who has not obtained an out-of-state dangerous drug or dangerous device distributor's license from the board. Persons not located in this state selling or distributing dangerous drugs or dangerous devices in this state only through a licensed wholesaler are not required to be licensed as an out-of-state manufacturer or wholesaler or have an out-of-state dangerous drug or dangerous device distributor's license.~~
~~(b) Applications for an out-of-state dangerous drug or dangerous device distributor's license shall be made on a form furnished by the board. The board may require any information as the board deems is reasonably necessary to carry out the purposes of the section. The license shall be renewed annually.~~
~~(c) The Legislature, by enacting this section, does not intend a license issued to any out-of-state manufacturer or wholesaler pursuant to this section to change or affect the tax liability imposed by Chapter 3 (commencing with Section 23501) of Part 11 of Division 2 of the Revenue and Taxation Code on any out-of-state manufacturer or wholesaler.~~
~~(d) The Legislature, by enacting this section, does not intend a license issued to any out-of-state manufacturer or wholesaler pursuant to this section to serve as any evidence that the out-of-state manufacturer or wholesaler is doing business within this state.~~

Add Section 4161 to the Business and Professions Code, to read:

4161. (a) No person shall act as a non-resident wholesaler without possessing a nonresident wholesaler license from the board.
(b) Any person located outside this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state shall be considered a nonresident wholesaler.
(c) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler. Each license shall be renewed annually and shall not be transferable.
(d) An applicant for a nonresident wholesaler license shall disclose to the board the location, names, and titles of:

(1) Its agent for service of process in this state.
(2) Principal corporate officers as specified by the board.
(3) General partners as specified by the board.
(e) A report containing the information required in subdivision (d) shall be made to the board within 30 days of any change of office, corporate officer, or partner.
(f) All nonresident wholesalers shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is located as well as with all requests for information made by the board.
(g) All nonresident wholesalers shall maintain records of dangerous drugs or dangerous devices sold, traded or transferred to persons in this state so that the records are in a readily retrievable form.
(h) The nonresident wholesaler shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the wholesaler in compliance with the laws of the state in which it is a resident. Applications for a nonresident wholesaler license shall include a license verification from the licensing authority in the applicant's state of residence.
(i) The board shall not issue or renew a nonresident wholesaler license until an exemptee-in-charge is designated and the board is notified in writing of the identity and license number of that exemptee.
(j) The exemptee-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers. Each nonresident wholesaler shall designate, and notify the board of, a new exemptee-in-charge within 30 days of the date that the prior exemptee-in-charge ceases to be exemptee-in-charge.
(k) For purposes of this section, "exemptee-in-charge" means a person granted a certificate of exemption pursuant to Section 4053 or a registered pharmacist who is the supervisor or manager of the facility.
(l) The registration fee shall be the fee specified in subdivision (f) of Section 4400.
(m) An applicant for a nonresident wholesaler license or an applicant for the renewal of a nonresident wholesaler license must submit a bond of $100,000 payable to the Pharmacy Board Contingent Fund. A separate bond shall be provided for each location. The purpose of the bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3. The board may make a claim against the bond if the licensee fails to pay a fine within 30 days of the issuance of the fine or costs become final.

Repeal Section 4162 of the Business and Professions Code:

~~4162. (a) No person acting as principal or agent for any out-of-state manufacturer, wholesaler, or pharmacy who has not obtained a license from the board, and who sells or distributes dangerous drugs or dangerous devices in this state that are not obtained through a wholesaler who has obtained a license, pursuant to this chapter, or that are not obtained through a selling or distribution outlet of an out-of-state manufacturer that is licensed as a wholesaler, pursuant to this chapter, shall conduct the business of selling or distributing dangerous drugs or dangerous devices within this state without registering with the board.~~
~~(b) Registration of persons under this section shall be made on a form furnished by the board. The board may require any information as the board deems reasonably necessary to carry out the purposes of this section, including, but not limited to, the name and address of the registrant and the name and address of the manufacturer whose dangerous drugs or dangerous devices he or she is selling or distributing.~~
~~(c) The board may deny, revoke, or suspend the person's registration for any violation of this chapter or for any violation of Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code. The board may deny, revoke, or suspend the person's registration if the manufacturer, whose dangerous drugs or dangerous devices he or she is selling or distributing,~~

~~violates any provision of this chapter or any provision of Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code. The registration shall be renewed annually.~~

Amend Section 4163 of the Business and Professions Code, to read:

4163. (a) Dangerous drugs or dangerous devices shall only be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices.
(b) No manufacturer or wholesaler shall furnish any dangerous drugs or dangerous devices to any unauthorized persons.
(c) On and after January 1, 2006, no wholesaler or pharmacy shall sell, trade, or transfer a dangerous drug or dangerous device without providing a pedigree.
(d) On and after January 1, 2006, no wholesaler or pharmacy shall acquire a dangerous drug or dangerous device without receiving a pedigree.

Amend Section 4165 of the Business and Professions Code, to read:

4165. (a) Any manufacturer or wholesaler licensed by the board who sells or transfers any dangerous drug or dangerous device into this state or who receives, by sale or otherwise, any dangerous drug or dangerous device from any person in this state shall, on request, furnish an authorized officer of the law with all records or other documentation of that sale or transfer.
(b) Any manufacturer who fails within a reasonable time, or refuses, to comply with subdivision (a), shall be subject to citation and a fine, an order of abatement, or both, pursuant to Section 125.9 and any regulations adopted by the board, in addition to any other remedy provided by law.

Amend Section 4166 of the Business and Professions Code, to read:

4166. (a) Any wholesaler ~~or other distributor~~ that uses the services of any carrier, including, but not limited to, the United States Postal Service or any common carrier, shall be liable for the security and integrity of any dangerous drugs or dangerous devices through that carrier until the drugs or devices are delivered to the transferee at its board-licensed premises.
(b) Nothing in this section is intended to affect the liability of a wholesaler or other distributor for dangerous drugs or dangerous devices after their delivery to the transferee.

Add section 4168 to the Business and Professions Code, to read:

4168. A county or municipality shall not issue a business license for any establishment that requires a wholesaler license unless the establishment possesses a current wholesaler license issued by the board.

Add Section 4169 to the Business and Professions Code, to read:

4169. (a) Notwithstanding any other provision of law, a the following violations may subject, in addition to any other remedy provided by law, the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board:

(1) Violation of Section 4126.5.
(2) Violation of Section 4163.
(3) Purchase, trade, sell or transfer drugs or devices that are adulterated as defined in Health and Safety Code Division 104, Part 5, Chapter 6, Article 2.

(4) Purchase, trade, sell or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

(b) For notifications made on and after January 1, 2005, the Franchise Tax Board, upon notification by the board of a final judgment in an action brought under this section, shall subtract the amount of the fine from any tax refunds or lottery winnings due to the person who is a defendant in the action using the offset authority under Section 12419.5 of the Government Code, as delegated by the Controller, and the processes as established by the Franchise Tax Board for this purpose. That amount shall be forwarded to the board for deposit in the Pharmacy Board Contingent Fund.

ASSEMBLY BILL No. 2682

Introduced by Assembly Member Negrete McLeod

February 20, 2004

An act to amend Section 4161 of, and to add Sections 4160.1 and 4161.1 to, the Business and Professions Code, relating to pharmacy, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

AB 2682, as introduced, Negrete McLeod. Pharmacy: out-of-state wholesalers.

The Pharmacy Act provides for licensing and regulation of wholesalers of prescription drugs and devices by the California State Board of Pharmacy. Existing law requires out-of-state wholesalers of prescription drugs and devices selling or distributing those drugs and devices in this state to obtain an out-of-state dangerous drugs and devices distributor's license from the board, unless they sell or distribute only through a licensed wholesaler. A violation of the Pharmacy Act is a crime.

This bill would require the board to adopt regulations governing any person engaged in the wholesale distribution of a dangerous drug or device and who is not the manufacturer or an authorized distributor of record of the dangerous drug or device, which regulations shall implement the same federal regulatory provisions applicable to wholesalers engaged in interstate commerce. The bill would require all out-of-state wholesalers selling or distributing prescription drugs or devices in this state to obtain an out-of-state dangerous drugs and devices distributor's license from the board. Because this bill would require additional persons to pay existing fees to the board to obtain a

license, it would result in the deposit of additional revenue in the Pharmacy Board Contingent Fund, a continuously appropriated fund, and would thereby make an appropriation.

Because a violation of the Pharmacy Act is a crime, the bill would impose a state-mandated local program by revising the definition of a crime.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: yes. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 4160.1 is added to the Business and
2 Professions Code, to read:
3 4160.1. Notwithstanding any other provision of law, the
4 board shall adopt regulations governing any person engaged in the
5 wholesale distribution of a dangerous drug or device and who is
6 not the manufacturer or an authorized distributor of record of the
7 dangerous drug or device. The regulations adopted by the board
8 shall implement the same regulatory provisions applicable to
9 wholesalers engaged in interstate commerce pursuant to the
10 federal Prescription Drug Marketing Act (21 U.S.C. Sec. 353(e))
11 and the regulations adopted pursuant thereto, as contained in 21
12 C.F.R. Part 205, as amended from time to time.
13 SEC. 2. Section 4161 of the Business and Professions Code
14 is amended to read:
15 4161. (a) No person shall act as an out-of-state manufacturer
16 ~~or wholesaler~~ of dangerous drugs or dangerous devices doing
17 business in this state who has not obtained an out-of-state
18 dangerous drug or dangerous device distributor's license from the
19 board. ~~Persons~~ *Manufacturers* not located in this state selling or
20 distributing dangerous drugs or dangerous devices in this state
21 only through a licensed wholesaler are not required to be licensed
22 as an out-of-state manufacturer ~~or wholesaler~~ or have an

out-of-state dangerous drug or dangerous device distributor's license.

(b) Applications for an out-of-state dangerous drug or dangerous device distributor's license *pursuant to this section* shall be made on a form furnished by the board. The board may require any information as the board deems is reasonably necessary to carry out the purposes of the section. The license shall be renewed annually.

(c) The Legislature, by enacting this section, does not intend a license issued to any out-of-state manufacturer ~~or wholesaler~~ pursuant to this section to change or affect the tax liability imposed by Chapter 3 (commencing with Section 23501) of Part 11 of Division 2 of the Revenue and Taxation Code on any out-of-state manufacturer ~~or wholesaler~~.

(d) The Legislature, by enacting this section, does not intend a license issued to any out-of-state manufacturer ~~or wholesaler~~ pursuant to this section to serve as any evidence that the out-of-state manufacturer or wholesaler is doing business within this state.

SEC. 3. Section 4161.1 is added to the Business and Professions Code, to read:

4161.1. (a) No person shall act as an out-of-state wholesaler of dangerous drugs or dangerous devices doing business in this state who has not obtained an out-of-state dangerous drug or dangerous device distributor's license from the board. This provision shall apply to any person, other than the manufacturer of a dangerous drug or device, who is engaged in the wholesale distribution of dangerous drugs or devices and who may be licensed by the state pursuant to 21 U.S.C. Sec. 353(e)(2)(A) and regulations adopted by the United States Secretary of Health and Human Services pursuant to 21 C.F.R. Part 205, and shall apply regardless of whether the out-of-state wholesaler maintains an office or any other facility in this state.

(b) Applications for an out-of-state dangerous drug or dangerous device distributor's license pursuant to this section shall be made on a form furnished by the board. The board may require any information as the board deems is reasonably necessary to carry out the purposes of the section. The license shall be renewed annually.

(c) The Legislature, by enacting this section, does not intend a license issued to any out-of-state wholesaler pursuant to this section to change or affect the tax liability imposed by Chapter 3 (commencing with Section 23501) of Part 11 of Division 2 of the Revenue and Taxation Code on any out-of-state wholesaler.

(d) The Legislature, by enacting this section, does not intend a license issued to any out-of-state wholesaler pursuant to this section to serve as any evidence that the out-of-state wholesaler is doing business within this state.

SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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No warning system for fake medicines

One man hit a wall of silence when he learned he had received a bogus prescription.

By Peter Jaret
Special to The Times

February 9, 2004

For months, Rick Roberts had been injecting himself with the drug Serostim to reverse the debilitating weight loss associated with HIV. Then suddenly the injections began to sting.

"I was a little worried about infection," said the 40-year-old communications professor at UC San Francisco. So when he went to pick up another batch of the vials, he mentioned the side effect to his pharmacist. "Very nonchalantly he said, 'Oh, you ought to check. You may have gotten some of the fake stuff.' I said, 'What? Fake stuff?' I couldn't believe my ears."

Roberts found that he had in fact received bogus Serostim. Alerts had gone out to pharmacies, but there is no system in place for notifying individual patients, even though the drug is used by a relatively small number of people nationwide.

"If there's something wrong with the transmission of your car, the manufacturer is required to recall every car," said Roberts. "But no one is required to notify patients when a drug they've been taking turns out to be counterfeit."

When he tried to find out what the vials contained, he hit a wall of silence.

"The drug manufacturer couldn't tell me. The FDA wouldn't tell me. I talked to my doctor, and even she couldn't find out. I had nightmares that the vial contained something deadly, or that it had been contaminated with hepatitis C."

It took him several months to learn that the counterfeit version he had taken contained a female fertility drug.

Roberts has stopped taking Serostim. But like many patients with HIV, he still takes a lot of medicine — 30 pills a day.

"Before I never questioned whether they were genuine," he said. "Now I never know. A lot of the drugs targeted by counterfeiters are the ones used by HIV and cancer patients, because they're so expensive. Whenever I pick up new medications, I study the boxes and the vials before I leave the pharmacy counter. I'd like to think I'll notice if something is different. But I can never be sure."

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Fake drugs, real threat

Seizures of counterfeit prescription medicines and arrests are on the rise, causing new concerns. The FDA insists the country's supply of pharmaceuticals is safe.

By Peter Jaret
Special to The Times

February 9, 2004

Doctors couldn't explain why the medicine they were giving Tim Fagan wasn't working. The 16-year-old boy had been rushed to New York University Medical Center for an emergency liver transplant last February.

Fagan was given daily injections of a drug called Epogen to treat severe anemia. But his red blood cell count wasn't improving. And there was another mystery: Shortly after each injection, the young patient was getting severe and painful muscle cramps.

After two months of treatments, Fagan and his family received shocking news. The version of the drug he had received was counterfeit. The small vials contained only one-twentieth the amount of active ingredient the label indicated.

"This wasn't a drug someone bought on the street," but rather from a major national pharmacy chain, said Eric Turkewitz, a New York lawyer who is representing the Fagans in a pending lawsuit. "The family never thought for a moment that it was anything but real."

It wasn't. Somewhere between the drug's manufacture and its arrival at the pharmacy, counterfeiters had taken low-dose vials and relabeled them as high-dose versions. The weaker drug sells for $22 a bottle. The high-strength bottle fetches $445. An estimated 110,000 bogus bottles reached the market without raising suspicions. Investigators say the counterfeit scheme may have netted criminals a staggering $48 million.

The Food and Drug Administration insists that the country's pharmaceutical drug supply is the safest in the world. But a growing number of counterfeit drug seizures and arrests has raised new worries that consumers can't be so sure the pharmaceutical medicines they buy are safe or even genuine.

• In the spring of 2001, a pharmacist in Sunnyvale, Calif., noticed something amiss with bottles of the growth hormone Neupogen, which is prescribed to HIV and cancer patients. The bottles were fake, filled not with medicine but with salt water.

• In February 2002, Robert Courtney, a Kansas City, Mo., pharmacist pleaded guilty to diluting cancer drugs. He later admitted that he had diluted at least 98,000 prescriptions since 1992.

• In 2002, bottles of Zyprexa, a drug used to treat schizophrenia, were found to be bogus. The pills inside had been replaced with aspirin.

• In May 2003, the FDA issued an alert that nearly 200,000 counterfeit bottles of Lipitor, widely used to control cholesterol, had made their way onto the market, representing "a potentially significant risk to consumers."

• Last month, a 31-year-old Glendale man was indicted by a federal grand jury in Los Angeles on charges of trafficking in tens of thousands of counterfeit Viagra tablets. The fake Viagra was manufactured in China to look like the real thing.

Officials acknowledge that they don't know the full extent of the problem of counterfeit drugs. But many believe that it poses a growing danger. "There are two things that worry us," said William Hubbard, senior associate commissioner for policy and planning at the FDA. "The number of criminal cases has tripled in the past few years. That tells us that counterfeiters are more active. And we're seeing more organized elements getting involved."

The experience in Florida, where a grand jury report last year helped spotlight the issue, offers a case in point. From 1985 to 2001, only five counterfeit drug cases were investigated in the state, contrasted with 10 such cases in the last two years. The FDA also has seen a surge in investigations of counterfeit drugs, from an average of about five a year in the 1990s to 20 last year. And those numbers almost certainly underestimate the extent of drug counterfeiting.

"The business of selling counterfeited and adulterated drugs is booming," Robert Penezic, former assistant statewide prosecutor in Florida, told a congressional subcommittee in June. "In the case of buying and reselling adulterated prescription drugs, the money that can be made from illegal activity is staggering."

The U.S. pharmaceutical industry generates $180 billion a year. Some genetically engineered drugs now go for several thousand dollars for a single vial, making counterfeiting a potentially attractive business. Consider Serostim, a drug often taken by AIDS patients to prevent debilitating weight loss. A 12-week course of Serostim costs about $21,000, which explains why counterfeiters have targeted the drug.

What's more, counterfeiting pills, labels and packages is relatively simple. Most of the tools needed to produce authentic-looking but counterfeit drugs and packaging can be bought on the Internet. In December, federal officials in Florida charged Julio Cesar Cruz, 41, of Miami and others with selling more than $1 million worth of counterfeit Lipitor. The government's affidavit cites testimony from a material witness who confirmed a scheme "to manufacture counterfeit Lipitor, including the purchase of punches, dies, plates and other items they used to create and manufacture a tablet that appeared to be genuine Lipitor." A federal grand jury is expected to review the charges filed in the complaint and determine if the evidence warrants an indictment.

"With each new case we are shocked at the level of sophistication in the reproduction of labels, seals and containers," Gregg Jones, an expert with Florida's Bureau of Statewide Pharmaceutical Services, testified at a hearing in June before the oversight and investigations subcommittee of the House Energy and Commerce Committee in Washington, D.C.

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Reaching the pharmacy

One avenue for the entry of counterfeit drugs is imported medications brought in by bargain hunters looking for cheaper versions on the Internet or in Mexico, Canada and other countries. To underscore the danger, the FDA and customs officials in July conducted a three-day search of suspicious international parcels passing through mail facilities in San Francisco and Carson. A hundred packages were examined at each location each day, netting investigators a total of 1,153 imported drugs.

Among the medications, 88% were in violation of U.S. drug laws. Some were unapproved versions of drugs sold in the U.S. Others were drugs that have been withdrawn from the market for safety reasons. Many were packaged without the original labeling and instructions for use. Some were sent in baggies, in envelopes or wrapped in tissue paper. "Although many drugs obtained from foreign sources purport, and may even appear to be, the same as FDA-approved medications," the agency warned, "these examinations showed that many are of unknown quality and origin."

The evidence from recent seizures of counterfeit drugs suggests that the more serious problem comes from inside U.S. borders. The problem: a lax drug distribution system that provides ample opportunities for counterfeit drugs to enter the supply chain.

Most Americans assume that medicines go directly from drug makers to pharmacy shelves. In reality, prescription drugs often pass through a tangle of wholesalers, ranging in size from major national companies to tiny operations that may consist of nothing more than a small office. An estimated 7,000 drug wholesalers do business in the U.S. Although most are legitimate, some are nothing more than fronts used to illicitly divert drugs and resell them at a profit. As many as 55 of the 1,458 licensed wholesalers in Florida are suspected of selling counterfeit drugs or medicines that were obtained fraudulently, according to a 2003 report released by the state. As drugs change hands — in some cases, half a dozen times between drug maker and patient — counterfeiters have plenty of opportunities to introduce bogus medicines.

In the case of the bogus Lipitor, for example, investigators traced drug shipments through a string of wholesalers, including two companies in Puerto Rico and one in Gatlinburg, Tenn. It's not known at which point the fake pills were introduced.

On Jan. 16, the Nevada Board of Pharmacy revoked the licenses of two such wholesalers, Dutchess Business Services Inc. and Legend Pharmaceuticals Inc. The companies were found guilty of falsifying their records, as well as buying and selling drugs illegally obtained from companies not authorized to possess them — including bogus versions of Serostim, the drug used by AIDS patients.

"The number of small secondary-drug wholesalers who typically sell drugs among themselves is increasing," Jones testified before the congressional subcommittee. "Many of the small secondary-drug wholesalers never handle products and only generate elaborate paper trails, their existence only serving to hide the original source of the drugs."

Investigators say some diverted drugs are sold to unscrupulous wholesalers by Medicaid patients who go from doctor to doctor, getting prescriptions, filling them at a discount, and then selling them to street wholesalers. HIV clinics, which often get deeply discounted drugs, may buy more than they need and sell the remainder to wholesalers at a profit.

The same tactic is used by so-called "closed-door pharmacies," or companies that buy drugs in bulk quantities from manufacturers, usually at a discount, and sell them to hospitals, nursing homes and other

healthcare facilities. These companies may buy more than they need and sell the rest to wholesalers.

Drugs can also be diverted through garden-variety thievery. In one instance, a trailer truck containing $3 million worth of drugs was hijacked and diverted to wholesalers.

Even when outright counterfeiting doesn't occur, diverted drugs may be stored improperly and lose their potency or effectiveness. In one case, Florida investigators traced more than $1 million worth of a drug sold by a small Fort Lauderdale, Fla., wholesaler to one of the largest wholesalers in the nation over a six-month period. All of it had come from the streets of Miami, where two unlicensed street brokers stored the temperature-sensitive injectable drug, which requires refrigeration, for hours at a time in the trunks of their cars.

As Cesar Arias, the investigator in that case, told congressional investigators, "No patient in the nation can know with 100% certainty that the drugs they are getting are what they are purported to be — or if they are, that they have not been in the trunk of someone's car, or sitting in a hot warehouse or a crack house in South Florida."

The shadowy wholesale market for prescription drugs, shot through with corruption, has provided ample opportunities for counterfeiters to introduce bogus versions of drugs. "In each instance in which counterfeits or diverted drugs have made their way into the mainstream distribution system, it has been through a dishonest wholesaler," Arias testified. "Once the drugs enter the system, they can end up in any pharmacy in the nation."

Another weak link in the system may be less dramatic but just as troubling. Many drugs are sold by pharmaceutical manufacturers in bulk. Along the way from drug maker to consumer, pills and other medicines are repackaged into the familiar 30-, 60- or 90-dose bottles that most people buy.

In the U.S., there are companies whose only business is repackaging drugs. (In Europe, by contrast, drugs are packaged by manufacturers in the amounts typically used in treatment, eliminating this step.) The FDA acknowledges that repackaging offers one more opportunity for counterfeiters to introduce bogus pills.

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Stricter laws, vigilance

The interim report of the FDA's task force on drug counterfeiting, released in October, describes a variety of strategies that could close loopholes in the country's distribution system and increase security in other ways. The final report is expected in the next few weeks. One recommendation under consideration is strengthening so-called "pedigree" laws, which require drug wholesalers to document in writing each time a drug changes hands. Meantime, several states, including Florida and Nevada, have instituted their own strict pedigree-paper regulations, which proponents say will help quash counterfeiting. Critics worry that the documents themselves could be counterfeited.

Another approach under review is the use of anti-counterfeiting technologies, such as tamper-proof packaging, special watermarks and holograms that are difficult for criminals to duplicate.

The FDA is evaluating the use of radio-frequency identification (RFID), which uses tiny electromagnetic devices placed in drug packaging to track products as they move through the distribution system.

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Seeking solutions

Critics say these high-tech fixes are nothing more than Band-Aids. "The FDA's meeting in October was like a trade show, with manufacturers hawking all kinds of anti-counterfeiting technologies," says Turkewitz, Tim Fagan's lawyer. "But technology isn't the solution. With thousands and thousands of wholesalers moving drugs, it's a little like trying to put burglar alarms on a house with 10,000 windows. Someone's going to find a way in."

The only permanent solution, he says, is eliminating the gray market of drug wholesalers, which allows counterfeiting and illegal diversion to thrive.

At least one drug maker agrees. When counterfeit versions of its drug Serostim began to appear, the Swiss-based drug maker Serono decided to abandon the existing distribution system entirely. The firm eliminated all wholesalers and authorized just 100 pharmacies around the country to handle the drug.

Using printed bar codes, it now tracks every box from the time it leaves the manufacturing plant to the time it reaches a patient.

Despite the increasing number of reports of counterfeit drugs, the FDA says that the nation's drugs are safe.

Yet even the agency recommends vigilance on the part of drug purchasers, advising online consumers to purchase only from state-licensed pharmacies or from Internet sites that have the Verified Internet Pharmacy Practice Sites seal. It also cautions consumers to check for "changes in packaging, labeling, color, taste or shape of a pill."

Vigilance could help. In several instances, authorities have been alerted to bogus pills by consumers who noticed a strange taste or something suspicious about the packaging.

But many of the counterfeit drugs that have been seized are so genuine-looking that even pharmacists are fooled.

When Florida undercover investigators bought 100 boxes of Epogen, the drug used by Fagan, "the investigators had no clue, even after examining the boxes, that the injectable products were counterfeit," according to congressional testimony. The boxes were identified as bogus only after being carefully examined by the FDA and the drug's manufacturer.

Fagan still has to take Epogen to fight anemia, according to his lawyer. After what he's been through, he scrupulously examines every box and vial label.

"But if a clever counterfeiter wants to pass off bogus vials as the real thing," says Turkewitz, "there's almost no way anyone would be able to tell the difference."

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NABP and FDA Partner on Combating Counterfeit Drugs

2/18/04

The National Association of Boards of Pharmacy® (NABP®) participated in a press conference in Washington, DC, on Wednesday, February 18, 2004, convened by United States Department of Health and Human Services Secretary Tommy G. Thompson and Food and Drug Administration (FDA) Commissioner Mark McClellan to discuss strategies for ensuring that the US medication distribution system remains the most secure and protected in the world. The press conference concluded months of discussions and investigations by FDA to address challenges to maintaining the integrity of the US medication distribution system.

In a report released at the press conference, FDA recognized the important role states play in regulating wholesale drug distributors and supported NABP's efforts, and corresponding efforts of the states, to adopt and implement NABP's revised Model Rules for the Licensure of Wholesale Distributors, which is a part of the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy.

NABP convened a task force in October 2003 to revise its Model Rules on the Licensure of Wholesale Distributors. The Task Force proposed major revisions to the Model Rules through an intense effort that focused on regulatory actions in Florida and Nevada and involved all aspects of the wholesale distribution industry, as well as federal and state regulators. The NABP Executive Committee approved the revised Model Rules, which include more stringent licensing requirements – background checks and extensive disclosure, reduced incentives to counterfeit through more complete pedigrees and accountability of responsible personnel, inspections and due diligence procedures prior to transactions, development and maintenance of a national list of susceptible products, electronic pedigree requirements by 2007, implementation of trace and track technologies, random and for cause authentications of pedigrees, and tougher administrative and criminal penalties for violations.

NABP believes that only through a partnership of federal and state regulators and the wholesale drug industry can the US distribution system retain its integrity and continue to serve as the standard by which other medication distribution systems in the world are compared. NABP President Donna S. Wall commented that, "Today marks another historic achievement for the FDA and NABP and a demonstration that a federal-state partnership works and provides the most effective means for combating counterfeit drugs. Patients in the US can rest assured that the medication distribution system remains safe and will improve as new technologies are implemented."

NABP will be releasing its revised Model Rules on Friday, February 20, and will work with its member state boards and the wholesale drug industry to adopt and implement the revised Model Rules. Adoption of the Model Rules by the state boards of pharmacy will provide national and uniform regulation for the licensure of wholesale distributors. NABP will also be releasing a List of Susceptible Drug Products next week to avoid

the need for individual states to develop their own list of drug products that are susceptible to counterfeiting.

The NABP Wholesale Distributor Clearinghouse, created to accredit wholesale distributors for the states, will be operational by mid 2004. NABP President Wall addressed the role of NABP and its Wholesale Distributor Clearinghouse, asking states "to adopt the Model Rules and recognize the NABP Wholesale Distributors Clearinghouse as the means for establishing uniform licensure requirements that will prevent illicit operators from locating in a state with the less stringent requirements. States supporting NABP and its Wholesale Distributor Clearinghouse will create uniform standards and regulation for a safe and productive environment for the wholesale distribution of medications."

If you have any questions or comments, please e-mail **custserv@nabp.net**.

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AGENDA ITEM C

State of California | Department of Consumer Affairs

Memorandum

To: **Enforcement Committee** **Date: March 8, 2004**

From: **Patricia F. Harris**
Executive Officer
Board of Pharmacy

Subject: **Conversion of Paper Invoices to Electronic Billing by Wholesalers for Drug Purchases**

The Board of Pharmacy received a letter from Ralphs seeking clarification regarding the conversion from paper invoices for drug purchases to electronic billing. Ralphs is seeking clarification of its record-keeping duties because its wholesale supplier(s) has/have decided to convert from paper to electronic invoices. Specifically, Ralphs wants to know if it is permitted to no longer keep paper copies of invoices on file but have such invoices electronically available. If so, it wants to know how long Ralphs must keep electronic invoices available for inspection.

The request for clarification from Ralphs was forwarded to board's counsel for review and comment. The following discussion incorporates the advice received from counsel. The pertinent statutes relating to this issue are Business and Professions Code sections 4081, 4105, and 4333. Section 4081 requires that records of "manufacture and of sale, acquisition, or disposition of dangerous drugs and of dangerous devices" be available for inspection at all times, and that such records be "preserved for at least three years from the date of making." (Bus. & Prof. Code § 4081, subd. (a)). Section 4105 similarly requires that records of acquisition or disposition be readily available on licensed premises, and that such records be preserved for three years from the date of making. (Bus. & Prof. Code § 4105, subds. (a), (c)). The same records-availability and three-year preservation period is applied to filled prescriptions by Section 4333. (Bus. & Prof. Code § 4333, subd. (a)).

The only one of these statutes, which mentions electronic record keeping, is Section 4105. Subdivision (d) thereof allows that records may be kept electronically so long as a hard copy and an electronic copy can always be produced. (Bus. & Prof. Code § 4105, subd. (d)).

Subdivision (d) of Section 4105 does not specify a different time period of preservation from the three-year period generally required by subdivision (c). Electronic records must therefore also be preserved and retrievable for a period of three years. Indeed, subdivision (d) begins "[a]ny records that are maintained electronically . . .," clearly indicating it is limited by the definition of "records" given by subdivisions (a) through (c). In other words, a licensed premises has the option of keeping its "records or other documentation of the acquisition or disposition of

dangerous drugs and dangerous devices" (Bus. & Prof. Code § 4105, subd. (a)) in electronic rather than paper form. If it chooses to do so, however, those records must also be "retained on the licensed premises for a period of three years from the date of making." (Bus. & Prof. Code § 4105, subd. (c)). This means that the electronic records must be retained on the licensed premises for a period of three years from the date of making, "so that the pharmacist-in-charge, [or] the pharmacist on duty if the pharmacist-in-charge is not on duty," shall "at all times during which the licenses premises are open for business be able to produce a hard copy and electronic copy of all records of acquisition or disposition . . ." (Bus. & Prof. Code § 4105 (d)).

In summary, board counsel has advised that pharmacies can keep records electronically rather than on paper so long as those records are retained on site and immediately available for inspection for a period of three years, and can at all times be produced in both hard copy and electronic form by an on-duty pharmacist.

RALPHS GROCERY COMPANY
P.O. BOX 54143, LOS ANGELES, CALIFORNIA 90054

RECEIVED BY CALIF. BOARD OF PHARMACY
2004 JAN 26 PM 1:25

REBECCA CUPP
DIRECTOR OF PHARMACY

(310) 884-4722
FAX (310) 884-2908

January 20, 2004

Ms. Patricia Harris
Executive Director
California State Board of Pharmacy
400 R. Street, Suite 4070
Sacramento, CA 95814

Dear Ms. Harris:

I am writing to obtain clarification from the Board on a matter that recently surfaced which affects Ralphs and Food 4 Less Pharmacies. Our primary wholesaler, on a national level, is converting from providing paper invoices for drug purchases, which we have historically kept on file in each pharmacy, to electronic billing. Specifically, with their new system, they will make all invoices accessible for viewing and printing electronically, if so desired, but will send no hard copies. Therefore, we are requesting clarification as to whether it is acceptable, from the Board's standpoint, if we no longer keep paper copies of invoices on file in the pharmacy but, rather, have such invoices readily available electronically should a copy be needed. In addition, if electronic invoicing is authorized, please specify the minimum length of time the Board requires these electronic records to be retrievable.

We appreciate your timely clarification of this matter that would apply to both controlled and non-controlled legend drugs. If you should have any questions regarding this matter, please feel free to contact me at (310) 884-4722.

Sincerely,

Rebecca Cupp

Rebecca Cupp
Director of Pharmacy

cc: Enforcement Committee, California State Board of Pharmacy
John Kronin, California Pharmacists Association

AGENDA ITEM D

State of California **Department of Consumer Affairs**

Memorandum

To: **Enforcement Committee** **Date: March 9, 2004**

From: **Patricia F. Harris**
Executive Officer
Board of Pharmacy

Subject: **Use of Robotic Technology in Hospital and Institutional Pharmacies**

The Board of Pharmacy received a request from McKesson to review and approve its proposal for a ROBOT-Rx protocol in hospital and institutional pharmacies that would not require licensed pharmacists to check every medication dispensed by the ROBOT-Rx. McKesson proposes a protocol whereby a pharmacist would check 100% of the medications packaged by the ROBOT-Rx on a daily basis, and would for a period of no less than 30 days after the ROBOT-Rx is first deployed check 100% of doses dispensed by the ROBOT-Rx, but would then taper off to sampling only 5-10% of these doses.

It is McKesson's opinion that the Board of Pharmacy statutes and regulations are silent on the duty of a licensed pharmacist (or pharmacy) to verify dispensed medications from an automated dispenser and McKesson concludes that "it is within the discretion of the Board of Pharmacy staff to approve a protocol that would apply specifically to ROBOT-Rx technology" in inpatient settings. It is McKesson's desire that the Board approve this proposal, for reduced error checking of dispensed medications, over a requirement that all dispensed doses be checked.

I asked board counsel to review this request. The following discussion incorporates the advice received from counsel. McKesson is correct that the Pharmacy Law is largely silent on the question of automated delivery systems, aside from those provisions relating to placement of such a system in nonprofit or free clinics contained in Business and Professions Code section 4186. There is no statute or regulation specifically requiring that a pharmacist check every dose dispensed by an automated drug delivery system located in an inpatient setting, nor is there any statute or regulation absolving the dispensing pharmacist of this responsibility. From this, it is McKesson's conclusion that there is a "gap" in the law that can be filled by its proposed "protocol."

However, it our counsel's opinion that in the absence of any statutes or regulations exempting a dispensing pharmacist or pharmacy working with an automated drug delivery system from the general requirements pertaining to prescription accuracy and propriety of drug delivery, it is the responsibility of the dispensing pharmacist and pharmacy to ensure 100% accuracy of dispensing. A licensee can only furnish dangerous drugs pursuant to valid prescription (Bus. & Prof. Code § 4059), except under specified circumstances (e.g., emergency,

Bus. & Prof. Code § 4062), and can only furnish those dangerous drugs as prescribed (except where substitutions and generics are permitted, Bus. & Prof. Code §§ 4052.5, 4073).

The Pharmacy Law is violated, *inter alia*, where a prescription is dispensed in an insufficiently or inaccurately labeled container (Bus. & Prof. Code §§ 4076, 4077, 4078), where the drug dispensed deviates from requirements of a prescription (Cal. Code Regs., tit. 16, § 1716), or where the prescription dispensed contains significant errors, omissions, irregularities, uncertainties, ambiguities, or alterations (Cal. Code Regs., tit. 16, § 1761). These provisions apply to all dispensing, regardless of setting.

Thus, the licensees' duties to ensure accuracy of prescription dispensing do not depend on a particular method of delivery. Whether dangerous drugs are dispensed by hand or by use of the ROBOT-Rx or some other automated delivery system, the licensees' duties do not change.

In other words, the same duty to seek 100% accuracy of dispensing that applies to hand-dispensing by way of California Code of Regulations, title 16, section 1716 (and section 1761) applies just as strongly to dispensing performed by an automated delivery system. If McKesson is correct that ROBOT-Rx is a more accurate method of filling prescriptions, taking out human error that might otherwise occur, it should increase the likelihood of compliance. The use of an automated system like ROBOT-Rx does not, however, give licensees a "free pass" for a certain number of dispensing errors that may nonetheless occur.

This interpretation is reinforced by Business and Professions Code section 4186, which says drugs may "be removed from the automated drug delivery system only upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient's profile" and "provided to the patient [only] by a health professional licensed pursuant to this division." (Bus. & Prof. Code § 4186, subd. (b)). Section 4186 also requires policies and procedures to "ensure safety, *accuracy*, accountability, [and] security . . ." of dispensing (Bus. & Prof. Code § 4186, subd. (a) [emphasis added]), says that the *stocking* of automated systems may only be performed by a licensed pharmacist (Bus. & Prof. Code § 4186, subd. (c)), and requires that drugs dispensed comply with all statutory labeling requirements (Bus. & Prof. Code § 4186, subd. (g)).

Section 4186 therefore clearly indicates that the placement of an automated drug delivery system in a nonprofit or free clinic does not eliminate or vitiate the responsibility of the licensee overseeing that system for the accuracy of the drugs dispensed. That licensee must still comply with all of the statutes and regulations requiring accurate dispensing, and Section 4186 reinforces this responsibility by requiring policies and procedures to ensure accuracy as well as the direct involvement of the licensee in the stocking of the machine and the dispensing of drugs. The licensee still remains responsible for any errors that result from this delivery system. There is no exemption stated by Section 4186 to the general duties of licensees in this regard. Moreover, there is no reason to think that such an exemption would apply to an automated delivery system placed in any other setting, including the inpatient setting.

Therefore, counsel has advised that any licensee that chooses to implement a reduced-error-checking protocol like that suggested by McKesson is assuming the risk of any errors that result. Even if such errors are less likely with the ROBOT-Rx system, the licensee is responsible for any errors that do occur. It may therefore be a risk for licensees to implement a protocol that

increases the chance that such error will occur, however minor, by eliminating human 100% double-checking that may, in at least some cases, catch and correct those few errors made by the machine(s). Any licensee implementing such a protocol will be subject to discipline for any errors that do occur (as would any licensee responsible for errors from any other delivery system). It is possible the severity of the violation may even be greater where the error could have been caught but for this protocol.

Counsel advises that there is at present no statutory or regulatory requirement that licensees check 100% of all prescriptions dispensed by an automated delivery system. While licensees may elect to save costs by reducing their level of error checking, they do so at their own risk and that of the patient's safety. If it is the desire of the board to require 100% error checking by a pharmacist, and not permit this election, then additional statutes or regulations are needed.

Counsel does not recommend that the board approve the protocol McKesson proposes. First, there is no authority for the board to approve a protocol and to do so, may constitute an impermissible underground regulation. Second, under current law, it is the decision of the individual licensees to determine the level of risk of error they are willing to assume, and the steps they take to reduce or eliminate that risk.

LIVINGSTON & MATTESICH

RECEIVED BY CALIF.
BOARD OF PHARMACY
2004 FEB 10 PM 4:52

JEFFREY LEACOX
ATTORNEY AT LAW

February 10, 2004

VIA HAND-DELIVERY
Patricia Harris
Executive Director
California State Board of Pharmacy
400 "R" Street, Suite 4070
Sacramento, California 95814

LIVINGSTON & MATTESICH
LAW CORPORATION
1201 K STREET, SUITE 1100
SACRAMENTO, CA 95814-3938
FACSIMILE: (916) 448-1709
E-MAIL: JLEACOX@LMLAW.NET
TELEPHONE: (916) 442-1111 EXT. 3012

Re: ***McKesson Automation, Inc.***

Dear Ms. Harris:

I am writing on behalf of McKesson Corporation, a California headquartered company, and its subsidiary McKesson Automation, Inc. I enclose a letter from Dr. Kevin Seip, Director of Professional Services with McKesson Automation, concerning McKesson's ROBOT-Rx technology and its use in California hospitals and institutional pharmacies.

In short, certain California hospitals or institutional pharmacies using McKesson's ROBOT-Rx technology believe that they are required to check every medication dispensed by the ROBOT-Rx. McKesson respectfully disagrees with this conclusion and is requesting that the California State Board of Pharmacy assist them in approving the ROBOT-Rx protocol as described in the enclosed letter.

We would appreciate your review of the enclosed letter and request an opportunity to meet with you in person to discuss this issue.

I look forward to speaking with you in the near future and appreciate your assistance with this matter.

Sincerely,

JEFFREY LEACOX
JL:sma
Enclosure
cc: Parke D. Terry (w/o encl.)
i:\00538-001\harris021004l-2.doc

McKesson Automation, Inc.
700 Waterfront Drive
Pittsburgh, PA 15222-4742

MCKESSON
Empowering Healthcare

February 7, 2004

Patricia Harris
Executive Director
California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento, CA 95814

Dear Ms. Harris,

It has come to our attention that certain California hospital or institutional pharmacies using McKesson's ROBOT-Rx technology believe they are required to check every medication dispensed by the ROBOT-Rx. In light of the applicable California laws and regulations, we respectfully disagree with this conclusion for the reasons specified below. We ask that the California State Board of Pharmacy assist us by approving the ROBOT-Rx protocol described in this letter, thereby enabling the hospital pharmacies to focus their professional time on such important discretionary functions as medication safety.

Background Information

The current process by which hospital pharmacies dispense medications is typically manual, labor intense and error prone. In the case of ongoing standing medication orders, a pharmacy technician reads a pick list generated by the pharmacy medication profiling system, selects the medication by dose and quantity, gathers all the medications for the indicated patient and then assembles the medication in a patient specific cassette drawer. Subsequently the Pharmacist must review the same pick list, check the contents of each drawer and verify that each medication selected by the technician is correct. This same process exists for new daily orders but is replicated much more frequently and in small quantities. The process for the dispensing of ongoing medication orders occurs for each patient (depending on hospital size 100-500 patients) each day. The process for new daily orders is conducted minute to minute on a continual basis. As a by-product of the dispensing process, the technician must manually restock any medication that is returned to the pharmacy, thus compounding the time, labor and potential error involved.

ROBOT-Rx Technology

ROBOT-Rx is a stationary robotic device that is located in the hospital pharmacy. Robot-Rx uses bar-code laser scanning technology to select and aggregate medications in a patient specific fashion in a hospital or institutional inpatient pharmacy setting. Each medication is packaged and contains a bar-coded label. This bar-code contains information that identifies the name of the medication, strength, lot number and expiration date.

McKesson Automation, Inc.
700 Waterfront Drive
Pittsburgh, PA 15222-4742

Linked to the Hospital Pharmacy Information system via a computerized interface, ROBOT-Rx uses a three axis robotic arm to select each of these bar-coded medications in a patient-by-patient manner. Robot-Rx will aggregate all the medications into patient specific envelopes or cassettes, as determined by the pharmacy. By utilizing bar-code scanning, Robot-Rx accurately identifies each medication in this process and eliminates the labor task associated with the process. As a result, ROBOT-Rx frees up the Pharmacists and Technicians formerly required to conduct the manual distribution process and allows for them to be utilized for patient centered clinical activities, while dramatically decreasing the potential for medication errors.

Robot-Rx bar-coded dispensing technology significantly improves dispensing accuracy and is superior and safer than the manual dispensing process. It is not uncommon to find documented human error rates between 4-6%. Many pharmacies have documented error rates of less than 1% with the use of Robot-Rx. Currently Robot-Rx is used in over 300 hospitals nationwide. Many states have officially recognized the improvement in care that Robot-Rx can provide and have provisions for its use.

Since Robot-Rx was introduced to the hospital industry in 1992 it has a proven acceptance record in the hospital pharmacy community. By decreasing medication errors, eliminating error prone manual tasks, freeing up pharmacists and technicians for patient clinical work, Robot-Rx improves hospital pharmacy efficiency and effectiveness. Given the continued need to improve patient care, decrease medication errors and make the best use of the limited pharmacist labor pool, Robot-Rx is a significant technological asset that should be embraced. We would be pleased to provide you with any additional information on the ROBOT-Rx operations and functions as you may request.

Proposed ROBOT-Rx Protocol

Though the accuracy of Robot-Rx is far superior to the current manual process in place at California hospital pharmacies, we encourage our customers to adopt a Quality Assurance program ("ROBOT-Rx Protocol"). This protocol provides the pharmacy and the State assurances that the technology is achieving the desired goals. We therefore respectfully request the support of the California State Board of Pharmacy in approving the following protocol for ROBOT-Rx in an inpatient pharmacy:

- **A licensed pharmacist will check 100% of the medications packaged for the ROBOT-Rx on a daily basis to ensure that the bar-coded packaged medications are labeled and packaged correctly prior to stocking.**

- **When ROBOT-Rx is first deployed, a licensed pharmacist will check 100% of the doses dispensed from ROBOT-Rx for a period of time (not less than 30**

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days) to ensure that the ROBOT-Rx is dispensing the correct drug and the correct strength with 100% accuracy.

- **Once the 100% accuracy target is validated, the pharmacy will institute a Quality Assurance Program. This program will consist of a daily random sample selection of 5 to 10% of all patient medications. All the medications in the sample will be checked to insure that ROBOT-Rx is meeting the accuracy requirements of 100%. The pharmacy will record the results of the sample check to provide documentation. If the sample, on any day, fails to meet the 100% accuracy target for the drug and strength dispensed the pharmacy would revert to a complete manual check of the ROBOT-Rx dispensed medications. This manual check will remain in place until the 100% accuracy target has been achieved for at least 24 hours and a root cause analysis is conducted and the source of error is remedied.**

California Pharmacy Law and Regulations Silent on the Use of Automated Drug Delivery Systems in an Inpatient Setting

We believe that the California Pharmacy Law (Business and Professions Code, Chapter 9, Division 2, Section 4000 et. seq.) and the California Pharmacy Regulations (Code of Regulations, Division 17, Title 16, Articles 2 (Pharmacies) and Article 12 (Ancillary Personnel)) are silent on a pharmacist's obligation to verify dispensed medications from an automated drug delivery system in an inpatient hospital/institutional setting. As a consequence, it is within the discretion of the Board of Pharmacy staff to approve a protocol that would apply specifically to ROBOT-Rx technology when used in those settings.

It is our view that the functions performed by ROBOT-Rx are **not** analogous to the functions performed by a pharmacy technician. Instead, ROBOT-Rx automatically performs functions as instructed by the licensed pharmacist and is merely one of many mechanical devices available in the industry to assist the pharmacist in the direct performance of his or her professional responsibilities. Because of the extreme accuracy of ROBOT-Rx technology, pharmacists using the device are far less likely to dispense an incorrect prescription.

Even if the Board takes the position that automated dispensing of drugs using ROBOT-Rx technology is analogous to the human functions performed by a pharmacy technician, we believe our suggested protocol would conform to existing law and regulations. In an inpatient pharmacy, "direct supervision" does not require the pharmacist to personally observe the technician's actions at all times or to initial each prescription filled by a technician. Id. at §4115(f). See also, CA BReg. § 1793.7(b). While the Regulations require that "any function performed by a pharmacy technician in connection with the dispensing of a prescription…must

be verified and documented in writing by a pharmacist" (Ca BReg. §1793.7(b)), it is unclear what level of verification is required. Id. In the case of ROBOT-Rx, implementing a tight quality control procedure in an environment of bar-coded laser scanning automation provides accuracy that is superior to the existing manual process and satisfies the pharmacist's responsibility for verification.

It is a well-known fact that human error in repetitive non-discretionary tasks is significantly greater than machine error. In addition, as described below, the Regulations that do address automated drug delivery systems do not require pharmacists to verify every prescription that is filled by an automated drug delivery system. Rather, they proscribe certain procedures similar to those we have incorporated into our proposal and grant the pharmacy discretion to determine the appropriate level of scrutiny.

Application of Current Regulations to Use of Automated Drug Delivery Systems

The Regulations address the use of automated drug delivery systems in a clinic or nursing home setting only. California Business and Professions Code, Chapter 9, Article 13, § 4186. Section 4186 states that a drug may be removed from the automated drug delivery system only upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. Section 4186 further states, "stocking of the automated drug delivery system shall be performed by a pharmacist."

While Section 4186 does not apply to hospital or in-patient settings, our suggested ROBOT-Rx protocol would nevertheless satisfy the two conditions the Legislature has previously established for use of automated drug delivery systems in clinics and nursing homes. The pharmacist will review 100% of the physician orders for each patient prior to dispensing the medication in the pharmacy and identify any risk of contraindications or adverse drug reactions. The pharmacist will check 100% of the doses packaged for ROBOT-Rx dispensing during the stocking process. After the pharmacist performs both of these functions, ROBOT-Rx uses extremely accurate bar-coded laser scanning technology to deliver the prescribed drug in the same pre-packaged dose to a pharmacy technician or nurse. Requiring the pharmacist to recheck pre-packaged drugs delivered by the ROBOT-Rx is equivalent requiring the pharmacist to repeat work already performed. If the pharmacist correctly entered the prescription and verified that the correct drug is contained in each package when stocked, ROBOT-Rx will accurately dispense the exact drugs prescribed for the patient.

Section 4186 also requires that the review of the drugs contained in the automated drug delivery system and the operation and maintenance of such system shall be the responsibility of the clinic or nursing facility and shall occur at least monthly. However, the Regulation does not require the pharmacist to check 100% of the dispensed medications.

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700 Waterfront Drive
Pittsburgh, PA 15222-4742

We believe our suggested protocol meets the intent of this Regulation. Our protocol requires the hospital to closely monitor the operation of the ROBOT-Rx, institute rigorous testing procedures to ensure the security and accountability of the system and to continuously inspect the use of the ROBOT-Rx. In fact, our protocol would require the pharmacist to review the operation of the system every day and to perform a check of 100% of the randomly selected patient's quality control group (5-10%) of total patients processed daily by the ROBOT-Rx.

Our suggested protocol is also consistent with several other regulations that appear to lessen a pharmacist's supervisory requirements in an inpatient setting (e.g. a pharmacist is not obligated to directly observe a pharmacy technician's actions in an inpatient setting. California Business and Professions Code, Article 7, § 4115(f)), presumably because a healthcare professional will be administering the medications. Since we believe the ROBOT-Rx protocol comports with the requirements of Section 4186 of the Pharmacy Law, we ask that you approve the protocol process to be used in an inpatient pharmacy. It is our belief that this will improve patient safety and allow pharmacists to focus more of their valuable time on direct clinical patient care.

Pharmacist's Role in Dispensing of Drugs

The Regulations require, among other things, that the pharmacist identifies, evaluates and interprets all prescriptions, supervises the packaging of drugs and checks the packaging procedure and product upon completion, and is responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients. California Code of Regulations, Division 17, Title 16 § 1717.

Our proposal meets the requirements set forth above. The proposal requires the pharmacist to review 100% of the physician orders for each patient prior to medications being dispensed by the pharmacy. This comports with the Regulation requirement that the pharmacist identify, evaluate and interpret all prescriptions. The pharmacist will also be required to check 100% of the doses packaged for ROBOT-Rx dispensing. This is consistent with the Regulation requirement that the pharmacist supervises the packaging of drugs and check the packaging procedure. Upon installation or in the event of a known quality control matter, the pharmacist checks 100% of the medications handled by ROBOT-Rx to ensure that no wrong drugs or wrong doses are selected. The pharmacist will develop and supervise a quality control procedure to ensure that the ROBOT-Rx device performs as specified. The pharmacist will check 100% of the randomly selected patients' quality control group. These proposals meet the Regulation requirement that the pharmacist check the product upon completion

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Pittsburgh, PA 15222-4742

McKESSON
Empowering Healthcare

Proposed ROBOT-Rx Protocol Meets Intent of Regulations

Not only do we believe that the proposed protocol for ROBOT-RX does not violate the Regulations, we also believe that it is consistent with the intent of the Pharmacy Law and Regulations, as well as recently enacted legislation (SB 1875, Chapter 816 of 2000), that seeks to eliminate or reduce medication-related errors in hospitals. The intent of these laws and regulations is to ensure consumer health and safety in the dispensation of drugs. The use of automated drug delivery technology will improve patient safety by eliminating the wrong drug and wrong dose medication errors associated with the manual picking process. The technology can also provide for better utilization of a pharmacist's time and allow for more patient specific clinical consultation. Specifically, the ROBOT-Rx will automate the non-discretionary drug distribution tasks in the medication use process thereby allowing the pharmacists and technicians to be redeployed into critical tasks to improve patient care. The roles of the pharmacist and technicians will be expanded into areas that can ensure safe medication practices such as clinical interventions, adverse drug reaction prevention and improved sterile product production processes. Given the accuracy of the ROBOT-Rx technology and the pharmacist's active role in monitoring such accuracy, a requirement that the pharmacist check every ROBOT-Rx dispensed medication will limit the pharmacist's ability to focus on the more important discretionary functions. We ask the Board to please consider our pharmacist check process proposal for the ROBOT-Rx technology in an inpatient setting and help us help California pharmacies improve medication safety.

Sincerely,

Kevin F. Seip, MS. R.Ph.
Director of Professional Services
McKesson Automation

AGENDA ITEM E

State of California **Department of Consumer Affairs**

Memorandum

To: **Enforcement Committee** **Date: March 9, 2004**

From: **Patricia F. Harris**
Executive Officer
Board of Pharmacy

Subject: **Public Disclosure Policy**

Attached is the board's revised public disclosure policy. The revisions are in italics and include "Letter of Admonishment" that was added this year through new legislation.

The board's "Record Retention Schedule" governs how long the board maintains its records. As long as the board maintains public records, they must be provided to the public upon request. Currently, the board's retains substantiated complaints such as citations for 5 years and disciplinary actions for 10.

When Business and Professions Code section 4315 was added to authorize the issuance of a letter of admonishment, it specifies that the pharmacy must keep the letter of admonishment for three years from the date of issuance. This three-year period is consistent with all other record keeping requirements required of board licensees.

When there is a public records request for a citation or letter of admonishment, only those documents are provided. A copy of the investigation report is not given.

At this time, staff is recommending that the "Record Retention Schedule" for substantiated complaints be changed to 3 years. Three years provides the board with sufficient complaint history to determine if disciplinary action is warranted. Moreover, 3 years is consistent with the record keeping requirements for licensees.

D R A F T ***(Changes in Italics)***

PUBLIC DISCLOSURE POLICY

Available Information Regarding Licensees

The following information regarding the license status and official action taken in connection with a licensee, if known, shall be disclosed to members of the public upon request.

Licensing Information:

- Licensee Name
- License Number
- Name of Licensed Facility Owner (including the corporation name and corporate officers) and the Pharmacist-in-Charge
- Address of Record
- Date Original License Issued
- ***License Expiration Date***
- Current License Status

Administrative Information and Actions - ***Issued within the last*** **five** ***(three) years***

- ***Letter of Admonishment***
- Citation

Discipline Information and Actions

- Referral for formal Disciplinary Action
- Accusation/***Petition to Revoke Probation***
- ***Board*** Decision
- Temporary Restraining Order, ***Automatic Suspension Order, Summary Suspension Order*** or Interim Suspension Order
- ***Penal Code 23 license restrictions***

This document provides an overview of available important information, not a limitation on documents otherwise available. The board observes and follows the Public Records Act.

Adopted October 24, 2002

Adopted:_____

AGENDA ITEM F

State of California | Department of Consumer Affairs

Memorandum

To: **Enforcement Committee** **Date: March 9, 2004**

From: **Patricia F. Harris**
Executive Officer
Board of Pharmacy

Subject: **Implementation of SB 151**

This is the same information that was provided at the last Enforcement Committee and Board meetings on the implementation of SB 151. The board's Web site has been updated with this same information and articles that will be appearing in the board's newsletter that should be available by the end of this month. To date, the board has received 5 security printer applications. This is an opportunity for licensees to seek clarification of the law.

Senate Bill 151 (Burton) repeals the triplicate prescription requirement for Schedule II controlled substance prescriptions and substantially revises California law regarding the prescribing of controlled substances generally. This memo will outline the changes contained in this legislation. Generally, this bill repeals the triplicate and replaces it with a tamper resistant prescription form that may be obtained from approved printers. This new form will be required for all controlled substance prescriptions after the phase-in period. The bill also will require pharmacies to report Schedule III controlled substance prescriptions to the CURES system.

EFFECTIVE JANUARY 1, 2005

- Triplicate prescription forms are no longer valid.
- All written controlled substance prescriptions (oral and fax orders for Schedules III-V are still permitted) shall be on the new controlled substance prescription forms.
- Pharmacies must report Schedule III controlled substance prescription information to the CURES system.
- Prescribers dispensing Schedule III controlled substances must report those prescriptions to the CURES system.
- The exemption for Schedule II prescriptions for the terminally ill remains in effect (H&S Code 11159.2)

IMPLEMENTATION PHASE I
January 1, 2004

- The Board of Pharmacy (board) and the Department of Justice (Department) may approve security printers to produce the new controlled substance prescription forms.

- California mail order pharmacies can apply the prescription requirements of the state in which the patient resides when filling schedule II prescriptions.

- Controlled substance prescriptions (Schedules II-V) are valid for six-months.

- Makes CURES permanent and requires all pharmacies to report Schedule II controlled substance prescriptions to the Department of Justice

- Prescribers only need to sign and date Schedule III-IV controlled substance prescriptions (consistent with current Schedule II prescription requirements)

- New controlled substance prescription forms may be acquired from approved security printers.

- Requires the new controlled substance prescription forms to have the following features:
  (1) Latent "void" protection so that if a prescription is scanned or photocopied, the word "void" shall appear in a pattern across the entire front of the prescription.
  (2) Watermark with the text "California Security Prescription" printed on the back of the prescription.
  (3) Chemical void protection that prevents alteration by chemical washing.
  (4) Feature printed in thermo-chromic ink (the ink changes color when exposed to heat).
  (5) Feature using micro printing (the text becomes a line if the prescription is copied or scanned).
  (6) Description of the security features included on each prescription form.
  (7) Quantity check off boxes printed on the form in the following quantities: 1-24, 25-49, 50-74, 75-100, 101-150, 151 and over.
  (8) Either of the following statements:
    (a) "Prescription is void if more than one controlled substance prescription is written per blank" or
    (b) Contain a space for the prescriber to specify the number of drugs prescribed on the prescription and a statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted."
  (9) The preprinted name, category of licensure, license number, and federal controlled substance registration number of the prescribing practitioner.
  (10) A check box indicating the prescriber's order not to substitute.
  (11) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.

IMPLEMENTATION PHASE II
July 1, 2004

- The Department of Justice no longer will produce or distribute triplicate prescription forms. However, prescribers can continue to use the triplicate prescription forms to prescribe Schedule II controlled substances.

- Prescribers may use the new controlled substance prescription forms for Schedule II controlled substance prescriptions.

- Oral and electronic orders for Schedule II controlled substance prescriptions for patients in skilled nursing facilities, intermediate care facilities, home health care programs, and hospice programs are permitted and must be reduced to a hard copy form of the pharmacy's design and signed by the pharmacist.

- Prescribers that dispense Schedule II controlled substances must report those prescriptions to the CURES system.

AGENDA ITEM G

State of California | Department of Consumer Affairs

Memorandum

To: **Enforcement Committee** **Date: March 9, 2004**

From: **Patricia F. Harris**
Executive Officer
Board of Pharmacy

Subject: Medication Shortages and Limited Distribution Practices of Manufacturers and the Impact on Public Health

Board and committee member Stan Goldenberg requested that this topic be discussed at the September Enforcement Committee meeting. His request was based on a Citation and Fine Committee's review of a consumer complaint regarding the inability of a pharmacy to fill the patient's prescription because the pharmacy didn't have the medication due to a manufacturer's shortage.

A patient had filed a complaint with the board against a pharmacy for not providing her with all the Enbrel that she was prescribed. The pharmacist only dispensed 4 kits instead of the 8. The pharmacist informed the patient that he was unable to fill her entire prescription due to a shortage of the medication. The patient was upset because she specifically had registered with the drug manufacturer to avoid such situations. The manufacturer assured her that they were sending the pharmacy her entire order. The patient felt that the pharmacy was giving her medication to other patients. In this specific case, the complaint was closed with no further action.

The committee discussed the issue and determined that these types of complaints should be handled on a case-by-case basis. If the pharmacist does not fill a prescription accordingly, then he/she is in violation of CCR, title 16, section 1716 (variation from a prescription). The board should not be involved in the contractual arrangement between the patient and the manufacturer.

It was noted that the National Association of Boards of Pharmacy (NABP) had appointed a task force to address this issue. The task force met on November 23, 2003, and attached is a copy of their report.

RECEIVED BY CALIF. BOARD OF PHARMACY
2004 FEB 17 AM 11:39

NABP 100 YEARS
1904 BUILDING A REGULATORY 2004
FOUNDATION FOR PATIENT SAFETY

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Charisse Johnson, Professional Affairs Manager

DATE: February 13, 2004

RE: Task Force on Limited Distribution and Shortage of Medications

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On November 20, 2003, NABP's 2003-2004 Task Force on Limited Distribution and Shortage of Medications met to examine how medication shortages and imposed limited distribution policies of manufacturers impact the availability of medications and the protection of the public health. The appointment of this task force came at the direction of the Executive Committee in response to Resolution 99-3-03, Task Force on Limited Distribution and Shortage of Medications, which was passed by the delegates during NABP's 99th Annual Meeting, May 3-7, 2003, in Philadelphia, PA. The resolution reads as follows:

RESOLUTION NO: 99-3-03

TITLE: Task Force on Limited Distribution and Shortage of Medications

Whereas, NABP recognizes the importance of all US citizens having access to medications; and

Whereas, access is sometimes limited by manufacturers through limited distribution policies; and

Whereas, limited access programs and policies can place patients at risk from beginning, continuing, or completing their medication therapy;

THEREFORE BE IT RESOLVED that the NABP Executive Committee in collaboration with the Food and Drug Administration (FDA) and the Pharmaceutical Research and Manufacturers of America (PhRMA) commission a task force to study the public health consequences of restricted access policies and programs.

National Association of Boards of Pharmacy

700 Busse Highway • Park Ridge, IL 60068 • Tel: 847/698-6227 • Fax: 847/698-0124
Web Site: www.nabp.net

For your reference, I have attached the final report of the Task Force on Limited Distribution and Shortage of Medications.

If you have any questions, please contact me via e-mail at cjohnson@nabp.net or by calling 847/698-2612.

Attachment: Report of the 2003-2004 Task Force on Limited Distribution and Shortage of Medications

cc: NABP Executive Committee
2003-2004 Task Force on Limited Distribution and Shortage of Medications
Carmen A. Catizone, Executive Director/Secretary
Mary A. Dickson, Associate Executive Director

Report of the Task Force on Limited Distribution and Shortage of Medications

Members Present:

Jennifer S. Nevins (WY), *Chair*; Timothy Armstrong (KY); James T. Carder (WY); Elwin D. Goo (HI); Sophie Heymann (NJ); Sheila L. Mitchell (TN); William T. Winsley (OH).

Others Present:

Oren M. Peacock, *Executive Committee Liaison*; Mary A. Dickson, Avery L. Spunt, Charisse Johnson, Chris Siwik, *NABP staff.*

Introduction:

The Task Force on Limited Distribution and Shortage of Medications met on November 20, 2003, at the Hyatt Rosemont Hotel in Rosemont, IL. The appointment of this Task Force came at the direction of NABP President Donna S. Wall in response to Resolution 99-3-03, Task Force on the Limited Distribution and Shortage of Medications, which was passed by delegates to NABP's 99th Annual Meeting, May 3-7, 2003, in Philadelphia, PA. The Resolution reads as follows:

Resolution No: 99-3-03

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Whereas, NABP recognizes the importance of all US citizens having access to medications; and

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Whereas, limited access programs and policies can place patients at risk from beginning, continuing, or completing their medication therapy;

THEREFORE IT BE RESOLVED that the NABP Executive Committee in collaboration with the Food and Drug Administration (FDA) and the Pharmaceutical Research and Manufacturers of America (PhRMA) commission a task force to study the public health consequences of restricted access policies and programs.

Review of the Task Force Charge

Task Force members reviewed their charge and, proposing no changes, accepted it as follows:

Examine the scope of medication shortages and imposed limited distribution policies of manufacturers and the impact on these practices on the availability of medications and the protection of the public health.

Recommendation 1: Proposed Changes in FDA Regulatory Authority of Pharmaceutical Manufacturer's Reporting of Drug Shortages and Drug Products Discontinuance

The Task Force recommends to the Executive Committee that NABP petition FDA to mandate through a revision of the Good Manufacturing Practices (GMP) requirements or other regulatory means that pharmaceutical manufacturers notify FDA at least 12 months (or as soon as the pharmaceutical manufacturer becomes aware) in advance regarding (1) the voluntary discontinuance of any drug product and (2) an impending or actual shortage of any drug product. The Task Force recommends further that the regulatory revision impart penalties to those pharmaceutical manufacturers who fail to abide by the above FDA mandate and require pharmaceutical manufacturers to promptly disclose to the public the discontinuance or shortage of any drug product.

Background:

Task Force members discussed the impact that medication shortages and limited distribution systems have on access to needed therapies and the public health. The Task Force reviewed information from the American Society of Health-System Pharmacists (ASHP) and the Healthcare Distribution Management Association (HDMA). Specifically, Task Force members discussed ASHP's Policy Position on the Causes of/and Solutions to Drug Product Shortages (0319) and HDMA's Ensuring Product Availability Recommended Voluntary Industry Guidelines.

Task Force members agreed that communication with other health care practitioners (prescribers and nurses, for example) was necessary and critical in order to help manage the situation and provide patients with alternative medications or therapies should the shortage or limited distribution preclude patients from receiving their medications. It was also agreed that as soon as feasible, patients should be informed of the shortage or limited distribution situation and invited to discuss the matter and possible solutions with their pharmacist and prescriber.

Recommendation 2: Task Force Stance on Drug Shortages Caused by Economic Decisions

The Task Force recommends to the Executive Committee that NABP oppose actions and practices of pharmaceutical manufacturers that create drug shortages to solely benefit the pharmaceutical manufacturer economically.

Background:

The Task Force members discussed potential and common causes of drug shortages including manufacturing difficulties, limited production capabilities, raw and bulk material shortages, and unusual product demands. The Task Force recognized that pharmaceutical manufacturers have little or no control over these factors and must manage shortages caused by such factors in the manner that balances patient needs and uncontrollable circumstances. Task Force members agreed that such situations differ from those in which a pharmaceutical manufacturer deliberately and directly causes a shortage by limiting production or distribution in order to achieve the desired financial objectives such as the early attainment of year-end sales totals. The Task Force

acknowledged that artificially created shortages undermine patient care and often result in patients and health care professionals scrambling to find alternative therapies. Task Force members also admitted that there are no safeguards or regulatory constraints in place to prevent such actions from occurring.

Recommendation 3: Drug Shortage Communication Among Key Stake Holders

The Task Force recommends to the Executive Committee that NABP work with the state boards and pharmacy associations to promote and strongly encourage the use of online drug shortage resources such as Web sites offered and managed by FDA and ASHP, publications (eg, newsletters, journals), and other communication vehicles to ensure that pharmacists are informed of shortages and can assist their patients and other health care practitioners in managing situations that may arise as a result of medication shortages.

Background:

Task Force members agreed that most pharmacists in the hospital and acute care settings were familiar with FDA and ASHP online drug shortage resources. However, the Task Force members conveyed concern for pharmacists in community chain and independent practice settings who often do not have access to or familiarity with the Internet. Task Force members proposed solutions to this dilemma, which included the use of existing in-house communications (intranet electronic mailings in the community chain pharmacies), and pharmacists contacting FDA and ASHP directly via phone or facsimile. The Task Force members also agreed that pharmacists in all practice settings should acquire access to the Internet or online updatable software programs. Furthermore, all pharmacists should be proactive in accessing drug shortage information regardless of practice setting.

Recommendation 4: Adopting Policies and Procedures to Address Drug Shortages

The Task Force recommends to the Executive Committee that NABP work with the state boards of pharmacy to require that pharmacies in all practice settings develop policies and procedures specific to their practice environment that address drug shortages.

Background:

The Task Force members agreed that, should a medication shortage or limited distribution situation arise, the pharmacist should exercise responsibility to manage the patient's medication therapy to ensure that therapy is not interrupted. The Task Force recognized that finding alternative sources for the medication is an option in some circumstances, but will not be applicable in situations where the medication supply is completely exhausted and production cannot ensure that the patient's therapy will continue uninterrupted. Task Force members emphasized that pharmacists must thoroughly investigate other reliable and alternative mechanisms to obtain quality drugs. The Task Force reviewed ASHP's Guidelines on Managing Drug Product Shortages and agreed that the document would be beneficial to all practice settings. In situations where alternative sources for the desired medications are not available, the Task Force discussed that the pharmacist could assume a more proactive role and collaborate

with the prescriber and patient to select an alternative medication or therapy. In this situation, if a Collaborative Pharmacy Practice Agreement exists between a pharmacist (community or institution based) and practitioner, a therapeutic substitution policy may be created to provide therapeutic alternatives for an unavailable drug product. Task Force members also agreed that pharmacists must be proactive in establishing policies and procedures that address current and impending drug shortages.

Recommendation 5: Restricted Medication Distribution Systems

The Task Force recommends to the Executive Committee that NABP communicate to pharmaceutical manufacturers that the implementation of restricted medication distribution programs should not be permitted unless the programs are based on sound scientific and clinical evidence that is in the best interest of the patient. The Task Force also recommends to the Executive Committee that NABP communicate to pharmaceutical manufacturers that such programs should be instituted to ensure equitable patient access to drugs that are used to treat rare conditions, manage significant abuse potential, or deter counterfeiting. Furthermore, these programs should only be established in conjunction with FDA and should preserve the pharmacist-patient relationship. Patients should be encouraged to inform the pharmacist of their choice about participating in such programs.

Background:

The Task Force recognizes that in certain rare circumstances, restricted drug distribution/limited access medication programs should be instituted to ensure the safe use of certain high-risk medications that have demonstrated or have a great potential to cause significant harm if not appropriately utilized (ie, Propulsid®). This may also include programs that attempt to deter counterfeiting (ie, Serostim®). However, the Task Force also recognizes that these types of programs may sometimes threaten the traditional pharmacist-patient relationship, thereby preventing pharmacists from providing a complete medication assessment, patient counseling, monitoring, and follow-up.

Recommendation 6: Amend NABP *Model Act*

The Task Force recommend that the Executive Committee amend the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy* (*Model Act*) (June 2003) to incorporate the following amendments:

Change the comment section of the *Model Act*, Model Rules for Pharmaceutical Care, Section 2, Part A, Subsection 2 (Duties and Responsibilities of the Pharmacist-in-Charge) to read:

1. The Pharmacist-in-Charge must develop, implement, and maintain policies and procedures that address drug shortages or drug product discontinuance. References such as the American Society of Health- System Pharmacists (ASHP) Guidelines on Managing Drug Product Shortages could be used in developing the policies and managing medication shortage or discontinuance situations.

Background:

The Task Force agreed that current rules in the NABP *Model Act* adequately address the responsibility of the pharmacist-in-charge with respect to drug shortages or discontinuances. The Task Force agreed that some additional guidance in the comments section would be useful.

AGENDA ITEM H

State of California **Department of Consumer Affairs**

Memorandum

To: **Enforcement Committee** **Date: March 9, 2004**

From: **Patricia F. Harris**
Executive Officer
Board of Pharmacy

Subject: **Board of Pharmacy Outreach Efforts – Continuing Education Program**

President John Jones will report on the board's education outreach efforts to licensees. President Jones and Supervising Inspector Robert Ratcliff have presented this program throughout California to licensees and pharmacy students. It has been well received and appreciated.

Attached is a copy of the continuing education program

California State Board of Pharmacy
Continuing Education Program

John Jones, Pharm.D., J.D., Board President

Bob Ratcliff, Pharm.D. Supervising Inspector

Board of Pharmacy Overview

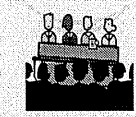
- Created in 1891
- Responsible for enforcing federal and state law pertaining to the acquisition, storage, distribution and dispensing of dangerous drugs (including controlled substances) and dangerous devices

Board Overview

- 11 Member Board – 7 pharmacist and 4 public members appointed by the Governor, and 2 public members appointed by the Legislature (1 Senate and 1 Assembly)
- Board's mandate is to protect the public

Board Overview

- **Board Meetings**
  - Public
  - Quarterly
  - Dates, Locations, Agendas, Minutes, and Materials are Available from Website
  - 6 Hours of CE for Attending Pharmacists



Budget and Staffing

- Budget : $7.2 million
- Staff: 55 staff of which 22.5 are pharmacist-inspectors
- Due to general fund budget deficit, the Board's $6 million reserve was transferred to the general fund
- Board also lost 10 critical support positions

Strategic Plan

- Guides the board's operations and activities
- Revised annually

7

Board Vision and Mission

Vision

Healthy Californians through quality pharmacists' care.

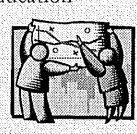
Mission

The Board protects and promotes the health and safety of Californians by pursuing the highest quality of pharmacists' care through education, communication, licensing, regulation, and enforcement.

8

Board Committees

- **Strategic Plan establishes 5 committees:**
  - Communication and Public Education
  - Licensing
  - Enforcement
  - Legislation and Regulation
  - Organizational Development



- **Articulates goals and develops action plans.**

9

Legislation and Regulation Committee

- **Goal:** Advocate legislation and promulgate regulations that advance the Board's vision and mission.
  - **Outcome:** Improve the health and safety of Californians

10

New Statutes

www.leginfo.ca.gov

- **Board of Pharmacy Sunset Bill – SB 361 (Figueroa)**
  - Extends Board of Pharmacy's sunset date to 2008
  - Adds 2 public members
  - Recognizes NAPLEX and a CA specific exam
  - Makes changes to Pharmacy Technician Program
  - Adds new enforcement compliance provisions

11

New Statutes

www.leginfo.ca.gov

Treatment and Drug Diversion Act – SB 151
Phased-in starting January 1, 2004

Will result in -

- No more triplicates
- New prescription forms for all controlled substances
- Pharmacies to report Schedule IIIs electronically

12

New Statutes

www.leginfo.ca.gov

- **Treatment and Drug Diversion Act – SB 151 (Burton) – January 1, 2004**
  - Approval of security printers by the Board and Department of Justice
  - Permit pharmacies to apply the prescription requirements of the state in which the patient resides when filling prescriptions.

13

New Statutes

www.leginfo.ca.gov

- **Treatment and Drug Diversion Act – SB 151 – January 1, 2004**
  - Controlled substance prescriptions (Schedules II-V) are valid for 6 months
  - Makes CURES permanent and requires all pharmacies to report Schedule II controlled substance prescriptions to the Department of Justice

14

New Statutes

www.leginfo.ca.gov

- **Treatment and Drug Diversion Act – SB 151 – January 1, 2004**
  - Prescribers only need to sign and date Schedule III – IV controlled substance prescriptions (consistent with current Schedule II requirements)
  - New controlled substance prescription forms may be acquired from approved security printers

15

New Statutes

www.leginfo.ca.gov

- **Treatment and Drug Diversion Act – SB 151 – July 1, 2004**
  - Prescribers may use the new controlled substance prescription forms for Schedule II controlled substance prescriptions.

16

New Statutes

www.leginfo.ca.gov

- **Treatment and Drug Diversion Act – SB 151 – July 1, 2004**
  - Oral and electronic orders for Schedule II controlled substance prescriptions for patients in skilled nursing facilities, intermediate care facilities, home health care programs, and hospice programs are permitted. Such orders must be reduced to hard copy form and signed by the pharmacist on a form of the pharmacy's design.

17

New Statutes

www.leginfo.ca.gov

- **Treatment and Drug Diversion Act – SB 151 – July 1, 2004**
  - Triplicate prescription forms may be used to prescribe Schedule II controlled substances.
  - Requires prescribers dispensing Schedule II controlled substances to report those prescriptions to the CURES system.

18

New Statutes

www.leginfo.ca.gov

- **Treatment and Drug Diversion Act – SB 151 – January 1, 2005**
  - Triplicate prescription forms are no longer valid
  - All written controlled substance prescriptions (oral and fax orders for Schedule III – V are still permitted) shall be on controlled substance prescription forms

19

New Statutes

www.leginfo.ca.gov

- **Treatment and Drug Diversion Act – SB 151 – January 1, 2005**
  - Pharmacies must report Schedule III controlled substance prescription information to the CURES system
  - Prescribers dispensing Schedule III controlled substances must report those prescriptions to the CURES system.

20

New Legislation

www.leginfo.ca.gov

- **SB 175 (Kuehl)**
  - Adds veterinary drugs to the definition of dangerous drugs
- **SB 292 (Speier)**
  - Requires prescription labels or auxiliary labels to have a description of the drug by January 1, 2006

21

New Legislation

www.leginfo.ca.gov

- **SB 490 (Alpert)**
  - Establishes a statewide protocol for pharmacists dispensing emergency contraceptives
- **SB 545 (Speier)**
  - Limits the nature of the consultation and the fee that may be charged by pharmacists dispensing emergency contraceptives

22

New Legislation

www.leginfo.ca.gov

- **SB 485 (Burton)**
  - Establishes the Naturopathic Doctor Act to be administered by the Bureau of Naturopathic Medicine
- **AB 1196 (Montanez)**
  - Permits Nurse Practitioners to order Schedule II drugs

23

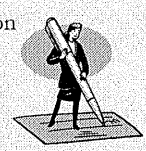
New Regulations

- **Coursework from Non-Accredited Providers** – 1732.2 (b)
  - Allows pharmacies to take continuing education from providers recognized by the Medical Board of California, the Board of Podiatric Medicine, the Board of Registered Nursing, or the Dental Board of California without petitioning the board

24

New Regulations

- **Citations and Fine Program – 1775 et seq.**
  - Delegates to the executive officer the authority to issue a citation and fine



Regulations - Board Approved

Pending Administrative Approval

- **Requirements for Compounding of Injectable Sterile Drug Products –**
  - Proposed regulation specifies requirements for compounding injectable sterile drug products

Proposed Regulations Awaiting Notice

- **Remote fill for hospital pharmacies** – Add 1707.5
- **Pharmacist-in-Charge at two locations** – Amend 1709.1
- **Quality Assurance Program – Patient notification of medication error** – Amend 1711

Proposed Regulations Awaiting Notice

- **Update to pharmacy self-assessment** – Amend 1715
- **Electronic prescriptions and records** – Amend 1717.2 and 1717.4
- **Clerk-typist ratio** – Amend 1793.3

Communication & Public Education Committee

- **Goal:** Provide relevant information to consumers and pharmacies.
  - **Outcome**: Improved consumer awareness and licensee knowledge.

Board Publications - Outreach

- **The Script**
- **Health Notes**
  - Pain Management
  - Care of Children and Adults with Disabilities
  - Pharmacist's Involvement in Anticoagulant Therapy
  - Women's Health
  - Alternative Medicines
  - Quality Assurance
  - Drug Therapy Considerations for Older Americans

Board Publications (continued)

- **Pharmacy Lawbook**
  LawTech Publishing Co.
  Ph: 949-498-4815
  email: sales@lawtech-pub-com

- Consumer brochures
- Board-sponsored continuing education course
- **Website: www.pharmacy.ca.gov**

31

Licensing Committee

- **Goal**: Ensure the professional qualifications of licensees.
  - **Outcome**: Qualified licensees

32

Licensee Population

License Type	# of Licensees
Pharmacies	6,120
Clinics	807
Pharmacists	29,638
Interns	3,886
Pharmacy Technicians	37,567
Other Sites *	1,546
Total	**79,564**

* Other Sites include wholesalers, veterinary retailers, non-resident pharmacies, hypodermic needle distributors, and out-of-state distributors.

33

Licensing Committee

- **Implementation of SB 361 – Pharmacists Licensure Exam**
  - NAPLEX and California Specific exam
  - Computerized
  - Available nationwide
  - Proposed regulations to implement

34

Licensing Committee

- **Pharmacist Licensure Examination**
  - Pass NAPLEX after January 1, 2004
  - Pass the California Pharmacist Jurisprudence Examination (CPJE)

35

Licensing Committee

California Application Process

- Submit application to the CA Board of Pharmacy
  - Affidavit of Intern Hours
  - Transcripts
  - Verification of out-of-state licensure (if applicable)
  - Fingerprints
  - Application fee of $155

36

Licensing Committee

- California confirms eligibility to NABP and Experior (CPJE)

37

Licensing Committee

NAPLEX Application Process

- Submit registration bulletin (the application) to NABP
- Application fee of $430 to NABP

38

Licensing Committee

- NABP issues "Authorization to Test"
- Applicant schedules appointment during eligibility dates to take NAPLEX
- Prometric Testing Centers Nationwide (Monday through Saturday)

39

Licensing Committee

CPJE Application Process

- Experior issues candidate guide and "OK" to test
- Submit testing fee of $40 to Experior
- Applicant schedules to take CPJE
- Experior Testing Centers Nationwide (Monday through Saturday)

40

Licensing Committee

- **Board of Pharmacy Sends Pass/Fail Letters**
  - Pass NAPLEX and CPJE – submit licensing fee to Board of Pharmacy
  - Pass NAPLEX and Fail CPJE – need Retest Form and $155 to the Board of Pharmacy
  - Fail NAPLEX and Pass CPJE – Need to reapply to NABP

41

Licensing Committee

- **Pharmacy Technician Provisions**
  - Associate degree in pharmacy technology
  - Certification by the Pharmacy Technician Certification Board
  - Graduation from a pharmacy school recognized by the board
  - Elimination of equivalent experience
  - Proposed regulations to implement

42

Licensing Committee

- **Special Licensure of Pharmacies that Compound Injectable Sterile Drug Products --by July 1, 2003 - Exceptions to Licensure**
  - Accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), Accreditation Commission on Healthcare (ACHC), and Community Health Accreditation Program (CHAP)
  - Inspected annually prior to renewal
  - Meet compounding requirements (CCR 1751 et seq.)
  - Applications and self-assessment on website (www.pharmacy.ca.gov)

43

Licensing Committee

- **Change of Ownership**
  - Requires temporary pharmacy permit for new owner.

44

Enforcement Committee

- **Goal**: Exercise oversight over all pharmacy activities.
  - **Outcome**: Improved consumer protection.

45

Enforcement Committee

- **General FY 2002/03 Statistics**

  - 1,608 complaints received
  - 507 are from the public
  - 290 are prescription errors (58.9%) – the #1 consumer complaint
  - 1,213 cases closed
  - 705 citations and fines issued
  - 3 ISO/TROs
  - 8 PC-23s

46

FY 2002/03 Disciplinary Actions

- 103 Cases referred to the Attorney General's Office
- 82 Accusations filed *
- 32 Accusations or Statement of Issues withdrawn or dismissed.
- 139 Total disciplinary actions

* An accusation may name many respondents however, only one accusation is counted for all respondents.

47

FY 2002/03 Routine Inspections

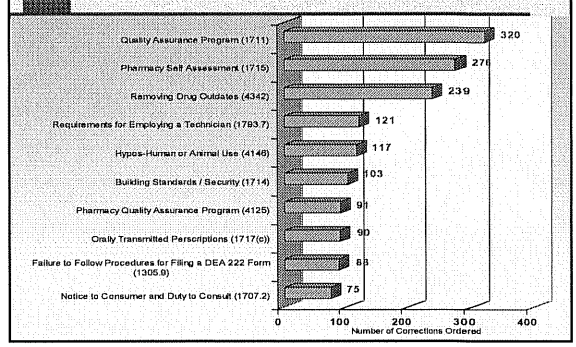
- 2,948 Routine Inspections
- 131 Investigations opened as a result of an inspection (4.4%)
- More than 1300 Separate Corrections of Pharmacy Law

48

The Inspection Process

- Open Book Test
- Self-Assessment Form
- Quality Assurance Program
- Patient Consultation Compliance
- Controlled Substance Recordkeeping
- Review for Compounding Equipment
- Review of Prescription Documents and Inventory
- Security and Sanitation

Top Ten Corrections Ordered



Complaints/Investigations

- Consumer Complaint – Letter Sent to Licensee Requesting a Response.
- Inspector Visits Pharmacy to Investigate the Alleged Violation of Pharmacy Law.
- Licensee Advised and Given 14 Days to Provide Additional Response and Correct.

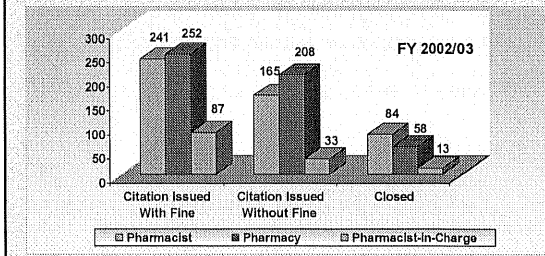
Investigation Outcomes

- Corrections ordered (Inspection)
- Closed with no further action
- Letter of Admonishment
- Citation and Fine – Order of Abatement
- Referral to Attorney General's Office for disciplinary action

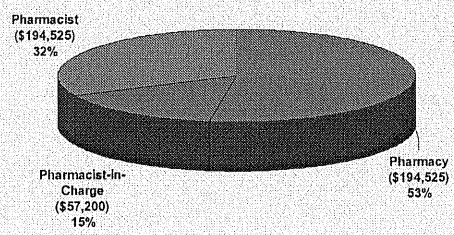
Citation and Fine Process

- **A citation is issued with or without a fine**
- **The licensee can:**
  - **Pay the Fine** – Payment of fine does not constitute an admission of the violation charged **OR**
  - **Informally Contest the Citation and Fine** – Action may be either to affirm, modify, or dismiss **OR**
  - **Formally Appeal the Citation and Fine through the APA** – Matter is then Referred to the Attorney General's Office for an Administrative Hearing.

Citation & Fine Statistics

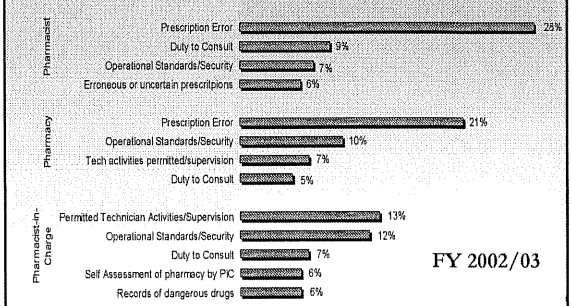


Fines Issued – FY 02/03 = $370,300



55

Top Violations By License Type



When is the PIC Responsible?

- Is there an ongoing problem?
  - Was it identified and not addressed?
  - If addressed, what was done?
- Is there a lack of training?
- Lack of policies and procedures?
- Should the PIC have known of the situation if he/she were adequately monitoring?

57

When is the PIC Responsible?

- Is the violation related to record keeping requirements?
- Is the PIC unable to identify the dispensing pharmacist?
- Is there a lack of security?
- Is there a disregard for pharmacy law?

58

Quality Assurance Program

- **What's Needed?**
  - Written policies and procedures
  - Maintained in the pharmacy
  - Immediately retrievable
- **The Basics:**
  - What happened?
  - How did it happen?
  - What was done so it will not happen again?

59

Quality Assurance Program

- **What's Required?**
  - Written policies and procedures in place
  - Pharmacist must notify patient and physician that the medication error occurred and steps required to avoid injury or mitigate the error.
  - Develop pharmacy systems and workflow processes to minimize future occurrences.
  - Investigate within 2 business days

60

QAP What's Required? (continued)

- **Medication Error Review Should Include:**
  - Date, location, & participants
  - Pertinent information related to the error to be analyzed
  - Documentation of patient & physician notification
  - Findings and determinations
  - Recommended changes to policy, procedures, systems or processes

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QAP What's Required? (continued)

- Maintain QA review records for at least one year.
- Records must be immediately retrievable
- Pharmacy may contract with outside entity to develop and/or audit their program.

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Health Insurance Portability and Accountability Act of 1996 (HIPAA)

- **Notice of Privacy Practices to Every Patient**
- **Accounting of Disclosure to Patients**
  - Routine Inspections
  - Investigations
    - Medical Release,
    - Investigative Subpoena, or
    - Investigative Demand (Receipt for Records)

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HIPAA (continued)

- Effective April 14, 2003
- Enforced by Health and Human Services Office of Civil Rights
- Questions?
  - California's Office of HIPAA Implementation (www.calohi.ca.gov)
  - Health and Human Services Office of Civil Rights (www.hhs.gov/ocr/hipaa)

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Emerging Pharmacy Issues

- Importation of Drugs from Other Countries
- Internet Pharmacies
- Counterfeit Drugs

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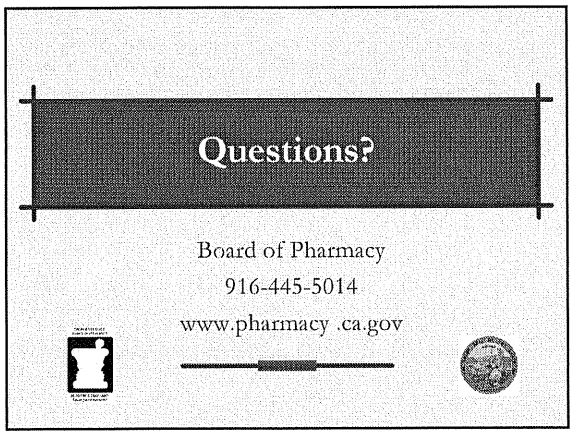
Pharmacist's Recovery Program

(800) 623-6116


Questions?
Board of Pharmacy
916-445-5014
www.pharmacy .ca.gov

AGENDA ITEM I

State of California **Department of Consumer Affairs**

Memorandum

To: **Enforcement Committee** **Date: March 10, 2004**

From: **Patricia F. Harris**
Executive Officer
Board of Pharmacy

Subject: **Review of Enforcement Committee Goal and Objectives**

As a part of the board's annual strategic plan update, the Enforcement Committee reviews its goals and objectives for any recommended changes.

One suggested addition is an objective similar to one of the licensing objective, which is: Evaluate five emerging public policy initiatives affecting pharmacists' care or public safety by June 30, 2005. One of the tasks tracked in this section is "the importation of drugs from foreign countries", which is done by the Enforcement Committee.

Since July, the Enforcement Committee has addressed various public policy initiatives related to compliance and compliance but there is no objective to track the tasks:

- Reimportation
- Modification to the Quality Assurance Regulation Regarding Patient Notification
- Proposals Regarding Wholesale Transactions
- Clarification Regarding Prescription Records by Authorized Officers of the Law
- Review of Pharmacy Law Regarding the Delivery of Medications After the Pharmacy is Closed and a Pharmacist is not Present
- Off-Site Order Entry of Hospital Medication Orders (Bus. & Prof. Code Section 4071.1)
- Prescriber Dispensing
- Implementation of federal HIPAA Requirements
- Prohibition of Pharmacy-Related Sinage
- Implementation of Enforcement Provisions from SB 361
- Implementation of SB 151 (Elimination of the Triplicate)
- Dispensing Non-Dangerous Drugs/Devices Pursuant to a Prescriber's Order for Medi-Cal Reimbursement
- Authorized Activities in a Pharmacy
- Review of Quality Assurance Program
- Limited Distribution and Shortage of Medications
- Conversion of Paper Invoices to Electronic Billing
- Automated Dispensing

Suggested language:
Initiate policy review of 25 emerging enforcement issues by June 30, 2005.

Measure: The number of issues

Board of Pharmacy
Second Quarterly Report
October – December 2003

Enforcement Committee

Goal 1:	**Exercise oversight on all pharmacy activities.**
Outcome:	**Improve consumer protection.**

Objective 1.1:	**To achieve 100 percent closure or referral on all cases within 6 months by June 30, 2005:**
Measure:	**Percentage of cases closed or referred within 6 months**
Tasks:	*(Based on 435 completed mediations/investigations sent to SI for review)* 1. Mediate all consumer complaints within 90 days. **0-90 Days 29 (7%)** **91-180 Days 53 (12%)** **181-365 Days 30 (7%)** **366-730 Days 1 (0%)** 2. Investigate all other cases within 120 days. **0-90 Days 157 (36%)** **91-180 Days 85 (20%)** **181-365 72 (17%)** **365-730 8 (2%)** *(Based on 463 closed investigations/mediations)* 3. Close (e.g. issue citation and fine, refer to the AG's Office) all board investigations and mediations within 180 days. **0-90 Days 138 (30%)** **91-180 Days 67 (14%)** **181-365 Days 186 (40%)** **366-730 Days 67 (14%)** **731+ 5 (1%)** 4. Seek legislation to grant authority to the executive officer to issue a 30-day Cease and Decease Order to any board-licensed facility when the operations of the facility poses an immediate threat to the public.

Objective 1.1, cont'd **Tasks**	5. Integrate data obtained from computerized reports into drug diversion prevention programs and investigations (CURES, 1782 reports, DEA 106 loss reports). ♦ *Board staff continues to work with BNE fine-tuning the new CURES database and resolving data errors and pharmacy non-compliance. Board staff developed additional reports including pharmacy transactions by drug, patient profiles, pharmacy by status code, pharmacies dispensing over a specified threshold, non-reporting pharmacies, and doctor profile. The Board has requested the addition of several critical date fields to the CURES system to ensure meaningful and accurate reports. For example, staff asked to have the date CURES was last updated by DOJ.* **11 CURES reports were provided to supervising inspectors and/or inspectors this quarter to aid in an investigation or inspection.** ♦ *DEA 106 Theft/Loss Report database is ready with the exception of a few minor programming modifications. Staff developed and implemented procedures to include CURES pharmacy transaction reports and CURES pharmacy drug profile reports when opening a complaint investigation for a theft or loss.* **47 CURES reports were provided to staff this quarter for investigations involving theft or loss.** 6. Re-establish the CURES workgroup that includes other regulatory and law enforcement agencies to identify potential controlled substance violations and coordinate investigations. ▪ *Board plans to meet with the CURES workgroup and BNE in January 2004 to work on pharmacy non-compliance and data error issues.* ▪ *Board met with representatives of BNE in November and in December, with those agencies impacted by SB 151 to discuss the implementation of the Security Printer program. Security printer draft application completed and to Legal for review.* ♦ *Inspector and supervising inspector continue to participate on*

	the monthly diversion task force meetings regarding the importation of dangerous drugs, repackaging and distribution in the U.S.; monthly Oxycontin task force meetings in Ventura; FBI task force meetings; and diversion task force meetings in San Diego. Additionally, an inspector, supervising inspector and the CURES analyst attended FBI diversion training in October 2003.
Objective 1.1, cont'd **Tasks**	7. Secure sufficient staffing for a complaint mediation team and to support an 800 number for the public. 8. Improve public service of the Consumer Inquiry and Complaint Unit. ▪ *Board staffed and attended **two** consumer health fair this quarter. Consumer brochures and Health Notes are taken to these fairs for distribution and a "Notice to Consumer" is displayed.* 9. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities. ▪ *No changes to automated reports for case management.* ♦ *Revisions made to the automated inspection system this quarter include:* o *Modified the inspector program to include CURES data when an inspector displays inspection assignments. With the click of a button next to the pharmacy name, a pop-up window displays that pharmacy's total number of CURES transactions for the previous 3 months and breaks the data down by drug.* *Installed program modifications to Inspector computers in December 2003.* o *Developed and implemented a data scrub program to import raw Cures data into Access format.* o *Developed and implemented a program to integrate zero-fill CURES data into the inspector program.* o *Developed and implemented several modifications to inspector data program to improve functionality for*

	the end-user through point and click menus and automated data transmission. o *Developed and implemented a program that allows office staff and inspectors easy access to inspection reports on the server.* o *Developed and implemented a behind-the-scenes weekly email delivery of an assigned versus completed inspection report to the supervising inspector. This is a weekly status report that shows inspections assignments completed and inspections assignments yet to be completed for each inspector.* ***Inspection assignment status reports are sent weekly to supervising inspectors.*** ▪ *Automated evidence database – Revisions made to the database during this quarter include:* ✓ Further defined data fields to specify type of evidence such as drug or paper and further define drug evidence as liquid, glass, syringe, needle, etc. ✓ Developed evidence inventory data form. ✓ Linked Teale CAS closure data to evidence database. ▪ *Automated sterile compounding database – Staff developed and implemented a monthly automated scrub update program for updating the licensing data extracted from Teale CAS licensing system.* ▪ *New Security Printer Database – SB 151 requires the board to approve security printers in advance of producing controlled substances prescription forms for Schedule II drugs beginning July 1, 2004. In December 2003, staff began development of a database that will track security printer applications. Plans for this database include programming for the automated generation of letters and automated updates to the list of "approved printers to the board's website.*
Objective 1.2:	**To achieve 100 percent closure on all administrative cases within one year by June 30, 2005.**

Measure:	**Percentage closure on administrative cases within 1 year**
Tasks: **Objective 1.2 cont'd.**	1. Pursue permanent funding to increase Attorney General expenditures for the prosecution of board administrative cases. ▪ *A BCP was not submitted for funding due to a July 2003 Finance Budget Letter directing agencies to offset any increase in expenditures through redirection of existing funds.* 2. Aggressively manage cases, draft accusations and stipulations and monitor AG billings and case costs. ▪ *Case management and review of pending cases is a continuous process.* ***Status memos sent this quarter: 25.*** ▪ *Disciplinary cases closed this quarter:* **0-365 days 9 (40.9%)** **366+ days 13 (59.1%)** ▪ Disciplinary cases reviewed this quarter: ***Accusations reviewed: 36*** ***Accusations needing revision: 5*** ***Accusations filed: 40*** ***Stipulations/proposed decisions reviewed: 12*** ***Cases reviewed for costs: 21*** 3. Establish a disciplinary cause of action for fraud convictions similar to current cash compromise provisions related to controlled substances. 4. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities. ▪ *Administrative Case Management Database Program – no changes this quarter.* 5. Review and update disciplinary guidelines. ▪ *Board staff identified the "examination" term as needing revision for consistency with the new pharmacist exam requirements.*

Objective 1.3: **Measure:**	**Inspect 100 percent of all licensed facilities once every 3 years by June 30, 2004.** **Percentage of licensed facilities inspected once every 3 years**
Tasks:	1. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities. ▪ *See response to Objective 1.1, Task #9.* 2. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public. *For this quarter:* *Total number of inspections to be completed by July 2004 is **2,339**.* *Total number of inspections completed this quarter: **590*** *(This is all inspections combined i.e., routine, diversion, probation/PRP, sterile compounding, status 3 (delinquent), CURES, inspections as a result of a complaint investigation, etc)* *Of those inspections, there were:* *Total Sterile Compounding Inspections: 15* *Total Status 3 (delinquent) inspections: **7*** *Total routine inspections resulting in a complaint investigation: **25*** 3. Seek legislation to mandate that periodic inspections be done on all board-licensed facilities.

Objective 1.4: **Measure:**	**Develop 4 communication venues in addition to the inspection program to educate board licensees by June 30, 2005.** **Number of communication venues (excluding inspection program)**
Tasks:	1. Develop the board's website as the primary board-to-licensee source of information. ▪ *The availability of disciplinary history on licensees is in the final stages of development and test. Once completed, employers will be able to query disciplinary status of a licensee.* ▪ *During this quarter website revisions included:* ✓ ***Update on California licensure exam requirements.*** ✓ ***Update on new pharmacy technician program requirements.*** ✓ ***Addition of new pharmacy technician application.*** ✓ ***Addition of new pharmacist exam application.*** ✓ ***Availability of board committee packets for download.*** ✓ ***Regulation Updates*** ✓ ***Lawbook Updates*** 2. Prepare two annual *The Scripts* to advise licensee of pharmacy law and interpretations. ▪ *Articles for January 2004 Script written and submitted for review.*

Objective 1.4, cont'd.	3. Update pharmacy self-assessment annually. ▪ *Being reviewed by Legislation/Regulation Committee.* 4. Develop board-sponsored continuing education programs for pharmacists in the area of pharmacy law and the expectations of the pharmacist-in-charge and coordinate presentations at local and annual professional association meetings throughout California. ▪ *C/E presentations given this quarter:* ✓ ***October** – CSHP's Seminar 2003* ✓ ***December** – Coachella Chapter of CPhA* ▪ *Held public Enforcement Committee meeting attended by licensee professional association representatives. Topics included the reimportation of prescription drugs, review of the quality assurance program, implementation of SB 151 and 361, wholesale violations, task force on prescriber dispensing and an overview of the Pharmacist Recovery Program, Probation Monitoring Program and the disciplinary penalty petition process. Meeting agenda and materials available for download from the Web.*
Objective 1.5: **Measure:**	**To monitor alternative enforcement programs for 100 percent compliance with program requirements by June 30, 2005.** **Percentage compliance with program requirements**
Tasks:	1. Administer effective alternative enforcement programs to ensure public protection (Pharmacists Recovery Program, probation monitoring program, citation and fine program). ▪ *Pharmacists Recovery Program: As of December 2003, there were **65** participants in the PRP. During this quarter the board referred **2** pharmacists to the program. Statistics for closures are not yet available.* ▪ *Probation Monitoring Program: As of this quarter there are **122** pharmacists, **21** pharmacies and **23** other individual licensees (technicians, interns, exemptees) on probation with the board. **Four** new probationers were added during this quarter, **seven** investigations for petitions to revoke probation for non-compliance were completed, and **two** non-compliance letters were sent.* ▪ *Citation and Fine Program:* ✓ ***October through December 2003: 202 citations issued. Total fines: $174,425.00***

Objective 1.5, cont'd.	▪ In December, reviewed compliance provisions of SB 361 for implementation – order of correction, letter of admonishment and revisions to the citation and fine program. 2. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities. ▪ *Citation and Fine Database Program –No changes this quarter. The database is scheduled for modification next quarter.*

Objective 1.6: **Measure:**	**Respond to 95 percent of all public information requests within 10 days by June 30, 2005.** **Percentage response to public information requests within 10 days**
Tasks: Objective 1.6, cont'd.	1. Activate public inquiry screens to expand public information. Establish web look-up for disciplinary and administrative (citation) actions. ▪ *Teale Public Disclosure Screen – In this quarter an estimated **100%** of the board's probationers were entered into the database and currently completed disciplinary actions are entered into the database on a going-basis.* ▪ *Web Enforcement Look-Up – Test records for "web look-up" have been designed and data imported into these records. Testing of program will be completed in January 2004.* 2. Establish on-line address of record information on all board licensees. ▪ *Licensee address of record information became available on-line to the public in December.* 3. Respond to specialized information requests from other agencies about board programs, licensees (e.g. subpoenas) and Public Record Act requests. ▪ *In the last quarter the board responded to:* ***38 public records requests –71% within 10 days; 29% over 10 days.*** ***14 requests from licensees – 86% within 10 days; 14% over 10 days.***

	23 requests from other agencies – 78% within 10-day response time; 22% over 10 days. ***178 written license verifications – 60% within a 10 days; 40% over 10 days.*** ***3 subpoenas – 100% responded to within 5 days.***