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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
Arnold Schwarzenegger, GOVERNOR

Enforcement Committee Report

John Jones, Chair
Stan Goldenberg
Bill Powers

Report of March 18, 2004

FOR ACTION

RECOMMENDATION 1

That the Board of Pharmacy revise its public disclosure policy and change the record retention for substantiated complaints/investigations to 3 years.

Discussion
The Enforcement Committee was provided with a revised public disclosure policy that included the disclosure of "Letter of Admonishment" that was added this year through new legislation and other technical changes to the policy were made. **(Attachment A)**

In addition the Enforcement Committee discussed the board's "Record Retention Schedule" which 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 20.

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.

Staff requested that the board consider changing the "Record Retention Schedule" for substantiated complaints to 3 years. Three years provides the board with sufficient complaint history to determine if disciplinary action is warranted and is consistent with the record keeping requirements for licensees. Also, with the board's diminishing resources, it is difficult to maintain the records for five year.

Collette Galvez from the Center for Public Interest Law suggested that the board not change its public disclosure of substantiated complaints to 3 years. She advised that such

a change is not consistent with the other health boards. She also cautioned that three years of information might not be enough for a consumer to make an informed decision about a pharmacy or pharmacist.

Staff reviewed the record retention for the other health boards. The Board of Registered Nursing keeps all its closed substantiated complaints and disciplinary actions for 101 years. The Dental Board of California keeps its closed substantiated complaints for 5 years and citations and disciplinary actions forever. Medical Board of California maintains its closed substantiated investigations for 5 years and disciplinary actions forever.

The board's Web site look-up for disciplinary actions will be available by May 1, 2004 and will include disciplinary cases as far back as January 1998. Letters of admonishment, citations, pending accusations will be added to the web look-up at a later time. However, this information is still available to the public by contacting the board. **(Attachment B)**

RECOMMENDATION 2

That the Board of Pharmacy add strategic objective 1.7 to the Enforcement Committee's Goal. The objective would state: "Initiate policy review of 25 emerging enforcement issues by June 30, 2005". The measure would be: "The number of issues".

Discussion

The Enforcement Committee reviewed its strategic objectives for implementation of its goal. Since July, the Enforcement Committee has addressed various public policy initiatives but discovered that there isn't an objective to track these tasks. The policy initiatives that the board has reviewed are:

- 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

NO ACTION

Importation of Prescription Drugs from Canada
The Board of Pharmacy has been discussing and has sought comments on the issue of prescription drug importation from Canada. This has been a sensitive and controversial issue. The board has been tasked with balancing consumer access to affordable prescriptions against the safety and effectiveness of drugs obtained from foreign sources. The board has heard from many interested parties on this issue during its committee meetings and at its quarterly board meetings. Attached are some articles that may be of interest on this issue. **(Attachment C)**

This year various legislative proposals have been introduced related to the reimportation of prescription drugs from Canada. Some of the bills impact the board in that the board would be required to establish a Web site to provide price comparisons between American and Canadian prescription drug prices and provide a link to certified Canadian pharmacies. The board would also be required to "certify" Canadian pharmacies. The other legislative bills are designed to increase the public and private sector buying power for lower prescription drug prices. The board will be discussing these bills during the Legislation and Regulation Committee report.

The board's mandate is to protect the public, which includes patient access to "safe and affordable" prescription medications.

Meanwhile, the Food and Drug Administration (FDA), on behalf o f the U.S. Department of Health and Human Services' (HHS) Task Force on Drug Importation, announced that it established a docket to receive information and comments on certain issues related to the importation of prescription drugs. The FDA also announced a public meeting on April 14th so that individuals, organizations and other stakeholders could present information to the Task Force for consideration in the study on importation mandated by the Medicare Prescription Drug, Improvement and Modernization Act of 2003. The Task Force is interested in information related to whether and under what circumstances drug importation could be conducted safely, and what its likely consequences would be for the health, medical costs, and development of new medicines for American patients. The public docket will formally remain open until June 1, 2004, so that commenters can submit written and electronic comments. **(Attachment D)**

Application of Pharmacy Law Regarding the Conversion of Paper Invoices to Electronic Billing by Wholesalers for Pharmacy 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. **(Attachment E)**

The request for clarification from Ralphs was forwarded to board's counsel for review and comment. Counsel advised that 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). I t was explained that 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 drug purchase records from wholesalers 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.

Application of Pharmacy Law Regarding the Use of Automation/Robotic Technology in All Pharmacy Practice Settings

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.

Board counsel reviewed the request and advised that McKesson is correct that the Pharmacy Law is 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." **(Attachment F)**

It was 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.

It was explained that 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 states 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 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. 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.

Further, 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.

While the initial request was for the use of an automated delivery system in a hospital inpatient pharmacy, 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 is any pharmacy practice settings. Further, 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.

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.

Implementation of SB 151 (Chapter 406, Statutes of 2003) – New Prescription Requirements for Controlled Substances and the Elimination of the Triplicate

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. Generally, SB 151 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.

The triplicate requirement has been in place for over 60 years and the implementation of the new law will be complex and confusing. The board anticipates many questions and has been working hard especially with its limited resources to educate prescribers and pharmacists.

The board's newsletter with these new changes was published at the end of March. Meanwhile, the articles on SB 151 are on the board's Web site. The articles have also been provided to the prescriber boards and professional associations so that they can educate their licensees and answer questions. Staff and board members have been working with various associations and pharmaceutical companies on educational programs and outreach efforts. The board's continuing education program on SB 151 is attached. **(Attachment G)**

Enforcement Committee Meeting Summary of March 18, 2004 (Attachment H)

Enforcement Team Meeting Summary of March 18, 2004(Attachment I)

Report on Enforcement Actions (Attachment J)

Report on Committee Strategic Objectives for 2003/2004 (Attachment K)

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ATTACHMENT A

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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:_____

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ATTACHMENT B

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PUBLIC DISCLOSURE

The Board will disclose to the public information and public documents on letters of admonishment, citations, referral of an investigation for formal disciplinary action, filed accusations, interim suspension orders, temporary restraining orders, penal code 23 license restrictions and final board decisions.

WEB-LOOK UP OF DISCIPLINARY ACTIONS

To determine whether board disciplinary/administrative action has been taken on a licensee, the user will select the "License Verification" button on the board's home page and follow the search steps indicated. The search results for the selected licensee will indicate "Yes" under the Actions column if there is disciplinary/administrative information on the record. *Currently only disciplinary information will be available. Letters of admonishment, citations, pending accusations will be entered into web look-up at a later time.* To see all the information for a licensee, including disciplinary action, the user would click on the highlighted name and the public disclosure information will appear. When selected, license status definitions will appear in pop-up boxes alerting the user to license practice restrictions.

Public disclosure information on the web page includes the case number, description of disciplinary action and an effective date of the disciplinary action.

Current web site information on board disciplinary actions only goes as far back as January 1998 following the effective date of the disciplinary penalty. The user may obtain information prior to January 1998, copies of public documents or more specific information on a selected licensee by submitting a written request to the board, attention Public Records Desk.

Search Results for Registered Pharmacist

Test record

The information on this page is updated five days a week (Monday - Friday).

To see all the information for a licensee, click on the highlighted name. This will also include disciplinary actions if any are present.

Name	Type	Number	Status	Address	City	Zip	County	Actions?
AJAYI CLEMENT OTANIYENOWA	RPH	46140	CLEAR	12798 BAY SUMMIT WY	VICTORVILLE	92392	SAN BERNARDINO	Yes

Record 1

First Previous

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Back | Return to Main License Listing

BOARD OF PHARMACY

Test record

Licensee Name: AJAYI CLEMENT OTANIYENOWA
License Type: REGISTERED PHARMACIST
License Number: 46140
License Status: CLEAR Definition
Probation/Suspension Definition
Expiration Date: July 31, 2004
Issue Date: April 02, 1993
Address: 12798 BAY SUMMIT WY
City: VICTORVILLE
State: CA
Zip: 92392
Actions: Yes

Related Licenses/Registrations/Permits

No records returned

Public Disclosure

Administrative Disciplinary Actions
Current web site information on Board of Pharmacy disciplinary actions only goes as far back as *January 1998* following the effective date of the disciplinary penalty.

Disciplinary actions rendered by the Board and penalties imposed become operative on the effective date of the action except in situations where the licensee obtains a court-ordered stay through the appeal process. This may occur after the publication of the information on this website.

To obtain information prior to January 1998 or for information on specific discipline listed submit a written request to the *State Board of Pharmacy, 400 R Street, Suite 4070, Sacramento, CA 95814, Attention Public Records Desk.*

Case Number:	AC199900227300
Description of Action:	BY STIPULATION:LICENSE REVOKED,REVOCATION STAYED,3 YEARS PROBATION SUBJECT TO TERMS AND CONDITIONS WHICH INCLUDE SUSPENDED FROM PRACTICING PHARMACY FOR 120DAYS,NO OWNERSHIP OF ANY BOARD LICENSED ENTITY,CANNOT SUPERVISE ANY INTERNS,PERFORM PRECEPTOR DUTIES OR BE PIC
Effective Date of Action:	August 29, 2002

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Back

ATTACHMENT C

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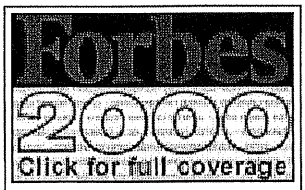
Forbes 2000

"Pssst ... Wanna Buy Some Augmentin?"

Richard C. Morais, 04.12.04

Move over, heroin pushers. Pharmaceutical arbitrage is rapidly emerging as the globe's hottest drug-dealing business.



•The World's Leading Companies

Map:

•A World of Big Companies

Slide Show:

•Top Ten Companies

Video:

•Editor's Introduction

Poll:

•Which global giant is most likely to top our Forbes 2000 list five years from now?

In January a truck pulled up to a loading dock in London's East End and discharged 3,997 boxes of Nasonex, Schering-Plough's prescription nasal spray for allergies. Earlier the drugs had been sold by Schering in France at around $11.80 per bottle, a price determined by the French government. But a middleman bought the product and shipped it to Britain, where Nasonex commands $3 more at wholesale. The East End buyer: $55 million (revenues) Medihealth, a specialist wholesaler.

Medihealth employees logged the Nasonex into their computer system and then passed the cartons over to East End women standing at tables in a back room. The women shuffled and repacked the boxes, covering the original French packaging with English-language stickers and substituting Schering's U.K.-approved leaflet for the French insert. The 3,997 boxes were soon legally bound for pharmacies across Britain.

"We actively trade 200 to 225 products," says P.R. Patel, Medihealth's chief executive. "Only the bestsellers."

Medihealth occupies a lucrative corner of the distribution world made possible by the peculiar pricing of prescription drugs. It's a "parallel trader" or "short-liner," an arbitrager buying in low-price markets and selling in high-price markets.

No one really knows the size of this drug arbitrage business, since much of it takes place in the shadows. Where it is legal, few in the pharma industry--neither the arbs nor the manufacturers nor big wholesalers--want to talk about it on the record. But this much is clear: The business of arbitraging drugs is huge, fast-growing and constantly morphing around the globe according to local laws and customs.

In Europe legal arbitrage of pharmaceuticals is already a $12 billion or so business. Paul Saatsoglou of IMS Health, a pharmaceutical consultant, says drug arbitrage along the Canadian-U.S. border was worth $1.1 billion (in U.S. prices) in 2003, up 70% in a single year. Add in the drugs coming up from Mexico, and legal pharmaceutical arbitrage in Europe's and North America's free-trade zones is probably approaching $15 billion. In comparison, United Nations statistics suggest the globe's entire heroin production is theoretically worth $20 billion at U.S. wholesale prices.

On top of all this legal, gray-market activity there is a thriving trade in illegally remarketed prescription drugs, a business whose dimensions can only be guessed at and whose markups dwarf those found on something like Nasonex. A single HIV/AIDS Combivir pill, priced at 33 cents for the African market, is worth $10 if it can be illegally diverted to the U.S. or Europe.

The U.S. has the toughest drug reimportation laws in support of manufacturers that want to segment markets by price: They strictly forbid the wholesale importation of drugs intended for distribution in other countries. The purchase of a 90-day supply of drugs for personal use while abroad is legal; overseas purchases via the Internet are illegal, but the law is rarely enforced*(see box)*. European laws are more lenient. The trade is actively encouraged within the European Union, but illegal for drugs coming from outside the EU.

Any law forbidding consumers from grabbing bargains across the border is going to be hard to enforce. The popular mood in the U.S., as reflected in politicians' speeches and many sympathetic press accounts, is that drug

companies are overcharging and the right legislation would save consumers a bundle. Bills working their way through Congress would, in effect, bar the FDA from blocking Nafta-sourced drug imports produced at previously FDA-approved manufacturing sites. The flow of cheap Canadian or Mexican drugs to the U.S. could become a flood. But the Philippines has taken this populist response further with the globe's first state-run arbitrage program, reimporting drugs sold more cheaply to India and other Asian countries.

Governments can do plenty of damage to drug company revenues just by looking the other way as drugs get redirected or shipped across their borders. Indonesia's Health Consumer Empowerment Foundation released a 2002 study claiming that almost half of all subsidized medicines intended for the poor found their way into the marketplace, including foreign government donations officially stamped by Indonesian authorities. An exaggeration? No one knows because Indonesia's health officials, claimed the *Jakarta Post*, never seriously investigated the charge. Meanwhile, according to the World Markets Research Centre, the Chilean Pharmaceutical Chamber estimated illegal cross-border trade represented 10% and 20%, respectively, of Chile's cancer and HIV/AIDS medicines in 2002. And last year the head of Lebanon's pharmacy association publicly accused 90% of that country's nonprofit clinics of reaping huge financial rewards by trading drugs originally given by donors; health authorities are now trying to better secure the country's distribution system.

Between June 2001 and July 2002, GlaxoSmithKline figured a quarter of its deeply discounted HIV/AIDS drugs bound for Africa never wound up at their intended destinations. In the summer of 2002 authorities in Belgium intercepted 800 Africa-intended packages of Glaxo's Combivir. A Dutch trader was allegedly behind this and 23 other trades involving 44,000 packs of Combivir, Epivir and Trizivir. Illegally diverted from five African countries, sometimes with the aid of government officials, $18 million worth of drugs were laundered through a number of routes to Brussels and Paris, then through Antwerp, all headed for ultimate sale in EU member states and Switzerland. (The civil case is in the courts; the Dutch police's criminal investigation is still in progress.) Manufacturers are now color-coding their poor-nation pills and creating special packaging to combat this illegal diversion.

On a risk-reward basis, trading pharmaceuticals is a far more attractive business than running heroin, confirms Thomas Kubic, executive director of the Pharmaceutical Security Institute, a drug industry group in Vienna, Va. fighting illegal pharma trade. Kubic says organized-crime busts frequently uncover drug inventories made up of a mixture of stolen drugs, diverted drugs and counterfeits. But the line between illegal substances and pharmaceutical trade is blurring. With 6 million Americans abusing prescription opiates and other pharma highfliers, prescription-drug abuse is second only to marijuana abuse in the U.S. The White House is now targeting so-called pill mills that sell diverted or stolen drugs over the Internet without prescriptions.

European governments have largely seen fit to embrace the arbitrage game, though it is doubtful they or their consumers are the primary gainers. Within the EU's free-trade zone stand government-run national health services, each negotiating its own drug prices with the pharmaceutical manufacturers: The wholesale price (daily dosage, adjusted for pack sizes) of fluoxetine, better known as Prozac, is 64 cents in Spain, $1.40 in Germany and $1.83 in Britain. With EU courts repeatedly ruling parallel trade is legal, companies like Medihealth have morphed into government-licensed repackagers. Germany's Kohlpharma alone booked $1 billion in 2002 revenue from drug arbitrage.

Britain is reimporting $2.6 billion, or 20%, of its drugs. The London School of Economics just concluded, in a study of 19 prescription drugs in six European countries, that parallel traders got 25% of branded drug sales in 2002. Low-price Greece was conversely exporting 22% of its drug supplies.

Because Europe's national health services are cash-strapped, EU governments actively protect their arbs, using pharma's murky gray market as a means of lowering health care costs. German law mandates that pharmacies have at least 7% of their stock coming from parallel trade or face penalties. Britain, meanwhile, financially rewards its pharmacists when they arbitrage.

Moss Pharmacy, a big drugstore chain, has shops in Shepperton, England. There, when a customer asks pharmacist Samir Beibars for Novartis' Famvir (famciclovir), a drug for shingles, Beibars uses his computer to scan his wholesaler's available stock in branded, discounted, generic and parallel-traded drugs. He finds a southern European import of famciclovir for $178; the National Health Service's listed reimbursement fee is $205.

So who gets the spreads in Europe's secondary market? "The patients don't benefit," says Panos Kanavos, an author of the LSE study and a lecturer on international health policy. Rather, he says, it's the middlemen--the parallel trader, wholesaler and, to a much lesser extent, the pharmacist and governments--who grab the differences.

The LSE's six-country study figured the total 2002 wholesale sales to pharmacists (but not hospitals) equaled $6.5 billion for the 19 drugs in question. The parallel traders skimmed off $680 million in trading profits. But complex government pricing mechanisms meant that national health insurance funds managed to claw back only $120 million of savings.

Studies commissioned by parallel traders claim governments are the big winners, but the LSE study (backed by Johnson & Johnson) is probably closer to the mark. Consider Medihealth's January trade in Nasonex. Medihealth bought the Schering spray from a French wholesaler for $11.80 a bottle; the English-language repackaging cost it another 37 cents. But Medihealth was able to sell the spray to British pharmacies for an average price of $16.51, capturing a $4.34 spread per bottle, or $17,347 for the in-and-out shipment. With the drug still competitively priced, the pharmacist then grabbed (after a government levy) a $1.48 trading profit, in addition to a standard dispensing fee allowed on the medicine.

On such backroom shuffles fortunes are made. Milan-born Stefano Pessina, 62, is the chief executive and major shareholder of publicly traded Alliance UniChem, a pan-European drug wholesaler with $17 billion in revenues. Pessina, a new member of FORBES' billionaires list, has built Europe's second-largest wholesaler and, in the form of Moss Pharmacy, its third-largest drugstore chain.

Alliance UniChem does not hold any parallel trading licenses itself but runs lower-priced stock from its Spanish and Greek warehouses through licensed parallel traders like Medihealth before returning the drugs to its northern warehouses; redirecting parallel product to its in-house chain of 1,100 pharmacies also significantly boosts its retail margins. Big wholesalers pay parallel traders 65 cents to 90 cents a pack for repackaging services, but also sell 5% to 20% of the pass-through to the traders so they can trade this inventory for their own accounts. It's a license to print money. Says a parallel trader who insists on anonymity: "The biggest problem for parallel traders is getting our hands on inventory."

Alliance UniChem maintains it was forced into the business by competition. "Wholesalers couldn't ignore it anymore," explains Geoffrey Cooper, deputy chief executive at Alliance UniChem. "The danger was, if we didn't supply our [pharmacist] customers with parallel imports, the short-liners could come in and sell them the imports and then say, 'By the way, we also have some generic.' Manufacturers hate it, and we don't like it, either. Long term we can earn better margins from manufacturers."

Of course, unlike its illegal cousin, Europe's secondary market does not hurt the poor, but hits big pharma in the pocket. But that doesn't mean it's only some bonus-happy execs and shareholders who pay a price.

At this year's World Economic Forum in Davos there was a fierce debate about Europe's "free ride" on America's lab-coattails. Europe spends 60% less per capita on pharmaceuticals than the U.S.; FDA Commissioner Mark McClellan says Americans, while consuming a fraction of the world's output of prescription drugs, are unfairly accounting for half of the industry's revenues.

So drug manufacturers--careful not to look like they are out to gouge the public--must quietly wage a guerrilla war, trying to catch parallel traders out in a supply squeeze.

"They are very clever," says Taybi Mohamedbhai, principal buyer at Medihealth. "A U.K. drug company will approach big parallel traders and say, 'Why are you importing that drug from Greece? We will give you the drug at the same price here in the U.K.' They will do this for six or seven months and then suddenly cut off the supply. During that time they collect the data on what Greek domestic demand is and what demand bound for the U.K. parallel import market is, and then limit Greek supplies accordingly. It took us a while to figure this out, but when they approached us again, we said, 'We're not interested.'"

Sidebars
The Odyssey
Robin Hood on 10% Commission
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IMS Reports 11.5 Percent Dollar Growth in '03 U.S. Prescription Sales

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Growth is Sustained by New Products Despite a Difficult Year

FAIRFIELD, CT, February 17, 2004 -- IMS Health (NYSE: RX) today reported that U.S. prescription drug sales grew 11.5 percent to $216.4 billion in 2003, compared with $194 billion in sales the previous year. Prescription product sales data are derived from the IMS National Sales Perspectives™ service and reflect wholesale prices. IMS is the world's leading provider of information solutions to the pharmaceutical and healthcare industries.

"As we predicted, 2003 pharmaceutical growth remains constant in comparison with 2002," said Paul Wilson, vice president, IMS Statistical Services. "This solid performance demonstrates the strength of the pharmaceutical industry given the economic climate this year and the scrutiny the industry has undergone by the government, the news media and the general public."

Generic and biotech dollar sales were key contributors to 2003 pharmaceutical sales results. Generic dollar sales grew by more than 22 percent and biotech grew by 22 percent as well. Also affecting results last year were the impact of prescription to over-the-counter (OTC) switching, continuing safety concerns about the use of hormone replacement therapy (HRT) and the growth of reimportation of prescription drugs from Canada. IMS estimates U.S. reimportation of prescription pharmaceuticals from Canada was equivalent to $1.1 billion U.S. dollars (based on U.S. prices) last year.

"The constancy of this year's sales growth is a by-product of the market traction produced by new products," Wilson explained. "The number of U.S. new molecular entities approved in 2003 was 21 vs. 17 in 2002.

"Notable new products introduced in late 2002 or 2003 included two new cholesterol treatments: AstraZeneca's new statin Crestor® and Schering/Merck's ZetiaTM, as well as the first non-stimulating ADHD treatment, Eli Lilly's Strattera®." Adds Wilson, "IMS's anonymized longitudinal prescription database shows that approximately seventy-five percent of patients newly prescribed with Strattera in August to December 2003 were from patients who were newly starting on ADHD treatment. During the same time period, seventy percent of patients

on ADHD treatment. During the same time period, seventy percent of patients newly prescribed with Crestor or Zetia were from patients who were newly starting on statins. Pfizer's Lipitor®, however, has maintained its lead position in the cholesterol reducers market with relatively few patients switching to the newer products."

Two additions to the erectile dysfunction market, GlaxoSmithKline's Levitra® and Lilly/Icos's Cialis®, had their U.S. launches in 2003. The impact of these drugs on sales of Pfizer's blockbuster Viagra® continues to be monitored, as these launches came late in the year. Initial IMS findings indicate, however, that Viagra is holding on to a high market share, currently over 85 percent. "Given the strong promotional campaigns of the two newcomers, Levitra and Cialis, this market will continue to expand and the battle for market share will play out in 2004," comments Mary Beth Lawrence, vice president, IMS Consulting. "Interestingly, we saw a trend change in overall Direct-to-Consumer (DTC) spending, which had been flat in 2002. Early indications are that full year 2003 spend will show a double-digit increase."

U.S. Prescription Distribution Channels

Retail pharmacies (chains, independents, food stores, mass merchandisers) remained the primary distribution channel for U.S. prescription drugs in 2003, capturing 59.8 percent total market share.

Chains and mass merchandisers were the largest sector with 36.3 percent of market and a solid growth of 11.4 percent. Mail service sales remained the fastest-growing retail sector last year, rising 15.5 percent and capturing 13.2 percent market share. Clinics were the fastest-growing non-retail channel last year, with more than 22 percent growth over 2002. Long-term care facilities continued to show strong growth with a 17.3 percent increase over last year, yielding a market share of 3.6 percent.

"We continue to see a higher growth rate in mail service, where 90-day supply is typical. The growth results from higher co-pay and incentives adopted by managed care plans," explains Wilson. "IMS also sees higher growth in the non-retail channels which is linked to introduction and growth rates of innovative injectable products such as Amgen's Aranesp® for anemia and Abbott's Humira® for rheumatoid arthritis."

U.S. Prescription Market Share by Distribution Channel, 2003
Wholesale prices, sales include prescription products only.
Source: IMS National Sales Perspectives™, 2/2004

		2003 Sales (US$ Billions)	Percent Growth Year-Over-Year	Market Share In 2003
1	Chain Stores/ Mass Merchandisers	78.6	11.4	36.3
2	Independents	31.6	7.5	14.6
3	Mail Service	28.6	15.5	13.2
4	Non-Federal Hospitals	22.9	6.2	10.6
5	Clinics	19.5	22.1	9.0
6	Food Stores	19.3	8.2	8.9
7	Long-Term Care	7.8	17.3	3.6
8	Federal Facilities	3.4	13.2	1.6
9	Home Health Care	2.2	6.3	1.0
10	HMO (Staff Model)	1.5	2.9	0.7
11	Miscellaneous	0.9	10.3	0.4

11	Miscellaneous	0.9	10.5	0.4
	Total	**216.4**	**11.5**	**100**

Note: Results for the Mail Service channel have not been projected, but IMS estimates they represent approximately 90% of sales. OTC insulins have not been included.

Leading U.S. Therapy Classes

The top ten therapy classes accounted for 35.1 percent of total U.S. prescription sales in 2003 and grew 10.5 percent over the prior year, as measured by U.S. dollars at wholesale prices. Seven of the top ten classes experienced double-digit growth.

The top six classes remained in the same position as 2002. Cholesterol-reducing statins were first, with sales of $13.9 billion and 6.4 percent total market share. Sales in the seizure disorders class grew fastest among the top ten therapy classes again last year, with 24.4 percent growth in 2003, yielding a sales volume of $6.9 billion.

Existing branded products drove most of the dollar growth in these therapeutic areas, with generic penetration and OTC availability lowering the growth in some of these classes. The antihistamines class was hit the hardest of the top ten and experienced a negative growth of 28.3 percent in 2003, the first full year that Claritin® was off patent.

"The proton pump inhibitors (anti-ulcerants) and the SSRI/SNRI (antidepressants), the number 2 and 3 classes respectively, held their market positions last year even though consumers had the choice of a generic substitute(s) in both classes, along with the additional competition of an OTC anti-ulcerant, AstraZeneca's Prilosec OTCTM," remarked Doug Long, vice president of IMS Industry Relations. "The antihistamine (allergy) class slipped to ninth position from seventh the prior year due to OTC competition from Schering-Plough's Claritin® OTC."

As the Food and Drug Administration looks to evaluate new OTC entrants and managed care focuses on encouraging generic and OTC options, tiering, co-pay and formulary analyses are becoming integral to pharmaceutical industry brand management decisions. "Many managed care plans introduced or extended the products covered in the more expensive co-pay tiers," commented Lawrence. "Payers are increasingly turning to benefit design, including multi-tier formularies, to more effectively manage prescription costs through incenting the use of generics, OTC, and lower price branded products.

Top 10 Therapeutic Classes by U.S. Prescription Sales, 2003
Wholesale prices, sales include prescription products only.
Source : IMS National Sales Perspectives™, 2/2004

		2003 Sales (US$ Billions)	Percent Growth Year-Over-Year
1	Cholesterol Reducers	13.9	10.9
2	Proton Pump Inhibitors (anti-ulcerants)	12.9	12.6
3	SSRI/SNRI (antidepressants)	10.9	11.9
4	Antipsychotics	8.1	22.1
5	Erythropoietins (anemia)	7.4	16.3
6	Seizure Disorders	6.9	24.4
7	COX-2 Inhibitors (anti-arthritics)	5.3	9.1
8	Calcium Blockers	4.4	0.5

8	Calcium Blockers	4.4	-0.5
9	Antihistamines	3.5	-28.3
10	Codeine & Combinations	3.2	14.3
	Total	**76.5**	**10.5**

Leading U.S. Prescription Products
Pfizer's Lipitor, a cholesterol reducer, was the leading U.S. prescription drug in 2003 for the third year running, with sales of $6.8 billion and 10.8 percent year-over-year growth. Merck's Zocor® – another cholesterol reducer – remained in second place, with $4.4 billion, while TAP's gastro-intestinal product, Prevacid®, kept its third place position. AstraZeneca's Prilosec® fell out of the top ten this year – it ranked No. 4 in 2002 and No. 2 in 2001 – as a result of the generic introduction of omeprazole in late 2002.

AstraZeneca's strategy to convert patients to Nexium® has been relatively successful, with that product filling the No. 7 place this year with $3.1 billion and the highest growth rate in the top ten with 57.7 percent.

Sales of Ortho Biotech's Procrit® were $3.3 billion, moving it up to No. 4 from No. 5 last year. Zyprexa®, Lilly's psychotherapeutic, moved into No. 5 with $3.2 billion in sales. Zoloft®, Pfizer's SSRI/SNRI antidepressant, managed another year of double-digit growth (11.5 percent) and remained in the top ten with $2.9 billion despite generic availability in the class.

Top 10 U.S. Prescription Products by Sales, 2003
Wholesale prices, sales include prescription products only.
Source: IMS National Sales Perspectives™, 2/2004

		2003 Sales (US$ Billions)	Percent Growth Year-Over-Year
1	Lipitor®	6.8	10.8
2	Zocor®	4.4	7.0
3	Prevacid®	4.0	11.8
4	Procrit®	3.3	3.7
5	Zyprexa®	3.2	6.6
6	Epogen®	3.1	6.5
7	Nexium®	3.1	57.7
8	Zoloft®	2.9	11.5
9	Celebrex®	2.6	-0.5
10	Neurontin®	2.4	19.3
	Total	**35.7**	**11.5**

Largest Pharmaceutical Companies by U.S. Sales
The rank order of the top seven pharmaceutical companies in 2003 remained consistent with 2002. "The challenge of growth is most steep for large companies already working off a large sales base. In addition, many of the large companies had to contend with the effects of patent expirations, for example, GlaxoSmithKline's Paxil® and Augmentin®, Johnson & Johnson's Ultram®, Bristol-Myers Squibb's Glucophage®, AstraZeneca's Prilosec and Zestril®, and Eli Lilly's Prozac®," explained Wilson.

Pfizer, the leading pharmaceutical company in 2001 and 2002 as measured by

prescription sales, experienced 9.7 percent dollar growth and $29.2 billion in sales in 2003, buoyed by its merger with Pharmacia in the spring of last year. GlaxoSmithKline, No. 2, had sales of $18.6 billion with 4.6 percent growth over 2002. Johnson & Johnson remained in third position with $15.2 billion in sales, a 14 percent increase over prior-year. AstraZeneca was the only company in the top ten to experience negative growth last year with sales down 5.8 percent. This dip was due primarily to continuing repercussions of Prilosec and Zestril going off patent. Even so, AstraZeneca has remained in fifth position.

Novartis had the second highest growth rate in the top ten with 23.8 percent and $9.5 billion supported by growth of Zelnorm®, the company's new irritable bowel syndrome product introduced late in 2002, and the growth of its generic business.

Amgen, the maker of Epogen® and other break-through biotech products, was the first biotech manufacturer ever to make the top ten. Breaking in this year at No. 8, Amgen acheived $7.7 billion in sales and significant growth of 34.7 percent, the highest growth rate in the top ten this year.
The ten largest pharmaceutical companies, as measured by U.S. prescription product sales, accounted for more than half of total U.S. prescription sales in 2003, with a combined market share of 59.6 percent – still a relatively fragmented industry.

Top 10 Pharmaceutical Companies by U.S. Prescription Sales, 2003
Wholesale prices, sales include prescription products only.
Source: IMS National Sales Perspectives™, 2/2004

		2003 Sales (US$ Billions)	Percent Growth Year-Over-Year
1	Pfizer	29.2	9.7
2	GlaxoSmithKline	18.6	4.6
3	Johnson & Johnson	15.2	14.0
4	Merck and Co.	14.1	9.1
5	AstraZeneca	10.4	-5.8
6	Bristol-Myers Squibb	9.6	6.6
7	Novartis	9.5	23.8
8	Amgen	7.7	34.7
9	Wyeth	7.6	4.9
10;	Lilly	7.5	11.7
	Total	**129.4**	**9.6**

Note: Excludes co-marketing agreements. Joint ventures assigned to product owner. Data run by custom redesign to include completed mergers and acquisitions.

Prescription Volumes
While year-over-year growth in the volume of brand drug prescriptions languished again last year, generic drugs grew at a healthy rate of 9.2 percent on a total dispensed prescription basis. The top five companies as measured by U.S. generic (excluding branded generic products) dollar sales were: Teva, Mylan/UDL, Watson, Sandoz/LEK and Alpharma.

"Generics reached new highs in both dollars and prescriptions in 2003," explained Long. "Total and new prescriptions dispensed climbed to 43 percent and 47 percent market share respectively."

Future Outlook

Looking forward to 2004 results, IMS predicts the U.S. pharmaceutical industry will continue to grow at a solid and steady rate of between 11-12 percent. This projected rate remains faster than the global growth rate, which is projected at 8-11 percent (compounded) through 2007. New product innovation, population demographics, the FDA acceleration of new product approvals, and an attractive list of potential blockbusters will help to drive this growth.

Top innovative products expected in 2004 in terms of sales potential include Eli Lilly's CymbaltaTM, Forest's NamendaTM and Genentech's AvastinTM. Cymbalta is entering the large antidepressant market and is expected to receive approval for urinary incontinence as well. Namenda is the first NMDA-receptor antagonist indicated for the treatment of patients with moderately severe to severe Alzheimer's disease and vascular dementia. Avastin is indicated for colorectal cancer.

"It will also be interesting to see whether several new combination products have successful launches, including Pfizer's Caduet® to treat hypertension and high cholesterol, Eli Lilly's SymbyaxTM to treat bipolar depression and Merck/Schering-Plough's Zocor/Zetia combination to treat high cholesterol," adds Wilson.

IMS forecasts about 30 new chemical/molecular entities launching in the U.S. during 2004, with a dozen having the potential to reach blockbuster status, once launched. Wilson explained that only three potential blockbusters launched in the U.S. last year (Crestor, Humira, Raptiva), which shows renewed strength in the market. Sales increases from these 2004 launches may, however, be offset by continuing generic penetration.
"2004 results will hinge on innovation, new products, the introduction of Medicare discount cards, and trends in cost containment. It looks to be another strong and exciting year for pharma," concluded Wilson.

About IMS
Operating in more than 100 countries, IMS is the world's leading provider of information solutions to the pharmaceutical and healthcare industries. With $1.4 billion in 2003 revenue and 50 years of industry experience, IMS offers leading-edge business intelligence products and services that are integral to clients' day-to-day operations, including marketing effectiveness solutions for prescription and over-the-counter pharmaceutical products; sales optimization solutions to increase pharmaceutical sales force productivity; and consulting and customized services that turn information into actionable insights. Additional information is available at http://www.imshealth.com.

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Pharmaceutical Cost Control In Canada: Does It Work?

by Devidas Menon

Although price controls have worked to a certain extent, drug expenditures continue to rise.

ABSTRACT: Governments in Canada have instituted mechanisms intended to control drug prices. These include the establishment of a semi-judicial body by the federal government to control factory-gate prices and of various measures at the provincial level, such as formulary management, use of generics, reference-based pricing, price freezes, and limits on markups. To a large extent, these measures have been effective in price control. Total drug spending in the country continues to rise, however; clearly, mechanisms other than price controls will need to be developed if drug spending is to be better managed.

THE RESPONSIBILITY FOR PROVIDING health care to citizens in Canada lies principally with provincial governments, although the federal Canada Health Act imposes some conditions on these governments. However, pharmaceuticals used outside hospitals lie outside the domain of the act. Consequently, there are many payers for pharmaceuticals. This paper discusses these payers' roles and the mechanisms that have been put in place to regulate and control drug spending, and comments on the implications of these.

The Legislative Context

The Canadian government's Hospital Insurance and Diagnostic Services Act went into effect in 1958. Under this act, a cost-sharing agreement was offered to provinces that developed publicly funded insurance programs for medically necessary hospital services, including inpatient prescription drugs. In 1968 this coverage was increased to include physician services with the passage of the Medical Care Act. Although a royal commission on health care appointed by the federal government (the Hall Commission, named after the chair, Justice Emmett Hall) had recommended inclusion of out-

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patient prescription drugs in this coverage, this did not happen. Finally, in 1984, these two pieces of legislation were repealed with the passage of the Canada Health Act, which is now in force. Because outpatient drugs are not considered "medically necessary services" covered by the act, there now are numerous payers for prescription drugs in the country, including the federal and provincial governments, health care institutions, private insurers, and patients.

In parallel with these developments, a number of legislative actions took place on intellectual property protection. The "compulsory licensing" provision of the Patent Act (introduced initially in 1923) was amended in 1969 to allow a manufacturer to import a patented drug, if a royalty were paid to the patent holder.[1] It was "compulsory" in that the patent holder had to allow the other manufacturer to do this, with a fairly small royalty (4 percent). Generic drug manufacturers gained significant market share after this. However, compulsory licensing was seen as contributing to low levels of research and development (R&D) investment (about 4.9 percent of sales in 1969) by the drug industry, and the patented drug manufacturers lobbied for change. In 1987 Bill C-22 was passed, which extended the period of patent protection before compulsory licensing could be possible. It also created the federal Patented Medicine Prices Review Board (PMPRB). The industry committed to increasing R&D investment in the country, up to 10 percent of sales by 1996. It also predicted an increase in numbers of scientific and research-related jobs as a result of the legislation.[2] Finally, in 1991, Bill C-91 was passed. This was in part the result of negotiations under the General Agreement on Tariffs and Trade (GATT) and the North America Free Trade Agreement (NAFTA); it increased patent protection to up to twenty years and eliminated compulsory licensing.

These legislative actions on both public health insurance and patent protection have had major impacts on who pays for drugs in Canada and what they pay for them. In 1997, for example, approximately U.S.$5.6 billion was spent on prescription drugs (including drug costs, copayments, and dispensing fees).[3] Half of this was paid by public-sector sources (predominantly provincial prescription drug benefit programs and hospitals), about 29 percent by individuals with some private insurance; and 21 percent, out of pocket.[4]

Price Control: The Federal Government Role

The federal responsibility for drug price control rests with the PMPRB, an independent, quasi-judicial body.[5] It is responsible for ensuring that prices charged by manufacturers of patented drugs are not excessive. The PMPRB reports to Parliament through the minister of health.

Classification scheme. The PMPRB does not set prices. Instead, it reviews factory-gate prices of individual products to determine if they are excessive. To do this, the board has instituted a set of processes, including review of individual drug prices, conduct of investigations, and application of enforcement mechanisms. The PMPRB process is based on the following classification scheme for all patented drugs: Category 1: a new drug product that is an extension of existing or comparable dosage form of an existing medicine, usually a new strength of an existing drug ("line extensions"); Category 2: the first drug to effectively treat a particular illness or that provides a substantial improvement over existing drug products, often referred to as "breakthrough" or "substantial improvement"; and Category 3: a new drug or dosage form of an existing drug that provides moderate, little, or no improvement over existing drugs ("me-toos").[6]

The board uses several criteria to classify a product. A manufacturer has to submit data (including price) to the PMPRB for classification of any drug. For a drug that is to be considered a breakthrough, the manufacturer also has to include reviews of the product in recognized journals (where available), results of two to five well-controlled trials, and results of a complete Medline search of articles and reviews of the drug. Once a drug is classified, its price is reviewed to determine if it is "excessive."

"Excessive" is interpreted based on the following guidelines: (1) The price of an existing patented drug cannot increase by more than the Consumer Price Index (CPI). (2) The price of a new drug (in most cases) is limited so that the cost of therapy with the new drug is in the range of the costs of therapy with existing drugs in the same therapeutic class. (3) The price of a breakthrough drug is limited to the median of its prices in France, Germany, Italy, Sweden, Switzerland, Britain, and the United States. In addition, no patented drug can be priced above the highest price in this group of countries.

Possible actions. The review of prices of all patented drugs is conducted on a regular basis. This is based on manufacturers' filings as well as on complaints about price. Manufacturers are supposed to file price and sales information each year that the drug remains patented. These figures are then reviewed by board staff. As an example, of the 840 patented drugs sold in 1999, 826 had undergone price reviews that year. Investigations are conducted when PMPRB staff determine that a particular price appears to exceed the guidelines. If it is established that a price is excessive, the manufacturer can make what is called a Voluntary Compliance Undertaking (VCU) to adjust the price and take remedial action. This could include a financial settlement with the federal government that re-

flects excess revenues earned since the price first exceeded the guidelines.

The board also can initiate formal proceedings and hold a public hearing. Following such a hearing, it can order the manufacturer to reduce the price so that it is no longer considered excessive, reduce it even further for a specified time period so as to offset previously earned excess revenues, reduce the price of one other patented drug of the same manufacturer, and, if required, order a payment to the government of Canada equal to excess revenues. The board has recourse to other legal action should compliance not be reached.

■ **Effect on prices.** The PMPRB uses the Patented Medicine Price Index (PMPI) as a measure of manufacturers' reported prices for patented products. This index shows how much more or less a fixed market basket of drugs would have cost in the current year than in a reference year, using the quantities sold in the reference year.[7] Between 1988 and 1993 the PMPI increased each year, representing an increase in average price in each of the years over the previous one. In the next five years the PMPI fell each year; that is, manufacturers' prices for patented medicines fell each year. Between 1988 and 1999 manufacturers' prices for all prescription and nonprescription drugs increased an average of 1.9 percent annually (compared with the average figure of 0.8 percent for prescription drugs), which is less than the average annual increase in the CPI (2.6 percent).[8]

These data lead to the conclusion that prices have been increasing modestly at worst, and in fact decreasing in some cases. What about the actual prices themselves? In 1987 the ratio of the Canadian prices of patented drugs to the median of the prices in the seven comparison countries was 1.23 (that is, prices were, on average, 23 percent higher in Canada); Canadian prices were higher than in all of the other countries except the United States. This ratio has declined since then, and in 1999 prices were on average about 10 percent below the comparison median; only the United States, Italy, and France had higher average prices.[9] Currency exchange rates could have some influence on these ratios.[10]

Breakthrough drugs are particularly important in the PMPRB review. Although they accounted for only about 12 percent of all patented drug sales in 1997, they have had much more impact than this share might suggest. They are generally more costly and innovative and may also establish a new therapeutic class and therefore a reference price for that class. In 1997, 97 percent of breakthrough drugs were priced below the international median, compared with 75 percent in 1990.

Price Control: The Provincial Governments' Roles

Various drug programs have been developed by provincial governments, particularly for the elderly and for persons requiring social assistance. This began in 1974 with the Ontario government's Drug Benefit Program for needy and elderly persons.[11] Now, all provincial governments provide some form of publicly funded drug coverage for seniors, for those requiring social assistance, and, to a certain extent, for the general population.[12] There are also special programs for diseases such as cystic fibrosis and multiple sclerosis and for catastrophic expenses. Each province manages its own mix of coverage plans, and rules of coverage vary considerably. These include who is covered; what drugs are covered; copayments, deductibles, and premiums; encouraging cost-effective prescribing; and measures limiting prices, markups, and other fees.[13] Despite interprovincial variations, there is general agreement that beneficiaries should be provided with the most cost-effective therapies. Price is therefore an important consideration for coverage by a provincial drug program.

A number of approaches have been, are being, or can be used to manage either prices or expenditures. These include the use of formularies, generic substitution, reference-based pricing, price freezes, controls on markups and dispensing, and "risk sharing."

■ **Formularies.** After a new drug has received approval to be marketed and sold in Canada, the manufacturer makes a submission to a provincial government to have the drug covered by a particular drug program, which "covers" a specified list of prescription drugs (the formulary). The drug program reviews effectiveness of a new product in relation to its costs and determines whether it has a therapeutic advantage over products already on the formulary. Usually, a new drug that is merely equivalent to an existing listed drug will be added only if it does not increase program costs. Manufacturers will therefore set prices so as to obtain market access to the publicly funded drug programs. "Value for money" data on new products are increasingly being demanded by drug plan managers. Canadian guidelines have been developed to assist manufacturers in designing, conducting, and reporting economic evaluations.[14]

In some cases, drugs may be added to the formulary under specific conditions. For example, if a new drug is generally equivalent to existing drugs for most uses but has a therapeutic advantage in a specific use, it may be covered under a "special authorization" and reimbursed for that use. Special programs may be created, as in Alberta, where new drugs for multiple sclerosis are available with specific criteria for patient selection/eligibility.

■ **Generics.** For many years Canada encouraged competition in

the drug market with the use of generics. This had in fact been a major part of pharmaceutical patent policy. Also, the drug regulatory review process allows generic drug manufacturers the option of providing data comparing the ingredients of their product with those of the patented product, instead of repeating all of the studies originally conducted by the manufacturer of the patented product. This helps to reduce generics' time to market. Naturally, generics are priced lower than the original innovative products, as R&D costs are considerably lower for these products.

Provincial (and other) drug programs use generic substitution to control expenditures. If a drug is available from multiple sources, provincial programs usually pay the price of the lowest-cost alternative. Generics make this possible when they exist. Some provincial governments have gone even further, requiring that, for example, the first generic available be priced at approximately three-quarters of the level of the patented drug already on the formulary.

■ **Reference-based pricing.** Reference-based pricing (RBP) is an extension of the notion of generic substitution and has been introduced in British Columbia. RBP categories are identified—for example, nitrates for the treatment of unstable angina.[15] The "reference product" in each category is that with the lowest price. The government uses an independent panel of pharmacists and doctors at the University of British Columbia to determine therapeutic equivalence of drugs. This panel evaluates and compares the effectiveness of existing and new drugs for individual conditions, based on research evidence. The drug benefits program will only reimburse—for any drug in the category—the price of this reference product. The major difference between RBP and generic substitution is that with RBP, drugs in a category need only to be therapeutically equivalent, not chemically identical. There are four drug classes for which there is a reference standard.[16] A physician can request a nonreference product for a specific patient. This requires the physician to apply for "Special Authority" to the drug program, in which the physician must identify a specific medical need.

■ **Price freezes.** In Ontario a price freeze was instituted from 1994 through 1998. Since then, price increases have been considered, if the manufacturer is prepared to provide a price reduction for a different drug so that the change is cost-neutral to the drug program.

■ **Markups and dispensing fees.** These made up about one-third of the purchase price of drugs in 1997. Provincial governments can limit markups, so that prices of drugs bought under the provincial drug program will be controlled. Similarly, they have some control over dispensing fees for drugs paid for by their programs, since they are set either by them or through negotiations with provincial

"Even when a drug has been launched in Canada, access for patients across the country may be an issue."

pharmacists' associations. In Canada there is little opportunity for discounting prices of patented drugs, although discounting is common with generics.

■ **"Risk sharing."** Recently, some governments have started to negotiate with companies to reach agreements aimed at limiting total expenditures on specific drugs. These could, for example, compel the company to pay the province for expenditures above an agreed-to figure. Specifically, since 1988, in Ontario, as a condition for listing a patented drug, manufacturers must enter into agreements with government forecasting what the drug will cost the program (excluding dispensing fees and markups) each year for three years.

■ **Other payers.** Health care institutions, private insurers (unions, employers, insurance companies), and individual patients also pay for drugs. The prices paid by these groups are influenced by what the provincial programs pay. In the retail sector, however, there is no control over markups and dispensing fees (as there is in the provincial programs); patients paying for their own medications may face higher final prices. This could also be true for third-party payers, although some of them may negotiate fees. In the hospital sector, discounts are possible. Hospitals often negotiate specific arrangements with individual companies.

■ **Effect on prices.** Three factors come into play: price trends, price levels, and drug expenditures. A recent analysis of prices and expenditures by six of the provincial drug programs from 1990 to 1997 provides some insight into all three areas.[17] (These six provinces contain approximately 70 percent of the population of Canada.)

Trends. Annual increases in retail prices of patented drugs (excluding dispensing fees) fell from 1990 on; since 1994 average prices have actually dropped. This is on average true for the prices of nonpatented single-source drugs as well, while for nonpatented multiple-source drugs, this trend of annual price decreases began in 1993. Such averages might be misleading, however, because the changes in the individual provinces were different. For example, in Ontario patented drug prices dropped more rapidly than in the other provinces, and in Alberta, following three years of annual reductions in price for these products, there was a slight increase in 1997. Clearly, different provincial policies affect prices differently. Over the entire period, price increases of the three types of drug

products were below the rate of inflation.

Prices. Patented drugs undergo PMPRB price control, but prices of nonpatented drugs are under less control. In 1996 Canadian prices for nonpatented single-source products (in the six provincial drug programs reviewed) were, on average, 30 percent higher than the median international price. In a country-to-country comparison, based on the top seventy-two drugs in this group, Canada ranked second-highest in overall average price, below the United States, where prices were, on average, 96 percent higher. At the other end of the spectrum is Italy, with prices on average being 47 percent of Canadian prices.[18] These higher Canadian prices may be due to the fact that there is only one supplier for the product in the country.

Expenditures. Exhibit 1 shows expenditures by these six provincial programs from 1990 to 1997. Despite price-control mechanisms, expenditures on drugs have been increasing in the provinces.

What Are The Issues And Tensions?

The objective of price-control measures is obviously to control price, and this has succeeded to some extent in Canada. But expenditures continue to increase. Also, it is not clear what some of the other effects have been, most of which relate to access to needed drugs. This is the source of major tension between governments and the drug industry in Canada.

Manufacturers in Canada are concerned with the interpretation of the criteria for breakthrough or Category 2 drugs, although they feel that the process of PMPRB review is itself transparent. In the eight years between 1988 and 1995, of the 581 drugs reviewed by the board, only 41 were classified as breakthrough and thus offered a potentially good price for the manufacturers. The industry has suggested that four categories be used by PMPRB. In one approach, breakthroughs and line extensions would be retained as categories,

EXHIBIT 1
Provincial Government Drug Spending, Millions Of U.S. Dollars, 1990–1997

	1990	1997	Percent change
British Columbia	$ 154.4	$ 257.0	67%
Alberta	120.9	171.1	42
Saskatchewan	58.7	43.2	-27
Manitoba	32.7	54.7	67
Ontario	589.9	871.5	48
Nova Scotia	55.8	60.5	8
Total	1,012.3	1,458.0	44

SOURCE: Federal/Provincial/Territorial Task Force on Pharmaceutical Prices.
NOTE: Includes ingredient costs, markups, and dispensing fees.

and two new ones—new class/form/indication and therapeutic class extension—created.[19]

It has been reported that because of some PMPRB rulings, certain drugs have not been launched in Canada, although they have undergone regulatory review and received a Notice of Compliance.[20] Price levels set by the PMPRB, especially when compared with U.S. prices, are claimed to be a disincentive to launch in a country that has only 2 percent of the world drug market. There certainly are a number of drugs that have been approved for sale both in Canada and the United States but that have not been launched in Canada. Examples include Ambien (zolpidem/Searle), a hypnotic; Capozide (captopril-hydrochlorthiazide/Bristol Myers Squibb), a combination of an angiotensin converting enzyme (ACE) inhibitor and a diuretic; and Lorabid (loracarbef/Eli Lilly) and Orelox (cefpodoxime/Aventis), both antibiotics. Price limits may have caused this (especially for Ambien), but this has yet to be rigorously proven.

The patented-drug manufacturers' association Rx&D has recently expressed concern about the pricing restrictions of the PMPRB: "It must be realized that attempts to lower prices below current levels will ultimately have a negative impact on Canadians' access to new medications, and the benefits of research and development investment."[21] This statement indicates the position of the manufacturers—namely, that investment by the industry in R&D is a benefit to Canadians, quite apart from direct health benefit. Exhibit 2 compares the ratio of R&D to domestic sales in the comparator countries and Canada in 1988 and 1995. The industry association has claimed that the number of jobs in the industry went from 14,500 in 1987 to 21,000 in 1999; of this, an increase of more than 3,000 has been attributed to R&D-related jobs. However, it is not clear exactly what the nature of these jobs is, or whether they are greatly increasing research capacity in the country.

EXHIBIT 2
Pharmaceutical Research And Development As A Percentage Of Domestic Sales, In Eight Countries, 1988 And 1995

	1988	1995
Canada	6.1%	11.7%
Italy	11.0	11.7
France	15.7	17.2
United States	16.2	18.4
Germany	16.7	20.5
United Kingdom	22.2	25.8
Sweden	32.8	58.1
Switzerland	141.1	47.2

SOURCE: Federal/Provincial/Territorial Task Force on Pharmaceutical Prices.

Even when a drug has been launched in Canada, access for patients across the country may be an issue. This is mainly a result of the fact that Canada really has ten formularies, about which decisions are made independently by provinces. A recent study that examined the 148 new drug molecules launched between 1991 and 1998 demonstrated significant variation in access in provincial drug programs.[22] For example, of the twenty-three drugs for cardiovascular disease, one province had ten under the drug program and another had all but one. Variations such as these were found even after correcting for known differences between provincial programs (for example, some cancer drugs are funded by the government through cancer boards and are not included on the provincial formularies). Price is certainly a consideration in these decisions and may well have something to do with these variations. Clearly, in some provinces individuals have to pay out of pocket for certain prescription drugs that would have been subsidized by government in another province, or worse, they may not take the drug at all.

Such findings raise questions about how provincial formulary decisions are actually made. Companies claim that they provide the same information to the various provinces, yet the decisions are different. In fact, for the economic evaluation component of the submissions (which is often a requirement by government), there are accepted national guidelines. Industry spokespeople express frustration that they spend time and effort having evaluations conducted according to the guidelines, yet governments seem to ignore them. This is despite the fact that based on two years' worth of experience with the guidelines, a review showed that economic evaluations were well presented, complete, and transparent, thanks in part to the guidelines.[23]

There are conflicting claims regarding the effects of reference-based pricing. A 1996 survey concluded that senior citizens in British Columbia supported the RBP program; more than 90 percent of those surveyed were in favor, and only 14 percent believed that it would affect access to care.[24] On the other hand, the industry association in Canada challenged RBP in the courts. This series of challenges lasted three years and involved two appeals by the association. Ultimately, the Supreme Court of Canada ruled in favor of the government, which then claimed that the $74 million saved through this program could be used to maintain and protect the drug program and to make other innovative drugs available in the province. The definitive study on the downstream effects of RBP has yet to be done, although some early results of studies are emerging.[25]

Finally, the assertion is made that decisions are being made on the basis of drug price alone (as opposed to considering overall cost-

effectiveness), and as such are inappropriate. Often it is cost containment within the drug program that drives formulary decisions, in isolation of cost reductions that might occur elsewhere in the health care system were the drug to be used. This is another source of frustration for the industry, which is usually asked to provide economic analyses from a societal perspective of the impact of their new product, only to have (from their point of view) the societal benefits accruing in another sector ignored when the decision is made.

A NUMBER OF CANADIAN federal and provincial government actions to control the price of drugs seem to have attained their objective to a large extent. At the same time, drug spending continues to increase. Between 1990 and 1997 drug spending (on all drugs) increased at an average of 5 percent a year. As a proportion of total health spending, there has been a constant increase as well. A recent report indicates that between 1990 and 1997 the percentage of total health care spending attributable to prescription drugs increased by 2.7 percentage points in Canada. This compares with the Organization for Economic Cooperation and Development (OECD) median increase of 1.3 percentage points.[26]

From a public policy perspective, expenditures are probably more relevant than prices. Clearly, price is merely one of the many factors that influence expenditures. Others include population demographics, prescribing practices, and introduction of new and innovative drugs, some of which might replace nondrug therapy. If pharmaceuticals are to better managed, as much (if not more) attention has to be paid to these factors, and their impacts as has been paid to drug prices.

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NOTES

1. P.K. Gorecki and I. Henderson, "Compulsory Patent Licensing of Drugs in Canada: A Comment on the Debate," *Canadian Public Policy* 7, no. 4 (1981): 559–568.
2. J. Lexchin, "Pharmaceuticals, Patents, and Politics," *International Journal of Health Services* 23, no. 1 (1993): 147–160.
3. Federal/Provincial/Territorial Task Force on Pharmaceutical Prices, "Drug Prices and Cost Drivers 1990 to 1997" (Ottawa: Health Canada, April 1999), 1. An exchange rate of Can$1.4849 for U.S.$1 is used in this paper; this is the rate used by the PMPRB for the period ending December 2000.
4. The federal government in Canada has constitutional responsibility for providing health services to specified populations, such as the First Nations peoples and military veterans. It runs a number of drug benefit programs as a

result. Drug costs for these groups are considerably smaller than what provinces pay through their programs.

5. The general powers granted to the PMPRB under the Patent Act include "all such powers, rights and privileges as are vested in a superior court."
6. Patented Medicine Prices Review Board, *Annual Report* 1999 (Ottawa: Government of Canada, 1999), 28.
7. PMPRB, "A Description of the Laspeyres Methodology Used to Construct the Patented Medicine Price Index (PMPI)," Paper S-9710 (Ottawa: Government of Canada, March 1997).
8. PMPRB, *Annual Report 1999*, 20.
9. Ibid., 22.
10. The PMPRB uses three-year blocs of time to calculate exchange rates, so that some smoothing of these rates will occur. However, the Canadian dollar fell against many other currencies over the period 1987–1999, and so Canadian prices in U.S. dollars might appear to be low.
11. *Report of the Pharmaceutical Inquiry of Ontario, 1990* (Toronto: Government of Ontario, 1990), 17, 18.
12. P. Jacobs and J. Bachynsky, "Public Policies Related to Drug Formularies in Canada: Economic Issues," Institute of Health Economics Working Paper 00-2 (Edmonton: IHE, 2000).
13. D.A. Freund et al.,

he braids in an account of Arshile Gorky's life because the painter, as a child, survived the massacre. His famous painting of himself and his mother becomes an icon to Egoyan. More: the Gorky expert whom the inner film's director engages as a consultant gets involved in the story, as does her son and his love life. Even more: the son visits Turkey and returns with cans of film. These are investigated by a customs inspector, and the son's answers provide flashbacks that are strands of the narrative. The customs inspector is played by, of all actors on earth, Christopher Plummer, and the moment we see him we know that the inspection is going to take time. Plummer would not be there for a few routine minutes.

The young man is touchingly played by David Alpay, and the director of the interior film is the grizzled, still attractive Charles Aznavour, himself of Armenian

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How the drug industry distorts medicine and politics.

America's Other Drug Problem

By ARNOLD S. RELMAN *and* MARCIA ANGELL

THE AMERICAN HEALTH care system cannot live without the pharmaceutical industry, but it may not be able to live with it either, unless the industry is greatly reformed. For better and for worse, this enormous and hugely profitable enterprise has become a dominating presence in American life. It uses its great wealth and influence to ensure favorable government policies. It has also, with the acquiescence of a medical profession addicted to drug company largesse, assumed a role in directing medical treatment, clinical research, and physician education that is totally inappropriate for a profit-driven industry. Like most other for-profit corporations, drug companies are impelled primarily by the financial aspirations of their investors and executives. This incentive may serve useful social purposes in the distribution of ordinary goods in most markets, but prescription drugs are not like ordinary goods, and the market for drugs is not like other markets. The misconception that drugs and their market are like other goods and markets explains most of the serious problems with the pharmaceutical industry today.

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Drug Costs

THE RISING COSTS of drugs are the immediate public issue. Expenditures on prescription drugs—now roughly $170 billion per year—constitute a rapidly growing fraction of our $1.4 trillion health care bill. Greater overall use of drugs, higher prices for new drugs, and steady increases in the prices of existing drugs all contribute to an annual inflation in drug expenditures of 14 percent (down from a high of 18 percent in 1999). Within a few years, this surge in costs will probably make drugs the second largest component of our national health care budget, after hospitalization. According to statistics kept by the Center for Medicare and Medicaid Services, American expenditures on prescription drugs, expressed as a percentage of GDP, were virtually steady between 1960 and 1980 but increased rapidly soon thereafter, and by 2000 they had almost tripled.

Last year, a prescription for one of the twenty top-selling brand-name drugs—which is usually for a one-month supply—cost on average about $100. Prices for prescription drugs are on average much higher in the United States than anywhere else in the world. Many patients, particularly the elderly, take several drugs, so drug costs have become a heavy burden for them; but the costs of prescription drugs are now a major problem for all who must pay for them. That includes government and private insurance plans, and uninsured and partly insured individuals.

Resistance to escalating drug expenditures is growing among all the purchasers, and the media is full of critical stories and commentaries. So far, however, none of this has had a noticeable impact on rising drug expenditures. The pharmaceutical industry has been fighting effectively against all efforts to control prices or to limit the markets for its expensive new brand-name drugs. It channels these efforts and most of its public relations and lobbying activities through its trade association, the Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA's membership includes virtually all American manufacturers of brand-name drugs, and many foreign manufacturers as well. With a full-time staff of 120 in its Washington offices and hundreds of lobbyists working the halls of federal and state government, and with a core budget of some $60 million and large additional subsidies from the industry for special projects, PhRMA conducts an extensive, virtually nonstop campaign on behalf of its clients. This is in addition to the millions spent in Washington by individual pharmaceutical firms promoting their own business objectives.

PhRMA adamantly opposes any regulation of expenditures for brand-name drugs. It argues that high prices simply reflect the very high costs of discovering and developing new drugs. Any form of price control, it claims, would eat into the industry's research and development budget, and thereby choke off the pipeline that brings the public important new drugs. Generic drugs are different, it points out, because they are merely copies of brand-

name drugs whose exclusive marketing rights have expired, and therefore their manufacturers do not have high research costs. Moreover, PhRMA contends that high profits are a necessary incentive for undertaking the risky and arduous business of discovering innovative drugs. These drugs are vital to the health of Americans, according to the industry, and it would be disastrously shortsighted to lessen the incentives to find them. PhRMA also maintains that, whatever the expenditures for prescription drugs, we get more than our money's worth. According to this argument, the output of the industry's research laboratories not only cures disease and extends and improves people's lives, but probably even saves money by avoiding hospitalizations and other more expensive kinds of treatment. In sum, the industry portrays itself as an exemplar of science-based free enterprise, primarily dedicated to discovering—through costly and risky research—new treatments for disease. It wants the public to believe the catchy slogan of the pharmaceutical giant Pfizer: "Life is our life's work."

THE RHETORIC IS stirring, but the arguments simply do not hold up. First, research and development (R&D) constitutes a relatively small part of the budgets of the large drug companies. Their marketing and advertising expenditures are much greater than their investment in R&D. Furthermore, they make more in profits than they spend on R&D. In fact, their profits are consistently much higher than those of any other American industry. Prices (which bear little relation to the costs of developing and manufacturing a drug) could be lowered substantially without coming close to threatening the R&D budgets of drug companies, much less their economic survival.

Second, the pharmaceutical industry is not particularly innovative, and it is growing less so each year. The great majority of new drugs coming to market these days, although patented, are not new at all. They are variations on older drugs already on the market. These are called "me-too" drugs, and they represent attempts to capitalize on the success of "blockbuster" drugs. (Blockbusters are defined here as drugs with over $500 million in annual sales.) The few drugs that are truly innovative have usually been based on taxpayer-supported research done in nonprofit academic medical centers or at the National Institutes of Health. In fact, many drugs now sold by drug companies were licensed to them by academic medical centers or small biotechnology companies.

Third, while there is no doubt that the best of the new drugs have greatly improved or saved many lives, this is certainly not true of all of them; most add little or no medical value. The use of some drugs has saved money by reducing hospitalizations or the need for expensive procedures, but whether prescription drugs reduce total expenditures for health care in the long run is an imponderable question. As expenditures on drugs continue to rise, the answer becomes more uncertain, the industry's insistence to the contrary notwithstanding.

Far from being a "research-based industry," as it likes to call itself, the pharmaceutical industry now devotes most of its resources to functioning as a vast marketing and advertising enterprise whose best products were discovered and often partially developed elsewhere—usually at public expense. And this industry is hardly a model of free enterprise. It may be free to decide which drugs to develop and to set its own prices, but its lifeblood is government-granted monopolies—in the form of patents and FDA-approved exclusive marketing rights. Drug companies apparently see no contradiction in manipulating existing laws and regulations to stave off competition from generic and foreign manufacturers and lobbying for even more governmental protections while at the same time using free-market rhetoric to demand less government involvement in the pricing and the marketing of drugs.

The industry wants to obscure a basic fact: there is not and there cannot be anything like a free market in prescription drugs. The pharmaceutical business is, for many reasons, critically dependent on government help. That is why it spends so much on lobbying. Moreover, its sales are not determined primarily by price or by consumer choice, but by the physicians who prescribe drugs. And that is why it spends so much more to influence the behavior of doctors.

R&D Costs: How High Are They Really?

BEFORE DISCUSSING THE costs of bringing a new drug to market, we must first explain the steps in that process. The discovery of a drug candidate is usually the result of research into the molecular basis of disease, which is done primarily in academic or government laboratories. The next step is the pre-clinical phase of the R&D work, which is usually done by industry—although not necessarily by the company that ultimately sells the drug. This involves biological screening and pharmacological testing in laboratory animals to determine how the drug is absorbed, metabolized, and excreted, and to learn about its toxicity. According to PhRMA's annual report, approximately one-quarter to one-third of all pharmaceutical R&D expenditures are involved in finding or acquiring a new drug candidate and taking it through the pre-clinical screening phase. The industry claims that only about one in one thousand screened compounds makes it through the pre-clinical phase to the clinical phase—that is, to testing in human subjects.

To begin clinical testing, a drug must be registered with the Food and Drug Administration (FDA), which by law must ultimately approve all drugs for safety and effectiveness before they can be sold. There are four phases of clinical testing. In Phase I, the new drug is given to a few human volunteers to establish safe dosage levels and to study its metabolism and side effects. If the drug looks promising, it moves into Phase II, which involves small clinical trials at various doses in patients with the relevant medical condition. Finally, if all goes well, Phase III clinical trials are undertaken. These evaluate the safety and the effectiveness of the drug in much larger numbers of patients (hundreds or thousands of them), with the expectation of gaining FDA approval if the trials are successful. No more than one in five drug candidates entering clinical testing make it through to FDA approval and reach the market, so the chances that a drug candidate, once selected, will ever get to the market are said to be less than one in five thousand.

The total time from the beginning of pre-clinical testing of a candidate drug to FDA approval ranges from about six to ten years. That includes the time the FDA spends on review of the application for approval (called a new drug application, or NDA), which averages about 16 months. But these times are quite variable, and in special cases they can be greatly shortened. After approval of a drug, the FDA requires the manufacturer to continue its surveillance of the drug and to report unanticipated side effects. The company may also want to do additional clinical studies to gain approval for new uses or formulations of the drug. All clinical studies after the initial approval are designated as Phase IV trials.

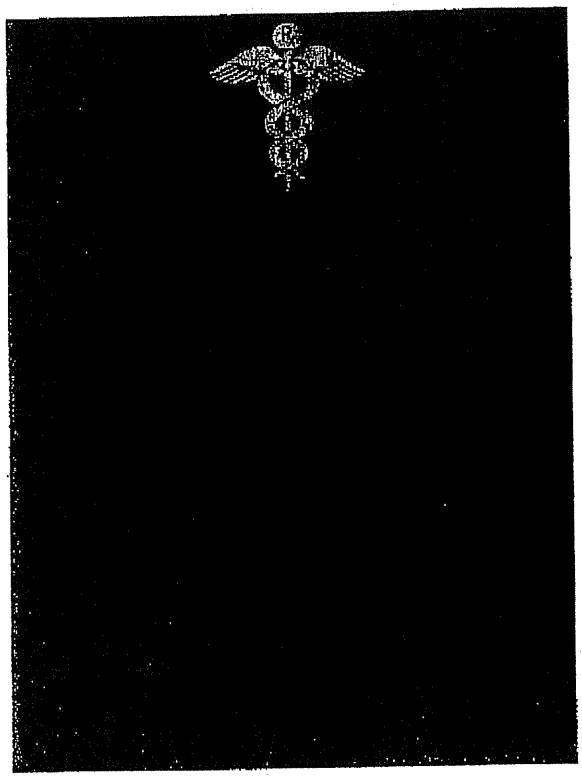
According to PhRMA's annual report, the large drug companies last year spent approximately 15 to 17 percent of their income on R&D (before adjustment for tax deductions and credits). This figure is necessarily soft, since in general the industry's accounting for its R&D expenses leaves a lot to be desired, and there are

also differing estimates of total income. Much R&D information is considered proprietary. Individual companies report total R&D expenditures in their Securities and Exchange Commission (SEC) filings, and PhRMA's annual report gives industry-wide averages for total R&D as well as average figures for the breakdown of expenses by general R&D functions. But the companies do not make available most of the really interesting details, such as what each company spends, and for what purposes, on the development of each drug. We also do not know how much marketing is concealed under the rubric of "development," particularly in Phase IV post-approval studies. Still, one financial detail of R&D expenses has been widely publicized by the industry: the estimated average total R&D cost of each new drug brought to market. That figure is currently said to be $802 million (in year 2000 dollars), including the amount spent on the many failures and false starts. This huge outlay, which we are told is rising rapidly with the growing expense of clinical trials, is said to justify—indeed to require—the high prices of new drugs.

Pre-clinical and clinical testing and the other tasks required before a drug can be brought to the FDA for approval can be long, difficult, and very expensive. But $802 million apiece? To put it in the kindest terms, that is an imaginary number. It is based on debatable accounting theory and it is premised on blind faith in the confidential information supplied by the industry to its economic consultants at the Tufts Center for the Study of Drug Development, the University of Rochester Graduate School of Business Administration, and the Department of Economics at Duke University, who arrived at this number. Over the years, these consultants have analyzed the costs of new drug development, and the $802 million estimate represents an updating of their work.

Although this latest analysis has not yet been formally published, it was announced at a forum and a press conference last year in Philadelphia. PhRMA, leaders of the industry, and its defenders in the media have been trumpeting the results ever since. Joseph DiMasi of Tufts University, the senior author of this work, kindly sent us a draft of the manuscript describing the analysis, and he discussed his views with us in several telephone conversations. He also shared his opinions about a critical analysis of this work that was released last year by Public Citizen, the Washington-based consumer watch group. Among Public Citizen's objections to the work of DiMasi's group, we consider the following to be most important.

First, the analysis concerns the costs only of new molecular entities (NMEs), sometimes called new chemical entities (NCEs). These are drugs whose active ingredients are newly discovered or synthesized molecules. The analysis was also restricted to NMEs developed entirely within the drug companies. The 68 drugs selected for study are never named; nor are the manufacturers or the individual costs. But NMEs are only a minority of the drugs that are newly approved. As we already noted, most are new dosage forms or combinations of drugs already on the market. Moreover, an increasing number of drugs are simply licensed from academic medical centers or biotechnology companies, and are not entirely developed in the drug companies. So, despite the implication by the industry that the DiMasi calculations tell us the average cost of the R&D needed for all the new drugs sold, these estimates seem to be based on sampling from a highly selected group of drugs. Full disclosure of the data, including the identity of the drugs selected for study and the costs for each, would have been important for the evaluation of the significance of this economic analysis.



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Second, the final estimate of the cost per drug is not the actual out-of-pocket cost, but what the authors call the "capitalized" cost—that is, it includes the estimated revenue that might have been generated over the long development period if the money spent on R&D had instead been invested in the equity market. This theoretically lost revenue is known as the "opportunity cost," and it is added to the industry's out-of-pocket costs of R&D. The authors seem to justify this interesting accounting maneuver on the grounds that from the perspective of investors, a pharmaceutical company is really just one kind of investment, which they chose among other possible investment options. But while this may be true for investors, surely it is not true for the pharmaceutical companies themselves. The latter have no choice but to spend money on R&D if they wish to be in the pharmaceutical business, so they have no "opportunity costs." To add the investors' opportunity costs to the company's out-of-pocket cost of developing a drug seems rather odd. DiMasi assures us that this calculation conforms with standard economic thought and accounting practice, but recent events on Wall Street make such reassurance less comforting than it might once have been. In any case, when DiMasi and his colleagues add the "opportunity cost" to their calculated out-of-pocket cost of pharmaceutical R&D ($403 million per drug), the final estimate is approximately doubled.

Finally, the Public Citizen analysis points out that since R&D expenses are deductible from a firm's tax base, calculation of the cost of R&D should be reduced by the amount of corporate tax avoided. This tax saving would reduce the net cost of R&D by a percentage equal to the corporate tax rate (currently about 34 percent). DiMasi says that the corporate tax applies to net income, and since the latter is already reduced by the R&D expenditures, there is, properly speaking, no tax saving and no need to adjust the calculation of the R&D cost that he and his colleagues are making. We are not qualified to debate the accounting terminology, but it seems to us only common sense that were it not for the full deductibility of R&D from the tax base, the pharmaceutical industry's taxes would be higher and its after-tax income would be lower. Why is it not reasonable, therefore, to deduct this difference—whether it is called a "tax saving" or not—from the out-of-pocket expenditures on R&D when calculating the net cost of

R&D to a pharmaceutical firm? The Office for Technology Assessment, whose report on this subject in 1993 is often cited incorrectly as supporting the DiMasi analysis because it also considers opportunity costs, agrees with Public Citizen's position on tax deductions.

IN SUM, WE believe that Public Citizen's criticisms are substantially correct, and we agree with the group's conclusion that even if one were blindly to accept the reliability of the unrevealed data used in the calculations, the $802 million estimate of "capitalized" cost produced by the industry's economic consultants should be reduced to an after-tax net of less than $266 million. But remember, that would be the average out-of-pocket R&D cost only for the new molecular entities developed entirely in-house, not the average cost of all of the drugs approved each year. Most approved drugs entering the market are not really new, or they are licensed from other sources, or both. Such drugs probably have lower R&D costs, although there are no good data on this point. We conclude that the average out-of-pocket, after-tax R&D cost of most of the drugs upon which the industry's revenue now depends was probably much lower than $266 million (in year 2000 dollars). Tax credits for certain types of R&D would probably reduce that estimate even more.

The suspicion that average R&D costs per drug are not nearly as high as claimed is further supported by other data provided by Public Citizen. If one divides the industry-supplied estimates of total R&D expenses by the total number of drugs entering the market, making appropriate allowances for the lag time between expenditures and the date of entrance into the market, the resulting net out-of-pocket, after-tax costs would probably be less than $100 million for each drug that was approved between 1994 and 2000. That, admittedly, is only a rough approximation; but the general conclusion seems inescapable: that the $802 million estimate now being promoted by the industry and its partisans is much too high.

Whatever the cost of bringing each new drug to market, the total R&D expenditures of the pharmaceutical industry—according to PhRMA, now about $30 billion for all its members in the United States and abroad—are indeed large. But they should be compared with reported expenditures on marketing and administration, which are more than twice as much as R&D expenditures. Moreover, the most important financial fact about the major pharmaceutical firms is that, despite their expenses, they are immensely profitable. The ten American pharmaceutical companies in the Fortune 500 list last year ranked far above all other American industries in average net return, whether as a percentage of revenues (18.5 percent), of assets (16.3 percent), or of shareholders' equity (33.2 percent). (For comparison, the median net return for other industries was only 3.3 percent of revenues.) And this has generally been the case for the past two decades. A business consistently this profitable cannot by any stretch of language be described as "risky" or as needing special protection of its revenues.

How Innovative Is the Pharmaceutical Industry?

THE PHARMACEUTICAL INDUSTRY justifies its extraordinary profits largely by the claim that they are necessary as an incentive to continue its vital research. The implication is that if the public wants new cures for diseases, it should give the industry free rein. It is important, then, to ask just how innovative the pharmaceutical industry really is. We think the answer is not very. Drug companies greatly exaggerate their role in the scientific work leading to the discovery of new drugs. As we have already noted, the development of important new drugs is usually the culmination of many discoveries in basic science laboratories outside the pharmaceutical industry. This work increases the understanding of the molecular basis of disease and thereby identifies promising targets and models for the design of new drugs. Most of this groundbreaking research, done with support from the National Institutes of Health (NIH) or other institutions, appears in scientific journals before the big companies become involved. The industry is certainly not the major engine of discovery and medical progress that it would have the public believe. Public investment in research has been primarily responsible for the great medical advances society is enjoying, and this is likely to be so in the future as well.

A general idea of the relative contribution of the pharmaceutical industry to the underlying medical research that leads to the development of new drugs can be gained from a recent study published in the journal *Health Affairs*. The study reported that in 1998 only about 15 percent of the scientific articles cited in patent applications for clinical medicine came from industry research, while 54 percent came from academic centers, 13 percent from government, and the rest from various other public and nonprofit institutions. Remember that these are patent applications for all new drugs and medical innovations, not simply for those ultimately judged to be clinically important. Had the data been limited to only major breakthrough drugs, the industry's role would undoubtedly have looked even smaller.

The relatively small contribution of industry is also clear from an unpublished internal document produced by the NIH in February 2000, which was obtained by Public Citizen through the Freedom of Information Act. The NIH had selected the five top-selling drugs in 1995 (Zantac, Zovirax, Capoten, Vasotec, and Prozac) and found that 16 of the 17 key scientific papers leading to the discovery and development of these drugs came from outside the industry. Looking at all the relevant published research, not just at the key studies, 85 percent came from American taxpayer-supported laboratories or foreign academic laboratories. While it is true that academic scientists may have more incentive to publish their research results than do their colleagues in industry, these data are persuasive: publicly funded medical research is by far the major source of pharmaceutical innovation—not the industry itself.

A MORE CONCRETE appreciation of the relative contributions of outside scientific laboratories and the drug industry can be gained by considering the histories of three important, groundbreaking drugs that have appeared on the market during the past two decades.

Zidovudine, commonly known as AZT, was first marketed in the United States in 1987 by the company then called Burroughs Wellcome Co., which is now part of a much larger firm called GlaxoSmithKline. AZT, sold under the brand name Retrovir, was the first drug shown to be effective in suppressing HIV infection. It has recently been joined by several other effective drugs, but it usually remains part of the combination drug therapy still in use. The AZT molecule was first synthesized at the Michigan Cancer Foundation in 1964 as a possible treatment for cancer and was studied in many laboratories for that purpose. In 1974, in a German basic science laboratory, it was found to be effective against experimental viral infections in mice. In 1983–1984, U.S. government-supported research at the NIH and at Duke University showed that this molecule also suppressed the AIDS virus in human cells in test tubes and, later, that it was effective in patients.

Encouraged by the Stevenson-Wydler and Bayh-Dole Acts of 1980 (more about Bayh-Dole later), NIH-supported scientists began to collaborate with Burroughs Wellcome. By 1985, the company was able to obtain a patent on the use of AZT in the treatment of AIDS and to proceed with clinical trials that enabled it to receive FDA approval after an expedited review that required only four months—one of the shortest on record. This history shows that the drug treatment of AIDS, certainly one of the major public health advances in our time, began with basic pre-clinical work conducted almost entirely outside the drug industry and largely supported by taxpayers.

ERYTHROPOIETIN, WHICH IS marketed by Amgen under the name Epogen, is a protein hormone normally produced in healthy kidneys that stimulates red blood cell production. Technically, it is a "biological," not a "drug," because it is a natural substance made in the body. We include it in our discussion because Amgen is an important member of PhRMA, and because many pharmaceutical firms sell biologicals as well as drugs. Erythropoietin was discovered through a long series of investigations in academic laboratories that began in the 1960s and was largely supported by the NIH. This work established that the severe anemia characteristic of chronic kidney disease was largely caused by the failure of the damaged kidneys to manufacture erythropoietin. The isolation and the definitive chemical identification of the substance was finally accomplished by a scientist at the University of Chicago in 1976, but the university did not patent the molecule or initiate any efforts to develop it for clinical use.

To use erythropoietin in the treatment of anemia requires a safe, efficient method of biosynthesis, and this was Amgen's contribution. The task of the company's scientists was facilitated by a recombinant gene technique that was developed and patented at Columbia University (again with NIH support). Amgen, then a small biotechnology start-up company, licensed the technique from Columbia, used it to develop a practical method for recombinant synthesis of erythropoietin, and patented the biosynthetic molecule. By 1987, Amgen had completed its first clinical trials and was able to show that Epogen was safe and effective in treating anemia in patients with kidney failure—a major medical advance in the field.

With FDA approval, Epogen has been widely and successfully used, and now generates for Amgen more than $2 billion in annual sales—mainly from Medicare, which pays for the treatment of kidney failure. Thus, it turns out that taxpayers pay whatever Amgen charges for a drug discovered largely through taxpayer-supported research. For license of its recombinant gene patent, Columbia receives 1 percent of all sales from Amgen.

IMATINIB MESYLATE, MARKETED as Gleevec, is a new molecule that was synthesized in the early 1990s in the chemistry laboratories of the Swiss pharmaceutical firm Novartis and has recently been shown to be spectacularly successful in the treatment of a type of blood cancer called chronic myeloid leukemia (CML). This form of leukemia affects about 20,000 adults in the United States at any given time, and it is usually fatal after about three to five years. The story of imatinib is particularly instructive and worth telling in some detail.

The long trail of basic scientific research leading to the development of this drug began back in 1960 with the discovery of a characteristic abnormal-looking chromosome in patients with CML. Subsequent work showed that the abnormal-looking chromosome is due to the breakage and the subsequent rejoining of parts of two chromosomes. Later studies from many different laboratories showed that this rejoining creates a new gene that directs the production of an abnormal enzyme, which causes white blood cells to become malignant. Other work had shown that similar types of enzymes were probably involved in a variety of other cancers, although not as directly; so chemists in Israel and in the laboratories of Novartis independently set about synthesizing molecules that would inhibit the action of these abnormal enzymes. Novartis patented several such inhibitor molecules in 1994 and added them to its collection of potentially useful drug candidates.

There was apparently no immediate interest at Novartis in determining whether any of these new inhibitors might be clinically useful in the treatment of CML until Dr. Brian J. Druker, a clinical research physician in hematology at the Oregon Health Sciences University in Portland, became interested in their possible use for this purpose. Much of the rest of this story we learned from Druker. Working with a scientist at Novartis, he obtained a small supply of several of the company's most promising enzyme inhibitors. He found that imatinib was the most potent in suppressing the growth of malignant CML blood cells in culture, and furthermore that it had no effect at all on normal

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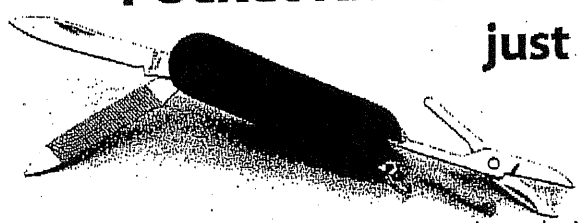

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blood cells. Such specific action is almost unheard of in cancer treatment, and Druker urged the company to explore this exciting lead. But there was little corporate enthusiasm for undertaking further clinical work on imatinib. Druker nevertheless persisted, and Novartis finally agreed to support cautious, limited tests of the drug in Druker's clinic and two other sites. By 1999, Druker was able to report spectacularly successful preliminary results before a large national meeting of American hematologists. The news about imatinib's remarkable effectiveness in CML quickly became public, and it aroused great interest. The company then decided to proceed with large-scale clinical trials to determine whether the drug was safe enough and effective enough to warrant FDA approval and general use in CML. Last year, once the positive clinical evidence was in hand, the FDA quickly gave its approval.

SO NOVARTIS'S R&D investment in testing imatinib for the treatment of CML was made several years after there was already good scientific evidence to suggest that it might be useful. Druker told us that he did not know how much the company's initial reticence was due to its finding that the drug had toxic effects in dogs at high doses; but given the relatively small number of patients with CML, he believes that a purely business calculation of the size of the likely market also played a role. In any case, the great initial success of this new drug in CML has sparked exploration, in clinical centers and laboratories around the world, of a similar approach to the treatment of other cancers. In the meantime, clinical studies to determine imatinib's long-term effects on CML continue. For most patients starting on Gleevec, Novartis now charges $25,000 for a year's supply of the drug, and the current expectation is that these patients will have to be on treatment for at least several years, with or without supplemental therapy.

How did the company decide on Gleevec's walloping price? We do not know, but in this connection it is interesting to consider the comment made last year by Raymond V. Gilmartin, the influential chairman and CEO of Merck, at the press conference announcing the latest R&D cost estimate by DiMasi and his colleagues. Referring to the $802 million per drug estimate, Gilmartin remarked: "The price of medicines isn't determined by their research costs. Instead, it is determined by their value in preventing and treating disease. Whether Merck spends $500 million or $1 billion developing a medicine, it is the doctor, the patient, and those paying for our medicines who will determine its true value." Since those who pay for a drug are not usually able to judge its value in comparison with other drugs or other forms of treatment, and since those who can make that judgment—the doctors—do not pay for the drug, we do not understand Gilmartin's comment. Taken literally, it would mean that the high prices of today's me-too drugs reflect their medical value—which seems very unlikely. Could he really be saying that the price is simply determined by whatever the market will bear?

THESE THREE STORIES about drug development could be multiplied many times and all the stories would make the same point: the discovery of the important and innovative drugs in the past few decades usually began with basic scientific work at NIH or academic research laboratories, supported by government grants. There have been exceptions, but the pharmaceutical industry has so far devoted most of its R&D resources not to scientific discovery, but to the practical application of discoveries generated at taxpayer expense and to the development of variations on or new uses for drugs already on the market.

All of this makes good business sense for the pharmaceutical industry if, like most industries, it is primarily interested in immediate profits. The kind of wide-ranging, open-ended, and relatively undirected basic research into the molecular biology of disease that is done mainly with NIH support is very expensive, and its results are unpredictable. Whether a given line of investigation will quickly (or ever) lead to the development of a new drug cannot be known in advance. But this kind of research is the only way in which genuine medical progress is made. Pharmaceutical companies, pressured by investors to keep delivering profitable new products—whether they are medically important or not—must use less risky strategies. They use their R&D dollars to imitate top-selling drugs already on the market or to find new uses for their own blockbusters.

That me-too's have come to dominate the new drug market is documented very clearly by the FDA, which classifies drugs under review by their likely therapeutic value and by whether they are NMEs or simply re-formulations and combinations of old drugs. Over the twelve-year period beginning in 1990, 1,035 drugs were approved, and of these only 23 percent were classified as likely to be a "significant improvement" on products already on the market. (In our own judgment as physicians, even many of these drugs would be more accurately described as modest, incremental improvements.) All the others were classified as appearing to have "therapeutic qualities similar to those of one or more already marketed drugs." Moreover, just 15 percent of the approved drugs were classified as both a significant improvement and an NME. Last year, the FDA approved 66 drugs for the entire drug industry. The agency classified only ten as a significant improvement, and only seven of these were NMEs. So the already small percentage of newly marketed drug products that are really novel and important seems to be dropping still further, with me-too's becoming the rule. This trend has continued during the current year.

INDUSTRY SPOKESPEOPLE sometimes justify the growing profusion of brand-name me-too drugs by arguing that they increase market competition and keep prices down. For this reason, they object to the term "monopoly" as applied to the exclusive marketing rights conferred by patents or FDA approval. But me-too drugs are not promoted on the basis of price. Instead, they are marketed as being especially effective—usually in total disregard of the facts. There is little evidence of price competition. Thus, although the availability of multiple similar brand-name drugs may have some modulating effect on prices, it is certainly not nearly as great as the price competition that results when unpatented generic drugs enter the market.

Other apologists claim that in drug therapy one size does not fit all. Very similar drugs, they say, may vary in their effects from patient to patient, so it is important to have choices among them. But there is a paucity of evidence to support the notion that if a particular drug does not work for a patient, a virtually identical one will. It might occasionally be useful to have a new, long-acting version of an identical short-acting drug that is already on the market. But we think most experts would agree that there is little or no rationale for having four or more me-too drugs, as is now the case in many fields. There are now five patented statins (a type of cholesterol-lowering drug) on the market, four patented anti-depressants of the so-called SSRI (selective serotonin reuptake inhibitor) type, and seven patented angiotensin blocking agents (drugs to treat high blood pressure and heart failure). We are aware of no good studies establishing the clinical need for so many.

Blockbusters have one thing in common besides their high sales: they are usually treatments for very common lifelong

conditions. The conditions are not so serious that they are lethal, but they do not go away either. Sometimes they are little more than annoyances, like hay fever. Consequently, large numbers of people may take drugs for these conditions for years, and that is why the markets are so large. People with uncommon or acute diseases are generally not of much interest to drug companies. The major difficulty in launching a me-too blockbuster, however, is in persuading doctors and patients that it is better than the others, since the evidence is at best marginal. Unfortunately, the FDA will approve a me-too drug on the basis of clinical trials comparing it not with an older drug of the same type, but with a placebo or a drug of another type. Drug companies would rather not have a head-to-head comparison, because they might lose. To launch a me-too drug successfully, then, requires a lot of marketing, which largely explains the industry's mammoth marketing expenditures.

Testing Drugs on People

THE ONLY WAY to determine a new drug's safety, effectiveness, and—if this important question is asked—its relative efficacy compared with existing drugs is through properly designed and conducted clinical trials, that is, tests on people. These trials represent the third phase of the R&D process that we have described, and they are the most expensive part of clinical development. Before the FDA will consider approving a new drug for marketing, the manufacturer must present the results of at least one (and usually more) Phase III trials for review by the agency as part of the new drug application. Although the FDA usually reviews the results of the trials submitted to it very carefully, it cannot guarantee the integrity of the work, so it is essential that clinical trials be well designed and executed without bias or manipulation of the results.

Until the past decade, around 80 percent of clinical trials were conducted on patients at academic medical centers and teaching hospitals under the direction of medical faculty, who usually initiated the application for support of the trial. Most of these trials were supported by grants from a pharmaceutical company to the academic institution, although some were funded by the NIH. The design and execution of the studies and the collection, interpretation, and reporting of the data were all the primary responsibility of the academic team, made up of experts in the field. They had no financial ties to the company or to the drug being tested, although part of their salary might have been paid from the grant as compensation for the time that they invested in the trial.

As the number and the size of clinical trials have grown and the industry's need for faster results and access to large numbers of patients has rapidly increased, more and more trials (over half of them) have been shifted to private-practice settings outside the academic centers, where pharmaceutical firms or their contractors have assumed direct responsibility for the conduct of the clinical studies. A large new industry has arisen to serve the pharmaceutical firms' needs. It consists mainly of companies called contract research organizations (CROs), which are hired by the drug companies to organize and to conduct clinical trials. Often working through other companies, they employ physicians in private practice to recruit patients as subjects for the studies. There are reportedly now over one thousand CROs worldwide, and they generated an estimated $7 billion in revenues last year from their contracts with the pharmaceutical and biotechnology industries. Although the physicians they hire to recruit patients also help with the conduct of clinical trials, the results of the studies are analyzed and interpreted by the companies. Control over most clinical trials is now largely in the hands of the pharmaceutical industry, and the influence of the academic centers and their clinical faculty is greatly reduced—even in trials conducted at those centers. These dramatic changes have transformed the entire system for the development and the marketing of new drugs, with troubling consequences.

In an effort to recapture income from the pharmaceutical industry, most of the leading academic centers have set up clinical-trials offices to provide the industry with the same quick, comprehensive services that the drug firms have been getting from the CROs and other private research businesses. These centers now openly court the pharmaceutical industry, offering the services of their clinical faculties, access to patients, and help with the design, the conduct, and the analysis of clinical trials. Although some of the stronger academic institutions still insist on faculty control of the studies and the reporting of results, the pendulum of power has shifted. Drug companies have increasing control over the evaluation of their own products. A very recent increase in NIH support of clinical trials may now be starting to reduce the dependence of major academic centers on contracts with the pharmaceutical industry.

Adding to the problem are the growing financial ties of clinical faculty with the pharmaceutical industry. Almost every academic expert who might be qualified to direct a clinical trial now is paid by one or more firms as a consultant or a speaker. Some medical schools have policies limiting these ties and preventing faculty with financial connections to a company from doing clinical research on that company's drugs, but many medical schools do not, and virtually all of them allow exceptions to their generally lenient rules. The consequence is that the public can no longer assume that clinical reports from academic centers are written by physicians who have no vested interests in the results. About the best to be hoped for is that these interests will be disclosed in the published reports, and that any bias resulting from these financial connections will be balanced by reports from other companies and researchers with competing interests. But the point is that the public can no longer be confident that the testing of new drugs is unbiased.

THE PERVASIVE CONNECTIONS between the pharmaceutical industry and academia are not limited to clinical trials. Virtually every research-intensive medical center in the country now has contractual ties with one or more drug firms, usually involving subsidies for or collaborations with particular research programs and faculty. In return, the firms gain information about new findings before publication, hands-on laboratory education for their research personnel, and rights of first refusal on patents for the products of this research. Drug companies are even beginning to locate their new research laboratories near academic centers to facilitate such relationships. Merck is now building a large new research facility on land in Boston immediately adjacent to the Harvard Medical School (the first such facility in an area previously reserved for academic and clinical institutions), and Novartis has leased two research facilities in Cambridge close to MIT, joining several biotechnology companies already there.

We do not doubt that collaboration in basic research between academic centers and industry, with appropriate safeguards to preserve the integrity and the independence of academic institutions and their faculties, can be very useful. Yet physical proximity and close economic ties between the industry and the academy have a serious drawback. They can involve academic centers and their faculty too deeply in commercial enterprises, at the expense of their traditional missions of education, patient care, and free-ranging research.

They also threaten the objectivity that is the essential hallmark of good scientific research and medical education. Recently the Association of American Medical Colleges (AAMC) suggested guidelines for managing financial conflicts of interest, but these guidelines are not binding, and they do not address the fundamental issue of whether medical schools and their faculties should have such extensive ties with industry in the first place.

Marketing: Where the Action Is

According to data published in their SEC reports for 2001, the big drug companies spent on average about 35 percent of their income on what most of them call "marketing and administration." At least one major company, Novartis, separates these two functions in its report, assigning 36 percent of total income to "marketing and distribution" and 5 percent to "administration and general overhead." It is unlikely that other companies differ very much from Novartis in this relative weighting. Still, not much is known about the exact distribution of expenditures within the "marketing" category. Whatever the exact figures, it seems clear that marketing and related activities account for the largest part of the industry's expenses. They certainly are far greater than the expenses for R&D or manufacturing. By following the money, we conclude that marketing, not the search for new drugs and their development for clinical practice, is the most important focus for the industry. This conclusion is also supported by the distribution of employees as reported by PhRMA. More than one-third of the industry's workforce is employed in marketing, much more than in R&D, manufacturing, or administration.

If the industry argues that drug prices necessarily reflect its high costs for R&D, then what can it say about its much higher costs for sales promotion? Those who pay for prescription drugs are paying for marketing, too. But if the current crop of new drugs were as valuable as the industry would like us to believe, and if there were not so many me-too drugs, surely it would not be necessary to spend so much money pushing them. A genuinely important new drug, such as Gleevec, does not have to be marketed widely. Cancer doctors treating patients with CML will know about this drug and use it. No sales pitch is needed.

Still, the extravagant expenditures on drug marketing and their effect on drug prices are not the worst part of this story. What should be of even greater concern is the effect of the industry's marketing and advertising money on the independence and the trustworthiness of the medical profession. As a learned profession, medicine has a fiduciary responsibility to patients in particular and to society in general to provide expert, unbiased advice on the use of drugs, based on the best available scientific information. Also, the profession has an obligation to educate its own practitioners about the selection and discriminating use of the best and most cost-effective drugs—old and new, patented and generic. This should be largely the responsibility of medical schools, resident training programs in hospitals, and the postgraduate or continuing medical education (CME) courses organized by professional societies, schools, and hospitals. The latter are required for renewal of doctors' licenses.

But the professional bodies that ought to be responsible for CME have been more or less co-opted by the pharmaceutical industry. There are guidelines, agreed to by the industry and the professional institutions, that are supposed to protect against commercial influence on the content of this education, but most of these guidelines are general and vague. They require that the medical institutions accepting industry support merely approve the CME programs, although the company paying the costs usually recommends the speakers—who, more often than not, are consultants for the company. The softness of the guidelines is hardly surprising, given the fact that they were drafted in 1992 by a task force consisting almost equally of representatives of industry and of the medical profession. They were adopted with only minor changes by the American Medical Association (AMA) and the national professional organization responsible for regulating CME.

The drug companies pay the piper, and by one means or another they call the tune; and the tune is keyed to their sales pitch. The results are clearly demonstrated by published studies showing that industry sponsorship of CME is usually followed by increased prescribing of the sponsor's products. Were there not clear marketing and sales benefits for the sponsoring companies, they would not spend the huge sums that they do on supporting these activities. Most companies pay for medical education from their marketing budgets: this fact should speak for itself.

Perhaps the clearest indication that what the industry calls "education" is really intended to promote sales is the growth of "medical education and communication companies," or MECCs. MECCs are for-profit businesses hired by drug companies to prepare teaching programs and procure medical speakers. The drug companies offer these programs to hospitals or medical groups that are accredited to provide CME. Many MECCs are also officially approved by the medical profession's CME accrediting body to award education credits on their own. The MECCs are candid in their advertising to their drug industry clients. They say their purpose is to increase their clients' sales through professional "education"—and that is what they do. If any further demonstration were needed of the true purpose of what the industry calls "medical education," it was clearly supplied by a recent front-page article in *The New York Times*, with an accompanying report on the PBS program *Now with Bill Moyers*. According to these sources, three of the largest advertising agencies handling pharmaceutical accounts are now investing in companies that do contract research and prepare "educational" packages for the drug industry. This astonishingly incestuous arrangement makes it clear that research and education have both become subordinate to sales promotion.

The largest single piece of the known drug-marketing budget is spent on the direct promotion of drugs to doctors by representatives of drug firms. (This is called "detailing.") There are some 88,000 sales representatives throughout the country, who are paid more than $7 billion per year by the drug companies to visit doctors in hospitals and offices to pitch their employers' products. The number and the ubiquity of these salespeople have increased greatly over the past few years. They roam the halls of almost every sizable hospital in the country seeking opportunities to talk with the medical staff and offering gifts (such as books, golf balls, and tickets to sporting events), drug samples, and free meals. In many teaching hospitals, drug representatives regularly provide lunches for the resident staff in order to gain their ear. They attend conferences, they are invited into operating and procedure rooms, and sometimes they are even present when physicians examine patients in clinics or at the bedside.

Sales representatives also regularly visit doctors in their offices, often armed with information about the doctor's prescribing habits obtained from local drugstores. (There are firms that buy this information from pharmacies and sell it to drug companies.) They make themselves welcome by taking practitioners to dinner in fine restaurants, where company-selected and -paid experts sometimes give talks, and they distribute favors and gifts of all kinds

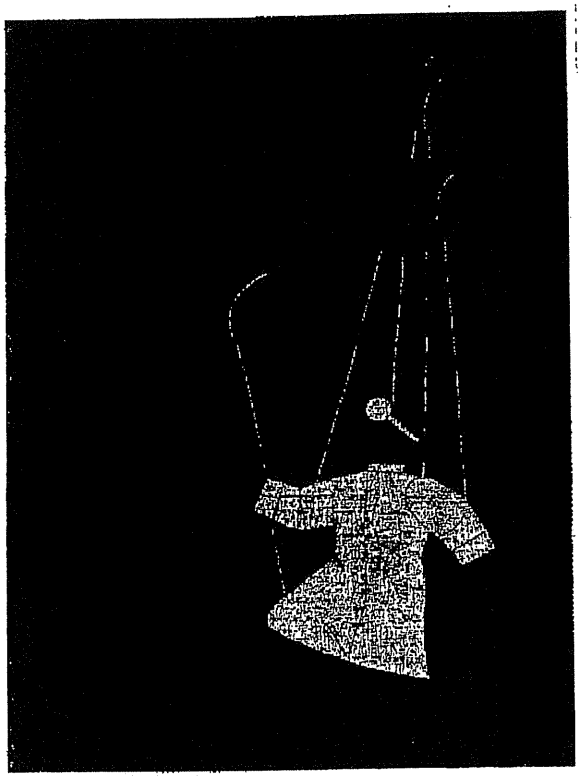
to doctors and their office staffs. Free samples of drugs for physicians to give to their patients are a major gift item provided by representatives of large drug companies. Industry sources say they spend about $8 billion per year on free samples. These samples are an effective way to get doctors and patients committed to the continued use of the sampled product—usually an expensive, newly approved drug, with a long period of exclusivity ahead of it.

Sometimes doctors are even paid to prescribe the product and to report on the results, under the guise of participating in a company's continuing "Phase IV" research. How much of this kind of drug promotion masquerades as R&D is an interesting but unanswered question. Recently, according to an article in *American Medical News*, at least two new businesses in the Cincinnati area have been established to broker meetings between drug representatives and physicians in office practice. One such business charges drug firms $105 for each ten-minute meeting with a doctor—of which $50 goes to the doctor and $5 to a charity selected by the doctor from a list of five.

An effective marketing technique used by many drug firms is to focus on so-called "opinion leaders" in a particular medical specialty. These are prominent experts, usually on medical faculties and hospital staffs, who write papers, contribute to textbooks, and give talks at medical meetings—all of which influence the use of drugs in their fields. Companies shower special favors on these physicians, offer them honoraria as consultants and speakers, and often pay for them to attend conferences in posh resorts ostensibly to seek their advice or to coach them in public speaking. In many medical specialties these days, it is almost impossible to find an expert who is not receiving payments from one or more drug companies in the field. Disclosure of these arrangements is said to be an adequate remedy for the conflicts of interest, but many observers worry about the loss of professional objectivity and independence that such financial ties produce, regardless of whether they are disclosed.

At medical meetings, drug companies are allowed to present symposia or other types of educational programs—with free lunches or dinners—to supplement the programs presented under the sponsoring society's auspices. The latter are themselves often supported by drug firms. The atmosphere at many large medical meetings resembles a bazaar, dominated by the presence of garish drug company exhibits and friendly salespeople eager to ply physicians with samples, gifts, and services while they pitch their company's drugs. In the exhibit areas adjacent to the meeting rooms, physicians wander through a carnival-like scene. Many carry large canvas bags, bearing drug company logos, stuffed with goodies. To some senior physicians who have watched the atmosphere at these meetings evolve from the sober professionalism of a few decades ago to the trade-show hucksterism of today, it is a dispiriting spectacle.

The cumulative effect of all of this is to blur the crucial distinction between drug marketing and professional education.



Medical education worthy of the name requires an unbiased analysis of all the available evidence, led by experts who have no vested interest in the drugs that they are discussing. That is how medical meetings used to be, and that is how they ought to be, but it is most assuredly not what the companies want to support. They are not philanthropists. They need to sell their drugs; and experience has shown that when they organize "educational programs," when they pay for sales representatives to shower favors on physicians while touting the company's products, and when they spend huge sums on creating trade shows at medical meetings, the sales of their products increase. We would like to know how much all of this costs, but the industry prefers to keep these matters secret.

This kind of promotion masquerading as "education" is what largely accounts for the market success of new and expensive drugs that are not significantly different or better than less expensive existing drugs. And for this both the industry and the medical profession must take responsibility. Although there has been criticism from some members of the profession, medical societies and associations have taken no effective steps to oppose these practices. Most of the profession, it seems, finds it difficult to break the habit of taking money and gifts from the drug industry. Over a decade ago the AMA issued guidelines on accepting gifts from industry, but they were voluntary and quite permissive. They have not been observed in practice nor monitored by the AMA. PhRMA recently issued guidelines of its own, which closely follow those of the AMA, but, not surprisingly, they are also voluntary and permissive. It remains to be seen whether this latest effort will have any significant effect on drug-industry practices or will prove to be just another public relations ploy.

The Office of the Inspector General (OIG) of the Department of Health and Human Services recently placed in *The Federal Register* for comment a draft of proposed guidelines for ethical and legal relationships between the pharmaceutical industry on the one hand and physicians, pharmacists, and various purchasers of drugs on the other. The OIG notes that many of the existing practices involving gifts and payments to physicians are intended to influence the prescribing of a drug company's products and may potentially violate federal anti-kickback laws. It urges drug companies to review existing laws and regulations to avoid civil and criminal penalties. The code recently adopted by industry, to which we have already referred, is a minimum standard that certainly ought to be met, the OIG says, but mere compliance with that code does not guarantee protection against persecution for illegal conduct. Although they are only general recommendations, not regulations, the tone of these proposed guidelines from the OIG is stern. It remains to be seen what will happen to them when the drug industry and other interested parties weigh in. In any event, the introduction of such guidelines suggests a rising concern about the influence of the industry on the

prescribing behavior of physicians and the costs of prescription drugs.

About the only organized sector of the medical profession that seems genuinely concerned about this issue is the national organization of medical students, the American Medical Student Association. Last spring, this group voted for a total ban on the acceptance of all drug-industry gifts and favors to medical students. It was a brave and laudable gesture, but its impact on practicing physicians and their organizations is doubtful. Recently we attended the annual meeting of the state medical society of Massachusetts, where student delegates urged their elders to pass a similar resolution that would apply to physicians. It was decisively defeated in favor of a resolution that recommended further study of the issue.

ONE OF THE most important developments in the marketing of prescription drugs is the recent explosion in direct-to-consumer (DTC) advertising. In 1997, the FDA changed its policies to allow DTC advertising without the requirement that it include medical details on the side effects of drugs. Since then, DTC advertising has burgeoned and is now estimated to be a nearly $3 billion industry. Drug firms now spend about as much on this advertising as they do on advertising to physicians in medical journals and other professional media. Advertisements for blockbuster drugs that are prescribed for common complaints such as allergy, heartburn, arthritis, "erectile dysfunction," depression, and anxiety are seen everywhere. Often celebrities—former politicians, famous athletes, movie stars—endorse the product. Consumers are urged to "ask your doctor" if a certain drug "would be right for you," and to "be sure to tell your doctor if you have kidney or liver problems" or some other medical condition—something we would hope doctors already knew or could find out for themselves.

A variant on the use of celebrities for the promotion of brand-name pharmaceuticals recently attracted much comment in the news. It seems that celebrities are being paid by drug companies to appear on television news and talk shows and enthusiastically mention their use of a particular drug. Audiences are not informed about the financial arrangement, and are thus allowed to assume that the celebrities are simply volunteering their personal experience. Embarrassed by these revelations, networks are now scrambling to require full disclosure.

Drug companies have been delighted with the effect of DTC advertising on their sales. Advocates like to describe this obvious form of selling as "education," just as they describe their advertising to doctors. But drug companies, owing to their clear conflict of interest, are not the ones to educate people about the drugs that they are selling. DTC ads mainly benefit the bottom line of the drug industry, not the public. They mislead consumers more than they inform them, and they pressure physicians to prescribe new, expensive, and often marginally helpful drugs, although a more conservative option might be better for the patient. That is probably why DTC ads are not permitted in other advanced countries less in the thrall of the pharmaceutical industry.

Market Exclusivity: Gaming the System

AS WE EMPHASIZED earlier, the lifeblood of the pharmaceutical industry is government-granted monopolies, in the form of patents and FDA approval for exclusive marketing. The two forms of exclusivity operate largely independently, almost as backups for each other. Both make it illegal, for a specified time, for competitors to sell the same drug. Stretching that privileged time by a variety of stratagems is arguably the most innovative activity of today's drug companies. For blockbuster drugs, it is certainly the most lucrative. Once a company loses its exclusive marketing rights and opens itself to competition from generic drugs, prices often fall rapidly to about one-fifth of what they were. For blockbusters, that can mean a yearly sales loss of hundreds of millions of dollars.

Patents are supposed to be granted only for discoveries or inventions that are useful, novel, and not obvious. In the past two decades, however, these three standards have been considerably relaxed, so that now nearly anything can be and is patented—including new uses, dosage forms, combinations of old drugs, even the coating of pills. In addition, as a result of a number of industry-friendly laws and regulations passed during the same two decades, the period of exclusivity has become stretched to the breaking point. In 1980, exclusivity lasted for the standard 17-year patent term (minus the time for clinical testing and FDA approval). Now, given the ingenuity of the industry's legions of patent lawyers, it can be extended for many more years.

In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act. It added up to five years of exclusivity for certain drugs to compensate for long FDA-approval times, and it also provided for three years of additional exclusivity for introducing changes in drugs already on the market, such as new dosage forms, new indications, or switches from prescription to over-the-counter status. In a misguided attempt to encourage generic manufacturers to enter the market as soon as possible, the act contained two other provisions. First, it made the FDA approval process simpler for generic companies, but it also stipulated that if a brand-name company sued a generic company for patent infringement, FDA approval of the generic drug would automatically be delayed for 30 months—whatever the merits of the lawsuit. Second, it said that the first generic company to challenge a patent would have six months of exclusivity after it finally reached the market, free from competition by other generics.

HATCH-WAXMAN HAS been a bonanza for the big drug companies. While it was meant to stimulate generic competition, it has often had exactly the opposite effect. Since the act was passed, brand-name drug companies routinely file not just one patent on their drugs, but a series of them spread throughout the life of the first patent. These secondary patents are on every conceivable attribute—never mind usefulness, novelty, or non-obviousness. The result is that generic companies are routinely charged with patent infringement, which immediately triggers 30 months of additional exclusivity. When a generic company challenges a secondary patent, the brand-name company sometimes strikes a deal with it that defers entry of the generic product into the market. Owing to the six-month exclusivity given to the first generic company that challenges a patent, other generic companies are also stopped. Through such shenanigans, exclusivity can be prolonged for years.

This sort of gaming of the system is not supposed to be possible. Under the law, only challenges to certain patents may trigger the 30-month stay on generic entry into the market. These are the patents on approved drugs that companies list with the FDA in a publication known as the Orange Book, available on the FDA website. To be listed in the Orange Book, patents are supposed to apply only to the drug itself and the use for which it was approved. Other patents related to the drug—such as those for new dosage forms or uses—are not supposed to be listed in the Orange Book.

But the FDA does not even attempt to

hold drug companies to that restriction. Instead, drug companies list any patents they choose, no matter how remote from the originally approved drug and no matter how frivolous its use. Sometimes they list virtually the same patent twice. And the secondary patents can be listed at any time, even years after the original approval. This means that there is nearly always some patent in effect that can be used as an excuse for suing generic companies, thus triggering the 30-month additional exclusivity. By filing new patents even after the first lawsuit and then suing for infringement of them, it is even possible to obtain successive 30-month stays. In the case of GlaxoSmithKline's anti-depressant drug Paxil, five lawsuits against the same generic company resulted in five 30-month stays, staggered so that, altogether, GlaxoSmithKline extended its exclusivity by over five years.

In a damning report issued in July 2002, the Federal Trade Commission (FTC) documented the widespread anti-competitive activities within the pharmaceutical industry. And it implicitly took the FDA to task for failing to enforce legal restrictions on the listing of secondary patents in the Orange Book. The FTC found evidence that Hatch-Waxman is regularly exploited to prevent generic competition, and it has taken antitrust action against several brand-name and generic drug companies that colluded to keep generic drugs off the market.

In addition to the Hatch-Waxman Act, other congressional actions have also added to the time during which companies can sell brand-name drugs without generic competition. In accord with the international GATT agreements of 1994, Congress increased the basic patent term from 17 years after issuance to 20 years after filing—which is usually longer. And the Food and Drug Administration Modernization Act (FDAMA) of 1997 added six more months of patent protection if drug companies test their drugs on children. One might think that drugs that would be used by children should be tested on them as a condition of FDA approval, but Congress seems to prefer the legislated bribery route. The effect of all this is much longer periods of exclusivity for brand-name drugs.

In 1980, the average time in which a drug could be marketed without competition was about eight years: the patent term of 17 years minus the time it took for clinical trials and FDA approval. Now it is nearly twice that, and not just because of shorter times for testing and FDA approval. The companies extend their exclusivity by using every possible stratagem simultaneously, so that if one fails another might work. First, the big drug companies change their top-selling drugs in ways that will add three years' exclusivity, in accord with Hatch-Waxman. Second, they stagger multiple secondary patents, which serve as the pretext for routine lawsuits to trigger a 30-month extension. Third, nearly every blockbuster is tested on children to get the extra six months of patent protection. That is true whether the drugs are likely to be used by children or not. Fourth, brand-name companies sometimes collude with generic companies to delay their entry into the market. And fifth, when all else has failed, they can get a new patent on a trivial variation of their blockbuster and promote it as an "improved" version of the original.

Near Morning

Cow's breath warms his swaddling
a brood mare snuffles her foal
crumbs of prayer
caught up in the mouse's paws
the shadows of the guests
linger along the wall
though the guests have gone

A leather drawstring pouch
embroidered with dialect
bulges with drachmas
the scent of sandalwood
a costly porcelain jar
rolled up in the rug on the back
of the little mule Ham
sleepily nibbling her fetlock
hock-deep in snow

The man has lain down
with the woman at last
It is nearly dawn
For a moment
there is a stillness
so absolute
even the stars don't blink

The infant beginning
to inhabit his body
is startled by the cold
kiss of air on his cheek
by an ember falling into ashes
a sound as soft as the step
of a friend in the garden
a serry of torches
marching across the wall.

Melissa Green

THREE STORIES ARE illustrative of the many ingenious, often questionable tactics that are used to extend exclusivity. The first concerns the blockbuster Claritin—an antihistamine said to cause less drowsiness than cheaper over-the-counter drugs such as Benadryl. (Claritin costs $80 to $100 for one month's supply, compared with about one-tenth that for Benadryl.) It was patented by Schering-Plough in 1981, but not approved by the FDA until 1993 (after much scientific controversy about whether it was really effective at the low doses necessary to prevent drowsiness). Last year Claritin had sales of about $2.7 billion and brought in about one-third of Schering-Plough's revenues. The 17-year patent should have expired in 1998, but, according to a story last year in *The New York Times Magazine* by Stephen Hall, Hatch-Waxman added two years, and GATT added 22 months, and pediatric testing added another six months. These three extensions added four and a half years to the drug's exclusivity—worth billions of dollars. Starting in 1998, Schering-Plough sued eight generic drug companies for infringement of one or more of its four patents listed in the Orange Book. Hall reported the company's legal costs to be about $5 million per case—still a pittance compared with the stakes.

Back in 1987, Schering-Plough, with great foresight, patented the active metabolite of Claritin—that is, the molecule into which the body converts Claritin, which accounts entirely for the action of the drug. In December last year, it received FDA approval to market the Claritin metabolite under the name Clarinex, and began a massive promotional campaign to switch Claritin users to the new drug before Claritin was scheduled to lose its exclusivity in December 2002. To that end, it also priced Clarinex slightly below Claritin. Clarinex was approved for the treatment of year-round indoor allergies as well as seasonal outdoor allergies. That means Schering-Plough can market it as an improvement, even though it is simply what Claritin turns into after it is swallowed.

This year Schering-Plough petitioned the FDA to change Claritin from a prescription drug to an over-the-counter product. By law, the same drug at the same dose cannot be sold both ways, so the move will stop generic companies from competing in the prescription market when the patent expires. Last month the switch was approved. Claritin will probably be on drugstore shelves by the end of this year

and Clarinex will be the only prescribed Schering-Plough allergy drug. We can see from the Claritin story that drug companies leave nothing to chance. They work simultaneously on every angle that might extend the exclusive marketing life of their blockbusters.

NEXT, THE PROZAC STORY. Prozac, made by Eli Lilly, was the first of a new type of anti-depressant called SSRIs. It was developed mainly on the basis of research done outside the company. In 1987, the FDA approved Prozac for the treatment of depression; in 1994, for the treatment of obsessive-compulsive disorder; in 1996, for bulimia; and in 1999, for geriatric depression. It rapidly replaced other types of anti-depressants because of its milder side effects. Prozac soon accounted for one-quarter of Lilly's revenues, with annual sales reaching $2.6 billion.

Like other companies in the same position, Lilly sued generic makers who hoped to enter the market. One of them, Barr Pharmaceuticals, charged that Lilly had listed essentially duplicate patents in the Orange Book. In 2000, the Court of Appeals for the Federal Circuit, which handles all patent appeals, agreed. It said Lilly had "double-patented" Prozac, and changed the expiration date from December 2003 to February 2001. The Supreme Court refused to hear an appeal, but Lilly used pediatric testing to extend the time to August 2001. Generic forms of Prozac are now on the market, and the price has come down accordingly. Usage has also dropped, as people respond to advertising for similar brand-name (and now more expensive) SSRIs such as Paxil and Zoloft, while advertising for Prozac has essentially stopped. In June 1999, however, Lilly patented Prozac Weekly, a new formulation that can be taken less often. It was approved by the FDA six months before the Prozac patent expired, and Lilly has exclusive marketing rights until 2004.

The most ingenious move to extend the life of Prozac was the creation of Sarafem—which is the identical drug in the identical dose, but colored pink and lavender instead of green, and taken for a new indication. In 1990, Dr. Richard Wurtman, the director of MIT's Clinical Research Center, and his wife, Dr. Judith Wurtman, took out a patent on SSRIs for the treatment of premenstrual syndrome. This is called a "method of use" patent. According to a CNN report on July 13, 2000, they tried to license the use to Eli Lilly, but the company was not interested—then. So they licensed it to Interneuron Pharmaceuticals, a small biotechnology company co-founded by Richard Wurtman, which is now called Indevus Pharmaceuticals. In 1997, Lilly, faced with the imminent loss of Prozac's exclusivity, decided to license its use for premenstrual syndrome from Interneuron—reportedly for $2 million plus a percentage of sales. Lilly renamed Prozac "Sarafem," colored it pink and lavender, and got FDA approval to market it for "premenstrual dysphoric disorder," which is not yet officially recognized as a distinct disorder in the psychiatric diagnostic manual. The Wurtmans and MIT get a portion of Indevus's royalties.

Sarafem's exclusivity was supposed to last until July 2003, but Lilly received a six-month extension because it tested the drug on children—which cannot have been scientifically very illuminating, since these "children" must have been beyond the age of menarche and therefore very nearly adults. Sarafem was priced slightly higher than the identical drug when it was called Prozac. Now that generic Prozac is on the market, Sarafem costs three and a half times as much—$8.70 per pill at our local drugstore, compared with $2.50 for the generic.

FINALLY, CONSIDER THE heartburn drug Prilosec, made by the British pharmaceutical firm AstraZeneca. This story was recently told in great detail in an article by Gardiner Harris in *The Wall Street Journal*. Prilosec was the number-one drug in the world, with sales of about $6 billion per year, until its patent expired in October 2001 after a six-month extension for pediatric testing. Like Schering-Plough and Lilly, AstraZeneca looked ahead. It sued generic companies for infringement of its layers of patents—eleven are listed in the Orange Book. To date, there is still no generic drug on the market: a delay worth billions to the company. At our local drugstore, Prilosec continues to sell for a whopping $6 per pill. And, like Schering-Plough, AstraZeneca patented a spin-off of its blockbuster drug. Prilosec consists of a mixture of two forms (or isomers) of the same molecule, only one of which is active. The company patented the active form, named it Nexium, and got FDA approval to market it just in time to switch people over to it before Prilosec's exclusivity ran out. This maneuver is very similar to Schering-Plough's Claritin story, except that users were switched to an isomer rather than a metabolite. (Lilly was even more audacious, since Sarafem is identical to Prozac.)

AstraZeneca launched a massive advertising campaign to persuade Prilosec users and their doctors that Nexium was somehow better, even though there is every scientific reason to expect that a double dose of Prilosec would be equivalent to Nexium. (This was never tested.) Very quickly, according to Harris, Nexium became the most heavily advertised drug in the United States. The media were blanketed with Nexium ads: "Today's purple pill is Nexium. From the makers of Prilosec." To help with the switch, AstraZeneca priced Nexium slightly below Prilosec, gave discounts to managed-care plans, barraged doctors with free samples, and even offered coupons in newspapers. The campaign reportedly cost the company $500 million in 2001.

Influencing Government

NONE OF THESE maneuvers to lengthen the lives of blockbuster drugs—all of which add to drug costs—could have occurred without the help of Congress. The drug industry has the largest lobby in Washington. In 2000, according to Public Citizen, it employed 625 lobbyists (more than one for each member of Congress) at a cost of $92.3 million—including 460 hired from 134 Washington lobbying firms. These lobbyists were extremely well connected. They included 21 former members of Congress and others of no doubt equal or greater influence, such as Haley Barbour, the former chairman of the Republican National Committee; Linda Daschle, the wife of outgoing Senate Majority Leader Tom Daschle; Scott Hatch, son of Senator Orrin Hatch; and Anthony Podesta, former counsel to Senator Ted Kennedy and brother of President Clinton's former chief of staff.

In addition, the industry made generous political contributions in the 1999-2000 election cycle, including $20 million in direct campaign contributions plus $65 million in soft money. Most of that money went to support Republicans, but these companies have cash enough to spread around. The top recipient in the past decade, according to government ethics watchdog Common Cause, was Hatch, a Republican, but powerful Democrats from states that are home to major drug companies, such as New Jersey Senator Robert Torricelli and Connecticut Senator Joseph Lieberman, also did well. As just one example of the industry's influence, in 1999 Torricelli introduced a bill to give Claritin and six other drugs a chance to lengthen their patents. According to Common Cause, this bill was introduced a day after Schering-Plough made a $50,000 contribution to the Democratic Senatorial Campaign Committee, which

Torricelli chaired. Hatch held hearings on the bill, despite the fact that Schering-Plough is one of the companies that employed the lobbying firm for which his son worked. As it turned out, the bill was apparently too embarrassing even for Congress, and nothing came of it. Drug companies also influence political campaigns by funding and sometimes creating supposed grassroots organizations, such as Citizens for Better Medicare, to promote drug company interests in media ads and on websites.

One of the most important congressional actions affecting not only the pharmaceutical industry, but also the academic medical centers and the biotechnology industry, was the Bayh-Dole Act of 1980. According to this act and related legislation, academic institutions could patent the fruits of government-funded research and license them to private industry for royalties. The law applied not just to biomedical research, but that is where it saw its greatest application. Virtually overnight, Bayh-Dole made drug companies and academic institutions partners, both benefiting from taxpayer subsidies. The original purpose of Bayh-Dole was to encourage "technology transfer," the translation of basic discoveries into practical use. Accordingly, it stipulated that the products of the research must be made "available to the public on reasonable terms." It also stipulated that the government agency that funded the research (usually the NIH) should be informed by grantee institutions of all such patent and licensing arrangements. These provisions were never enforced. Last year, at the behest of Senator Ron Wyden, the NIH attempted to account for its contributions to a list of 47 blockbusters on the market. The fact that four of them (Taxol, Epogen, Procrit, and Neupogen) were developed largely with public funding was widely publicized. What was not so widely publicized was the fact that the NIH did not seem to know one way or the other about many of the other 43 drugs.

Whether the Bayh-Dole Act has been an overall success is controversial. Certainly the number of biomedical patents increased rapidly after it was passed. But many critics say that the effect of the legislation has often been opposite to its purpose. By encouraging thickets of licenses on every aspect of new technologies and producing a proprietary culture of secrecy, it may actually have slowed technology transfer and the exploration of new scientific leads. And it has certainly done nothing to ensure that drugs licensed from academic institutions are available "on reasonable terms."

In the past year or so, public dismay with high drug prices has begun to have an effect in Congress. In July, the Senate passed a bill introduced by Charles Schumer and John McCain that would prevent many of the abuses of Hatch-Waxman. It also included an amendment to permit the commercial re-importation of prescription drugs from Canada. (Congress passed a re-importation bill during the Clinton administration, but it was not signed by the president.) It did not pass the House, and there is every reason to doubt that anything like it will, given the implacable opposition of the drug industry.

THE TRICKIEST ISSUE for Congress concerning the pharmaceutical industry has to do with growing public pressure for a Medicare drug benefit. Everyone agrees that something has to be done to relieve senior citizens of the heavy burden of paying for prescription drugs out-of-pocket, and everyone, including the pharmaceutical industry, is on record as favoring some sort of extension of Medicare to cover outpatient prescription drugs. Widely differing versions of bills to provide such coverage passed the House and Senate this year, but could not be reconciled. The House version (the one favored by the pharmaceutical industry) proposed that coverage for prescriptions be paid in part by a set contribution from Medicare administered through private insurers. The Senate version was more generous, and provided for direct reimbursements by Medicare—without the intermediary of a private insurance plan.

Political posturing on both sides obscured a critical question in this debate: how much influence should the agency administering the program have on the approved list of covered drugs and on the prices paid to the manufacturers? A program administered directly through Medicare would probably drive harder bargains and involve more regulations than a program contracted out to private insurers, and these policies would very likely spread to drug benefit programs in the private sector as well. This is a prospect that the drug industry, understandably, greatly fears, and that is undoubtedly why drug companies contributed an estimated $30 million in the recent campaign, most of which went to Republican candidates and Republican-leaning special-interest groups. The Republican victory now ensures that if a Medicare prescription-drug benefit ever does emerge from the 108th Congress, it will certainly be much more to the industry's liking than the version that passed the Senate earlier this year.

Like Congress, the FDA is also on the industry's payroll. In 1992, Congress passed the Prescription Drug User Fee Act (PDUFA), which required drug companies to pay user fees to the FDA, but stipulated that they would be used only to speed up approval of drugs. These fees now account for about half the budget of the FDA's Center for Drug Evaluation and Research. This makes the FDA dependent on the industry it regulates.

For the industry, the fees are easily outweighed by the increased sales that come from getting faster approval, and by its greater clout with the agency. PDUFA has to be renewed by Congress every five years. In this year's version, which was tacked onto a bioterrorism bill, the fees were increased substantially. Although a small fraction can be used to monitor drug safety, the lion's share is earmarked to further speed drug approval. Yet the faster the approval, the more likely that dangerous drugs will reach the market. Indeed, over the decade since PDUFA was enacted, 13 prescription drugs have had to be withdrawn from the market because they were found to be dangerous—but not before they caused hundreds of deaths.

The FDA is also subject to industry pressures through its 18 standing advisory committees on drug approvals. These committees, which consist of outside experts in various specialties, are charged with reviewing new drug applications and making recommendations to the agency about approval. Many members of these committees have financial or other connections to interested companies. For example, three of the eight members of the FDA's Psychopharmacologic Advisory Committee, which recommended approval of Sarafem, reportedly had ties to Lilly.

The influence of the pharmaceutical industry on government clearly reaches into the Bush administration. Defense Secretary Donald Rumsfeld was CEO, president, and chairman of G. D. Searle, a major drug firm that recently merged with Pharmacia, which is now in the process of merging with Pfizer. Mitchell E. Daniels, White House budget director, was senior vice president of Eli Lilly. Bush *père* was on Lilly's board of directors before becoming president. When added to the industry's large contributions to the Bush campaign in 2000, these connections could well have had something to do with the last-minute withdrawal of Dr. Alastair Wood's nomination as FDA commissioner earlier this year.

Wood, a widely respected professor of clinical pharmacology at Vanderbilt University in Nashville (and a former colleague of ours on the editorial staff of

The New England Journal of Medicine), reportedly was warmly recommended by Senator Bill Frist and Health and Human Services Secretary Tommy Thompson. But he was also known as a supporter of strong regulatory action by the FDA and had evidently ruffled feathers among drug industry executives and other champions of a "free market" for drugs, including the editors of *The Wall Street Journal*. According to an article last May in *The Boston Globe*, the result was behind-the-scenes pressure on the White House, which led to an abrupt change of heart. Frist was quoted as saying that "there was a great deal of concern that he [Wood] put too much emphasis on [drug] safety." And Dr. Raymond Woosley, also a distinguished clinical pharmacologist and an earlier candidate for the post (who opted instead for a major academic position), remarked, "It is pretty clear that anyone who has said anything that industry doesn't like isn't going to make it."

Dr. Mark McLellan, the newly confirmed commissioner, evidently was not opposed—he may even have been supported—by industry, but he has not taken public stands on any of the critical issues discussed here that might have influenced the views of the pharmaceutical companies. He is both a physician and an economist who has served recently on the president's Board of Economic Advisers, but he has no experience in drug regulation or clinical pharmacology, so he has much to learn about his new job. Morale at the FDA is said to be very low, and it remains to be seen whether the young commissioner can improve it with the policies and management style he will bring to this critical task. Only time will tell whether he intends to stand up to the pressures from the industry and from a Congress that is now more friendly to the industry than ever before.

What Should Be Done?

THE PHARMACEUTICAL INDUSTRY dominates just about every aspect of the American health care system that is related to its business interests. It uses its wealth and its political clout to influence all who might check or monitor its activities—including physicians, professional and academic institutions, Congress, and the FDA. Hiding behind a screen of public relations and advertising, it expects consumers to sit still for its excesses, with the clearly implied threat that otherwise it will be forced to stop producing its medical miracles.

What reforms might remedy the situation and direct the industry toward more socially useful behavior? First, the laws and regulations relating to the patenting of drugs and the granting of exclusive marketing rights need to be changed. The U.S. patent system is based on Article I, section 8, of the Constitution: "Congress shall have power ... to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." Patents were supposed to protect the intellectual property rights of inventors while enabling them to share information that others might use to advance the field, all in the public interest. But in the modern pharmaceutical business, as we have shown, the system is being grossly abused to allow companies to patent drugs that cannot reasonably be called new inventions, and to permit extensions of exclusivity on the flimsiest of legal pretexts.

The system has allowed the companies to flood the market with expensive me-too drugs and absurdly trivial variations on existing products. The system has also been used by the companies to delay, and sometimes to prevent altogether, competition from generic drugs. There is no question that modifications of Hatch-Waxman are needed. The FTC and Schumer and McCain are correct in their criticisms of the system, and we certainly support the general thrust of their proposals for reform. But more is needed. The whole patent system needs a new look, in view of the recent relaxation of standards for both usefulness and originality. The issues are technical and complicated, and the details of the needed changes will require careful consideration by experts to avoid making a bad situation even worse. We suggest study by a commission of experts (free of industry control) before any legislative or regulatory action is taken, but the completion of the study and the enactment of reforms deserve a high congressional priority.

STRENGTHENING THE FDA and improving its operations also should be a high priority for Congress. The FDA needs more help from congressional appropriations in meeting its growing responsibilities. Its dependence on user fees from industry should be replaced by adequate government support. This is an agency with an agenda of enormous importance to the public health, and it should not have to depend on the industry it is supposed to be regulating, any more than the SEC, for example, should have to depend on contributions from publicly traded corporations.

Of crucial importance, FDA regulations should be changed to require that new drug applications include evidence not only of the safety and the efficacy of a new drug, but also of the drug's effectiveness in relation to existing products of the same type. Approval should depend in part on whether the new drug adds something useful in terms of greater effectiveness, greater safety, fewer side effects, or substantially greater convenience. The FDA should be allowed reasonable flexibility in its judgments, of course; but it should not approve drugs that on balance offer trivial advantages or no advantages at all over products already available, and may even be worse. That policy change alone would dramatically improve the medical value of new prescription drugs, since drug companies would have no incentive to turn out me-too drugs and would have to shift their R&D emphasis to finding more innovative ones.

The requirements for membership on FDA advisory committees, upon which the agency depends for advice in the evaluation and approval of new drugs, should be strengthened to avoid conflicts of interest. Given the pervasiveness of the financial ties with the drug industry that now exist among clinical experts in most fields, it is admittedly difficult to find qualified consultants without such conflicts. But the task is not impossible, and the agency should be required to show that it is making every reasonable effort. Without unbiased experts, the FDA cannot get the help it needs to withstand the pressures from industry to approve drugs that really ought not to be allowed on the market or to keep drugs on the market that ought to be withdrawn.

We have already explained why we believe that direct-to-consumer ads are not in the public interest. The FDA should reverse its policy and prohibit such ads in the future, or at least greatly restrict their use. The drug industry and the advertising agencies, which have a financial interest in such ads, will strongly resist, so any such action would probably require a congressional mandate. For reasons of public health and safety, however, the FDA is acknowledged to have purview over pharmaceutical advertising, so there is no question of an unfettered "right to commercial free speech" in this case. The issue is how, and how much, it should be regulated.

Reforms are also needed in the current system for conducting clinical trials. The drug industry should not control the medical evaluation of its own products. The industry has a legitimate interest in seeing that these clinical trials are carried out, and it should pay for most of them. But the

conduct of the trials, and ...n, the analysis, and the inter- ... of the results, should be the ...sibility of the independent clinical ...estigators who do the work—not of the sponsoring drug companies. This will require stringent oversight or elimination of the hired businesses that conduct clinical trials for the drug companies, as well as substantial reforms at the academic centers and teaching hospitals that would then carry out most of the studies. Perhaps drug-company trials might best be monitored through some centralized, not-for-profit institution that could be a repository for contract proposals from the companies and an intermediary for the distribution of funds. What should be avoided in any case is the market competition among academic centers for drug-company business. This threatens to transform our medical centers into commercial enterprises, with the inevitable weakening of their commitments to education, clinical care, and unrestricted research. Guidelines such as those recently promulgated by the AAMC will be helpful in preventing this transformation, but the outright elimination of a commercial market for clinical trials would probably be most effective.

IN DEVISING REMEDIES for the problems described here, we must not lose sight of the fact that the prescription-drug industry can sell only the drugs that doctors are willing to prescribe. We have noted the costly and excessive lengths to which drug companies go to influence the prescribing behavior of physicians. But this is done only with the acquiescence of the doctors and their professional associations and educational institutions. If the drug industry presumes to take responsibility for the "education" of physicians, it is because the profession allows—or even invites—the industry to do so. In so doing, the profession abdicates its responsibility to act as fiduciaries and advisers for patients. The profession must take the necessary steps to end its financial and intellectual reliance on the pharmaceutical industry. We believe that many physicians (including medical educators) share this view but hesitate to voice it publicly. The public should be able to get trustworthy expert advice from physicians on what drugs are safe and effective and which of these, if any, are needed for optimal and cost-effective treatment. This is unlikely if much of the profession and its institutions are in the industry's pocket.

Finally, we note that most of the reforms we have suggested are intended to improve the quality of prescription drugs and the discrimination with which they are prescribed. Most would probably also reduce expenditures. But the greatest contribution to the control of prescription-drug costs could come from the bargaining power of large purchasers. The largest potential purchaser is the government—through Medicare, Medicaid, and the Veterans Affairs System. If payment for all the drugs used by the patients in these programs were to be negotiated by the government, there is no doubt that major savings would be achieved, particularly if physicians were also to use formularies that limit the routine use of me-too drugs. Such measures would undoubtedly spread to the private insurance system. However, with Republicans now in control of Congress, federal policies will probably become even friendlier to the pharmaceutical industry.

Prescription drugs are an essential part of modern medical care. Americans need good new drugs at reasonable prices. Yet the pharmaceutical industry is failing to meet that need. There is a widening gap between its rhetoric and its practices. Neither the medical profession nor government has so far done much to remedy the situation, but sooner or later they will have to act. The increased conservative complexion of the new Congress and the growing dependence of physicians on pharmaceutical money will probably delay such action. Nevertheless, the public is aroused and some kind of reform seems ultimately inevitable. The consequences of continuing to allow an essential industry to put profits above the public interest are simply too grave. ■

CORRESPONDENCE

continued from page 4

Red scare

TO THE EDITORS:

Tony Judt, in his review of *Koba the Dread: Laughter and the Twenty Million* by Martin Amis, almost arrives at the point of the book but falls just shy ("The Information," November 4). He doesn't recognize that Amis, like so many others, is disgusted that the halo effect of communist-style political propaganda infected not only his father's generation but, even after the collapse of the Soviet Union, his own contemporaries—most notably the odious and self-promoting Christopher Hitchens.

Judt also misses the point that a comparison of Nazism and communism has to include the added dimension of the effect of Bolshevism on the intellectual community of the West. While the residue of Nazism is relegated to the skinheads and rednecks, communist ideology still reigns in left-leaning intellectual cadres and continues to undermine democratic societies. Consequently, the horrors of Joseph Stalin, mostly ignored on campus and in the media, need to be remembered over and over again until the fellow Western traveling intelligentsia repent.

BERNIE REEVES
Editor and Publisher
Raleigh Metro Magazine
Raleigh, North Carolina

TO THE EDITORS:

Judt asks an excellent question: "[W]hy are we not offended by ex-Communists, or those who still evince some nostalgic sympathy for the Communist project, whereas we execrate Nazi sympathizers and shun the company of ex-Nazis?" Judt, like everybody else, does not consider the possibility that communism comes from Marxism. Nobody is willing to explain why Stalin—and Pol Pot, Mao Zedong, and Kim Jong Il—brought totalitarianism and mass starvation to their countries. Writers and journalists cannot bring themselves to think that the cruelty of Marxist regimes comes from the writings of Karl Marx.

Marx opposed human variety. Marxists described a future when there would be no disagreement and the state would wither away. In *The German Ideology*, Marx wrote of a world where there would be no specialization and everyone would "hunt in the morning ... rear cattle in the evening, [and] criticize after dinner." A philosophy that disapproves of individuality cannot be expected to tolerate individuals. And a state that attempts to change human nature is necessarily cruel and repressive.

GEORGE JOCHNOWITZ
Professor Emeritus of Linguistics
College of Staten Island, CUNY
Staten Island, New York

TONY JUDT REPLIES:

Bernie Reeves and George Jochnowitz are both one-idea men. For Reeves, it's all the fault of unrepentant, "left-leaning," fellow-traveling campus and media, and Western "intellectual cadres." Jochnowitz at least has the virtue of brevity: It's all the fault of Marx. Nice tidy answers to messy, complicated problems. If only it were that easy. ■

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ATTACHMENT D

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[Federal Register: March 18, 2004 (Volume 69, Number 53)]
[Proposed Rules]
[Page 12810-12811]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr18mr04-17]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. 2004N-0115]

Prescription Drug Importation; Public Meeting and Establishment of Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting and establishment of docket.

The Food and Drug Administration (FDA), on behalf of the U.S. Department of Health and Human Services' (HHS) Task Force on Drug Importation, is announcing that it is establishing a docket to receive information and comments on certain issues related to the importation of prescription drugs. FDA is also announcing a public meeting to enable interested individuals, organizations, and other stakeholders to present information to the Task Force for consideration in the study on importation mandated by the Medicare Prescription Drug, Improvement and Modernization Act of 2003. The Task Force is particularly interested in information related to whether and under what circumstances drug importation could be conducted safely, and what its likely consequences would be for the health, medical costs, and development of new medicines for American patients.

Date and Time: The public meeting will be held on April 14, 2004, from 9 a.m. to 5 p.m.

Location: The public meeting will be held at the Natcher Auditorium, Building 45, National Institutes of Health (NIH), 9000 Rockville Pike, Bethesda, MD 20892. Parking will be limited and there may be delays entering the NIH campus due to increased security. We recommend arriving by Metro if possible. NIH is accessible from the Metro's red line at the Medical Center/NIH stop.

Contact Person: Karen Strambler, Office of Policy, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3360, e-mail: Karen.Strambler@fda.gov.

Registration and Requests for Oral Presentation: No registration is required to attend the public meeting. Seating will be on a first-come, first-serve basis. If you wish to present at the public meeting, please submit your request and a summary of your presentation to Karen Strambler the contact person listed in this document. Requests should be identified with the docket number listed in brackets in the heading of this document. (To ensure timely handling, the outer envelope should be clearly marked with the docket number listed in brackets in the heading of this document and the statement ``Prescription Drug

Importation Public Meeting.'')

Speakers must submit requests for presentations along with a short summary of their presentation by close of business on March 30, 2004. Presenters must send final electronic presentations, if any, in PowerPoint, Microsoft Word, or Adobe Portable Document Format (PDF) to Karen Strambler the contact person listed in this document by close of business on April 7, 2004.

The public docket will formally remain open until June 1, 2004, and we encourage commenters to submit written and electronic comments before that date. However, FDA recognizes that there may be a need for further public input, and will be prepared to accept additional comments beyond this date as necessary. Submit electronic comments to http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&

Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Requests to present should contain the following information:

Presenter's name;
Address;
Telephone number;
E-mail address;
Fax number;
Affiliation, if any;
Summary of the presentation; and
Approximate amount of time requested for the presentation.

FDA encourages persons and groups having similar interests to consolidate their information and present it through a single representative, if possible, to enable a broad range of views to be presented. After reviewing the requests to present, the agency will schedule each appearance and notify each participant by e-mail or telephone of the time allotted to the participant and the approximate time the participant's presentation is scheduled to begin.

Presenters must send final electronic presentations, if any, in Microsoft PowerPoint, Microsoft Word, or PDF to Karen Strambler the contact person listed in this document by close of business on April 7, 2004.

If you need special accommodations due to disability, please inform Elizabeth French, Office of Policy (HF-11), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, rm. 14-101, Rockville, MD 20857, 301-827-3360, FAX: 301-594-6777, e-mail: efrench@oc.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On December 8, 2003, President Bush signed the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Medicare Modernization Act) (Public Law 108-173). Section 1121 of this legislation gives the Secretary of HHS (the Secretary) the authority to implement a system in the United States for the importation of Canadian prescription drugs. However, the Secretary is permitted to implement such a system only if he is first able to certify to the Congress that it would be safe and cost-effective. Section 1122 of this legislation also directs the Secretary to conduct a study that examines whether and under what circumstances drug importation could be conducted safely, and what its likely consequences would be for the health, medical costs, and development of new medicines for American patients. To comply with the Congressional mandate, the Secretary has formed the Task Force on Drug Importation to advise and assist HHS in this study.

The Task Force plans to consider several issues in the study, including several that Congress specifically asked HHS to consider. To assist in this effort we are asking for public comment on the following issues, which the Conference Report to the Medicare Modernization Act directs us to address in the study:

Impact of Unapproved Drugs: What is the scope and volume of unapproved drugs entering the United States through mail shipments and at border crossings? What are the safety concerns posed by these products? What evidence exists to substantiate these concerns? Can they be quantified? What is the scope and

[[Page 12811]]

volume of FDA-approved drugs commercially available in other countries?

FDA's Ability to Assure Safety: What should FDA do to assure safety of imported products? Should FDA examine all imports, or should a sampling method, along with testing, be used to assure safety? What resources would FDA need for different levels of oversight, which could include visual inspection, sampling, and other testing methods to determine quality? Is there a need for, and what is the feasibility of, modifications to the U.S. pharmaceutical distribution system that would help to ensure the safety of drug products imported into the United States under section 1121 of the Prescription Drug, Improvement and Modernization Act of 2003?

Regulatory/Legislative Issues: What, if any, limitations in current legal authorities, such as sections 505, 502, and 801 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355, 352, and 381), may inhibit the Secretary's ability to certify that prescription drugs imported into the United States from Canadian wholesalers or pharmacies are safe? What, if any, limitations in current legal authorities may inhibit the Secretary's ability to certify whether the imported drugs comply with sections 505, 502, and 501 of the act (21 U.S.C. 351) (e.g., Are the drugs approved by FDA?, Do they contain appropriate labeling?, Are they manufactured according to current Good Manufacturing Practice)? If FDA could not assure the same level of safety for imported drugs as consumers expect from drugs purchased at a State-licensed pharmacy, what level of risk would be acceptable?

In what ways would importation of drugs, if permitted under section 1121 of the Medicare Modernization Act, impact U.S. and international intellectual property rights as well as obligations under existing trade agreements? Are there additional legal protections needed for effective enforcement of these rights and agreements?

Technology: What anti-counterfeiting technologies are available and feasible to use to improve the safety of products in the domestic market as well as to prevent the importation of unapproved or counterfeited drug products? What costs would be associated with the implementation of such technologies?

Financial Impact: What would be the short and long term financial impact on drug prices, on drug manufacturers, on pharmacies, on wholesalers, and on patients if section 1121 were to be implemented? What other system costs could be associated with importation of pharmaceuticals from Canada and other countries into the United States?

Research and Development: What would be the impact on research and development of drugs and the associated impact on consumers and patients, if section 1121 of the Prescription Drug, Improvement and Modernization Act of 2003 were to be implemented? Would a reduction in domestic pharmaceutical sales result over time in reduced investment in developing new drugs for the future?

Liability Issues: What, if any, liability concerns would exist for entities in the U.S. pharmaceutical distribution system if importation of drugs from Canada or another country were permitted? If liability concerns do exist, what liability protections do you believe should be implemented?

Regulation by Foreign Health Agencies: What protections do other countries have in place to ensure the safety of drugs that are exported or transshipped from their country to the United States? If these protections are lacking, to what extent are foreign health agencies willing or able to implement new or additional protections to ensure safety of exported or transshipped drugs?

II. Comments

Interested persons should submit to the Division of Dockets Management (see Registration and Requests for Oral Presentation) written or electronic comments regarding this document by June 1, 2004. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be reviewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Transcripts

Transcripts of the public meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page or a CD at a cost of $14.25 each.

IV. Electronic Access

Persons with access to the Internet may obtain additional information on the public meeting at http://frwebgate.access.gpo.gov/cgi-bin/leaving

Dated: March 15, 2004.
Jeffrey Shuren,
Assistant Commissioner for Policy.
[FR Doc. 04-6145 Filed 3-16-04; 8:45 am]

BILLING CODE 4160-01-S

ATTACHMENT E

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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

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ATTACHMENT F

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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.

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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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Pittsburgh, PA 15222-4742

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

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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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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

McKESSON
Empowering Healthcare

July 3, 2002

Enforcement Committee
California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento, CA 95814

The use of dispensing automation in hospital pharmacies has provided many benefits to the facilities from improved operational efficiencies to improved patient care.

- Automated dispensing technologies have been used to automate nondiscretionary drug distribution tasks in the medication use process thereby allowing for redeployment of pharmacists and technicians into critical tasks to improve patient care. The roles of the pharmacist and technicians have expanded into areas that can insure the safe medication practices such as clinical interventions, adverse drug reaction prevention and improved sterile product production processes.

- Robot-Rx bar-coded dispensing technology has been shown to improve the dispensing accuracy over the manual dispensing process thereby reducing the potential for medications errors.

- The basis for the Robot-Rx technology is utilizing barcodes to pick and dispense medications. Pharmacists do check 100% of medications packaged for the Robot on a daily basis to ensure that the bar-coded packaged medications are labeled and packaged correctly.

- Following the implementation of Robot-Rx, the pharmacist will check 100% of doses dispensed from the Robot for a period of time that provides both the appropriate level of documentation and assurance for the pharmacy that the Robot is dispensing the correct drug and correct strength with 100% accuracy.

- Once the 100% accuracy is validated, the pharmacies may elect to institute a random quality check of 10% of the patients on a daily basis to validate the accuracy and to streamline the pharmacists' manual checking process. Failure to meet the 100% accuracy of drug and strength dispensed on the daily quality check would require checking of 100% of the Robot dispensed medications until the 100% accuracy has been obtained for 24 hours and a root cause analysis of the cause for the dispensing error has been completed.

- While most states require a pharmacist check of doses dispensed by non-licensed personnel, many states do not address the issue of medications dispensed from an automated device. Similar to California, states such as Colorado have general language in their state regulations that addresses the pharmacist role in the dispensing process. Robot-Rx users in Colorado have asked the state board for and have been granted approval of their daily quality check process as part of their internal checking and documentation of the dispensing accuracy. Based upon the accuracy validation step, the pharmacist will then initial or sign-off the daily accuracy of the Robot dispensed doses.

In summary, we feel that the Robot-Rx dispensing technology can reliably support inpatient pharmacy medication processes to promote safer medication practices and improve patient care while streamlining the pharmacist manual dispensing tasks. We would like the opportunity to work with the State Board of Pharmacy to address the Pharmacy Rules and Regulations needed to support the use of technological advancements and promote patient safety.

Thank you for your consideration and I would welcome the opportunity to assist the committee in the future.

Respectfully,

Neil DiBernardo, Pharm.D.
License #35563
Pharmacist Consultant
McKesson Automation

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ATTACHMENT G

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California State Board of Pharmacy Continuing Education Program Senate Bill 151 (Burton)

Put Patients First

SB 151 shifts complexity away from the patient onto the health professionals.

2

Senate Bill 151 (Burton)

Legislative Intent

1. *Increase* patient access to appropriate pain medication and prevent the diversion of controlled substances for illicit use.
2. Provide that the forms required by the act for controlled substance prescriptions may be used to prescribe *any prescription drug or device.*

3

These intent statements are taken directly from uncodified intent language included in Senate Bill 151.

Overview of SB 151

Eliminates Triplicates

New Prescription Forms

Simplifies Prescribing Rules

Retains Terminal Illness Exemption

Makes CURES Permanent

Extends CURES to Schedule III

4

Triplicate Elimination

January 1, 2004:

All **controlled substance prescriptions (including Schedule II) are valid for 6 months.**

5

Previous to this bill Schedule II controlled substance prescriptions were only valid for 14 days.

The DEA allows prescribers to write multiple CII prescriptions at a single office visit with instructions not to fill before a certain date. For example, the prescriber could write a prescription for a one month supply of oxycodone on six scripts with instructions to the pharmacy to not fill the script before the first of each month ("Do not fill before March 1, April 1, May 1, etc.). This reduces the number of office visits required for patients on chronic CII drug therapy. The Board of Pharmacy accepts this practice as well.

Triplicate Elimination cont'd

July 1, 2004:

Triplicate is *not* required for Schedule II prescriptions.

Prescribers *may* use new security prescription forms for Schedule II prescriptions.

New triplicate forms may *not* be ordered.

6

It would be prudent for prescribers who regularly prescribe CII drugs to order a supply of triplicates to bridge this transition period. Extra triplicate forms are insurance in the event there is difficulty obtaining the new prescription forms.

Printers have indicated that once they have initially verified the prescriber's credentials, orders for additional forms can be filled in 1-2 days.

Triplicate Elimination cont'd

January 1, 2005

All *written* controlled substance prescriptions (Schedules II-V) must be on security prescription forms.

Fax and oral prescriptions for Schedules III-V are *allowed.*

7

If faxed, the new prescription forms will result in the pharmacy receiving a prescription with "void" on the face. The Board of Pharmacy recommends that prescribers faxing prescriptions use plain paper prescriptions for that purpose. A pharmacy that receives a prescription with this "void" faxed prescription can fill it if they confirm the prescription with the prescriber's office.

New Prescription Forms

Forms obtained from approved *private printers.*

Forms may be ordered in *any quantity.*

Forms may be ordered in *any format.*

Forms are *not* serialized.

Forms are *not* multi-copy.

Forms have required *security features.*

8

The Board of Pharmacy and the Department of Justice must jointly approve the printers who sell the new prescription forms.

The Board of Pharmacy and other appropriate licensing boards will have the name and contact information for the approved printers on its website.

SB 151 only specifies the minimum security features on the forms. Prescribers may order forms in any format (size, multiple copy, etc.) that they desire. Logos and other customizations are permitted.

Forms may be customized for organizations using electronic medical record systems or electronic prescribing systems. The forms must contain the required security features when purchased from the printer but computer printers can fill out the form leaving only the signature and date to be written by the prescriber.

New Prescription Forms cont'd

Security Features:

- **Latent Void**
- **Chemical Void**
- **Thermo-Chromic Ink**
- **Watermark**
- **Microprinting**
- **Preprinted Prescriber Information**
- **Quantity Check-off Boxes**

9

The new forms must include a lot number representing each shipment to the prescriber and each script in that lot must be numbered beginning at "1". Taken together these numbers do constitute a unique identifier for each prescription form, but this information is not tracked by CURES. The numbers need not be located next to one another on the script.

Each form must include a description of the security features included on the form (the logo is printed in thermochromic ink, latent void protection is included, micro-printing is in this location, etc.).

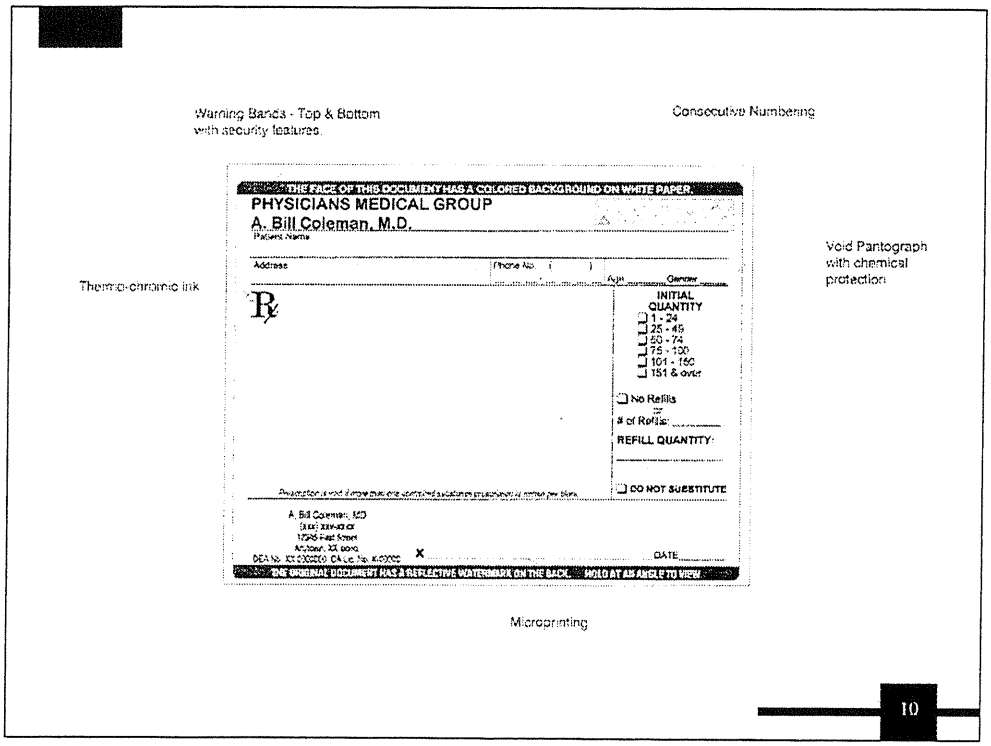
Latent Void – if copied the copies will come up with "void" on them.

Chemical Void – if exposed to ink solvents (e.g. acetone) the original prescription will come up "void."

Thermo-Chromic Ink – a single feature must be printed in this ink which changes color when exposed to heat. The feature will return to the original color when it cools.

Watermark – this requires a printed watermark on the back of the prescription that reads "California Security Prescription." This is not a watermark in the paper but a printing process.

Microprinting – this feature prints very fine and small text that will appear as a solid line if copied or scanned.



This sample form is missing the description of security features that is required to be printed on the form.

Multiple Prescriptions

SB 151 requires one of two statements on each prescription form.

1. "Prescription is void if more than one controlled substance is written per blank."
2. "Prescription is void if the number of controlled substances prescribed is not noted."

11

If a form is used to prescribe multiple controlled substances it must include a preprinted space for the prescriber to note the number of drugs prescribed.

Prescribers must decide when ordering forms if they wish to prescribe multiple controlled substances on a single form and have the printer produce the appropriate form.

New Prescription Forms cont'd

Institutional Forms:

- **Can Be Used In Licensed Health Facilities**
- **Do Not Require Preprinted Prescriber Info**
- **Require Preprinted Facility Info**
- **Ordered by "Designated Prescriber"**
- **Issued by "Designated Prescriber"**
- **Records Maintained by "Designated Prescriber"**

12

This institutional form was created to allow hospitals and other health facilities to provide institutionally appropriate forms to temporary physicians, residents, and other short term providers. Prescribers regularly working in the facility should each have their own forms provided and not use these institutional forms.

Designated Prescriber

- May be any prescriber eligible to order forms.
- Designated prescriber's name, license number and DEA number are preprinted on the forms.
- Designated Prescriber must keep records of the prescribers to whom the forms are issued.
- Records must include the name, license number, DEA number and the quantity of forms issued.
- Records must be maintained for three years.

13

The designated prescriber does not need to personally hand out the institutional forms. That task may be delegated to other facility staff. However, the designated prescriber will be held responsible regardless of the system used to provide the forms.

Simplified Prescribing Rules

July 1, 2004:

- **All controlled substance prescriptions must be signed and dated by the prescriber.**
- **Other information required on the prescription may be written or printed by the prescriber's agent.**

14

The only elements of the prescription that must be written by the prescriber is the date the prescription is issued and the signature of the prescriber.

Terminal Illness Exemption

- Prescribers may continue to use normal prescription forms when ordering Schedule II drugs for terminally ill patients.
- Note Section 11159.2 on Prescription.
- Same Prescribing Rules as for all other controlled substance prescriptions.

15

The need for this exemption should diminish over time as all prescribers acquire the new prescription forms and will therefore be able to prescribe CIIs.

Special Care Settings

- SNF, INT, HH, & Hospice patients can receive Schedule II prescriptions faxed or phoned into a pharmacy serving those patients. Effective July 1, 2004.
- "Pharmacy Generated Triplicate" is replaced by a form of the pharmacy's design effective July 1, 2004.
- Health and Safety Code 11167.5

16

CURES

CURES system made permanent.

Schedule III drugs added to CURES on January 1, 2005.

17

CURES = Controlled Substance Utilization Review and Evaluation System

CURES was established to test electronic monitoring of CII prescribing as an alternative to the triplicate form. The system has been collecting information since 1997 as a pilot project. SB 151 makes this system permanent and expands the data collected to include CIII information.

Electronic monitoring allows law enforcement and regulatory agencies to more efficiently identify potential drug diversion.

Currently, the CURES system logs approximately 3.5 million CII prescriptions per year and the addition of CIII information is expected to increase that by up to a factor of 10.

CURES is funded jointly by the affected regulatory boards and the Department of Justice.

What is CURES

CURES collects CII prescription information (patient, prescriber, pharmacy, drug, amount, strength, etc.) from pharmacies.

This information is submitted in electronic format on a monthly basis.

The information is aggregated into a statewide database used by law enforcement and regulatory agencies.

18

Prescribers dispensing CII and CIII drugs will have to submit the same information to the CURES system. For CII dispensing this reporting begins on July 1, 2004. For CIII information the reporting begins on January 1, 2005.

Patient Activity Reports

Prescribers and pharmacists can obtain "patient activity reports" from the Department of Justice.

The request form can be found at:

http://ag.ca.gov/bne/content/trips.htm

19

Prescribing Privileges

- Physicians
- Physician Assistants
- Nurse Practitioners
- Nurse Midwives
- Dentists
- Veterinarians
- Osteopaths
- Podiatrists
- Optometrists

20

Schedule II Drugs (Examples)

- Morphine
- Oxycontin
- Demerol
- Dilaudid
- Ritalin
- Fetanyl
- Methadone

21

Schedule III Drugs (Examples)

- Vicodin
- Tylenol with Codeine
- Anabolic Steroids
- Ketamine
- Dronabinol

22

Schedule IV Drugs (Examples)

- Valium
- Xanax
- Darvon
- Halcion
- Ambien
- Talwin
- Sonata

23

Dangerous Drugs v. Controlled Substances

Dangerous Drugs = Any Drug that Requires a Prescription

Controlled Substances = Dangerous Drugs that have Abuse Potential

24

Questions?

Board of Pharmacy

916-445-5014

www.pharmacy .ca.gov

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ATTACHMENT H

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
Arnold Schwarzenegger, GOVERNOR

ENFORCEMENT COMMITTEE MEETING

Meeting Summary
March 18, 2004

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

Present: John Jones, Chair and Board President
Stan Goldenberg, Board Member
Bill Powers, Board Member
Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Dennis Ming, Supervising Inspector
Joan Coyne, Supervising Inspector
Board of Pharmacy Inspectors
Dana Winterrowd, Staff Counsel
Paul Riches, Legislation/Regulation Chief

Call to Order

Enforcement Committee Chair John Jones called the meeting to order at 9:30 a.m.

Reimportation of Prescription Drugs from Canada

Committee Chair John Jones reported that the board has been discussing and has sought comments on the issue of prescription drug importation from outside of the United States. This has been a sensitive and controversial issue. The board has been tasked with balancing consumer access to affordable prescriptions against the safety and effectiveness of drugs obtained from foreign sources. The board has heard from many interested parties on this issue during its committee meetings and at its quarterly board meetings.

President Jones reported that FDA Commissioner Mark McClellan was named to lead a committee that will conduct a study on the reimportation of lower-cost, U.S. manufactured prescription drugs from Canada. The one-year study was required under the new Medicare law and will examine whether the United States could safely reimport prescription drugs.

Paul Riches described various legislative proposals that have been introduced relating to the reimportation of prescription drugs from Canada. Some of the bills impact the board in that the board would be required to establish a Web site to provide price comparisons between American and Canadian prescription drug prices and provide a link to certified Canadian pharmacies. The bill would also require that the board "certify" Canadian pharmacies. The other legislative bills are designed to increase the public and private sector buying power for lower prescription drug prices. The board's Legislation and Regulation Committee will review these bills at its public meeting on March 30th, in Sacramento.

The committee discussed its purpose of public protection, which includes patient access to "safe and affordable" prescription medications and that the board should not be building a barrier to this access. The committee acknowledged that ideally the federal government should be establishing national policy to ensure this access and that the board should be supportive of all efforts in this regard.

Update on Implementation of Legislation Regarding Wholesalers

At its January meeting, the Board of Pharmacy acted 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 included 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 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 introduced AB 2682, which would require the board to adopt regulations requiring pedigrees and governing wholesale distribution in California consistent with the federal regulations. The bill would also require all out-of-state wholesalers selling or distributing prescription drugs into California to be licensed. Another bill, SB 1427 was introduced by Senator Ackerman and would establish felony penalties for counterfeiting drugs.

Legislation Chief Paul Riches noted that the Board of Pharmacy's vote to support this legislative proposal was a difficult one because the board didn't want to impede legitimate business. Mr. Riches reported that he has been working constructively with the wholesale community to resolve some of their issues and believes that an agreement will be reached. One solution has been to include language that would give the Board of Pharmacy flexibility to extend the implementation date of the pedigree requirement for at least one year. Another issue is the prohibition that a wholesaler cannot own a "closed pharmacy". A proposed resolution may be a

due diligence requirement on the wholesale facility instead. This proposal would be in addition to the current proposed provision that prevents a pharmacy from wholesaling prescription drugs.

SB 1307 is scheduled for hearing in the Business and Professions Committee on April 12th.

Conversion to Paper Invoices to Electronic Billing by Wholesalers for Drug Purchases

Executive Officer Patricia Harris explained that 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. Counsel advised that 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). I t was explained that 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)).

Ms. Harris summarized by stating that board counsel has advised that pharmacies can keep drug purchase records from wholesalers 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.

The Enforcement Committee accepted counsel's advice and application of pharmacy law relating to electronic records of drug purchases from wholesalers.

Use of Robotic Technology in Hospital and Institutional Pharmacies and the Interpretation of Pharmacy Law that Pharmacist Must Check Each Medication

Executive Officer Patricia Harris stated that the board 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.

Board counsel reviewed the request and advised that McKesson is correct that the Pharmacy Law is 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."

It was 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.

It was explained that 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 states 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 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.

Further, Ms. Harris explained that 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.

The Enforcement Committee agreed with the conclusion of board counsel and clarified that this application of pharmacy law pertains to all pharmacies that use an automated delivery system not just to hospital or institutional pharmacies.

Proposed Revisions to the Public Disclosure Policy

Executive Officer Patricia Harris provided the Enforcement Committee with a revised public disclosure policy that included "Letter of Admonishment" that was added this year through new legislation and some other technical changes were made.

She stated that 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.

Staff recommended 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. Also, with the board's diminishing resources, it is difficult to maintain the records for five year.

Collette Galvez from the Center for Public Interest Law suggested that the committee not recommend that the board change its public disclosure of substantiated complaints to 3 years. She advised that such a change is not consistent with the other health boards that maintain these records for at least 5 to 10 years. She also cautioned that three years of information may not be enough for a consumer to make an informed decision about a pharmacy or pharmacist.

Other comments were made that a licensee is more likely to challenge a citation and fine, if the licensee is aware that the citation is on the licensee's record for a minimum of five years. It was also noted that some type of a disclaimer should be included when a citation and fine is disclosed in that a citation is considered an administrative action (not discipline) and payment of the fine is considered resolution to the violation of law.

The Enforcement Committee agreed to recommend to the Board of Pharmacy that it amend its public disclosure statement and change its record retention schedule for substantiated complaints to three years.

Implementation of SB 151 – Changes to the Prescribing and Dispensing of Controlled Substances

Committee Chair John Jones commented that he anticipates over the next year that the implementation of SB 151 will be a standing agenda topic for this committee and the Board of Pharmacy. The triplicate requirement has been in place for over 60 years and the transitional changes to implement the new law over the next year are confusing. The board anticipates many questions and has been working hard especially with its limited resources to educate prescribers and pharmacists. The educational process will not be an easy feat.

Ms. Harris reported that the newsletter is scheduled for distribution at the end of March. Meanwhile, the articles on SB 151 are on the board's Web site. The articles have also been provided to the prescriber boards and professional associations so that they can educate their licensees and answer questions. Staff and board members have been working with various associations and pharmaceutical companies on educational programs and outreach efforts.

Questions were asked as to how pharmacies that do not fill schedule II prescriptions need to report the data to the Department of Justice (DOJ). It was explained that the law specifies that this is a decision of the DOJ. However staff will seek clarification from DOJ for licensees. It was noted that the board has received 6 security printer applications. The board has been advising prescribers that if they are concerned that they will run out of their triplicate prescription forms before they will have their new controlled substances forms, then they should reorder triplicate prescription forms before

July 1, after which time, the triplicates will no longer be available. Many pharmacists have been contacting the board seeking validation that triplicate prescriptions are good for six months.

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

The Enforcement Committee was provided a copy of the NABP task force report on the limited distribution and shortage of medications. The task force met in November 2003 after the Enforcement Committee discussed this issue last September. The committee discussed this issue at the request of Stan Goldenberg. 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.

Last September, when the Enforcement Committee discussed this issue, it determined that these types of complaints would be handled on a case-by-case basis. If the pharmacist does not fill a prescription according the prescriber's order, then he/she may be in violation of CCR, title 16, section 1716 (variation from a prescription). The reason would be that the prescriber wrote for a specific quantity and if the pharmacist didn't dispense this quantity (for whatever reason), but labels the prescription as if he/she had, then it may be considered prescription error (mislabeled prescription container). However, the final disposition would depend on the specific facts of each case.

There was discussion that the committee's decision last September was contrary to the recommendation to the NABP task force. The task force recommended that the pharmacist-in-charge develop, implement, and maintain policies and procedures that address drug shortages or drug product discontinuance. Also, that implementation by pharmaceutical manufacturers 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.

Continuing Education Outreach Program to Licensees

President John Jones reported that Board of Pharmacy is going on its second year of providing continuing education to pharmacists. The program has been updated and a copy was provided in

the meeting materials. He explained that the program was also modified for presentation to the graduating classes of the four pharmacy schools.

Review of Strategic Plan

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

Staff provided a recommendation to add an objective similar to that of the licensing goal. The objective 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

The Enforcement Committee agreed to recommend to the Board of Pharmacy that the following objective be added to the enforcement goal: Initiate policy review of 25 emerging enforcement issues by June 30, 2005. And the measure would be: The number of issues

Adjournment

Committee Chair John Jones adjourned the meeting at 12:30 p.m.

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ATTACHMENT I

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California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
Arnold Schwarzenegger, Governor

Enforcement Team Meeting
March 18, 2004
2:00 p.m. – 4:00 p.m.

Present: Committee Chair and Board Member John Jones
Board Member Stan Goldenberg
Executive Staff
Supervising Inspectors
Inspectors

Announcements/Introductions
Committee Chair John Jones called the meeting to order at 2:00 p.m.

Quality Improvement Efforts
The Enforcement Team reviewed the enforcement data for this quarter. Training was given to the inspectors on CURES compliance and implementation of SB 151.

Supervising Inspector Robert Ratcliff stated that the 2001/03 collective bargaining contract for board inspectors established a joint labor-management committee on inspector workload issues. There have been three meetings, one in December 2002, February 2003 and February 2004. The inspector members on this committee have provided updates to other board inspectors about the discussions.

During this last meeting, the inspector representatives discussed the results of a survey that the inspector representatives sent to all the inspectors in November 2003. After the joint labor-management committee meeting, the inspector representatives shared the survey results with all the inspectors. The survey results were from self-reported information. Supervising Inspector Robert Ratcliff compared the self-reported survey results to the data that the inspectors report routinely every month. The data used for comparison included monthly activity reports, mileage logs and inspection data.

He emphasized that discussions about team activities, significant accomplishments and workload management has been an integral component of every quarterly Enforcement Team meeting since 1998, and contribute significantly to the board's commitment to public protection.

Discussion of Enforcement Committee Meeting
The Enforcement Team discussed the agenda items from the Enforcement Committee meeting.

Adjournment
Committee Chair John Jones adjourned the meeting at 4:00 p.m.

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ATTACHMENT J

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Board of Pharmacy Enforcement Statistics
Fiscal Year 2003/2004

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 03/04
Complaints/Investigations					
Initiated	372	337	419		1128
Closed	430	469	511		1410
Pending (at the end of quarter)	935	867	1049		1049
Cases Assigned & Pending (by Team)					
Compliance Team	89	82	59		59
Drug Diversion/Fraud	67	69	73		73
Mediation Team	71	78	137		137
Probation/PRP	45	28	20		20
Enforcement	194	164	98		98
Application Investigations					
Initiated	82	21	25		128
Closed					
Approved	122	42	22		186
Denied	5	2	1		8
Total*	139	57	24		220
Pending (at the end of quarter)	73	33	35		35
Citation & Fine					
Issued	359	281	303		943
Abated	231	73	392		696
Total Fines Collected	$93,425.00	$377,200.00	$149,636.00		$620,261.00

* This figure includes withdrawn applications.

** Fines collected and reports in previous fiscal year.

Board of Pharmacy Enforcement Statistics
Fiscal Year 2003/2004

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 03/04
Administrative Cases (by effective date of decision)					
Referred to AG's Office*	50	42	23		115
Pleadings Filed	24	26	38		88
Pending					
Pre-accusation	85	97	65		65
Post Accusation	67	76	87		87
Total	153	179	159		159
Closed**	26	22	41		89
Revocation					
Pharmacist	3	6	3		
Pharmacy	2	2			
Other	4	3	3		
Revocation,stayed; suspension/probation					
Pharmacist	1		2		
Pharmacy					
Other					
Revocation,stayed; probation					
Pharmacist	4	3	1		
Pharmacy			1		
Other	1	2			
Suspension, stayed; probation					
Pharmacist					
Pharmacy					
Other					
Surrender/Voluntary Surrender					
Pharmacist	2	2	2		
Pharmacy			3		
Other	2	1	4		
Public Reproval/Reprimand					
Pharmacist		3	2		
Pharmacy			1		
Other					
Cost Recovery Requested	$42,992.25	$68,512.50	$84,155.00		$195,659.75
Cost Recovery Collected	$36,714.86	$47,847.87	$41,556.37		$126,119.10

* This figure includes Citation Appeals

** This figure includes cases withdrawn

Board of Pharmacy Enforcement Statistics
Fiscal Year 2003/2004

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 03/04
Probation Statistics					
Licenses on Probation					
Pharmacist	129	122	113		
Pharmacy	21	21	19		
Other	22	23	22		
Probation Office Conferences	8	5	11		
Probation Site Inspections	35	17	33		
Probationers Referred to AG for non-compliance	1	7	0		8

As part of probation monitoring, the board requires licensees to appear before the lead inspector at probation office conferences. These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset, 2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.

Pharmacists Recovery Program (as of June 30, 2003)

Program Statistics					
In lieu of discipline	0	1	0	0	1
In addition to probation	1	3	1	5	10
Closed, successful	3	0	3	3	9
Closed, non-compliant	2	3	5	4	10
Closed, other	0	0	1	0	1
Total Board mandated Participants	50	50	49	50	50
Total Self-Referred Participants*	15	15	15	15	15
PRP Site Inspections**	29	1	6	8	44
Treatment Contracts Reviewed	31	37	26	23	26

Monthly the board meets with the clinical case manager to review treatment contracts for scheduled board mandated participants. During these monthly meetings, treatment contracts and participant compliance is reviewed by the PRP case manager, enforcement coordinator and lead inspector and appropriate changes are made at that time and approved by the executive officer. Additionally, non-compliance is also addressed on a needed basis e.g., all positive urines screens are reported to the board immediately and appropriate action is taken.

* By law, no other data is reported to the board other than the fact that the pharmacists and interns are enrolled in the program.

**Some PRP Participant Inspections are included in the Probation Site Inspections total.

As of March 31, 2004.

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ATTACHMENT K

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Board of Pharmacy
First Quarterly Report
January - March 2004

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 423 mediations/investigations sent to SI for review)* 1. Mediate all consumer complaints within 90 days. **0-90 Days 47 (46%)** **91-180 Days 39 (38%)** **181-365 Days 16 (16%)** **366-730 Days 0 (0%)** 2. Investigate all other cases within 120 days. **0-90 Days 165 (51%)** **91-180 Days 85 (26%)** **181-365 Days 54 (17%)** **366-730 Days 17 (5%)** *(Based on 308 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 118 (38%)** **91-180 Days 49 (16%)** **181-365 Days 132 (43%)** **366-730 Days 8 (3%)** **731+ 1 (0%)** 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). • *The BNE has been working hard upgrading software and adding new servers in preparation for receiving Schedule III prescriptions into CURES. Additionally, BNE is developing a new web-based interface for board access to CURES that is expected to be much faster and easier to use. BNE anticipates this new interface to be ready for testing in early May.* • *The board is now receiving monthly reports from Atlantic Associates indicating pharmacies reporting that they did not fill any Schedule II prescriptions. Board staff is utilizing this report along with other board developed CURES reports to identify and separate those pharmacies transmitting under old license numbers, not transmitting at all, did not fill any Schedule II prescriptions* • *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.* **49 CURES reports were provided to supervising inspectors and/or inspectors this quarter to aid in an investigation or inspection.** • *1782 Wholesaler Database has been temporarily placed on hold mainly due to the additional workload derived from implementing SB151 (Burton). Staff plans to continue work on this project this summer.* • *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.* **19 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.

	♦ *The CURES Users Group began meeting the third Tuesday of every month. Meetings were held on February 24 and March 16 to work on pharmacy non-compliance and data error issues as well as improving database functionality.* ***Next meeting: April 13, 2004*** ♦ *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.*
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 staff is searching for consumer health fairs to attend second quarter.* 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:* ○ *The following enhancements were made to the inspector data program to force correct data entry, improve overall functionality, and provide additional data elements and reporting capability:* . *Modified access reports: statement of issues, written notification, and evidence receipt programs to change to new Governor.* . *Modified various fields to prevent blank and/or invalid entries by inspectors that will improve data quality and consistency.* . *Implemented additional inspection visit type categories needed for statistical purposes.* . *Developed and implemented new menu bar buttons: CURES access, spell check and print closure.* . *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. • *Added code to support new Hewlett Packard 450 printers.* *<u>Installed on Inspector laptops March 2004</u>* 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.*** ♦ *Each month staff extracts license data in various forms from one large chuck of data to meet the needs of several different internal and external requestors. Board staff is in the process of developing a data scrub program to automate this function.* ▪ *Automated evidence database – No changes this quarter.* ▪ *Automated sterile compounding database* ✓ *Updated program to generate report for licensing renewals.* ✓ *Added query to automatically integrate current Teale licensing records to database.* ♦ *Implemented New Security Printer database –SB151 (Burton) requires the board to approve security printers in advance of producing controlled substance prescription forms beginning July 1, 2004. Staff began development of a database in December 2003 that will track the security printer applications through to "approval".*

Objective 1.2: **Measure:**	**To achieve 100 percent closure on all administrative cases within one year by June 30, 2005.** **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. ▪ *April 1st DAG costs increased from $112-$120 per hour to $132 per hour and Legal Assistants hourly costs increased from $53 to $91. Before this increase in fees, the board projected a deficit of $35,000. For 2003/04 the board will have to absorb the increased costs. For 2004/05 the board redirected $70,000 to the AG budget line item rather than pursuing an augment by a BCP.* 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: 3.*** ▪ *Disciplinary cases closed this quarter:* **0-365 days 26 (63.4%)** **366+ days 15 (36.6%)** ▪ Disciplinary cases reviewed this quarter: ***Accusations reviewed: 38*** ***Accusations needing revision: 9*** ***Accusations filed: 38*** ***Stipulations/proposed decisions reviewed: 7*** ***Cases reviewed for costs: 10*** 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* ✓ Modifications made to program for easier milestone and DAG time tracking. ✓ Automated tasks of creating new labels and a disciplinary tracking sheet and referral memo.

	✓ Modified case cost report, ✓ Automated processing of mail vote ballots and tally sheets. ✓ Automated preparation of accusation review memo and label. 5. Review and update disciplinary guidelines. ▪ *No changes from last quarter.*

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 **2,089**.* *Total number of inspections completed this quarter: **654*** *(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: **42*** *Total Status 3 (delinquent) inspections: **9*** *Total routine inspections resulting in a complaint investigation: **12*** 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. ▪ *Public disclosure of disciplinary history on licensees is in the final stages of development and test. Projected production date: April 19, 2004.* ▪ *During this quarter website revisions included:* ✓ ***Regulations updates.*** ✓ ***New pharmacy technician application.*** ✓ ***CPJE Handbook for pharmacist exam.*** ✓ ***Sample CPJE test questions.*** ✓ ***Security printer application for approval to produce controlled substance prescription forms.*** ✓ ***Information for prescribers and pharmacists for prescribing controlled substances.*** ✓ ***2004 Lawbook*** ✓ ***Key facts about emergency contraception in 10 languages.*** 2. Prepare two annual *The Scripts* to advise licensee of pharmacy law and interpretations. ▪ *March 2004 Script published.*

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:* ✓ ***January 21st board meeting** – presentation on board key policies and pharmacy law-including investigation, inspection and enforcement processes.* ✓ ***January 26th*** - SB 151 presentation at FBI Drug Diversion meeting ✓ ***February** – CPhA Outlook 2004.* ✓ ***February 5th*** - Law Update 2004 presentation at USC. ✓ ***February*** - SB 151 presentation at San Francisco Health Plan P & T Committee ✓ ***February 24th*** - Presentation on Pharmacy Law changes to UCSF students. ✓ ***February 27th*** - Presentation on board activities for Pharmacy Access Partnership. ✓ ***March 2nd*** - Presentation to UCSF students ✓ ***March*** - SB 151 presentation to California Coalition of Compassionate Care ✓ ***March 8th*** - SB 151 presentation to Northern California Pain Coalition ✓ ***March 17th*** - Presentation to Medical Board ▪
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 April 2004, there were **70** participants in the PRP. During this quarter the board referred **1** pharmacist to the program. Statistics for closures are not yet available.* ▪ *Probation Monitoring Program: As of this quarter there are **113** pharmacists, **19** pharmacies and **22** other*

Objective 1.5, cont'd.	*individual licensees (technicians, interns, exemptees) on probation with the board.* ***Five*** *new probationers were added during this quarter,* ***0*** *investigations for petitions to revoke probation for non-compliance were completed, and* ***three*** *non-compliance letters were sent.* ▪ *Citation and Fine Program:* ✓ ***January thru March: 303 citations issued. Total fines: $149,636.00*** ▪ 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.*

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 – Completed disciplinary actions are entered into the database on a going-basis.* ▪ *Web Enforcement Look-Up – Testing of program completed and targeted for production April 19, 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:*

	36 public records requests 61% within 10 days; 33% over 10 days. *30 requests from licensees – 77% within 10 days; 23% over 10 days.* *21 requests from other agencies – 76% within 10-day response time;21% over 10 days.* *245 written license verifications – 77% within a 10 days; 23% over 10 days.* *4 subpoenas – 100% responded to within 5 days.*