Mail Order Pharmacy: First Class or Second Rate?

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FOREWORD

This study was prepared in response to House Concurrent Resolution No. 403, adopted during the Regular Session of 1992. The resolution requested a survey of the laws regulating mail order pharmacy in other states; an assessment of the need to regulate mail order pharmacy in Hawaii; and an analysis of the impact such regulation would have on mail order pharmacies, local pharmacies, group insurance coverage, and health maintenance organizations.

The Bureau wishes to extend its appreciation to all who cooperated and assisted with this report. Specific thanks are extended to Roy Yamauchi, Manager of Pharmacy Benefits at the Hawaii Medical Service Association; Cenric Ho, Administrator of the Hawaii Public Employees' Health Fund, and Paul A. Tom, President of Benefit Plan Consultants (Hawaii) Inc.

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INTRODUCTION

Nature and Scope of the Study

The Sixteenth Legislature of the State of Hawaii, Regular Session of 1992, adopted House Concurrent Resolution No. 403 (see Appendix A) requesting the Legislative Reference Bureau to conduct a comprehensive review of the commercial practices and regulation of out-of-state pharmacies. Earlier in that session, House Bill No. 3027, an administration bill drafted by the state board of pharmacy, was introduced to regulate out-of-state (mail order) pharmacies. See Appendix B. Objections of mail order proponents to the regulation were brought out at the hearing by the House Committee on Consumer Protection and Commerce, including testimony that states cannot regulate the area due to federal Commerce Clause considerations. The Committee on Consumer Protection and Commerce held the bill and passed this resolution instead, to obtain more information on the industry.

Objective of the Study

H.C.R. No. 403 highlighted three concerns of representatives within the pharmaceutical community that regulation of mail order pharmacies (MOPs) would:

(1) Place a competitive advantage in the marketplace to Hawaii's local retail pharmaceutical industry;

(2) Limit the options available to the consuming public with regard to the purchase of pharmaceutical goods; and

(3) Threaten the livelihood of out-of-state pharmacies based in Hawaii that have provided efficient and problem-free services to the public for decades.

The Bureau's report was asked to include:

(1) A survey of the laws used in other states to regulate the commercial operations of out-of-state pharmacies;

(2) An assessment of the need for similar laws in the State of Hawaii;

(3) A cost analysis of the ramifications of potential regulatory controls for out-of-state pharmacies on both out-of-state business conduction operations [sic: conduct of business] in Hawaii and the local retail industry;

(4) An analysis of the impacts the establishment of such laws would have on group insurance coverage for drugs and other medications, as well as on the operations of health maintenance organizations; and

(5) Proposed legislation as is deemed necessary to address this issue.

The study is organized into eight chapters. Chapter 1 discusses the nature and scope of the study. Chapter 2 discusses the nature and history of the mail order pharmacy business and highlights the key players and their relationship. Chapter 3 examines the comparative cost of MOP and local pharmacies, and analyzes the impact of potential regulatory controls on mail order pharmacy in Hawaii and third party payors. Chapter 4 looks at the safety record of the MOP industry. Chapter 5 details a survey sent out to all local pharmacists on issues relating to the impact of MOP on their businesses. Chapter 6 surveys the laws of other states on regulating MOPs. Chapter 7 assesses the need for regulation in Hawaii, and proposes legislation. Chapter 8 makes findings and recommendations.

Chapter 2

MAIL ORDER PHARMACY: BACKGROUND TO THE BATTLEGROUND

Mail order pharmacy is the business of selling prescription drugs through the mail directly to the consumer. Mail order pharmacy differs from the traditional practice of pharmacy in three primary ways. First, the cost of mail order is alleged to be significantly less than that of traditional pharmacy. This is an important consideration given the high and ever-increasing price of prescription drugs. Second, some safety concerns have been voiced, as mail order has been alleged to be a high volume, primarily profit-oriented business with little consumer contact, as opposed to traditional pharmacy's allegedly safer and slower pace, offering face-to-face contact and an opportunity for consultation with consumers.

Third, mail order pharmacy often involves the sending of prescription drugs across state lines. This leads to questions of jurisdiction and accountability. Which states' laws -- that of the mail order company, or that of the consumer -- should apply? Does regulation by the consumer's state lead to problems with the Commerce Clause of the United States Constitution? If a consumer is injured, does the consumer's state have the right to discipline the company? Should the federal government take part in regulating interstate drug sales?

These three issues, cost, safety, and ability to regulate, will form the crux of this study.

Terminology

There are various terms in use for the mail order pharmacy industry. While the most widespread seems to be mail order pharmacy, other terms such as mail service pharmacy, extraterritorial pharmacy, and nonresident pharmacy are also in use. Since prescription drugs are often sent through means other than the U.S. Postal Service, the researcher prefers the term "nonresident pharmacy"[1] as the most accurate, but this study will also use the term "mail order pharmacy" (MOP) as that term is in such extensive use. The traditional pharmacists are also known by a variety of names, such as in-state pharmacy, community pharmacy, and local pharmacy. This study will use "local pharmacy" to indicate that type of business.

Brief History of Mail Order Pharmacy

Mail order pharmacy had its start with the United States Veteran's Administration in the late forties.[2] This mail order service has grown to encompass nearly half of all prescriptions dispensed by the present Department of Veterans' Affairs (DVA).[3]

The next major organization to offer mail order drug services was Retired Persons Services, Inc. (RPS), d/b/a AARP Pharmacy Service. The American Association of Retired Persons (AARP) allows RPS to use its name, and collects royalties in exchange. Although AARP attempts to make a distinction between itself and RPS, as one article puts it, "to the world at large, AARP and its pharmacy services are the same".[4] To conform to the literature in this area, this report will also refer to AARP, and not RPS, when discussing these services.

Attempts were subsequently made by other organizations and companies to offer mail order pharmacy, but these wilted under the concentrated barrage of opposition from doctors, pharmacies, and associations such as the American Pharmaceutical Association (APhA), the National Association of Retail Druggists (NARD), the National Association of Boards of Pharmacy, and the American Medical Association.[5] Litigation was brought in 1977 by a mail order pharmacy against APhA and NARD alleging that they led boycotts designed to influence the public, pharmacists, and health organizations against mail order pharmacy, and sought the passage of state laws and regulations prohibiting mail order pharmacy (at the time of the lawsuit sixteen states forbade mail order pharmacy, and over thirty prohibited the advertising of prescription drugs). The federal district court found some acts to be protected first amendment activity, but ruled that others violated antitrust law. On appeal, the United States Circuit Court found more activities to be protected, and concluded that while "evidence may support a conclusion that [APhA] engaged in a number of activities violative of the spirit of the antitrust laws" there was no material contribution to the plaintiff's injury.[6] The court permitted attempts by APhA and others to influence the passage or enforcement of laws, but prohibited sham campaigns, ostensibly aimed at the passage of legislation, that interfere directly with the business relations of mail order pharmacy.[7]

Perhaps this litigation caused traditional pharmacy to pull back in its efforts to block mail order pharmacy, for in the early 1980s, about the time that the cases were decided, the for-profit mail order pharmacies experienced phenomenal growth that continues to this day. Mail order pharmacy became a union benefit through companies such as Ford Motor Company and General Motors and unions such as the United Auto Workers and the International Ladies Garment Workers Union. Mail order pharmacy services were provided by large companies such as Sears, traditional drugstores such as Walgreens, and companies specializing in mail order business such as Medco Containment Services, Inc., the industry leader,[8] and Baxter.

Today's mail order businesses can be divided into three categories: federal nonprofit (the DVA), commercial nonprofit (AARP), and the commercial for-profits. The DVA has by far the largest share of the market.[9] As it is a federal program, and not subject to or influenced by the state regulation under review in this study, it will not be discussed further in this study. AARP has the next largest share of the market,[10] for a combined market share with the DVA of about twenty-five percent of all mail order sales.[11] The commercial for-profit companies are led by the American Managed Care Pharmacy Association (AMCPA), a group representing the top eight mail order pharmacies. Most of the discussion in the rest of this study will equate AMCPA's positions with those of the commercial for-profits as a whole, as AMCPA members account for ninety percent of the commercial for-profit mail order market. [12] It is difficult to obtain business statistics from AMCPA members because, except for Medco, the companies are not publicly traded and some are subsidiaries of other companies.[13]

The tremendous growth of mail order in the eighties pushed mail order sales from the millions of dollars into the billions. Estimates place sales in the early 1980s in the $50 to $100 million range.[14] While industry figures tend to vary according to source, higher for AMCPA and lower for retail druggists, it appears that the total mail order sales figures for 1989 were about $1.5 billion,[15] $2.5 billion for AMCPA members alone in 1990,[16] $2.8 billion to $3 billion in 1991,[17] and will be over $2.3 billion in 1992.[18] Future projections are $5 billion in 1993[19] and between $6 and $9 billion for 1995,[20] although one projection is that mail order sales will level off in 1993 and then drop off.[21] While these figures are impressive, they are only a fraction of the total prescription industry. A 1992 article calculated the total percentage of prescriptions handled by the DVA, AARP, and the AMCPA members at only about twelve percent of the total prescription drug market.[22] Future projections of mail order's strength vary, from 10 percent[23] to 20-25 percent of the market by 2000.[24] These sales directly decrease the income of local pharmacies, and it is not surprising to find that they are still attacking mail order on the issues of cost and safety.

ENDNOTES

1. This is also the term preferred by the National Association of Boards of Pharmacy.

2. Gregory S. Munro, "Regulation of Mail-Order Pharmacy", 12 The Journal of Legal Medicine 1 (1991) at 3.

3. Id.

4. Stanley Siegelman, "The Growing Threat of AARP", American Druggist (January 1990) at 28.

5. Munro, supra note 2, at 21.

6. Federal Prescription Service v. American Pharmaceutical Association, 663 F.2d 253 at 272 (D.C. Cir. 1981), cert denied, 445 U.S. 928 (1982).

7. Munro, supra note 2, at 21-22.

8. *Id.* at 4.

9. Telephone interview with Jimmy Miyashiro, Chief Pharmacist, Department of Veteran's Affairs, Honolulu, Hawaii, October 8, 1992.

10. "Mail order becomes crucial Rx component", Chain Drug Review, Vol. 11, No. 24 (August 28, 1989).

11. "Growth Ahead for Mail Order Drug Market" (box), in Siegelman, supra note 4, at 32.

12. Munro, supra note 2, at 6. Medco Containment Services, parent of National Prescriptions Inc., is the leader among the commercial for-profits, coming after the DVA and AARP in volume of sales. The other seven are Baxter Prescription Service, America's Pharmacy, Inc., Express Pharmacy Services (a subsidiary of J.C. Penney), Flex Rx Prescription Services, Inc., Health Care Services, Pharmacy Management Services, Inc., ArcVentures, d/b/a Home Pharmacy. Id. at 6, n. 26.

13. Id. at 6.

14. AMCPA says $100 million in sales in 1981, (Carol Ukens, "Is Mail Order Bombing?" Drug Topics (July 20, 1992) 56 at 57), while another source says $50 million in 1983 (Lorraine Brady, "Mail order writes its own prescription for success", Dallas Business Journal, Vol. 14, No. 44 (June 28, 1991) at 5).

15. "Mail order becomes crucial Rx component", supra note 10, citing AMCPA figures.

16. Mark L. Fuerst, "The Future of Mail Order", American Druggist (January 1991) 25 at 25, citing AMCPA figures.

17. Siegelman, supra note 4, at 32, based on 1990 projections from Arthur D. Little, and "Is Mail Order Bombing?" supra note 14, at 57, based on AMCPA figures.

18. Brady, supra note 14.

19. "Mail order becomes crucial Rx component", supra note 10, based on AMCPA figures.

20. "The Future of Mail Order", supra note 16, at 25, citing AMCPA figures, and "Mail order grows despite controversy", Drug Store News, Vol. 12, No. 4 (February 19, 1990).

21. "Is Mail Order Bombing?", supra note 14, at 56-57.

22. Id. at 57.

23. Id.

24. Siegelman, supra note 4, at 32.

Chapter 3

COST SAVINGS: REAL OR ILLUSORY?

While safety of nonresident pharmacies may be the primary concern for the State, cost is the major selling point for employers, insurance companies, and consumers. During the eighties, prescription drug prices increased at almost three times the general rate of inflation, and some drug prices increased one hundred, two hundred, and even three hundred percent.[1] This chapter will attempt to address two issues: (1) whether nonresident pharmacies are a more cost-effective alternative today, and (2) what fiscal impact regulation would have on local pharmacies, nonresident pharmacies, group insurance for drugs, and health maintenance organizations. The cost issue is relevant to this study as the amount of mail order business in Hawaii will probably rise or fall as the cost savings of mail order are seen to be greater or lesser.

Cost Savings

The 1980s

Mail order pharmacies, which generally lay dormant in the 1960s and 1970s, exploded onto the pharmacy scene in the 1980s based on promises of substantial cost savings. Savings may have been actually realized at first. Mail order combined aggressive substitution of generic drugs[2] (cheaper than brand-name drugs), bulk purchase volume discounts from drug manufacturers, and public relations pitches portraying themselves as the cost-effective choice in offering programs to insurance companies and employers (third party payors) that promised substantial savings. (Mail order's focus is on third party payors; few major players aside from AARP go after individual consumers.)

The interest of third party payors in mail order grew throughout the decade as health costs soared. Prescription drug prices were and are one of the fastest-growing component of health costs.[3] What was once a minor option became a crucial element of managed medical care as third party payors scrambled to keep up with spiralling costs. Local pharmacies, hemorrhaging dollars that were now sent out of state, fought back, cutting their prices and engaging in vigorous public relations as to their advantages.

Both sides have adopted cost-saving tactics. The larger mail order pharmacies reduce costs by buying in such volume that the manufacturer gives them the lowest possible price. The giant nonresident pharmacy Medco has a program in which its pharmacists call doctors who prescribe drugs not preferred by Medco's drug supplier to tell the doctor of the monetary and clinical benefits of substituting a preferred drug, and ask for permission to switch the

prescription. Medco has reportedly been successful in persuading physicians to change prescriptions.[4]

The AARP Pharmacy Service (AARP),[5] keeps its prices low by purchasing generic and multisource patented drugs through bidding, a process not available to local pharmacies. Its mailing costs are half of what commercial companies are charged because it uses reduced price nonprofit postal rates.[6] It is also exempt from paying state and local taxes on out-of-state sales.[7]

Local pharmacies have fought back to regain their market. One observer has noted three factors which tend to level the cost playing field: (1) more pharmaceutical manufacturers are moving to one-price policies (so everyone gets the same price), (2) more competition from pharmacy-based major medical plans, and (3) local pharmacies lobbying for laws that "cramp mail order's operating style".[8] Other tactics used by local pharmacies to blunt mail order's economic edge are negotiating price discounts with manufacturers, using more generic substitution, and charging only one dispensing fee for maintenance supplies.[9] One company developed a marketing program for local pharmacies that includes low prices on selected drugs, a bimonthly newsletter for customers, news releases, letters to local doctors, and customized newspaper ads and radio spots.[10] A generic drug firm has actually created "The Mail Order Battle Kit" to help local pharmacies inform consumers of the drawback of mail order and the benefits of using local pharmacies. The kit contains sample letters to consumers and physicians, brochures for customers, and a newspaper release.[11] Local pharmacies are also touting their abilities as a "full service" pharmacy, part of the "physician-patient-pharmacist triangle", able to supplement the patient's health care with personal consultation and the ability to track all of the medication a customer is taking to guard against potentially troublesome drug combinations (mail order pharmacies typically deal only with long-term maintenance medication, not acute care or over the counter drugs). One article suggests use of local pharmacies is desirable despite somewhat higher prices because these local pharmacies offer personal attention and counseling that can ultimately reduce costs for employers, insurers, and consumers.[12]

Freedom of Choice

Insurance companies, sold on the idea that mail order will save costs, have tried to steer customers to mail order by placing barriers to the use of local pharmacies. One of those barriers is to require customers who use a local pharmacy to meet a deductible before their pharmacy costs will be covered, while waiving the deductible for customers using mail order. Another method is to provide a much shorter length of prescription for local pharmacies, while permitting a long period for mail order pharmacies. The HMSA plan for the State of Hawaii uses the latter tactic. Prescriptions filled in local pharmacies will be filled only for a twenty-

one day supply, while prescriptions filled through mail order can be filled for as long as ninety days. In addition to the inconvenience of having to go to the pharmacy every three weeks for a refill, the customer of local pharmacies also pays more copayments for the same period of time. But while the mail order customer pays less, the employer usually pays more, as it must come up with the "lost" copayments out of its own pocket.[13] Customers of local pharmacies may also have to pay a higher copayment for a brand name drug if Hawaii's drug formulary does not permit substitution with a generic product, while a mail order company, not automatically bound to follow Hawaii's generic substitution law or drug formulary, could substitute a generic drug not available in Hawaii and charge the customer only a lower generic drug copayment.

The cumulative effect of these incentives was illustrated by a recent Star-Bulletin article:

> Say you have high cholesterol and need a three month supply. If you had to buy that on a monthly basis under the prescription drug program (for a brand name drug), you would have to go to the pharmacy each month and pay $7, or a total of $21 [for the three months].
>
> By mail order, you could get a three month supply of the equivalent generic drug and it would cost you $2.[14]

Mail order drug plans such as this arouse consumer enthusiasm because the plans are constructed to offer a lower out-of-pocket payment by consumers, with the plan's third party payor picking up the difference. But the fiscal bottom line is not how much the consumer pays; it is how much the employer pays. As one article points out, "patients may have lower out-of-pocket costs, but because they use and waste more drugs, the provider ultimately pays more".[15]

The local pharmacies in many states have fought against these restrictive tactics by lobbying for "freedom of choice" or "open access" legislation.[16] This would give consumers the right to choose where they want to fill their prescriptions, and give local pharmacies the right to compete on an equal footing with mail order by mandating equal copayments and deductibles.[17]

The Sieben Study

One major, though older, study of comparative costs is a study done for the Pharmaceutical Card System, Inc. (PCS), by the firm of Sieben and Associates, Inc.[18] The study focused on a mail order drug option plan offered by PCS and is based on actual data from participants. The study found that, while actual prices of drugs through the mail order

plan were four percent lower than those of local pharmacies, the overall cost of the mail order plan was an average of five percent higher than the local pharmacies.[19] The overall higher costs were due to increased amounts of medication dispensed. Most of the plans dispensed medication for a maximum of 180 days, while the rest dispensed for a maximum of ninety days. The longer periods led to more wastage. As stated in the report: "While the unit cost savings in mail order fills are significant, they are more than eliminated by the increased volume dispensed".[20] Wastage is increased by the common medical practice, especially when starting out on maintenance medication, of prescribing medication for a patient on a trial basis and then reexamining and adjusting the medication until the proper amount and type to obtain the best clinical response from the patient is discerned. The more frequently these changes are made, the more often customers are left with obsolete medication. If each mail order prescription is obtained with a six-month supply, as opposed to a local pharmacy's thirty-day supply, this wastage can mount up quickly. Sieben noted that, while plans with the ninety-day limit showed less wastage than those with the 180-day period, the overall cost for mail order still remained higher and that differential was "highly unlikely to disappear".[21]

The Brandeis Study

The Brandeis Medicaid study, discussed in more detail in Chapter 4, attempted to determine cost data, as the mail order pharmacies repeatedly emphasized that their maintenance drug costs were substantially lower than those of local pharmacies. However, the Brandeis researchers were unable to substantiate this as the mail order companies were generally unwilling to share cost and financial information. The reasons cited for the unwillingness to cooperate were the highly competitive nature of the industry, the positions that the information was proprietary, and the concern that the information would go beyond the research team.[22] The Brandeis study then turned to existing literature on cost, reviewing the Sieben study, a followup to the Sieben study, a 1989 study analyzing the Sieben study, two studies commissioned by Medco (a leader in the mail order pharmacy field), reports by large employers on their experience with mail order plans, and a study sponsored by Blue Cross/Blue Shield of Michigan. It also looked at consumer surveys, including two that found that the number of tablets discarded was higher with mail order. It came to no conclusions from this data, probably because the data was contradictory.

The study then surveyed a number of mail order pharmacies on prices. Comparing that data with data reported in the literature on local pharmacy prices, the study found that the average daily cost for a mail order prescription was fifty-six cents per day, while that for local pharmacies was fifty-eight cents a day, a difference of two cents per day.[23] The study does warn that these figures should be viewed with caution as the pharmacies differ in types of medication dispensed as well as length of prescription. The study says these factors

"make direct comparisons inconclusive", but finds that mail order claims that their prices are substantially lower are not substantiated.[24]

These caveats have been largely ignored by NARD and others who trumpet the "two cent difference" between the two groups. Typical is one story[25] covering the Brandeis study citing a senior director of APhA who stated that for this extra two cents a day, a local pharmacy can also offer complete review of medication files, screening of symptoms not apparent to the patient, and referral services for additional care. While the story repeats the caution that the findings "may be inconclusive since many of the firms questioned failed to provide information[,]"[26] the APhA theorized that if the information had been in the mail order firms' favor, the information would have been disclosed.

State Reports

Other state legislatures have taken a hard look at the cost issue. Michigan studied the issue in late 1988. Michigan concluded that "cost savings may be illusory to the payor of the benefit".[27] Michigan looked at the Sieben study, which found that mail order was more costly, but also received testimony from General Motors stating that it had experienced a savings of sixteen percent with mail order.[28] The Michigan report also noted that cost savings may be more difficult to realize in Michigan than in other states due to Michigan's highly competitive health care environment, where providers are already being reimbursed at a lower rate and where a large percentage of generic drugs are being dispensed.

Maine studied the issue twice, once in late 1989 on the general issue of cost containment for prescription drugs,[29] and again in late 1991 on the specific issue of applying mail order to Maine's Low Cost Drugs for the Elderly program.[30] The 1989 study acknowledged that one of the major problems in researching this issue is that virtually all of the cost studies have been done by persons representing or sponsored by one of the interested parties. The 1989 study declared only three of the studies to be "significant". The first of these is the Sieben study, which, as stated above, found that mail order was more expensive due to larger volumes dispensed. The 1989 Maine report adds that, due to criticism of the report, another actuarial firm was contracted to review the methodology, and reported that the study must be interpreted with care and was principally useful in providing hypotheses for the future.[31]

The second study was done by the Boston Consulting Group for Medco, one of the for-profit mail order giants, which concluded that mail order has the potential to offer a savings of twenty to twenty-five percent. The third study was also sponsored by Medco and also found cost savings through mail order.

The 1989 Maine study also mentioned the 1987 United States Senate hearing (discussed in chapter 4), which it characterizes as "a large enough document for anyone to read in it what they wished",[32] an AARP study which does not appear to have addressed the cost issue, and the Brandeis study, which was then being finalized and which was discussed with the Maine researchers over the phone. The researcher reported that the Brandeis researchers were at that time "unable to take a firm position on the cost issue".[33]

Maine found that the most definitive study was the Michigan study referred to above, which concluded that "cost savings may be illusory to the payor of the benefit", a statement that Maine said it had no reason to disagree with.[34]

Maine then evaluated its own mail order program and found that its use had exceeded all projections, leading to an exceptionally high and unforeseen cost to the state. The report raised three conjectures as to the cause of this increase: an increased awareness of the benefit, the increased convenience of the mail order option, and the fact that the program was structured to be less costly to the consumer than local pharmacies. This last factor seems to be the key. One of Maine's existing drug plans, using local pharmacies and major medical coverage, had a $100 deductible, and after the deductible was met, covered only eighty percent of the cost of each prescription. Maine's existing card plan, also using local pharmacies, had no deductible, but required a copayment of $3 for generic and $5 for brand drugs. Maine's new mail order plan, in contrast, had no deductible and required no copayment. It is not surprising that a plan requiring no out-of-pocket expenses for consumers was more popular than those that did. One of the study's recommendations was to require a copayment for the mail order plan.

The 1991 Maine study again found that there was little empirical data on the aggregate costs of mail order versus other drug distribution systems.[35] It found the overall literature "mixed" as to whether overall program costs would be reduced, noting that program costs can rise if use increases due to increased visibility of the program or if the consumer's share is reduced.[36] The study does review the Brandeis report, which at this point in time was published, and notes that it found only a two cent price differential between local and mail order prices.

The 1991 study looked back at the 1989 report, which had found the cost of the mail order program had risen twice as high as the year before the program started, and noted that price increases had dropped in succeeding years. The report projected cost savings, if mail order was implemented in the drugs for the elderly program, of between $140,000 to $205,000.[37]

Costs Today

The question of cost savings remains unresolved. Some articles are still reporting substantial cost savings. One study reported in January 1990 found that mail order pharmacies are charging consumers up to twenty percent below the average wholesale price of a drug.[38] Yet other sources are finding that mail order currently is not living up to its reputation as a cost-cutter. For instance, one dean of pharmacy analyzed a proposed mail order plan for his university, and concluded that "the particular Medco plan would not save the university any more money than if it removed the typical 34-day supply restriction and let local retail pharmacists fill prescriptions".[39] Additionally, a 1992 article noted that Texas Instruments recently abandoned its mail-order benefit as the expected savings did not materialize.[40]

The Bureau conducted a survey of local pharmacists on a number of issues, including cost. The survey is reported in full in chapter 5. Local pharmacists were asked their prices on the ten most frequently sold prescription drugs in Hawaii. These prices were then compared to the AARP and Allscrips' prices. Some of the local pharmacies were quite competitive, especially when the mail order companies' handling fees of $1 and $3, respectively, are considered. Others, generally the independents rather than the chain stores, had prices that were quite a bit higher.

Low Prices Versus Full Service

A new phase of the cost issue is whether mail order can achieve superior monetary savings in the context of total health care costs. Local pharmacy use has the potential of achieving better overall health cost savings by providing direct drug therapy management. Local pharmacies argue that their ability to offer face-to-face consultations, to personally evaluate the consumer, monitor their drug therapy and expected outcomes, and to keep track of all medications a consumer is taking (including acute care medications generally not handled by mail order pharmacies) can head off potentially dangerous complications. This is a concern especially when the consumer is taking multiple medications that could interact with each other, or when the consumer is elderly, as the physiological changes of aging alter the way in which drugs affect the elderly.[41] In the case of multiple medications prescribed by different doctors, a local pharmacist may be the only person who know the full range of medication a consumer is taking.[42] This type of patient contact can avert the need for more expensive health care intervention. HMSA is considering this argument in structuring its new prescription drug plans.[43]

As could be expected, AMCPA responds to this issue by stating that consumer consultations can also be done through nonresident pharmacies' toll-free numbers, and that

many nonresident pharmacies include literature with the medications to help ensure proper and safe use.[44]

Cost Analysis

House Concurrent Resolution No. 403 requested the Bureau to perform a cost analysis of regulatory controls on nonresident pharmacies and local pharmacies, as well as an analysis of the impacts on group health insurance for drugs and on health maintenance organizations. It is important to note that mail order pharmacy is already present in Hawaii, through employers such as the State of Hawaii, through special interest groups such as AARP,[45] and through plans open to individual members of the public, such as the Sears plan. As a matter of law, the State could not abolish mail order pharmacy even if it wanted to, as discussed in detail in Chapter 6. The range of regulation possible under the State spans statutes that would just require the mail order pharmacy to register with the State, to those that require full compliance with all state laws just as local pharmacies must do. The more onerous the regulation, the more likely that a mail order pharmacy might find it untenable to do business in the State. The operative word is "might". Mail order pharmacy is a rapidly growing field. If it is as lucrative as its proponents claim, it may well be that the mail order pharmacies will put up with quite a bit of state regulation in order to retain access to the state market. The regulation proposed by this study is more in the nature of a registration statute, not one imposing a wide variety of controls on a mail order pharmacy. It is discussed in Chapter 7, and a draft of this proposed legislation is contained in Appendix C.

Local Input

The researcher contacted personnel at HMSA, HDS-Medical,[46] and AARP for their input, which is detailed below. The researcher also contacted personnel at Kaiser, Island Care, and Honolulu Medical Group, and was told that they do not use nonresident pharmacies. A copy of the Sears health care 1992-1993 catalog now offering the mail order drug plan Allscrips was reviewed. The researcher also contacted Cenric Ho, Administrator of the State Health Fund, and consultant Paul Tom, President of Benefit Plan Consultants (Hawaii), Inc., a firm that provides consulting and actuarial services to multi-employer trust funds, employee organizations, and employers in Hawaii. The description of the state plan below comes from that discussion.

Roy Yamauchi, Manager of Pharmacy Benefits at HMSA, characterizes nonresident pharmacy as less costly per prescription unit in the short run, but questions the cost impact on the patients' total health care costs.[47] Yamauchi finds value in the increased range of services potentially available from local pharmacies, such as face-to-face consultation and the

ability of local pharmacists to monitor the consumer's reaction to his or her medication. These services, when applied, improve the patients' overall outcomes and can avert the need for additional medication or treatment. If they could consistently demonstrate effective drug therapy management, it would be a positive trade-off. Yamauchi also would advocate removing the restriction imposing a shorter time period for refills for local pharmacies. In his experience, the main reason people use mail order is for the convenience of obtaining a ninety-day supply rather than having to return to the pharmacy every three or four weeks for a refill.

The State of Hawaii adopted its mail order plan as an afterthought. In the late 1980s, the Legislature mandated that the State offer an extended range of health benefits, including prescription drug coverage. The health fund board put together three option packages: a direct reimbursement plan, a preferred provider option (PPO), and a card system with a mail order option. The winning contractor was HDS-Medical on the PPO system. After acceptance, HDS-Medical came to the board and proposed to add a mail order option, at no extra cost to the board. The board accepted this proposal, and a mail order option through National Rx Services was established (the mail order provider was later changed to Expresscripts).

The mail order plan cost the State nothing, though it cost HDS-Medical plenty. Estimates are that HDS-Medical lost millions due to underbidding on the pharmacy and other health benefits. But the State had no problem with its implementation, receiving only one consumer complaint during this period.[48] When it came time to negotiate the pharmacy benefit for 1991-1993, the board again placed three plans out for bid: Plan A, a direct reimbursement plan; Plan B, a PPO with mail order; and Plan C, a PPO with higher copayments, mandatory use of generic drugs, and mandatory mail order for maintenance drugs. At this point, the length of prescription for local pharmacies was reduced from 30 days to 21 days, with an exception for certain generic drugs that could be purchased in a 60 day or 100 unit package supply. The board also permitted anyone who bid on one of the three options to put together its own option. HMSA was the lowest bidder on all three of the board's option. Plan A was the most costly, Plan B the next, and plan C the least. The board, satisfied with the existing plan, voted to accept plan B. Proposals for 1993-1995 were due in November 1992, and this time the board has only one plan out for bid, again a PPO with optional mail order pharmacy. The Hawaii Public Employees Health Fund Administrator and his consultant, Paul Tom, President of Benefit Plan Consultants (Hawaii) (BPC) state that the current plan design indirectly encourages the use of mail order pharmacy.

In every case, the proposal specifications have required that the mail order pharmacy comply with Hawaii's drug formulary and generic drug substitution law. A toll free 800 number for consultation with a pharmacist at the pharmacy is not in the specifications, but is

in the agreement between the contractor (HMSA, HDS-Medical) and the mail order pharmacy.[49]

In addition to serving as consultant for the State of Hawaii plan, BPC represents 65,000 employees in twenty companies in the areas of construction, tourism, public utilities, and general trades. All of these companies offer a pharmacy benefit, and half offer an optional mail order pharmacy program. These companies typically became aware of mail order through cost containment informational mailings from HMSA. BPC says that there is no questioning the fact that mail order does have an impact on containing prescription drug costs, but that to date there have been no complete local studies on the amount of the savings.[50] Tom finds, roughly speaking, that there is a cost containment effect of five to ten percent. Due to the rapidly rising cost of prescription drugs, there is generally not a cost reduction.[51]

Tom notes that for all his plans, compliance with Hawaii's drug formulary and generic drug substitution law is mandated. He says that he deals with national companies and that this requirement has not been a problem.

When asked if he thought that requiring mail order pharmacies to comply with California's nonresident pharmacy disclosure act would cause mail order pharmacies not to do business with Hawaii, he replied that, off the top of his head, he would not think it would be a problem with the national firms. He excepted AARP from this statement, as his company does not have contact with AARP whose plan is for individuals, not companies.

Tom takes the position that it is not mail order pharmacy that has an adverse financial impact on local pharmacies. In his opinion, the worse impact is experienced by pharmacies that are not in the preferred provider networks established by the contractors.

Two major private companies in Hawaii were contacted concerning their experiences with MOP. One company that has been offering MOP for two years said that it offers mail order as an employee benefit, to allow employees to buy maintenance drugs at a reduced cost to them, and for a longer period of time than is otherwise available locally. The MOP program does not keep costs down for the employer, however. The other company has yet to implement its plan, but based on the benefits manager's experience elsewhere with mail order, it is expected to be more economical, a "win-win" situation for both employer and employees. The plan will require the MOP to comply with Hawaii's generic drug substitution and drug formulary laws.

Conclusion

The issue of cost savings has an impact on how much nonresident pharmacy will be used in Hawaii, and how much business will be taken away from local pharmacies. At this point it is a public relations war between the mail order faction crying "more savings"! and the local pharmacists declaring "better care"! While the national surveys are inconclusive on how much, if any, money is saved by using mail order, the local survey contained in chapter 5 indicates that some, but by no means all, local pharmacies can successfully compete with some mail order pharmacies. But even this is not the ultimate answer, because the new issue is whether there are more cost savings in the long run with local pharmacies. Their full range of services are alleged to provide a higher level of health care, and their ability to physically monitor the patient can save money by obviating conditions such as drug interactions and adverse effects before they become serious and require expensive medical intervention. The battle is still cost savings: only the front has changed. The data are not available yet, but when they are, it will be this factor -- cost savings, however they are calculated -- that will determine the level of nonresident pharmacy business in Hawaii, not the modest governmental regulation proposed by this study.

ENDNOTES

1. United States, General Accounting Office, Prescription Drugs: Changes in Prices for Selected Drugs (Washington, D.C.: August 24, 1992) at 1, 3.

2. Generic drugs are medications that are supposed to have the same active ingredients as the original patented version. Patented drugs are more expensive as the drug companies raise prices to try to recoup the moneys spent researching and developing the drug. Generic drugs are cheaper because they do not have to recoup these costs.

3. "Prescription drug prices soaring, GAO says", Honolulu Advertiser (August 26, 1992) at D-2; "Prescription drugs in the U.S. among the world's costliest", Honolulu Star-Bulletin (May 27, 1991) at A-10; Carol Ukens, "Is Mail Order Bombing?" Drug Topics (July 20, 1992) 56 at 56; Lorraine Brady, "Mail order pharmacy writes its own prescription for success", Dallas Business Journal, Vol. 14, No. 44 (June 28, 1991) at 5. According to Brady's source, "[d]rugs have historically outpaced other medical costs in cost increases", noting that while health care costs have risen between 6 and 8 % per year, prescription drugs costs, which can be 15% of health care costs, have risen at a rate of 10 to 13 % in the same period.

4. Mark L. Fuerst, "The Future of Mail Order", American Druggist (January 1991) 25 at 30.

5. Retired Persons Service, Inc., d/b/a AARP Pharmacy Service, is closely identified with, although not identical to, AARP. It is a separate company that is allowed to use AARP's name for a royalty. However, AARP backs the program so strongly that "to the world at large, AARP and its pharmacy service are the same". Stanley Siegelman, "The Growing Threat of AARP", American Druggist (January 1990) 27 at 28.

6. Id.

7. Id. at 32.

8. Ukens, supra note 3, at 57.

9. Id. at 57.

10. "Independents fight mail order", American Druggist (March 1990) at 15. The lower prices are placed on only six percent of the prescriptions, but "the impression is conveyed to patients that other products, with normal markups are also discounted".

11. Ukens, supra note 3, at 58. Box: "Mail-Order Battle Kit Arms Community R.Ph.s".

12. Id. at 58.

13. See "Competing head on with mail order's savings claims", Third-Party Rx (NARD: August 1992) at 1, and "Mail order pharmacy - an expert's viewpoint", Third-Party Rx (NARD: August 1992) at 7.

14. Lois Taylor, "A prescription filled with concern", Honolulu Star-Bulletin (October 21, 1990) at B-1.

15. Fuerst, supra note 4, at 29.

16. See, e.g., Drug Store News (June 24, 1991) at A6 (untitled article on Illinois bills that would ban third party insurers and program administrators from requiring mail order pharmacy), and Drug Store News (May 20, 1991) at A8 (untitled article on New York bill prohibiting health care insurers from requiring mail order use or charging a copayment for local pharmacy but not for mail order pharmacy).

17. Ukens, supra note 3, at 61.

18. Richard B. Sieben, "Statistical Studies and Surveys on Mail-Order Pharmacy", subtitled "Actuarial Study of the Mail Order Drug Option Experience" (Sieben & Associates, Inc.: August 1, 1986). A copy of the study was included in the Senate hearing referred to in Chapter 4 of this study at footnote 12 and can be found starting on page 452 of the volume referenced in that footnote.

19. Id. at 3, and at page 456 of the Senate hearings.

20. Id. at 3.

21. Id. at 4.

22. Brandeis University and the University of Maryland, "Study to Evaluate the Use of Mail Service Pharmacies", for the United States Health Care Financing Administration (September 21, 1989) at II-5.

23. Id.

24. Id.

25. Sara Martin, "Mail Order and Community Pharmacy Prices are Similar, Study Finds", American Pharmacy, Vol. NS30, No. 7 (July 1990) at 23.

26. Id.

27. Michigan, Senate Joint Study Committee, "Mail Order Prescriptions (Senate Concurrent Resolution 179) (November 1988) at 6.

28. Id. at 6-7.

29. Maine. Joint Standing Committee on Business Legislation, "Cost Containment for Prescription Drugs" (December 1989), 114th Legislature, First Regular Session (hereafter Maine 1989).

30. Maine. Staff Report to the Joint Standing Committee on Human Resources, "The Feasibility of Mail Order Pharmacy and other Cost Containment Strategies in the Low Cost Drugs for the Elderly Program", (December 1991), 115th Legislature, First Regular Session (hereafter Maine 1991).

31. Maine 1989, supra note 29, at 4.

32. Id.

33. Id. at 6.

34. Id.

35. Maine 1991, supra note 30, at 4.

36. Id.

37. Id. at 9.

38. Siegelman, supra note 5, at 32, box: "Growth ahead for mail-order drug market".

39. James T. Doluisio, Ph.D., Dean of the University of Texas College of Pharmacy, in Fuerst, supra note 4, at 25.

40. Ukens, supra note 3, at 57.

41. Box: "Why drugs affect the elderly differently", in Mark St. John Ericson, "Be sure to ask about the drugs doctors prescribe", Sunday Star-Bulletin & Advertiser (September 27, 1992) at D-1.

42. Id. at D-1 - D-2.

43. Interview with Roy M. Yamauchi, Manager of Pharmacy Benefits, Hawaii Medical Service Association, September 2, 1992.

44. See, e.g., Elizabeth Richardson, "Mail order grows despite controversy", Drug Store News, Vol. 12, No. 4 (Feb. 19, 1990) at 1.

45. According to testimony on H.B. No. 3027, over 12,000 Hawaii residents receive prescription and nonprescription products from Retired Persons Services Inc, the AARP Pharmacy Service. Testimony of F. Nicholas Willard, Director, Governmental Affairs, Retired Persons Services Inc., the Pharmacy Service

of the American Association of Retired Persons, to Representative Mazie Hirono, Chair, House Committee on Consumer Protection and Commerce, on H.B. No. 3027, Regular Session of 1992, on (February 10, 1992).

46. Although a letter was sent to HDS-Medical on September 28, 1992, and a follow-up phone call was made on October 22, HDS-Medical did not respond.

47. Interview with Roy M. Yamauchi, supra note 43.

48. According to Ho, the complaint was that "old insulin" was received. The situation was satisfactorily resolved through the mail order provider.

49. The specifications require the applicant to maintain an office in Honolulu and provide an 800 number for neighbor island calls.

50. Tom says that some of the factors complicating such a study are (1) the fact that studies are generally based on "AWP" (average wholesale price) for drugs, but that there are five different standards labelled "AWP"; (2) that some contractors update their prices more frequently than others; and (3) the "doubling up" effect of buying drugs for two months in advance (e.g., February's drugs bought in January). Interview with Paul Tom, October 20, 1992.

51. Although Tom tracked the data on one plan that required mandatory mail order, and found that the average prescription price for 1990 was $31.16, and for 1991 was $32.18, an increase of only $1.02, or 3.3 percent. This plan is no longer in existence.

Chapter 4

THE SAFETY OF MAIL ORDER PHARMACY: THE KEY TO STATE LEGISLATION

The key determinant for those states that have elected to regulate nonresident pharmacies is safety. Allegations have been made that the accelerated pace and assembly-line techniques employed by nonresident pharmacies can lead to an unacceptable level of prescription errors. This chapter discusses those allegations.

The first pitfall encountered by a researcher in this area is the polarization between the nonresident pharmacies and the local retail pharmacies. Each group is battling for the same consumer dollar and studies done by each group tend to support that group's position.

NARD and APhA

The primary organization representing the retail pharmacies is the National Association of Retail Druggists (NARD). Their articles and testimony over the past five years cite an abundance of anecdotal evidence that the high-volume method of business utilized by the nonresident pharmacies lead to a high level of prescription error.[1] These errors can result in injury to consumers, and in some case, can even cause fatalities. In 1988, NARD adopted a resolution supporting legislation that would designate all prescription drugs as poisons and dangerous substances, thereby totally prohibiting mailing them to consumers. NARD delegates adopted the resolution overwhelmingly.[2]

NARD believes that the safest and best type of pharmacy practice is through the oversight of a local pharmacist who is aware of and monitoring all drugs taken by a consumer, including acute care drugs and over-the-counter drugs. It sees pharmacy not as merely the dispensing of drugs, but, as referred to in one article, "ambulatory drug therapy management".[3]

Another group opposing nonresident pharmacies is the American Pharmaceutical Association (APhA). Its opposition dates back to 1965, and is based on the premise that the nonresident pharmacy "does not offer the comprehensive pharmacy services essential to good health care".[4] APhA takes the position that mail order is even more risky for consumers on long-term medication, or on multiple medication, as those consumers are at risk for adverse reactions and improper compliance. Retail pharmacy is the better choice for these patients as the pharmacist can monitor medication compliance and intervene as necessary. The APhA states that:

> "[a]s health care dollars become more scarce, it has become absolutely critical that patients use every resource.... Even if patients were to initially save money by buying prescription medication through mail order, the lower level of service they receive may not detect mismedication problems, and, as a result, more expensive health care may be required."[5]

AMCPA

The primary organization representing the nonresident pharmacies is the American Managed Care Pharmacy Association (AMCPA) (formerly known by the more straightforward name of the National Association of Mail Service Pharmacies). AMCPA members encompass the larger nonresident pharmacies, such as Medco and Baxter. AMCPA represents about ninety percent of all business done by commercial for-profit mail order pharmacies.

NARD and AMCPA oppose each other strenuously, and the dialogue between the groups often turns into a diatribe. NARD has called for the excision of the "cancer of mail order" by banning any mailing of drugs to the consumer,[6] while AMCPA has called for NARD to discard its "rotting fictions" about mail order pharmacy.[7] The two groups' studies on common issues, to no one's surprise, take opposing positions. The Legislature should be aware of this polarization when studies in this area are cited by players on either side of the issue. To date, there have been very few independent studies on the safety issue.

The Brandeis Study

One of the few independent studies on mail order pharmacies was done by Brandeis University and the University of Maryland in response to a federal law mandating an evaluation of the use of nonresident pharmacies to reduce costs under a new outpatient prescription drug benefit. The study[8] was not presented to Congress because the funding for the federal program authorizing the study was later repealed. The Brandeis study evaluated the quality of pharmacy services through responses to questionnaires and on-site visits to nonresident pharmacies.[9] It based its evaluation on the Standards of Practice prepared by the American Association of Colleges of Pharmacy. The study concluded that:

(1) The division of labor between pharmacist and nonpharmacist personnel seemed appropriate.

(2) Appropriate controls and supervision by pharmacists over the dispensing of solid oral doses were present.

(3) Eight of the nine sites surveyed maintained computer-based patient medication profiles, for eighty-eight percent of the customers, tracking data such as patient allergies, medical conditions, and age.

(4) The large MOPs included patient informational leaflets with a large proportion of prescriptions.

(5) All pharmacies had a final check of the finished prescription by a pharmacist.

(6) The nonresident pharmacies conform to industry standards regarding inventory.

Specifically, regarding prescription error, the report states:

> Since mail service pharmacy is a young industry, historical data are not available related to error rates as compared to other outlets. In reality, no consensus exists over the definition of "error rate", since arguably, no error rate exists if it is corrected before a prescription is released to the patient. All firms report infinitesimal rates of reported errors from patients or physicians.[10]

AMCPA hailed the study as favorable to the mail order industry.[11]

The Congressional Hearing

In 1987, a congressional subcommittee held a two-day hearing on the safety and soundness standards in the mail order prescription industry.[12] The first testimony concerned a consumer who had received Coumadim, a blood thinner, labeled as Corgard, her usual hypertension medication. The consumer, concerned that the medication appeared different from her usual supply, contacted her local pharmacist, who identified the error. He submitted a written letter stating that the mistake could have been life-threatening.

Three anonymous pharmacists, former employees of a major nonresident pharmacy, National Prescription Services, Inc. (a division of Medco) also testified as to the mistakes and high pressure atmosphere at their firm. They testified that pharmacists had to meet extremely high hourly requirements -- in some situations averaging a prescription a minute, with a bonus for prescriptions over the weekly minimum. This rate was so high that it was alleged to encourage accidents and errors in dispensing the drugs. They also stated that generic drugs would sometimes be distributed without authorization of the consumer.

A pharmacist from Tennessee, a representative from NARD, testified that nonresident pharmacy-related errors experienced in his area averaged one complaint a week.[13]

A representative from the federal Office of Personnel Management (OPM), which included a mail order pharmacy benefit as part of its Blue Cross package, testified that the OPM sees the nonresident pharmacy benefit as quite positive and has "seen no substantial evidence to suggest that mail order drug programs pose significant safety hazards to ... enrollees, and the utilization rate for these programs suggest that enrollees concur with this opinion".[14] She did later admit, however, that there might be problems that were brought to the attention of the insurance carrier that were resolved at that level, and that these problems would not then come to OPM's attention.[15]

Administrators from the Department of Veteran's Affairs (formerly the Veteran's Administration), which runs its own mail order drug program, testified that a recent random survey of its facilities found only one to two valid complaints out of an average daily mailout of 918 prescriptions per day, per facility.[16] Almost all of these complaints were about timeliness of the medication. In calculating actual errors in dispensing the prescriptions, the Department of Veteran's Affairs looked at five facilities. One had two errors in one month, but dispensed over 400,000 prescriptions per year, of which 204,000 were mail order, and another also had two errors, with a yearly load of 395,000 prescriptions. These figures demonstrate an almost infinitesimal error rate.

At the Senate hearing, a past president of NARD testified on the findings of that organization's Mail Order Task Force. A survey had been published in the NARD Newsletter concerning problems with nonresident pharmacies, and "several hundred" responses were received. Thirteen of these, presumably the most serious, were highlighted in the testimony, including four reports of the wrong drug being sent, and three of the wrong strength of drug being sent. In one case where the wrong drug was sent and used by the consumer, the consumer later died of a heart attack, and the report concluded that this was one of the causes of the fatal heart attack.

Written testimony later submitted included an article from the March, 1986 Ohio Pharmacist that contained anecdotal evidence of complaints about nonresident pharmacies received by the Michigan Pharmacists Association. These problems included one case of a consumer ordering one drug, Valium, and receiving the anti-cancer drug Nolvadex instead, and some reports of prescriptions being received in the wrong quantity or strength.

The written testimony also included a thorough report prepared for the Louisiana Board of Pharmacy.[17] As regards safety, the study cited the errors reported by the Michigan Pharmacists Association above, and cited other anecdotal reports that were really more pertinent to patient or doctor error, not pharmacy error. The issue of obtaining prescription on a forged signature was also addressed, but that is not germane to the issue of safety by legitimate users.

To buttress its safety claims for nonresident pharmacy, AMCPA listed two pages of safety precautions that its members are to abide by, including computerized patient profiles, toll-free consultation numbers, and inventory controls.[18]

While some of the anecdotes indicated serious problems, the total errors, when compared to the huge volume of mail order sales, are few. That may have been the reason why the subcommittee did not follow up with either a bill or further studies, either in 1987 or to date.

A few months after the federal hearing, an Idaho woman died from a brain hemorrhage when her prescription for prednisone was accidentally filled with coumadin.[19] This sparked another explosion of articles in NARD publications on nonresident pharmacy safety.[20] Mail order proponents fought back, arguing that no pharmacy has a perfect safety record, and that mail order, because of its protocols, was far safer than local pharmacies.

State Reports

The Michigan legislature held hearings on mail order pharmacies in 1988.[21] The report concluded that mail order pharmacy "appears to be a safe and convenient method for obtaining pharmaceuticals"[22] (emphasis added), adding that there is anecdotal information citing problems with mail order pharmacy but little or no documentation to support alleged problems.[23] The report noted that a major reason for this lack of documentation is that, as state boards lack jurisdiction over MOPs, "they have no reason and possibly no authority to document or even handle the complaints [on MOPs] they receive".[24]

Medco, the parent company of National Prescription Services, which was the focus of the 1987 Senate hearings, was again criticized in a 1990 Texas legislative hearing on mail order pharmacy. Three former employees testified, alleging that Medco "compromised safety standards and endangered patient welfare".[25] Specific allegations included substituting one consumer's Tolinase with Talwin, resulting in the consumer's hospitalization; unauthorized generic substitution; excessive supplies of medications, including controlled substances, mailed to consumers; improper supervision of nonpharmacist personnel; use of high quotas for filling prescriptions, leading to an increased error rate; failing to abide by the triplicate prescription requirements for prescriptions shipped to New York, and violation of Florida's nonsubstitution laws. It was also alleged that the pharmacists' access to computerized patient records and to each other for consultation was barred, and access to professional reference books was limited, to reserve the pharmacists' time for filing prescription quotas. Medco called these allegations "misleading" and "nothing more than innuendo".

The Maine Legislature made two reports on the issue of mail order and cost control for prescription drugs, one in 1989 and one in 1991. The 1989 report[26] cursorily stated that "it was unable to develop any evidence that there was any difference in safety between prescriptions filled by mail and those filled at a pharmacy".[27] The 1991 report[28] noted that anecdotal evidence of dispensing errors was offered by retail pharmacy organizations and by Maine officials, but stated that "national studies" suggest that mail order firms are as safe as community pharmacies. The program administrator had had five incidents of error reported to her office since 1987, all of which were traced to physician error.[29] The executive summary states that "although anecdotal evidence suggests that the quality of mail order service should be closely monitored, the quality of mail order pharmacy has not been found to be different for the quality of community pharmacies".[30]

In 1991, the magazine Drug Topics polled more than 900 independent and community pharmacists on the effects of mail order on their practices.[31] One out of every three respondents had customer question them about mail order drugs, and these queries led to the discovery of serious dispensing errors. The survey results listed sixteen occasions where the wrong drug was sent.

On the other hand, the California State Board of Pharmacy submitted a report[32] to the Legislature in early 1991 on nonresident pharmacy complaints received in a two and a half year period. The board reported only thirteen[33] complaints, nine of which were referred to the pharmacy's home state regulatory agency. Out of the thirteen, the investigations were still pending in six. Of the remaining seven, four had a finding of no violation, one had a finding of no jurisdiction, the consumer withdrew the complaint in another, and a letter of warning was issued in the last.

The Munro Article

The safety issue for American nonresident pharmacies[34] still remains unresolved. A 1991 law review article by Gregory S. Munro[35] found "scant research" (as opposed to anecdotes) on the safety of mail order dispensing, local pharmacy dispensing, and a comparison of the two. In a published critique, representatives of AMCPA charged that Munro had ignored a substantial and growing body of literature attesting to the generally high quality of mail order pharmacy.[36] Munro's response was that the studies which AMCPA referred to were not scientific studies; rather, they were unscientific testimonials, occasional or incidental investigation reports, or anecdotes.[37] Specifically, Munro states:

> [T]he ... Brandeis [report] concludes only that the quality of the drug products (made by FDA-regulated drug manufacturers) dispensed by mail service firms is "very good", and that the dispensing procedures ... "compare favorably" with those community pharmacists whose size precludes checking by more than one

> pharmacist. The statement of the American Medical Association's House of Delegates that "obtaining drugs from mail service pharmacies appears to be relatively safe", is not a testimonial to "high quality of dispensing". The Tennessee College of Pharmacy report is based entirely on testimonials from consumers and focuses on customer service as opposed to health and safety[.] *** The ... reports, such as those of the respective Joint Committees in Maine and Michigan ... are not based on empirical data, but on testimonials.[38]

Munro points out that no one -- not even the FDA -- has the authority to demand safety figures from the industry.

The AARP Testimony

The AARP Pharmacy Service submitted forty-three pages of testimony on House Bill No. 3027, Regular Session of 1992, which proposed to regulate MOPs. Most of the testimony pertains to cost effectiveness and constitutional issues; very little of it mentions the safety issues. The discussion on safety is long on assertions and short on pertinent references. It states that "every official investigation ... about the safety of mail service pharmacy has reached the same conclusion: aside from some anecdotes which are repeated over and over, investigators from 1973 through 1990 have found no credible evidence to substantiate the allegations".[39] Investigations cited include those by the United States Bureau of Narcotics and Dangerous Drugs; its successor agency, the Drug Enforcement Administration (DEA); the Federal Trade Commission; the California Board of Pharmacy; the Michigan State Senate; the Maine Legislature; Brandeis University; and the United States Food and Drug Administration.

The only investigation on which specifics were given was the California Board of Pharmacy report referred to above, which found only thirteen complaints filed against nonresident pharmacies in the two and a half years since the implementation of its Nonresident Pharmacy Registration and Disclosure Act. This is an impressive record. But what of these other studies? No specific citations are given for the references to the federal studies. However, other sources have mentioned federal studies, but they relate to the possibilities of drug diversion, not to the safety records for legitimate users. For example, the FDA released a mail order pharmacy survey report for fiscal years 1988 and 1990 to identify any problems in the industry in relation to adulteration or misbranding of drugs or "gray market" drug diversion.[40] The report spells out the differences between federal and state interest in this area: "FDA's traditional regulatory and enforcement emphasis is directed at manufacturers to ensure the efficacy, quality, and safety of drug products. This readily complements the states' traditional role in regulating pharmacy practice to ensure that ... quality ...[is] maintained as [the drugs] are dispensed for patient use".[41] (emphasis added). While it is reassuring to find that nonresident pharmacies are in compliance with federal drug quality laws, those federal safety reports should not be confused with and are not relevant to

the separate issue of whether these drugs are being properly dispensed when sent to legitimate consumers.

As discussed above, the Michigan, Maine, and Brandeis studies generally found no safety problems with drugs dispensed to their ultimate consumers, but all three reports added caveats: one noted that there was little documentation of problems because state boards lack jurisdiction over nonresident pharmacies and therefore do not collect information on their errors (Michigan), another stated that historical data are not available on error rates (Brandeis), and the last recommended that nonresident pharmacies should be closely monitored (Maine). While the reports were generally positive, they are not ringing endorsements of mail order's safety.

Local Pharmacy Error Rates

Until such time as reliable empirical data are available, the issue of safety cannot be conclusively decided. However, it is clear that errors occur at the local level too. The Bureau contacted the Regulated Industries Complaint Office of the Hawaii Department of Commerce and Consumer Affairs for data on complaints submitted to the Hawaii Board of Pharmacy. The office provided the following statistics in regard to violations:[42]

Year	Number
1985	2
1986	0
1987	5
1988	4, plus one transferred to another agency and one transferred for legal action
1989	12
1990	3
1991	2, plus 3 pending legal action
1992	1 to date, and four pending.

All of the pharmacies and pharmacists were local, except three listed as "mainland". None were for nonresident pharmacies, but this may be because the Board of Pharmacy did not believe itself to have jurisdiction over nonresident pharmacies, and thus refused to handle complaints about them. It would be difficult to try to compare error rates even if reliable mail order data were available, as the Hawaii data themselves vary widely, from no reported complaints to twelve per year.

State Law Equivalency

All American nonresident pharmacies are regulated by the state in which they are located. The question then is to what extent do these other jurisdictions' laws adequately protect the Hawaii consumer. Munro finds that information on the equivalency of state pharmacy statutes is "anything but clear".[43] However, an attempt at comparison is possible through the National Association of Boards of Pharmacy annual survey of pharmacy law.[44] Some significant differences between Hawaii's law and those of other states are that:

(1) Hawaii has the second highest requirement for hours of practical experience as a requirement for licensure. Hawaii requires 2000 hours; most other states require only 1500;

(2) While all states except California require applicants for licensure to pass the NABPLEX examination, Hawaii is one of only sixteen states to require the Federal Drug Law Examination as well;

(3) Hawaii is one of only six states not to require continuing education;

(4) Hawaii is one of thirty-seven states to have a model food and drug act;

(5) Hawaii is one of thirty-four to have a dangerous drug law;

(6) Hawaii is one of only nineteen states to have a positive formulary (a list of drugs that can be substituted for each other); and

(7) Hawaii is one of forty states that require the consumer to consent to the substitution of generic drugs for brand name drugs.

While time constraints precluded research into every facet of the pharmacy laws in all fifty states, it is clear from the NABP survey that Hawaii requires more of its candidates for licensure than most states, although it requires less of them after licensure by not requiring continuing education. Hawaii actively seeks to protect its residents by enacting drug control laws, and by establishing a positive formulary tailored to the concerns of the State Department of Health. (A positive formulary is a list of drugs that can be substituted for one another, as opposed to a negative formulary, a list of drugs that cannot be substituted for each other.)

While it appears from the survey that not all states would provide the same level of protection that Hawaii does, the real question is whether the differences lead to substantially less protection than Hawaii provides. In at least one area, the State of Hawaii apparently thinks that Hawaii's laws are significantly better. The State has its own nonresident

pharmacy program through HMSA, and that contract requires compliance with Hawaii's formulary and generic drug laws.[45] The president of Benefit Plan Consultants (Hawaii) Inc., a company offering consulting services on health care plans to businesses and organizations, states that all of its clients with mail order plans also require conformance with these laws.[46] The state Board of Pharmacy has also endorsed requiring nonresident pharmacies to conform to these laws.[47] The rest of Hawaii's consumers should expect at least that level of protection.

Conclusion

Safety is an important component of the mail order issue for, as is discussed in Chapter 6, the State can only regulate interstate commerce if the safety of its citizens is involved. The greater the danger to its citizens, the more regulation a state will be allowed under federal law. The actual safety record of the mail order pharmacy industry is unclear. Proponents claim the mistake rate is "infintesimal", while opponents cite anecdotes of errors. The studies, taken as a whole, are contradictory and lead to no firm conclusion on safety. Until such time as the MOP industry is able to provide scientific, empirical data conclusively proving an exemplary safety record, it should expect state legislators to attempt to ensure the safety of its citizens by imposing some type of regulation.

ENDNOTES

1. See, e.g., "NARD leader: Mail Order Menace to Public Health," American Druggist (March 1989) at 14.

2. Martha Glaser, "Techs, mail order draw fire from NARD delegates", Drug Topics, Vol. 132, No. 21 (November 7, 1988) at 78.

3. Mark L. Fuerst, "The Future of Mail Order", American Druggist (January 1991) 25 at 32.

4. "APhA Opposes Mail Order Pharmacy", American Pharmacy, Vol. NS30, No. 7 (July 1990) at 392.

5. Id.

6. *Glaser, supra note 2, at 78.*

7. Carol Ukens, "NARD gets lots of letters, but it's not all fan mail", Drug Topics, Vol. 135, No. 14 (July 22, 1991) at 60. The article describes AMCPA's letter-writing campaign calling on NARD to "set aside its deceptive rhetoric, unevidenced anecdotes, and rotting fictions". See also, "Mail order goes on the attack", Drug Topics, Vol. 135, No. 15 (August 5, 1991) at 8 (editorial).

8. Brandeis University and the University of Maryland, "Study to Evaluate the Use of Mail Service Pharmacies", for the United States Health Care Financing Administration (September 21, 1989). The study was undertaken under section 202 of the Medicare Catastrophic Coverage Act of 1988.

9. Id., VI-2 - VI-4.

10. Id. at VI-4.

11. "Study says MSPs are not bad guys", Drug Store News, Vol. 12, No. 21 (November 19, 1990) at 26.

12. United States, Congress, Senate, Subcommittee on Government Efficiency, Federalism, and the District of Columbia, Safety and Soundness Standards in the Mail Order Prescription Industry, Committee on Governmental Affairs, S. Hrg. 100-288 (Washington, D.C.: August 5 & 6, 1987) (hereafter "Senate hearing").

13. Id. at 33-35.

14. Id. at 63.

15. Id. at 65.

16. Id. at 70.

17. Ed Reed, "Mail Order Pharmacy in the United States" (Ed Reed Organization: July 1986).

18. Senate hearing, supra note 12, at 78-79.

19. "Mail-dispensing firm under fire in drug death", Drug Topics (March 21, 1988) at 78.

20. See, e.g., "NARD Leader: 'Mail Order Menace to Public Health'," supra note 1, at 14.

21. Michigan, Senate Joint Study Committee, "Mail Order Prescriptions (SCR 179)" (November 1988).

22. Id. at 7.

23. Id. at 8.

24. Id. at 9.

25. Daniel M. Bergin, "Texas eyes new regulations for mail-order pharmacy", Drug Topics, Vol. 134, No. 19 (Oct. 8, 1990) at 16.

26. Maine, Joint Standing Committee on Business Legislation, "Cost Containment for Prescription Drugs" (December 1989).

27. Id. at 3.

28. Maine, Staff report to the Joint Standing Committee on Human Resources, "The Feasibility of Mail Order Pharmacy and Other Cost Containment Strategies in the Low Cost Drugs for the Elderly Program" (December 1991).

29. Id. at 11.

30. Id. at i.

31. Michael F. Conlan, "Mail order's big bite", Drug Topics, Vol. 135, No. 4 (Feb. 18, 1991) at 42. Sixty-eight percent (647 people) responded to the survey.

32. California, Department of Consumer Affairs State Board of Pharmacy, "Report to the Legislature, March 29, 1991: Complaints Involving Nonresidential Pharmacies".

33. While the text of the report states that twelve violations were found, the breakdown of dispositions lists thirteen. Id. at 5.

34. Some reports of false foreign mail order pharmacies have been reported. NARD reports that the FDA has identified six foreign mail order pharmacies producing bogus pharmaceuticals: InterPharm and Northam in the Bahamas; In-Home, Switzerland; International Products of Germany; Azteca, Mexico; and Interlab, England. "Not Always Better in the Bahamas", Third Party Rx, Vol. 3, No. 12 (August 1992) at 2.

35. Gregory S. Munro, "Regulation of Mail-Order Pharmacy", 12 The Journal of Legal Medicine 1 (1991) at 52.

36. Thomas H. Stanton and Delbert D. Konnor, "Regulation of Mail-Order Pharmacy: a Critique", 12 The Journal of Legal Medicine 257 (1991) at 257.

37. Gregory S. Munro, "A Response to the Critique of Regulation of Mail-Order Pharmacy", 12 The Journal of Legal Medicine 267 (1991) at 268-69.

38. Id.

39. Testimony of F. Nicholas Willard, Director, Government Affairs, Retired Persons Service, Inc., the Pharmacy Service of the American Association of Retired Persons, to Representative Mazie Hirono, Chair, House Committee of Consumer Protection and Commerce on H.B. No. 3027, Regular Session of 1992 (February 10, 1992) at 3.

40. United States, Food and Drug Administration, FDA Center for Drug Evaluation and Research, "Mail Order Pharmacy Survey Report" (1991).

41. Id. at 3.

42. Letter from Cynthia Nakamura, supervising attorney, Regulated Industries Complaint Office, to researcher, dated September 16, 1992. The specific charges, including those in which no violation was found, are:

Year	Number	Charge	Violation
1985	2	professional misconduct (2)	yes (2)
1986	0		
1987	6	negligence, incompetence	yes
		neg., prof. misc., unethical pr.	yes
		negligence	yes
		misrepresentation	yes
		negligence	no
		prof. misc., uneth. pract, *failure to comply with law*	yes

1988	8	negligence	withdrawn
		prof. misc., substance abuse (2)	yes
		negligence	yes
		prof. misc., negligence	to court
		unlicensed activity	insuff. evid.
		prof. misc., gross neg.	yes
		prof. misc., negligence	sent to another agency
1989	15	unlicensed activity (5)	yes
		negligence	yes
		prof. misc., unethical pr.	yes
		prof. misconduct (3)	yes
		fail to disclose info (2)	no viol.
		neg., prof. misc.	yes
		failure to abide by condition	insuff. evid.
		dishonest/fraudulent acts	yes
1990	8	negligence	no viol.
		failure to disclose info (2)	no viol.
		gross neg.	yes
		negligence	withdrawn
		negligence	yes
		prof. misconduct	no viol.
		dishonest acts, prof. misc., unethical pract.	yes
1991	9	negligence	no viol.
		prof. misc., failure to comply	yes
		negligence	withdrawn
		failure to comply, dishonesty	insuff. evid.
		failure to disclose	pending
		failure to disclose, dishonesty	yes
		discipline in another state	pending
		dishonest acts	pending
1992 (to 9/16/92)	5	substance abuse	no viol.
		failure to comply	pending
		prof. misc., unethical pract.	pending
		failure to comply, prof. misc. unethical pr., dishonesty	pending
		unlicensed act, failure to maintain, unfair trade practices	pending

43. Munro, supra note 35, at 41.

44. National Association of Boards of Pharmacy, Survey of Pharmacy Law (Illinois: 1991-1992).

45. Interview with Roy M. Yamauchi, Manager of Pharmacy Benefits, Hawaii Medical Service Association, September 2, 1992; interview with Cenric Ho, Administrator of the Hawaii Public Employees Health Fund and Paul A. Tom, President, Benefit Plan Consultants (Hawaii) Inc., October 20, 1992.

46. Id.

47. Lois Taylor, "A prescription filled with concern", Honolulu Star-Bulletin (October 31, 1990) at B-1.

Chapter 5

SURVEY OF HAWAII PHARMACIES

Local pharmacies were surveyed on three primary areas: the impact of MOPs on their operations, the safety of MOPs, and the comparative costs of MOPs and local pharmacies. A copy of the survey is included as Appendix D. Surveys were sent out to all 182 pharmacies currently registered with the state Board of Pharmacy. Eighty were returned, for an approximate response rate of forty-four percent.[1] The responses below do not add up to a hundred percent because not every pharmacy answered every question, and some questions permitted more than one response. Additionally, figures are rounded to the nearest whole number.

Impact on Local Pharmacies

Almost 79 percent of all respondents felt that they lost business to mail order pharmacies. A quarter of them could not estimate the amount of loss, but of those who could, 8 percent found a loss of 1 to 10 prescriptions per week, 10 percent found a loss of 11 to 20 per week, another 10 percent found a loss of 21 to 30 per week, and 26 percent found a loss of over 30 prescriptions per week. When asked how these losses affected their business, 21 percent (all independent pharmacies) found that it had a severe impact. Thirty percent found a moderate impact, 25 percent a slight impact, and two pharmacies, one independent, the other a chain, found no impact.

In calculating the impact of mail order on their business in previous years, 59 percent found that there was a greater loss now than last year, 15 percent found the same impact as last year, and only one pharmacy found a lesser impact than last year. When asked the same question regarding business two years ago, 66 percent found a greater loss than two years ago, 6 percent found the same, and again only one pharmacy found a lesser impact.

When asked which MOP was their biggest competitor, 29 percent cited AARP, 23 percent cited other for-profit companies in general, and another 29 percent cited specific for-profit companies. The most frequently cited in the last category were HMSA or "insurance companies like HMSA", Baxter, "the State plan" (which is now Baxter), and HDS-Medical (Expresscrips). Others cited were Medco, Argus, and Pharmacy Management Services. Only one pharmacy cited the Department of Veteran's Affairs.

Comparative Costs

The majority of local pharmacies (55 percent) thought that customers chose mail order because of its cost. Thirty-five percent also cited financial pressure from third party payors (such as lower copayments for mail order or larger amounts for the same copayment). Only 3 percent thought it was due to convenience.

A large number of varying responses were given for the reasons that MOPs were able to offer lower costs, or that local pharmacies had to offer higher ones. Most focussed on why mail order prices were lower. The largest number of responses in this category were that MOPs bought prescription drugs in bulk, enabling them to get a price break. The second most popular answer was that MOPs were able to get "contract prices" from suppliers (i.e., special prices based on buying all their drugs from one supplier). These contract prices are not available to retail outlets. Other answers receiving a significant number of responses were the savings resulting from limited customer contact, assembly-line type of operations, lower overhead on the mainland, and doing business in a business-friendly state. Other answers were lack of a middleman, a central location, no need to fill low-profit Medicaid prescriptions, less limit on generic drugs, and high ratio of non-pharmacists to pharmacists.

Other answers revolved around the reasons pharmacies here had to charge higher prices. The most popular responses in this category was the need to do time-consuming face-to-face consumer consultation (including consultation for MOP customers) and the higher cost of doing business in Hawaii. Other responses were the inability to buy in bulk, and the greater shipping costs experienced by local pharmacies.

Some respondents seemed quite bitter with what they termed "financial arm-twisting" by third party payors to get customers to use mail order. They commented that they are not allowed to compete "on a level playing field" with mail order pharmacies. Some accused the State of "talking out of both sides of its mouth" by promoting "Buy Hawaii First" and then adopting a drug plan for state employees that provides incentives to use out-of-state pharmacies.

Customer Inquiries

Three-quarters of the respondents had been contacted by local consumers who had questions about their mail order prescriptions. The number of these inquiries ranged from infrequently to daily. When asked about the specific reasons they had been contacted, twenty-five pharmacies reported cases where the wrong medication was sent;[2] seventeen reported incidents where the wrong dosage was sent; seven reported situations in which the incorrect amount of medication was sent; and forty-nine reported tardiness in receiving the

mail order medication. Twenty reported other problems, such as generics sent in violation of Hawaii's generic drug substitution law, lack of counseling on use and side effects of the medication, change in appearance of medication (so the consumer was not sure whether it was the correct medication or not), receipt of medication that would have had an adverse effect when combined with other medication the consumer was taking, and inability to understand the person on the mail order pharmacy's consultation line.

When asked whether they themselves mail medication to their customers, 28 percent said they never do, 41 percent said that they rarely do; 18 percent said that they do it occasionally; and 3 percent said that they do it frequently.

Thoughts on Regulation

Is there a place for mail order pharmacy in the health care field? Local pharmacists were split. Thirty-nine percent said yes, and 49 percent said no. When asked, however, whether mail order should be regulated by the State, an overwhelming 85 percent said yes, while only 4 percent said no. By far the most popular choice for regulation was to require compliance with all state laws, as though the MOP were located in the State. The next three most popular choices were to register with the board for licensing (and to give the board jurisdiction over MOPs), to require "freedom of choice" laws that would permit local pharmacies to compete with MOPs on a level playing field, and to provide adequate patient consultation. Also cited in significant numbers were the requirements that any mail order pharmacy be located in the state, the payment of state taxes,[3] abiding by the State's generic substitution law, and being subject to inspection by the State. Other suggestions occurring less frequently include forbidding mail order by for-profit companies, checking for drug interactions, allowing mail order only if there is no local pharmacy available (one respondent added "within a three mile radius"), using a better quality of generics and using them consistently, mailing the medications by registered mail with return receipt, and charging a larger registration fee for taking business out of the State.

Price Comparisons

Last, the local pharmacies were asked for their retail prices on the ten most widely prescribed drugs in Hawaii.[4] Prices from AARP and Allscrips were obtained for comparison purposes. The following caveats to these figures should be noted: (1) the AARP and Allscrips prices listed here do not reflect their shipping charge, which is $1 per order for AARP, and $3 per order for Allscrips; (2) some of the local prices would be a little lower for senior citizens, as a number of local pharmacies wrote in to say that they give seniors a 10 percent discount; (3) AARP indicated that there would be a "price break" for larger orders

(such as 100 tabs instead of 30); (4) Allscrips gives a 20 percent discount for first time orders, which is not reflected in these figures.

Local Range[5] (mean price in parenthesis)		AARP	Allscrips
Premarin 0.625 mg (100 tabs)	$29 to 45 ($37)	$29.60	$39.21
Seldane 60 mg (20 tabs)	$16 to 27 ($21)	$16.00	$15.42
Lopid 600 mg (60 tabs)	$53 to 83 ($59)	$52.15	$49.97
Zantac 150 mg (60 tabs)	$73 to over 99 ($93)	$80.20	$80.79
Proventil Inhaler (17 g)	$ 7 to 31 ($24)	$20.95	$23.47
Procardia XL 30 mg (30 tabs)	$29 to 61 ($37)	$29.05	$29.48
Tenormin 50 mg (30 tabs)	$14 to 40 ($28)	$22.00	$21.36
Mevacor 20 mg (30 tabs)	$37 to 89 ($59)	$47.50	$47.30
Provera 2.5 mg (30 tabs)	$10 to 18 ($14)	$10.30	$10.10
Dyazide (100 caps)	$30 to 52 ($38)	$28.95	$32.97

These figures show that some local pharmacies can compete quite well with some mail order pharmacies, although the average local pharmacy price is higher than those of the mail order pharmacies studied. Price alone may not be the deciding factor in selecting a pharmacy: some customers may prefer a local pharmacy with its personal consultation component and ability to monitor the consumer's total drug profile for interactions. The value of these consulting and monitoring capabilities is being touted by NARD and others as leading ultimately to more overall health cost savings.

Conclusion

The overwhelming majority of local pharmacies are reporting some type of adverse financial impact due to mail order. Fifty percent report it as moderate or severe. A majority also find that this impact had increased over the past two years. AARP and the for-profit

companies are cited as the companies having the most impact. Most local pharmacies believe that cost considerations make mail order attractive to their customers, and a large number also feel that financial incentives established in third party payor drug plans also encourage consumers to use mail order.

How can mail order offer generally lower prices? Hawaii pharmacists blame it on a combination of mail order pharmacies' ability to buy in bulk and obtain a volume discount, to arrange for contract prices, to spend less time handling consumer questions, and by using assembly-line techniques. They also cite their own need to do time-consuming consumer consultation, and the higher cost of doing business in Hawaii.

Many report receiving questions from mail order customers on their mail order medications. The top two questions concern delay in receiving the medication, and receiving the wrong medication. Other complaints are the MOPs' failure to comply with Hawaii's generic drug substitution law, and providing incorrect dosages or amounts of medication.

Not all local pharmacies are hostile to mail order: while 49 percent believe it should be abolished, 39 percent think that there is a place for it. However, an overwhelming number think that that place would include state regulation, including requiring nonresident pharmacies to abide by all the laws that local pharmacies must. Other top choices include licensing by the state Board of Pharmacy, mandatory patient counseling, and "freedom of choice" laws. Pharmacists are upset that they are not able to compete for the consumer health care dollar due to financial incentives built into the consumer's drug plan that favor mail order. While the validity of this type of "freedom of choice" legislation is not relevant to a study focussed on the commercial practices and regulation of out-of-state pharmacies, it may be appropriate for future study.

Selected drug prices were compared, and while some local pharmacies appear to be able to compete directly with mail order companies open to the individual, the mean price for all ten drugs was higher than those of AARP and Allscrips.

Overall, the survey reflects the concern of many local pharmacists not only over their futures, but of those of their customers. One pharmacist wrote:

> I find that out of 25 prescriptions, I have to call the doctor on at least two occasions to find out the correct strength or quantity, or even at times to find out the correct drug. I have also found that at times the doctor has written for the wrong medication. [It is] very important to be able to check with the patient, the doctor, and have a history or record of the patient on hand. [I] have found several contraindicated meds (drug interactions) which could have been fatal.

Another stated:

> Can anyone honestly say that a patient is better off when a pharmacist is not there to answer a patient's questions?

ENDNOTES

1. The actual response rate may be higher: one chain contacted the researcher and wanted to know if just one survey could be returned for the entire chain. If the chain did so, the real response rate would be almost 50 percent.

2. This may seem high when compared to the local pharmacies' complaint record as compiled by the Regulated Industries Complaint Office of the Department of Consumer and Consumer Affairs described in Chapter 4. However, it is safe to say that not every incident of error on the part of a local pharmacy is formally reported to the Department of Commerce and Consumer Affairs. Many are undoubtedly resolved at the store level. Comparing errors reported by consumers, therefore, with errors reported the Regulated Industries Complaint Office for investigation is not appropriate.

3. It should be noted that Hawaii has not imposed the general excise tax on prescription drugs since 1986. See section 237-24(23), Hawaii Revised Statutes.

4. This information was obtained from Gerry Fujii, member of the state Board of Pharmacy.

5. It should be noted that for the local pharmacies, the higher prices generally came from the independent pharmacies. For example, while the local price range for Premarin is $29 to $45, the highest price for any chain is only $39. Similarly, while the price range for Tenormin was $14 to $40, the top price for any chain was $29.

Chapter 6

WHAT OTHER STATES DO

One of the components of this study was to survey the laws used by other states to regulate the commercial operation of nonresident pharmacies. The National Association of Boards of Pharmacy's 1992 survey of the other forty-nine states indicates that twenty-seven states[1] require that nonresident pharmacies be licensed, nineteen do not,[2] one state did not respond,[3] and two had legislation pending.[4]

The variation between the states as to whether to regulate nonresident pharmacies, and what form that regulation should take, may have its roots in the complex questions of competing federal and state responsibilities in this area. The act of nonresident pharmacies transporting prescription drugs across state lines constitutes interstate commerce. The ability of a state to regulate interstate commerce is governed by the relationship between the Commerce Clause of the United States Constitution, the states' power to protect the health of their citizens, and the federal government's preemption powers.

The Commerce Clause, States' Rights, and Federal Preemption

The Commerce Clause of the United States Constitution states that:

> The Congress shall have the Power ... To regulate Commerce with Foreign nations, and among the several States[.]"[5]

This section reserves to Congress the power to regulate commerce among the states.[6] Yet this congressional right is not absolute. States may pass laws affecting interstate commerce if the state's interest in protecting the health, safety, and welfare of its citizens transcends the federal interest. However, the federal government may override a state's legitimate attempts at addressing these issue if the federal government enacts its own specific legislation on the topic, thereby preempting the states from action.

The states' ability to regulate interstate commerce in specified circumstances has long been recognized. The basic test can be found in the United States Supreme Court decision *Pike v. Bruce Church*:[7]

> Where the state regulates evenhandedly to effectuate a legitimate local interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits. If a legitimate local interest is found, then the question becomes one of degree. The extent of the burden that

> will be tolerated will of course depend on the nature of the local interest involved, and on whether it could be promoted as well with a lesser impact on interstate activities. (citations omitted)[8]

So the requirements for state regulation are:

(1) Evenhanded regulation;

(2) Serving a legitimate local interest;

(3) With an incidental burden on interstate commerce.

The incidental burden requirement is actually a balancing test, involving an assessment of the nature of the burden, the nature of the interest, and whether there are alternatives with less impact on interstate commerce.

Even though a state may meet these requirements and pass the balancing test, the state regulation may still be invalidated if the federal government enacts general legislation meant to preempt the field. The doctrine of federal-state preemption is one of long standing, and several general rules have been firmly established. The underlying rationale is that the Supremacy Clause of the United States Constitution invalidates state laws that interfere with or are contrary to federal law. This rationale has led to two general rules. First, any state law that directly conflicts with a valid federal law will be superseded.[9] Second, any state law that is merely incompatible with the federal law will be superseded if any one of three tests are not passed:

(1) Is the scheme of federal regulation so pervasive that it is reasonable to infer that Congress meant to leave no room for the state to enter it?

(2) Does the law involve an area in which the federal interest is so dominant that the federal system must be presumed to exclude any state attempts to become involved?

(3) Does enforcement at the state level present a serious danger of conflict with the administration of the federal program?[10]

Because these tests involve balancing the statutes, not merely as they are written, but as they are actually applied, the Supreme Court has recognized that there are no rigid

formulas to determine whether preemption exists. Each case is judged within its own context.[11]

State Attorney General Opinions

Given the legal intricacy of the areas, it is not surprising that the ten states that have issued Attorney General opinions on nonresident pharmacies have reached vastly different conclusion. Some permit regulation and require the nonresident pharmacies to meet all of the standards for an in-state pharmacy; some permit regulation but impose limited requirements; and some take the position that they are preempted from regulating the area at all. A synopsis of the opinions follows.

California

The California law provides for licensure of out-of-state distributors, including pharmacies, that do business in California. The attorney general opinion[12] analyzing this law discusses the Pike v. Bruce Church test referred to above, and finds that the state interest in public health and safety and close control of drug distribution is legitimate and constitutes "an interest of the highest order". The opinion finds that the effects on interstate commerce are incidental as they also apply to in-state distributors, and points out that the state is not barring the mail order traffic or restricting it in a way that in-state pharmacies are not. The opinion also dismisses the issues of denial of due process or equal protection, and finds that there is no federal preemption by the federal drug laws.

Delaware

The Delaware opinion[13] dealt with two topics: whether nonresident pharmacies could be regulated, and if so, whether they would be regulable under the current Delaware statute. The opinion states that the current Delaware scheme did not encompass nonresident pharmacies. The opinion did not fully discuss what type of law might be appropriate. It just noted that there are potential legal problems such as infringement on interstate commerce.

Kansas

The Kansas opinion[14] dealt with the issue of whether the existing law, facially applicable only to Kansas pharmacies, should be applied to nonresident pharmacies as well. The opinion concludes that the statute contains no language of limitation, and that therefore it

applies to nonresident pharmacies as well. Interestingly, there is no discussion of the commerce clause or any other federal law issues.

Louisiana

The Louisiana opinion[15] cursorily states that requiring an out-of-state pharmacy to obtain a permit from the board is merely an express restatement of the existing law. It concludes, without discussion or analysis, that the department finds no fault in that policy under the Commerce Clause or any other state or federal constitutional provision.

Nebraska

Nebraska has three opinions on this topic. Apparently Nebraska had been trying for several years to pass some type of legislation regulating nonresident pharmacies, and had asked for the Attorney General's opinion on three pending bills. The first opinion, from 1985[16] concerns the constitutionality of a bill that would have required nonresident pharmacies to obtain Nebraska pharmacy licenses, and to follow all Nebraska laws in dispensing drugs to Nebraska residents. The opinion discusses the preemption aspect of the Commerce Clause and concludes that the federal Drug Abuse Prevention and Control Act of 1970[17] does not preempt the Nebraska bill as long as the bill does not have a "positive conflict" with the Act. The opinion then cites the *Pike v. Bruce Church* test and finds that the state interest is legitimate and important, and facially appears to be evenhanded, but finds that the burden on interstate commerce would be substantial, assuming that every state makes the same requirements. The opinion also considers whether a substantial regulatory equivalent is available to the state, and concludes that the federal Drug Abuse Prevention and Control Act extensively regulates pharmacies and substantially duplicates the requirements of Nebraska law. This weakens the need for the state's intervention and makes the bill "of suspect constitutional validity".

The Nebraska Legislature attempted to regulate nonresident pharmacies again in 1986, by amending the bill to provide for an exemption to compliance with Nebraska laws for nonresident pharmacies that hold a pharmacy permit in the state where they are located if the requirement for licensure in that state are substantially equivalent to those required by Nebraska law.

The second attorney general opinion[18] found enforcement problems with the general rule but concluded that the exemption would probably not violate the Commerce Clause. It suggested deleting the old general rule and making the exemption the new general rule.

Apparently that attempt was unsuccessful, because in 1988 the Attorney General was asked to review the constitutionality of a bill providing that a nonresident pharmacy cannot deliver prescription drugs into Nebraska unless the pharmacy is licensed in a state with substantially equivalent requirements to those of Nebraska. The third opinion[19] discussed the issue in light of the Commerce Clause and the restrictions on state action stated in the federal Drug Abuse Prevention and Control Act, and found that the more stringent Nebraska requirement conflicted with the federal act and was thus preempted. It concluded that the state could properly require that a nonresident pharmacy be licensed in the state in which it is located but cannot impose additional, more stringent requirements concerning the nature of those requirements.

Ohio

Ohio's opinion[20] examined the issue in light of the Commerce Clause and the Federal Controlled Substances Act of 1970 (this appears to include the Drug Abuse Prevention and Control Act found so crucial by Nebraska's Attorney General) and concluded that Congress has passed a "comprehensive system of registration and regulation" that permits state regulation unless the state regulation is inconsistent with the federal law. The opinion examined the law in light of *Pike v. Bruce Church* and found a legitimate local purpose with apparently evenhanded application. However, the opinion concludes that interstate commerce would "almost certainly" be substantially impeded if the nonresident pharmacy is forced to meet local requirements in all fifty states.

The opinion also stated that the fourth requirement under the Commerce Clause focuses on the need for uniformity of regulation, and finds that the federal act would "effectively control the manufacture and distribution of controlled substances and protect consumers", and allowing the state to interfere with this federal system would "arguably destroy the purpose behind the Federal Controlled Substances Act". The opinion concluded that nonresident pharmacies are not subject to regulation by the Ohio State Board of Pharmacy.

Tennessee

The Tennessee opinion[21] found that the state has a strong interest in regulating prescription drugs and that the language of the applicable statutes expressed a clear legislative intent to regulate all pharmacies, whether in-state or out-of-state. The opinion examined the Commerce Clause issue and found a strong and legitimate state interest, evenhanded application, and a lack of preemption by Congress. The opinion concluded that due process would not be offended by application of the statute. Last, the opinion was asked whether a nonresident pharmacy must comply with all Tennessee laws when doing business

with a Tennessee resident. The opinion concluded that the nonresident pharmacy would have to comply, so long as the rules do not discriminate against or unduly burden interstate commerce.

Texas

The Texas opinion[22] found that, while the Texas Legislature had given the board the ability to regulate nonresident pharmacies, the person requesting the opinion did not specify how the board would perform this function. Therefore, while the opinion upheld the general concept of state regulation of nonresident pharmacies, using a Commerce Clause/Pike v. Bruce Church analysis, and found no preemption under the federal Drug Abuse Prevention and Control Act, the opinion warned that specific regulation would have to pass the balancing test and would have to use the least burdensome regulation that would effect the state's objectives.

Utah

Utah issued an informal opinion[23] on regulation of nonresident pharmacies. The opinion examines the Commerce Clause and *Pike v. Bruce Church* body of law, and finds the state's objective of protecting the public health, safety, and welfare by regulating nonresident pharmacies is legitimate. The opinion finds no undue burden and no adverse impact on due process or equal protection rights. The opinion concludes that Congress did not preempt the field and that the state can validly require nonresident pharmacies to conform to the same laws that in-state pharmacies must follow.

Wisconsin

The Wisconsin opinion[24] answers the question as to whether the current state law authorizes the state Board of Pharmacy to regulate nonresident pharmacies. The opinion states that it does, briefly discusses the Commerce Clause and concludes that it poses no problem. It states, however, that there may be enforcement problems against the nonresident pharmacy, and notes that the Wisconsin resident who received drugs from a nonresident pharmacy not in compliance with the state regulations would also be in violation of the law.

The National Association of Boards of Pharmacy

The National Association of Boards of Pharmacy (NABP) at one time had adopted a resolution[25] entitled "Model Regulation on Out-of-State Pharmacies". This resolution required mail order pharmacies to:

- Be licensed by the state board of pharmacy;
- Designate a resident agent for service of process, or the secretary of state would be designated instead;
- Maintain readily retrievable records of drugs;
- Provide a toll-free consultation number;
- Comply with state drug laws unless they violate the pharmacy's home state laws; and
- Develop and provide a policy and procedures manual addressing concerns such as out-of-stock drugs, delayed delivery, and prescriptions for acute conditions.

However, this resolution has been superseded by the NABP's 1992 Model State Pharmacy Practice Act.[26] While section 105 includes the definition of non-resident pharmacy, the Act itself does not mention that term. Instead, article V of the Act establishes requirements for all persons, in or out of state, that practice pharmacy. The requirements are to:

- Be licensed by the state board of pharmacy;
- Submit a verified application;
- Have a pharmacist-in-charge;
- Designate an agent for service of process, or the secretary of state would be designated instead; and
- Report designated occurrences, such as permanent closing, theft or loss of drugs, and change in ownership.

In addition, the model act permits the board to enter into agreements with other entities for the purpose of exchanging licensing information or conducting inspections on out-of-state pharmacies. The Act also includes blanket language permitting the state board to establish minimum standard of responsibility and for licensure classifications.

State Statutes

Twenty-seven states have chosen to regulate nonresident pharmacies. The statutes can be generally classified in three separate categories. The first group is composed of states that implicitly regulate by defining in their pharmacy codes the terms "practitioner" and "prescription" so broadly or ambiguously that nonresident pharmacies are encompassed.[27] In these states, nonresident pharmacies would be required to follow the same laws that local pharmacies follow. A second approach, with the same result, is to expressly cover nonresident pharmacies in the statute, and require them to follow the same laws as local pharmacies do, with no special requirements.[28]

The third approach, followed by states such as California[29] and Utah,[30] is to explicitly regulate nonresident pharmacies, and to impose special requirements on them, which may be more or less than the requirements imposed on local pharmacies in those states. An excellent law review article by Gregory Munro on the regulation of the mail order pharmacy industry evaluates some of the state laws using this third approach and gives an opinion as to whether the author thinks certain of the state requirements will pass constitutional muster.[31]

The Munro Article

1. Registration

Munro notes that all five states in this last category (California, Florida, Idaho, Nebraska, and Utah) require the nonresident pharmacy to be licensed in its home state, while only three require licensing by the consumer's state. Each requires the nonresident pharmacy to register with their board and to provide basic information similar to that required by out-of-state corporations doing business in the state.[32] Three states also require information about the owners of the pharmacies and about the pharmacists. Two states require the identifications of a "pharmacist in charge" but do not require that the pharmacist be licensed in their state. One requires the Secretary of State to be designated as their agent for service of process. Munro concludes that the courts are "more likely to find the burden [of these registration requirements] outweighed by the local interest in protection of public health and safety".[33]

2. Compliance with home state laws

The statutes also require the nonresident pharmacy to provide evidence of compliance with their home state's requirements, and to cooperate and comply with their home state laws and regulations. Two states require the reporting of accidents, disasters, or events causing problems in the purity, labeling, or strength of drugs, and one mandates this information to be provided on request. Munro concludes that this requirement is relatively insubstantial and probably would not be a burden on interstate commerce.

3. Reporting requirement

Four of the states also have some kind of reporting requirements for controlled substances. Two states require quarterly reports, and provide for inspection of the nonresident pharmacy facilities if the home state's inspections are not adequate. Two others insist only that the information be available on demand. Munro concludes that the more stringent requirements requiring quarterly reports may be deemed unreasonably burdensome.

4. Inspections

Inspections by the consumer's board of pharmacy may be unconstitutional. One state gives its board the power to inspect the nonresident pharmacy if the home state's board does not do so or fails to obtain the necessary records in doing so. While Munro concedes that this is a "critical regulatory tool", he concludes that, given the potential burden if fifty states insist on such inspections, the inspection requirement is likely subject to successful legal challenge.

5. Toll-free telephone consultations

Three states require toll-free numbers for telephone consultation for a minimum of forty hours per week over six days. Munro finds that mandating toll-free telephone counseling would pass constitutional muster due to the state's interest in safety. Munro notes that a 24-hour toll-free number, while "highly favored by community-based pharmacists who resent the irony of being forced to spend office time fielding telephone requests for counseling from patients of mail order pharmacies", would be particularly susceptible to legal challenge as local pharmacies do not have to provide service this extensive.

6. Product substitution

Munro also mentions that two states place restrictions on product substitutions, but does not make a specific prediction on how the courts would treat that issue. This is an issue of particular interest to Hawaii as Hawaii is one of the few states that has its own drug formulary.

Amount of Burden Imposed by State Regulation

Munro makes the general statement that statutes placing special requirements on nonresident pharmacies are more susceptible to judicial challenge than statutes imposing the same requirements as those placed on local pharmacies. This statement is too broad: for example, toll-free telephone consultation for a reasonable number of hours is a special burden on nonresident pharmacies but one almost sure to pass muster according to Munro himself, while requiring out-of-state pharmacists to take Hawaii's pharmacy examination, or to be subject to state inspection as local pharmacies are, would probably be considered too burdensome. But Munro does validly state a real issue: whether it is an unreasonable burden on nonresident pharmacies to require them to meet existing state requirements in each state into which they mail. Munro states that, as a matter of policy, courts should uphold two types of legislation: (1) those informing the pharmacy board of the consumer's state of the identity, nature, and location of the nonresident pharmacy and ensuring that the pharmacy is in compliance with its home state laws, and (2) those necessary by the very nature of nonresident pharmacy, such as reasonable toll-free telephone consultation.

The argument by the nonresident pharmacies against regulation by other states is that additional state regulation is too burdensome, and that the current system of regulation by the home state board of pharmacy along with existing federal regulation on quality control is sufficient. Munro says that the states' response to this argument would be that this restriction denies the states their inherent power to determine minimum standards of safety with regard to pharmacy. Munro notes that some states require pharmacists to keep individual patient profiles, limit the number of times a "PRN" prescription may be refilled,[34] and require patient counseling by pharmacists. In Hawaii, an additional safety measure imposed by the State is a 292-page drug formulary that restricts the type of generic drug substitution that can be made. To the extent that a state is not permitted to impose these safety considerations on nonresident pharmacies, its residents are receiving two classes of care.

Munro has two theories on treatment of nonresident pharmacies. If nonresident pharmacies are considered the practice of pharmacy, he thinks the best treatment is to allow the states considerable liberty in regulating them. He analogizes the practice of pharmacy to the practice of law, which also requires its practitioners to be licensed by, and subject to the authority of, the state in which they operate, not just the state in which the firm is located. On the other hand, Munro argues that nonresident pharmacy could also be considered just a drug dispenser. Under that theory, regulation should come from the federal government. However, at this time, federal regulation of this area appears unlikely.[35]

A number of attorney general opinions endorse the practice of imposing the same requirements on in-state and nonresident pharmacies on the grounds that it is evenhanded, imposing no greater burden on nonresident pharmacies than it does on in-state pharmacies.

However, this appearance of fairness might in practice lead to an undue burden on nonresident pharmacies. If a substantial number of states impose their differing standards on the nonresident pharmacies, the administrative burden arguably might be overwhelming, or even paralyzing, if the nonresident pharmacy has fifty differing procedures to follow. The primary reason the nonresident pharmacies are so popular is their allegedly lower cost, which is made possible in part by a low profit/high volume method of business. Slowing the volume down by imposing many differing methods of compliance could cost the nonresident pharmacies the profit they need to survive.

However, if a state is not allowed to impose its laws on nonresident pharmacies doing business within its borders, it is possible that the quality of care mandated by the regulations will not be achieved for residents using mail order. As many insurance companies use economic tactics to compel consumers to mail order, two standards of care could evolve: a higher standard (in terms of the goals sought to be achieved by state regulation) for those able to afford local pharmacies, and a lower one for those only able to afford mail order.

Jurisdictional Dilemmas

Another troubling aspect arises when the requirements of the nonresident pharmacy's home state clash with the requirements of the consumer's state. For instance, if the MOP's home state permits the substitution of generic drug X for brand name drug Y, but the consumer's state does not, can the nonresident pharmacy legally dispense the generic? What if the MOP's state allows pharmacy technicians to assist in the dispensing process, but the consumer's state does not? Can the pharmacy legally dispense the drug if the technician is involved in the process?

The California Compromise

In its testimony against H.B. No. 3027, the Hawaii bill proposing regulation of nonresident pharmacies, the AARP endorsed the California approach. The full text of the California statute is contained in Appendix E. In brief, the California law[36] requires nonresident pharmacies to:

(1) Register with the Board of Pharmacy;

(2) Disclose to the Board the location, names, and titles of all principal corporate officers and all pharmacists dispensing controlled substances and dangerous drugs to the state;

(3) Comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as all requests for information by the California board;

(4) Maintain a valid license, permit, or registration in that state where it is located;

(5) Submit a copy of the most recent inspection report by the state in which it is located;

(6) Maintain its records of drugs dispensed so that information related to California residents may be readily retrieved;

(7) Offer toll free service for a minimum of forty hours over a six day per week period; and

(8) Pay a registration fee.

The statute permits the Board of Pharmacy to discipline the nonresident pharmacy[37] and restricts advertisements for non-registered pharmacies. It attempts to put teeth into the Board's regulation by permitting the Board to act against the pharmacy for conduct causing either serious bodily or psychological injury to a state resident if the Board has referred the matter to the board of the State in which the pharmacy is located and that board fails to initiate an investigation within forty-five days.[38] The California approach has been copied, with some modification, by a number of states, such as Washington,[39] Wyoming,[40] and Arkansas.[41]

House Bill No. 3027

The administration bill that ultimately prompted this study, H.B. No. 3027, Regular Session of 1992, a copy of which is contained in Appendix B, would have required a nonresident pharmacy to:

(1) Obtain a permit from the Board of Pharmacy;

(2) Not have been found, or have any personnel found, to have been in violation of any state or federal drug law;

(3) Have a registered pharmacist whose registration is in good standing;

(4) Have a 24-hour toll-free number providing access to a pharmacist of the pharmacy;

(5) Abide by the standards of practice established by the Board's laws and rules; and

(6) Obtain, at the Board's request, a permit for each location.

Based on the above discussion, the only controversial requirements were the 24-hour toll free line and the standards of practice rule. The 24-hour toll free line, while according to Munro perhaps unduly burdensome for other parts of the United States, is not necessarily unreasonable for Hawaii. Given Hawaii's geographical isolation from mainland facilities, extended hours of consultation would seem to be reasonable. If a facility on the East Coast offered a toll free number only during its eight-hour work day, Hawaii residents would be deprived of consultation as early as 11 a.m. -- before many of them had even received their mail for that day. Perhaps an acceptable compromise would be to require a minimum forty hours but make these hours coincide with regular business hours in Hawaii. This would put the consultation facilities of nonresident pharmacies more on par with those of Hawaii's local pharmacies, and alleviate the burden on local pharmacies to handle informational requests from mail order patients, as discussed in Chapter 5.

The toll-free consultation requirement may be more of an apparent than an actual problem since, according to HMSA, the major mail order pharmacies already do provide a 24-hour toll free number,[42] and AARP is also planning to establish one.[43] The only exception of which the researcher is aware is that of the new Sears drug plan, Allscrips, which has a pharmacist on telephone duty only between the hours of 8:00 a.m. and 5:00 or 6:00 p.m., Central time.[44]

The real point of controversy on H.B. No. 3027 was the requirement that the nonresident pharmacy abide by the standards of practice established by the Hawaii board. It is not clear what those standards would be. It is not clear whether the statute meant to apply all of the current rules now applicable to local pharmacies, or whether the language was intended to refer to new rules that the Board of Pharmacy would be authorized to adopt. It may be significant that the statute did not require that the nonresident pharmacies comply with the same statutes that local pharmacies do. This omission could signify an intent by the Board (which drafted the bill) to make minimal demands on nonresident pharmacies, demands that could easily be met without unduly burdening the nonresident pharmacies. On the other hand, this language could also be used to underscore the necessity of compliance with all Hawaii laws, including the restrictions imposed by Hawaii's drug formulary.

Conclusion

House Bill No. 3027 and the action of the twenty-seven states that have regulated the area of nonresident pharmacies indicate a strong desire by the states to protect their residents by imposing controls on nonresident pharmacies. Anecdotes of mail order mistakes by NARD AND APhA, and allegations of mail order's exemplary safety record by AMCPA, both lack sufficient empirical data to allow an unbiased researcher to come to a firm conclusion on the safety of obtaining medication from mail order pharmacies. Neither side's extreme claims can be verified. But mail order does not claim a perfect safety record, and since the potential for harm if errors do occur is great, the prudent state policy would be to allow the Hawaii Board of Pharmacy leeway to impose some kind of restriction on nonresident pharmacies. Proposed legislation will be discussed in the next chapter.

ENDNOTES

1. Alabama, Arkansas, California, Delaware, Florida, Idaho, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Minnesota, Missouri, Nevada, New Mexico, North Dakota, Oregon, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, Wisconsin, and Wyoming. Letter from Bart Clark, M.S., R. Ph., Professional Affairs Manager of the National Association of Boards of Pharmacy, dated August 18, 1992, to researcher, enclosure entitled Pharmacy Licensure Update.

2. Alaska, Arizona, Colorado, Connecticut, Georgia, Indiana, Maryland, Massachusetts, Michigan, Mississippi, Nebraska, New Hampshire, New Jersey, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, and South Dakota. Id.

3. Vermont. Id.

4. Montana and Rhode Island. Id.

5. United States Constitution, Article I, section 8, clause 3.

6. Gregory S. Munro, "Regulation of Mail-Order Pharmacy", 12 The Journal of Legal Medicine 1 (1991) at 7. The paper from which the article was developed received the James Hartley Beal award for the Best Paper in Pharmacy Law at the 1990 annual meeting of the American Society for Pharmacy Law.

7. 397 U.S. 137 (1970).

8. Id. at 142.

9. 2 Am.Jur.2d Administrative Law §211, 16 Am.Jur.2d Constitutional Law §291.

10. Id.

11. Id., Administrative Law §214, Constitutional Law §291.

12. Memorandum to Lorie Garris Rice, Executive Officer, California State Board of Pharmacy, from the Office of the Attorney General, October 29, 1984.

13. Letter to Mr. Martin Golden, Chief of Narcotics and Dangerous Drugs, from Edward F. Kafader, Deputy Attorney General, June 7, 1985.

14. Attorney General Opinion 84-71, from Robert T. Stephan, Attorney General, and Kenneth R. Smith, Assistant Attorney General, to Lynn E. Ebel, Kansas Board of Pharmacy, July 20, 1984.

15. Opinion Number 85-837, State of Louisiana Department of Justice, from William J. Guste, Jr. Attorney General, by Kenneth C. DeJean, Chief Counsel, to the Honorable Garey J. Forster, November 7, 1985.

16. Opinion No. 57, State of Nebraska, Department of Justice, April 4, 1985.

17. 21 U.S.C. §§801 et seq.

18. Opinion No. 86016, by Robert M. Spire, Attorney General and Marilyn B. Hutchinson, Assistant Attorney General, February 13, 1986.

19. Opinion No. 88007 by Robert M. Spire, Attorney General, and Dale A. Comer, Assistant Attorney General, February 10, 1988.

20. Opinion No. 82-032, by William J. Brown, Attorney General, May 4, 1982.

21. Opinion No. 86-132, by W.J. Michael Cody, Attorney General. John Knox Walkup, Chief Deputy Attorney General, and Daryl J. Brand, Assistant Attorney General. July 29, 1986.

22. Opinion No. JM-555, by Jim Mattox, Attorney General, October 8, 1986.

23. Informal Opinion No. 87-13, by J. Stephen Mikita, Assistant Attorney General, March 16, 1987.

24. OAG No. 33-83, by Bronson C. LaFollette, Attorney General, August 23, 1983.

25. Resolution 85-3-89 (1989). See also "NABP adopts model regs on out-of-state pharmacies", Drug Topics (July 3, 1989) at 46.

26. Telephone interview with Bart Clark, Professional Affairs Manager, National Association of Boards of Pharmacy, November 4, 1992.

27. See Munro, supra note 6, at 26-27.

28. See, e.g., Louisiana Rev. Stat. §§37:1184 and 1188, requiring nonresident pharmacies to obtain a permit from the board, and requiring full compliance with the rules of the board.

29. See discussion accompanying footnote 35 et seq. below.

30. Utah Code Annotated, section 58-17-15 (1991 cum. supp.) requires nonresident pharmacies to either submit quarterly reports listing each prescription for a controlled substance or submit to onsite inspection.

31. Munro, supra note 6, at 26-34.

32. Id. at 29.

33. Id.

34. PRN stands for "pro re nata" and is defined as "'according to circumstances.'... and 'for the occasion as it may arise[.]'" Id. at 33, fn. 226. Doctors use PRN to authorize unlimited refills, but the majority of states place a time requirement on PRNs.

35. Telephone interview with Robert Wesley, resident in charge, Food and Drug Administration, Honolulu office, with researcher on August 20, 1992.

36. California Business & Professions Code §4050.1.

37. Id., sections 4084.6, 4350.6, and 4355.

38. Id., section 4350.6.

39. Revised Code of Washington, §18.64.360.

40. Wyoming Statutes §33-24-152.

41. A copy of the Arkansas regulations are found in Appendix F.

42. Interview with Roy M. Yamauchi, Manager of Pharmacy Benefits, Hawaii Medical Service Association, September 2, 1992.

43. Telephone interview with F. Nicholas Willard, Director of Governmental Affairs, AARP Pharmacy Service, October 1992.

44. Telephone call to Allscrips, October 5, 1992. Central time is either four or five hours earlier than Hawaii, depending on the time of year.

Chapter 7

PROPOSED LEGISLATION

Assessment of the Need for State Regulation

It is difficult to state precisely the degree to which state regulation is needed, based on safety considerations. The national studies and reports generally cite anecdotes, not unbiased scientific studies, in their findings on the safety of the mail order pharmacy industry. No one, not even the Food and Drug Administration, has the ability to compel the industry to release these data or to cooperate with a neutral research organization. The industry has not been forthcoming about sharing that raw data, although they do conclude that they have an exemplary safety record.

Until such time as compelling evidence is presented that demonstrates the safety of mail order pharmacy, the State's concerns about the health, safety, and welfare of its citizens should be respected. The state Board of Pharmacy does have some concerns along this line, as demonstrated by its introduction of House Bill No. 3027 during the 1992 session to regulate the industry. Additionally, well over half of the local pharmacies surveyed had had state residents contact them because of problems with their prescriptions, including the receipt of the wrong drug, the wrong dosage or amount of the drug, or drugs not in compliance with the state generic drug laws. These errors are serious, and potentially fatal. While it may be alleged that some local pharmacies, especially those who reported a severe impact on their business due to mail order, might have an incentive to misreport these data, it is unlikely that the majority of respondents to the survey did so.[1] As long as there are legitimate safety concerns, some degree of state regulation should be permitted, within federal constitutional limitations.

The cost factor does not really seem to be a problem at this time. As discussed earlier, the amount of cost savings realized from mail order is unclear, and it may be that to the extent a local pharmacy charges more, that pharmacy also provides more services which can help keep the consumer's overall health costs down. It appears that many companies in the State using mail order, including the State's plan for public employees, already impose the more controversial requirements discussed below on the mail order companies with which they do business. The proposed legislation will in general neither encourage nor discourage more mail order companies to do business here. It will have little impact on group insurance coverage or health maintenance organizations.

Proposed Legislation

A draft of the proposed legislation can be found in Appendix C. The salient features of this legislation are:

(1) Registration with the state pharmacy board;

(2) Disclosure of the locations, names, and titles of all principal corporate officers and all pharmacists who dispense controlled substances of dangerous drugs or devices to state residents. The disclosure shall be reported annually and within thirty days after any change of office, corporate officer, or pharmacist;

(3) Compliance with all lawful directions and requests for information from its home regulatory board;

(4) Maintenance of a valid unexpired license in its home state and the submission of the most recent inspection report by the home state;

(5) Compliance with requests for information made by Hawaii's state board of pharmacy;

(6) Maintenance of records of controlled substances or dangerous drugs or devices so that information relating to Hawaii's consumers is readily retrievable;

(7) Permitting the state board to deny, revoke, or suspend its Hawaii registration for failure to comply with these requirements, or for conduct causing serious bodily or psychological injury to a Hawaii resident, if the board has referred the matter to the home state, and the home state has failed to initiate an investigation within forty-five days;

(8) Forbidding advertising in the State unless the mail order pharmacy is registered in Hawaii;

(9) Establishment of a toll-free phone number for patient consultation available, at a minimum, weekdays during the hours of 8:00 a.m. to 5:00 p.m. Hawaii standard time, and 8:00 a.m. to noon on Saturday and Sunday;

(10) Compliance with Hawaii's drug formulary and generic drug substitution law except where they directly conflict with home state law.

Items one through eight come from the California Nonresident Pharmacy Registration law, which was endorsed by AARP. AARP also testified that the California model "is being complied with by every other significant mail service pharmacy in the country".[2]

Number nine, the toll-free number requirement, is potentially more controversial. California also includes a toll-free number requirement, but limits it to forty hours over six days and does not specify the time period. This proposed legislation would specify availability from 8:00 to 5:00 during Hawaii business hours, and would also provide weekend morning hours. However, California is much closer in distance and in time to mail order pharmacies. It is not as crucial for them to specify the time as it is for Hawaii residents. This concern over this requirement may ultimately turn out to baseless. The biggest opponent to a 24-hour toll-free number requirement in House Bill No. 3027 came from AARP. But according to a recent interview with personnel there, AARP is now putting in place its own 24-hour toll-free number.[3] Perhaps this is an example of how adaptable mail order pharmacies can be when they want to retain access to a market.

Item ten, compliance with Hawaii's drug laws, is new and may cause some constitutional concerns. However, it should be noted that many mail order pharmacy plans in Hawaii, including the State of Hawaii's plan for public employees, require compliance with these laws, and to date there have not been any reports of mail order pharmacies refusing to do business in Hawaii because of these requirements.[4]

As a potential constitutional concern exists with legislation in this area, a copy of the proposed legislation was transmitted to the department of the attorney general. Comments from that department were not available by the time this report was finalized.

Conclusion

The State has a legitimate interest in regulating the mail order pharmacy industry. Proposed legislation, derived from the California model, will basically provide for registration of the mail order pharmacy, give the board the ability to regulate it if its home state board does not, require a toll-free consultation number during Hawaii business hours, and require compliance with Hawaii's drug laws. These requirements would be no surprise to the mail order industry. Major mail order companies doing business in the State, such as Baxter and Medco, already comply with the drug laws and provide a 24-hour toll-free consultation number. The regulation will probably not affect mail order companies' business in Hawaii. It also will not affect group insurance coverages or health maintenance organizations.

ENDNOTES

1. It should be noted that five of the pharmacies who reported that the impact of mail order on their business was only "slight" also reported incidents of customers receiving the wrong drug, potentially the most dangerous type of error.

2. Testimony of F. Nicholas Willard, Director, Governmental Affairs, Retired Persons Services Inc., the Pharmacy Service of the American Association of Retired Persons, to Representative Mazie Hirono on H.B. No. 3027, Regular Session of 1992, February 10, 1992, at 6.

3. Telephone interview with F. Nicholas Willard, Director, Governmental Affairs, Retired Persons Services Inc., the Pharmacy Service of the American Association of Retired Persons, October 1992.

4. Although it should be noted, as discussed in chapter 5, some pharmacies report noncompliance with the drug substitution laws.

Chapter 8

FINDINGS AND RECOMMENDATIONS

Findings

1. Mail order pharmacy (nonresident pharmacy) is currently taking place in the State of Hawaii through group health plans and by individuals. This type of pharmacy practice is not regulated by the State.

2. There is no federal regulation or review of mail order pharmacies as far as their activities in distributing prescription drugs to legitimate consumers. No entity has the ability to control or compel compliance with, or information from, the mail order pharmacy industry. The only entity regulating mail order pharmacies is the individual state regulatory or licensing board of the state in which each mail order pharmacy is physically located.

3. States do not agree as to whether they have the ability to regulate mail order pharmacy. The majority of states conclude that they do have the ability to regulate, citing the states' inherent powers to protect the health, safety, and welfare of their citizens. However, some believe that states do not have this ability, citing federal preemption and Commerce Clause considerations.

4. Mail order pharmacies challenge the ability of states other than their home states to regulate them. They find particularly burdensome the requirement that they comply with laws other than those of their home state. To the extent that any regulation is deemed tolerable, a statute that merely requires registration is preferred. California's statute was cited by one mail order company as acceptable.

5. Local pharmacies find that some of their business is going to mail order pharmacies, and that in general, this amount is increasing. There is considerable animosity between mail order pharmacies and local pharmacies nationwide. Each side has participated in studies and given testimony that favors its own position. In Hawaii, half of the local pharmacists responding to a Bureau survey find that the impact of mail order pharmacy on their businesses is moderate or severe. Well over half have had to help customers who have

had trouble with their mail order prescription, including customers who have received the wrong drug, the wrong dosage or amount, or who have received the drug late.

6. Local pharmacists are bitter over insurance and third party payor requirements that they feel compel customers to use mail order instead of local pharmacies. These incentives include allowing customers to get up to a ninety-day supply through the mail, as opposed to a three week supply locally.

7. In response to the survey, some local pharmacies listed prices that were competitive with Allscrips (the Sears mail order plan), and the AARP Pharmacy service. However, the mean prices for local pharmacies was higher.

8. Some now question whether the short-term cost of drugs should be the ultimate criteria for determining cost-effectiveness, and suggest that local pharmacies, despite charging a generally higher cost for drugs, actually keep the bottom line on overall health costs down due to their ability to consult with and monitor their customers in person.

9. Safety statistics for mail order are unclear: most studies rely on anecdotes and testimonials.

10. The type of regulation suggested in this study does not appear to be likely to drive mail order business out of the State or limit the options available to the consumer. As major mail order companies already doing business in the State already comply with the state drug laws, provide or are in the process of providing a 24-hour telephone line for consultations, and comply with California's Nonresident Pharmacy Act, this regulation should not prove to be unduly burdensome. Conversely, this type of regulation would not place local pharmacies at an unfair competitive advantage.

Recommendations

1. As safety data are unclear and as the potential dangers with prescription drugs errors are so great, the State should adopt some type of regulation for mail order pharmacies doing business in Hawaii.

2. The issue of cost savings is important as prescription drug prices are one of the fastest-rising health costs. However, one new issue in this area is the question of whether local pharmacies, with their generally higher up-front costs,

may actually lead to long-term cost savings due to their ability to more closely monitor the customer. To the extent to which the ultimate bottom-line on savings is uncertain, the State may wish to consider restructuring its pharmacy benefit to remove disincentives to the use of local pharmacies.

3. Regulation of mail order pharmacies, based on the California model, is reasonable, as testified to by the AARP Pharmacy Services. Additional reasonable requirements for Hawaii are a toll-free consultation number with hours that are reasonable for Hawaii, and compliance with Hawaii's generic drug substitution law and drug formulary law except where they may directly conflict with the mail order pharmacy's home state's statutes. To the extent that the Legislature and the Department of Health made the effort to enact these laws to protect Hawaii residents, these laws are important and they should be extended to cover all Hawaii residents. Not to do so might cause two classes of care: one for those able to afford local pharmacy prices, and a lesser standard for those forced to use mail order. It should be noted that the State's own prescription drug plan contains these requirements. Other residents deserve the same degree of protection.

HOUSE OF REPRESENTATIVES
SIXTEENTH LEGISLATURE, 1992
STATE OF HAWAII

H.C.R. NO. 403

HOUSE CONCURRENT RESOLUTION

REQUESTING A COMPREHENSIVE REVIEW OF THE COMMERCIAL PRACTICES AND REGULATION OF OUT-OF-STATE PHARMACIES.

WHEREAS, the Legislature finds that current statutes prohibit the Board of Pharmacy from regulating the commercial practices of out-of-state pharmacies or entities engaged in the disbursal of prescriptive drugs or devices into the State; and

WHEREAS, proponents of regulatory controls on out-of-state pharmacies have noted that consumers have little or no protection should they be given the wrong prescription, faulty products, or require drug counseling as the result of the improper handling of medication by an out-of-state pharmacy; and

WHEREAS, in addition, with the onset of health insurance programs mandating or promoting the use of mail order pharmacies for drug coverage based on cost advantages, it appears that the number of out-of-state pharmacies operating in the State will likely increase in the near future; and

WHEREAS, however, representatives within the pharmaceutical community have noted that the establishment of regulatory controls on out-of-state pharmacies would:

(1) Place an competitive advantage in the marketplace to Hawaii's local retail pharmaceutical industry;

(2) Limit the options available to the consuming public with regard to the purchase of pharmaceutical goods; and

(3) Threaten the livelihood of out-of-state pharmacies based in Hawaii that have provided efficient and problem-free services to the public for decades;

and

WHEREAS, in light of these concerns, the Legislature finds that additional information is needed before a determination can be made regarding whether regulatory controls should be established for out-of-state pharmacies; now, therefore,

BE IT RESOLVED by the House of Representatives of the Sixteenth Legislature of the State of Hawaii, Regular Session of 1992, the Senate concurring, that this body requests the Legislative Reference Bureau to conduct a comprehensive review of the commercial practices and regulation of out-of-state pharmacies; and

BE IT FURTHER RESOLVED that the Legislative Reference Bureau submit a report to the Legislature at least twenty days prior to the convening of the Regular Session of 1993, that shall include, but not be limited to:

(1) A survey of the laws used by other states to regulate the commercial operations of out-of-state pharmacies;

(2) An assessment of the need for similar laws in the State of Hawaii;

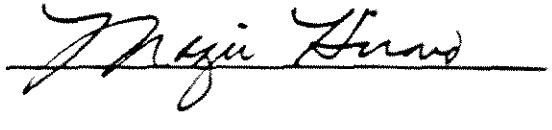
(3) A cost analysis of the ramifications of potential regulatory controls for out-of-state pharmacies on both out-of-state business conduction operations in Hawaii and the local retail industry;

(4) An analysis of the impacts the establishment of such laws would have on group insurance coverages for drugs and other medications, as well as on the operations of health maintenance organizations; and

(5) Proposed legislation it deems necessary to address this issue;

and

BE IT FURTHER RESOLVED that certified copies of this Concurrent Resolution be transmitted to the Director of the Legislative Reference Bureau; the Director of Commerce and Consumer Affairs; the Chair of the Board of Pharmacy; and to the President of Benefit Plan Consultants (Hawaii), Inc.

OFFERED BY: 

Appendix B

H. B. NO. 3027

A BILL FOR AN ACT

RELATING TO MISCELLANEOUS PERMITS FOR PHARMACY

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

SECTION 1. Section 461-15, Hawaii Revised Statutes, is amended to read as follows:

"§461-15 Miscellaneous permits. (a) It shall be unlawful:

(1) For any person to sell or offer for sale at public auction, or to sell or offer for sale at private sale in a place where public auctions are conducted, any drugs without first having obtained a permit from the board of pharmacy to do so;

(2) For any person to in any manner distribute or dispense samples of any drugs or medical supplies without first having obtained a permit from the board to do so; provided that nothing in this paragraph shall interfere with the furnishing of samples or drugs directly to physicians, druggists, dentists, veterinarians, and optometrists for use in their professional practice;

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(3) For wholesalers to sell, distribute, or dispense any drug, except to a pharmacist, physician, dentist, veterinarian, or optometrist who is allowed to use pharmaceutical agents under chapter 459 or to a generally recognized industrial, agricultural, manufacturing, or scientific user of drugs for professional or business purposes; provided that it shall be unlawful for wholesalers to sell, distribute, or dispense any pharmaceutical agent which is not listed under section 459-15 to any optometrist; [and]

(4) For any person, as principal or agent, to conduct or engage in the business of preparing, manufacturing, compounding, packing, or repacking any drug without first having obtained a permit from the board to do so[.]; and

(5) For any out-of-state pharmacy or entity engaging in the practice of pharmacy to in any manner distribute, ship, mail, or deliver prescription drugs or devices into the State of Hawaii without first having obtained a permit from the board to do so in accordance with the following:

(A) On evidence satisfactory to the board a permit may be issued; provided that:

(i) The applicant or any personnel of the applicant has not been found in violation of any state or federal drug laws including the illegal use of drugs and improper distribution of drugs;

(ii) The out-of-state pharmacy has in its employ, a registered pharmacist whose registration is current and in good standing;

(iii) The out-of-state pharmacy provides to the board and the consumers, a twenty-four hour toll-free number for accessibility to a pharmacist who is an employee of the out-of-state pharmacy; and

(iv) The out-of-state pharmacy agrees that the pharmacy operation dispensing the prescription for a Hawaii resident shall abide by the standards of practice established by the board's laws and rules.

(B) The board may require a person to obtain a permit for each separate location from which the person is operating and application shall be

made on a form provided by the board.

(b) The board may adopt rules not inconsistent herewith to establish additional requirements for permits.

(c) A person whose application for a permit has been denied may file for an administrative hearing in conformity with chapter 91."

SECTION 2. Section 461-16, Hawaii Revised Statutes, is amended to read as follows:

"**§461-16 Fees for permits; renewal.** (a) The board shall collect application and permit fees for each permit to operate a pharmacy and a fee for the issuance of a permit in accordance with section [461-15(1) or (4).] 461-15(a)(1),(4), and (5).

(b) Permits issued under sections 461-14 and 461-15 shall be conspicuously displayed in the place for which the permit was granted. The permits shall not be transferable, shall expire on December 31 of each odd-numbered year following the date of issuance, and shall be renewed biennially.

(c) The holder of an expired permit may have the same restored within three years of the date of expiration upon due application therefore and payment of the delinquent fees and a penalty fee[.]; provided that the holder of the expired permit meets the requirements for the renewal of permits."

SECTION 2. Statutory material to be repealed is bracketed. New statutory material is underscored.

SECTION 3. This Act shall take effect upon its approval.

INTRODUCED BY: _____

CCA-24(92)

HOUSE OF REPRESENTATIVES
SEVENTEENTH LEGISLATURE, 1993
STATE OF HAWAII

H.B. NO.

A BILL FOR AN ACT

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

SECTION 1. Chapter 461, Hawaii Revised Statutes, is amended by adding a new part to be appropriately designated and to read as follows:

"PART II.

NONRESIDENT PHARMACIES

§461-1 Disclosure. A nonresident pharmacy shall register with the board and provide the following information:

(1) The location, names, and titles of all principal corporate officers and all pharmacists who are dispensing prescription drugs to state residents. The report shall be submitted annually on a schedule to be determined by the board and shall be updated annually and within thirty days after any change of office, corporate officer, or pharmacist;

(2) That it is in full compliance with all lawful directions and requests for information from the regulatory or licensing agency of its home state, as well as all requests for information made by the board under this section. The nonresident pharmacy shall

maintain at all times a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws of its home state. As a prerequisite to registering with the board or submitting its annual report, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of its home state;

(3) That it maintains its records of prescription drugs dispensed to patients in this State so that the records are readily retrievable from the records of other prescription drugs dispensed; and

(4) That neither the applicant nor any personnel of the applicant have been found in violation of any state or federal drug law, including laws concerning the illegal use of drugs or the improper distribution of drugs.

(b) Every nonresident pharmacy shall provide a toll-free telephone number for patient consultation with a licensed pharmacist who has access to the consumer's records between the hours of 8 a.m. and 5 p.m. Monday through Friday, and 8 a.m. to noon on Saturday and Sunday, Hawaii Standard Time. This toll-free number and its hours of operation shall be disclosed on a

label affixed to each container of drugs dispensed to patients in this State.

(c) Every nonresident pharmacy shall abide by Hawaii's drug product selection law, section 328-92, Hawaii Revised Statutes, and by Hawaii's drug formulary as established by the department of health, to the extent that they do not violate any statute of the nonresident pharmacy's home state.

(d) The board shall establish and collect application, permit, and renewal fees for nonresident pharmacies.

(e) Any person violating this part or the rules duly prescribed under it by the board of pharmacy shall be subject to sections 461-17 and 461-18.

(f) A person whose application for a permit or for a renewal has been denied may file for an administrative hearing under chapter 91.

§461- Advertising. It is unlawful for any nonresident pharmacy not registered under this part to advertise its services in this State, or for any state resident to advertise the pharmacy services of a nonresident pharmacy that is not registered under this part, with the knowledge that the advertisement will or is likely to induce members of the public in this State to use the pharmacy to fill prescriptions.

Violation of this section shall subject the violator to a fine of not more than $500, or imprisonment for not more than six months, or both. This section shall be enforced by the department of the attorney general.

§461- Disciplinary action. (a) The board may deny, suspend, or revoke any nonresident pharmacy registration for failure to comply with the requirements of this part. The board may also impose an administrative penalty of up to $500 per violation for each violation of section 328-92 or of Hawaii's drug formulary. The only defense for these violations shall be that compliance would violate a statue of the nonresident pharmacy's home state.

(b) The board may deny, suspend, or revoke any nonresident pharmacy registration for conduct that causes serious physical or serious psychological injury to a resident of this State, if:

(1) Within forty-five days after a written referral by the board to the home state's regulatory or licensing agency, the home state fails to initiate an investigation; or

(2) After initiation of an investigation within forty-five days after referral, the home board finds culpability on the part of the nonresident pharmacy."

SECTION 2. Section 461-1, Hawaii Revised Statutes, is amended by adding the definitions of "home board", "nonresident pharmacy", "prescription drug", and "resident pharmacy" to read as follows:

"'Home board' means the regulatory or licensing agency that regulates a nonresident pharmacy in the state in which it is physically located."

"'Nonresident pharmacy' means a pharmacy located outside this State that ships, mails, or otherwise delivers prescription drugs to residents in the State."

"'Prescription drug' means any drug available only by prescription."

"'Resident pharmacy' means any pharmacy located within the State."

SECTION 3. Section 461-14, Hawaii Revised Statutes, is amended by amending subsection (a) to read as follows:

"(a) It shall be unlawful for any person to operate, maintain, open, change location, or establish any pharmacy within the State, or do business as a nonresident pharmacy in this State, without first having obtained a permit from the board."

SECTION 4. Chapter 461, Hawaii Revised Statutes, is amended by designating section 461-1 to 461-22 as:

"PART I.

RESIDENT PHARMACIES"

SECTION 5. New statutory material is underscored.

SECTION 6. This Act shall take effect upon its approval.

Appendix D

CONFIDENTIAL SURVEY

The State Legislature has requested the Legislative Reference Bureau to study the issue of regulating mail order pharmacies (MOPs). Your input can be an important part of this study. Please take a few minutes to answer this questionnaire and return it to the Bureau in the enclosed stamped envelope by October 23. Your confidentiality will be respected and you will not be identified in the report.

Please answer the questions below by circling the letter of the answer that best describes you or your opinion. Do not circle more than one answer per question, unless noted otherwise.

1. Are you an:

   a. Independent pharmacy
   b. Chain (more than ten)

2. Do you believe that you lose business to MOPs?

   a. Yes
   b. No (If "No", go to Question No. 7)

3. If yes, can you estimate how may prescriptions per week you lose to MOPs?

   a. 0
   b. 1-10
   c. 11-20
   d. 21-30
   e. Over 30
   f. Can't estimate

4. Is this impact on your business:

   a. Severe
   b. Moderate
   c. Slight
   d. None

5. If you feel that you are losing prescriptions to MOPS, compared to one year ago, are you losing:

   a. More
   b. Fewer
   c. The same

6. If you feel that you are losing prescriptions to MOPs, compared to two years ago, are you losing:

   a. More
   b. Fewer
   c. The same

7. Which MOP is your biggest competitor?

   a. Veteran's Administration (VA)
   b. American Association of Retired Persons (AARP)
   c. For-profit companies
   d. Other (specify)_____

8. *Why do you feel that customers choose mail order?*

   a. Cost
   b. Convenience
   c. Financial incentives
   d. Reliability or safety
   e. Other _____
      _____
      _____

   If it is due to cost, what factors reduce the price for MOPs or raise the price for your pharmacy?

   _____
   _____
   _____

9. Have customers ever contacted your store with questions relating to their mail order prescription?

   a. Yes
   b. No (If "No", go to Question No. 11)

   If yes, how often? _____

10. *Which, if any, errors in MOP prescriptions have been brought to your attention by your customers?* Circle all that apply.

    a. Wrong medication sent (No. of reports _____)
    b. Incorrect strength of medication (No. of reports _____)
    c. Incorrect amount of medication (No. of reports _____)
    d. Tardiness in receiving medication (No. of reports _____)
    e. Other _____
       _____
       _____

11. Do you ever mail prescriptions to your customers?

a. Never
b. Rarely
c. Occasionally
d. Frequently

12. Is there a place for mail order pharmacy in the health care scene?

a. Yes
b. No

13. Do you think that the State of Hawaii should regulate MOPs?

a. Yes
b. No

If yes, what requirements should the State impose?

_____
_____
_____
_____

What are your prices for the following medications:

14. $_____ Premarin 0.625 mg (100 tabs)
15. $_____ Seldane 60 mg (20 tabs)
16. $_____ Lopid 600 mg (60 tabs)
17. $_____ Zantac 150 mg (60 tabs)
18. $_____ Proventil Inhaler 17 g
19. $_____ Procardia XL 30 mg (30 tabs)
20. $_____ Tenormin 50 mg (30 tabs)
21. $_____ Mevacor 20 mg (30 tabs)
22. $_____ Provera 2.5 mg (30 tabs)
23. $_____ Dyazide (100 tabs)

Thank you for your time and cooperation. Please include any additional comments on the back of this sheet. If you have any questions, please call Susan Jaworowski or Ken Takayama at 587-0666.

act for a specified reason.

Appropriation: yes.

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

SECTION 1. (a) The Legislature finds and declares that the practice of pharmacy is a dynamic, patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use and drug related therapy.

(b) The Legislature recognizes that with the proliferation of alternate methods of health delivery, there has arisen among third-party payers and insurance companies the desire to control the cost and utilization of pharmacy services through a variety of mechanisms, including the use of mail order pharmacies located outside the State of California.

(c) As a result, the Legislature finds and declares that to continue to protect the California consumer-patient, all out-of-state pharmacies that provide service to California residents shall be registered with the board, disclose specific information about their services, and provide pharmacy services at a high level of protection and competence.

SEC. 2. Section 4050.1 is added to the Business and Professions Code, to read:

4050.1. (a) Any pharmacy located outside this state which ships, mails, or delivers, in any manner, controlled substances or dangerous drugs or devices into this state shall be considered a nonresident pharmacy, shall be registered with the board, and shall disclose to the board all of the following:

(1) The location, names and titles of all principal corporate officers and all pharmacists who are dispensing controlled substances or dangerous drugs or devices to residents of this state. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, or pharmacist.

(2) That it complies with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident pharmacy shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

(3) That it maintains its records of controlled substances or dangerous drugs or devices dispensed to patients in this state so that the records are readily retrievable from the records of other drugs

dispensed.

(b) Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.

(c) The registration fee shall be the fee specified in subdivision (a) of Section 4416.

(d) The registration requirements of this section and Sections 4350.6 and 4363, shall apply only to a nonresident pharmacy which only ships, mails, or delivers controlled substances and dangerous drugs and devices into this state pursuant to a prescription.

SEC. 3. Section 4084.6 of the Business and Professions Code is amended to read:

4084.6. No out-of-state manufacturer, wholesaler, or pharmacy doing business in this state who has not obtained a certificate, license, permit, registration, or exemption from the board and who sells or distributes drugs in this state through any person or media other than a wholesaler who has obtained a certificate, license, permit, registration, or exemption pursuant to the provisions of this chapter or through a selling or distribution outlet which is licensed as a wholesaler pursuant to the provisions of this chapter, shall conduct the business of selling or distributing drugs in this state without obtaining an out-of-state drug distributor's license from the board or registering as a nonresident pharmacy.

Applications for an out-of-state drug distributor's license or a nonresident pharmacy registration, under this section shall be made on a form furnished by the board. The board may require such information as the board deems is reasonably necessary to carry out the purposes of the section.

The board may deny, revoke, or suspend such out-of-state distributor's license for any violation of this chapter or for any violation of Division 21 (commencing with Section 26001) of the Health and Safety Code. The license or nonresident pharmacy registration shall be renewed annually on or before the first day of January of each year.

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

The Legislature, by enacting this section, does not intend a license or nonresident pharmacy registration, issued to any out-of-state manufacturer, wholesaler, or pharmacy pursuant to this section to

serve as any evidence that such out-of-state manufacturer, wholesaler, or pharmacy is doing business within this state.

SEC. 4. Section 4350.6 is added to the Business and Professions Code, to read:

4350.6. (a) The board may deny, revoke, or suspend a nonresident pharmacy registration for failure to comply with any requirement of Section 4050.1 or 4353 or for any failure to comply with Section 11164 of the Health and Safety Code.

(b) The board may deny, revoke, or suspend a nonresident pharmacy registration for conduct which causes serious bodily or serious psychological injury to a resident of this state if the board has referred the matter to the regulatory or licensing agency in the state in which the pharmacy is located and the regulatory or licensing agency fails to initiate an investigation within 45 days of the referral. The board shall obtain and maintain a record of referrals pursuant to this subdivision and any action taken thereon and shall report its findings to the Legislature on or before March 31, 1991.

This section shall be operative until January 1, 1992, and as of that date, is repealed unless a later enacted statute deletes or extends that date.

SEC. 5. Section 4350.6 is added to the Business and Professions Code, to read:

4350.6. The board may deny, revoke, or suspend a nonresident pharmacy registration for failure to comply with any requirement of Section 4050.1 or 4353 or for any failure to comply with Section 11164 of the Health and Safety Code.

This section shall become operative on January 1, 1992.

SEC. 6. Section 4353 is added to the Business and Professions Code, to read:

4353. It is unlawful for any nonresident pharmacy which is not registered pursuant to Section 4050.1 to advertise its services in this state, or for any person who is a resident of this state to advertise the pharmacy services of a nonresident pharmacy which has not registered with the board, with the knowledge that the advertisement will or is likely to induce members of the public in this state to use the pharmacy to fill prescriptions.

SEC. 7. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs which may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, changes the definition of a crime or infraction, changes the penalty for a crime or infraction, or eliminates a crime or infraction.

Appendix F

FROM Arkansas Board Regulations, Board Reg. 41.

Out-of-State pharmacies shall comply with the following qualifications to be and remain licensed in Arkansas by the Board.

1. A. The pharmacy holds a current license in good standing in the state(s) in which it is located.

B. Each pharmacist dispensing drugs into Arkansas shall be licensed as a pharmacist in Arkansas or in the State where he practices if that State has standards of licensure at least equivalent to those of Arkansas.

2. A pharmacist licensed in Arkansas or by the state where he practices having standards of licensure at least equivalent to Arkansas standards shall be named in the application as the pharmacy's contact person for communications by the Board.

A. That pharmacist will be responsible for receiving and maintaining publications distributed by the Board.

B. If at anytime the pharmacist so designated shall leave the employment of the pharmacy or be absent from the pharmacy in excess of 14 consecutive calendar days, the pharmacy shall promptly notify the Board and designate another pharmacist to perform this function.

3. The out-of-state pharmacy shall apply for licensure and renewal on forms approved by the Board. The Board may require such information as reasonably necessary to carry out the provisions of A.C.A. 17-91-401, including, without limitation, the name, address and position of each officer and director of a corporation or of the owners if the pharmacy is not a corporation.

Provided, however, the Board may grant an exemption from licensing under A.C.A. 17-91-401 upon application by any non-resident pharmacy which confines its dispensing activity to isolated transactions. In determining whether to grant an exemption, the Board shall consider:

(a) The number of prescriptions dispensed or reasonably expected to be dispensed into Arkansas.

(b) The number of patients served or reasonably expected to be served in Arkansas.

(c) Whether the pharmacy has promoted its services in Arkansas.

(d) Whether the pharmacy has a contract(s) with any employer(s) or organization(s) to provide pharmacy services to employees or other beneficiaries in Arkansas.

(e) Medical necessity.

(f) The effect on the health and welfare of persons in Arkansas.

(g) Any other relevant matters.

4. The pharmacy shall pay an annual license fee of $100.00.

5. The pharmacy shall maintain records of drugs dispensed to Arkansas addresses in such a manner so as to be readily retrievable upon request. Said records shall be made available for inspection by the Board or by Arkansas law enforcement authorities.

6. The pharmacy shall timely respond to any request for information from the Board or law enforcement authorities.

7. The pharmacy shall maintain an incoming toll free telephone number for use by Arkansas customers to be answered by a pharmacist with access to patient records This service shall be available a minimum of 40 hours a week, six days per week during normal business hours. This telephone number plus others available for use shall be printed on each container of drugs dispensed into Arkansas. The toll free number shall have sufficient extensions to provide reasonable access to incoming callers.

8. Generic drugs shall be dispensed into Arkansas pursuant to the Arkansas Generic Substitution Act; provided, however, nothing herein shall be construed to mandate that an out-of-state pharmacy comply with the Arkansas Generic Substitution Act if such compliance would cause the out-of-state pharmacy to violate the generic substitution act of the state wherein the facility of the dispensing out-of-state pharmacy is located.

9. The facilities and records of the pharmacy shall be subject to inspection by the Board: provided, however, the Board may accept in lieu

thereof satisfactory inspection reports by the licensing entity using similar standards of the State where the pharmacy is located.

10. Each out-of-state pharmacy doing business in Arkansas by dispensing and delivering or causing to be delivered prescription drugs to Arkansas consumers shall designate a resident agent in Arkansas for service of process.

(2/14/85) (Revised 12/12/86 & 10/9/90)