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

Communication and Public Education Committee Report

Ken Schell, PharmD, Chair
Bill Powers, President and Board Member
Hank Hough, Board Member
Andrea Zinder, Board Member

Report of the
Communication and Public Education Committee Meeting of April 3, 2007

And a Report of the
Forum on Medicare Drug Benefit Plans Meeting of February 1, 2007
and
Forum on Medicare Drug Benefit Plans Meeting of March 30, 2007

The Communication and Public Education Committee met April 3, 2007. Minutes from this meeting are provided in **Attachment A**.

1. Discussion and Action on the Board's Public Forums on Medicare Prescription Drug Plans

a) Meeting Summaries of the February 1, 2007 and March 30, 2007 Forums on Medicare Drug Benefit Plans

FOR DISCUSSION AND ACTION:

A forum on the Medicare Drug Benefit, which was created, with the Medicare Modernization Act (MMA) was held on February 1, 2007, during the second day of the Board Meeting. Minutes of this meeting are provided in **Attachment 1**.

Although the board allocated 2.5 hours for this discussion, it was insufficient time for all those present to speak. As a result, the board scheduled a second forum, which was held on March 30 in Los Angeles, and was scheduled for six hours. Minutes of this meeting are provided in **Attachment 2**.

Since 2006 when the prescription drug benefit was established under the MMA, there have been problems for some patients getting their medicine. The board, as a consumer protection agency, has fostered discussion among patient advocates, stakeholders and policymakers to resolve problems and to benefit patients.

Although generally the belief is that the program is working better than when initially implemented in January 2006, there remain problems that prevent patients from getting necessary care timely, with an impact on higher health care costs, delayed therapy and impaired health.

Over the six meetings the board has convened in this area since January 2006, the board has facilitated discussions that have aided some patients. However, those who have heard the discussions believe there are still problems that can and should be corrected.

Some of the issues that have been brought to the board's attention are:

- 1) Prior authorization requirements that delay patient drug therapy – if the pharmacy doesn't provide the medicine before knowing whether it will be reimbursed, patients may wait 3-5 days for before a medicine is authorized (which may not be the one initially prescribed)
- 2) Poor "coverage" information for billing
- 3) Co-pay problems in skilled nursing facilities, where patients are told to make copayments
- 4) Plans changing formularies and creating coverage problems
- 5) Multiple formularies and physician prescribing that does not correspond to a formulary
- 6) Poor continuity of care when a patient is discharged from an acute hospital on "non-covered" drugs, impacting the patient's drug therapy and health
- 7) Poor understanding of IV product/coverage/billing by plans (and therefore determining such services are "not covered" with the resultant care problems for patients, or continued hospitalization until the coverage is secured)
- 8) Poor "timely" response by plans to the pharmacy when the law requires in a skilled nursing facility a 1-hour or 4-hour delivery of medication under Title XXII
- 9) Requirements that physicians must do prior authorizations (not allowing the pharmacist to do this, which further delays therapy for patients, and redirects pharmacies to additional phone calls, away from other care functions)
- 10) Drugs on plan formularies that are "not" geriatric friendly" per federal and state regulations and guidelines.

As a consumer protection agency, the board's role is to aid patients in getting their prescribed medicine timely. At this meeting, the board should be prepared to discuss what actions it seeks to take in this area.

2. Report and Action of Items Discussion at the Communication and Public Education Committee Meeting of April 3, 2007

Note: The Communication and Public Education Committee met April 3, 2007. Minutes from this meeting are provided in Attachment A.

A. Update of the Committee's Strategic Plan for 2007-08

FOR RECOMMENDED ACTION:

Approve the committee's strategic plan for 2007-08 by adding two activities to Objective 4.1 "Develop a minimum of 10 communication venues to the public by June 30 2011"; specifically, to add:

- 6. Evaluate the practice of pill splitting as a consumer protection issue.**
- 7. Evaluate the SCR 49 Medication Errors Report for implementation.**

At this Board Meeting, each of the board's strategic committees will provide a report to the board on the need to amend the committee's respective strategic plan for relevance and currency.

Staff have identified two recommendations to amend the plan of the Communication and Public Education Committee, but because there were only two committee members present at the April 3, 2007 Meeting, no formal recommendation for action to the board was made.

A copy of the committee's strategic plan with the two proposed changes is provided in **Attachment 3**.

A motion and second will be needed to take action on this item.

B. Discussion on Pill Splitting by Patients

FOR INFORMATION :

At the January 2007 Board Meeting, the board heard a discussion on pill splitting. This presentation was initiated by Charles Phillips, MD, an emergency room physician, who indicated that he is concerned with the practice of pill splitting and the resultant crumbled residue of drug product in the bottom of pill containers. He stated the practice of pill splitting is a problem because pills do not split evenly, and patients get uneven doses of medicine. He has asked the board to initiate steps to prohibit pill splitting.

Comments from others in the audience disagreed with Dr. Phillips concerns with pill splitting. As a result, the subject was directed for a more lengthy discussion at both the Legislation and Regulation Committee and the Communication and Public Education Committee.

At the April 3, 2007 Communication and Public Education Committee, Dr. Phillips appeared and provided additional information about pill splitting. The minutes of this meeting detail some of his presentation.

Dr. Phillips stated that because he thought that perhaps the board may not take instant action to prohibit pill splitting, he had developed an "informed consent" sheet that could be provided to patients warning them about the dangers.

Fred Mayer and Sandra Bauer, who also attended the committee meeting, both encouraged the board to prohibit pill splitting.

There were no comments from individuals present in support of pill splitting.

However, as there were only two committee members present at this meeting, no action was voted upon to recommend to the board. However, Dr. Schell suggested that the board:

- 1) Develop a document about the myths and facts involving pill splitting, providing information to the public so they can make informed decisions
- 2) Look at the clinical impact of pill splitting to see if harm is done to patients, and whether patients remain stable (based on clinical outcomes).

(The Legislation and Regulation Committee, which had a shorter presentation by Dr. Phillips due to time constraints, did not recommend action items to the board either.)

At issue for the board is that, in addition to perhaps preparing consumer information on pill splitting, is there other action that the board is interested in pursuing?

- Is there sufficient evidence of harm to the public in the literature to take other steps aimed at curtailing or prohibiting pill splitting?
- Can the board or the California Legislature mandate that manufacturers produce pills at costs that do not result in pill splitting?
- Are there patients who would go without drug therapy if they could not split pills?
- Should consumers have the right to decline to split pills?
- Should patients who are physically unable to split pills be required to split pills?

A number of articles on pill splitting are provided in **Attachment 4**. They are labeled as "pro" or "con."

C. Update on the Development of Consumer Fact Sheet Series with UCSF's Center for Consumer Self Care

FOR INFORMATION:

Three years ago, the board approved a proposal by the committee to integrate pharmacy students into public outreach activities. The project involves UCSF

pharmacy students developing one-page fact sheets on diverse health care topics for public education.

An important objective of the fact sheets was to develop new educational materials for issues that emerge in the health care area and for which there is no or little written consumer information available. This would aid the interns who develop the materials and gain the experience of developing consumer informational materials. It also benefits the board, because it gains an invigorated set of public informational materials that are topical and not generally available.

The UCSF's Center for Consumer Self Care works directly with the students to develop the fact sheets, which are then reviewed by faculty members and then by the board.

The board distributes these fact sheets at community health fairs and has them available online. The fact sheet format is intended to be attractive whether printed or photocopied.

So far, nine fact sheets have been developed in the first year. These fact sheets have been translated by the board into Spanish, Vietnamese and Chinese, and are available on the board's Web site.

The UCSF Center for Consumer Self Care is overseeing this project. Currently underway are final revisions to four fact new sheets first developed in September 2006:

- An Aspirin a Day? . . . Maybe, Check it Out!
- Uncommon Sense for the Common Cold
- Medication Errors Mistakes Happen . . . Protect Yourself!
- Putting the Chill on Myths about Colds and Flu

These fact sheets should be completed and ready for distribution by the July Board Meeting.

Additionally four more fact sheets were provided to the committee for its initial review:

- Falls - with emphasis on medicines that put you at risk - talk to your pharmacist/read the label
- Consumer reporting of adverse drug events - based on the FDA quote,
"Consumers can play an important public health role by reporting to FDA any adverse reactions or other problems with products the Agency regulates. When problems with FDA-regulated products occur, the Agency wants to know about them and has several ways for the public to make reports. Timely reporting by consumers, health professionals, and FDA-regulated companies allows the Agency to take prompt action. FDA evaluates the

reports to determine how serious the problem is, and if necessary, may request additional information from the person who filed the report before taking action."

- Driving when you are taking medicines
- Tips for Parents - read the label (teaspoons and tablespoons, more is not better, ask your pharmacist)
- Allergies to medicines - what to look for, what to do, before purchase, read label/ask your pharmacist, consumer reports to MedWatch current listing on your Web site.

The Center for Consumer Self Care agreed to allow interns from other schools of pharmacy to participate. The executive officer has been approached by two interns at other schools of pharmacy who are interested in developing fact sheets for this project.

C. Update on Activities of the California Health Communication Partnership

FOR INFORMATION:

The board is a founding member of California Health Communication Partnership. This group is spearheaded by the UCSF's Center for Consumer Self Care to improve the health of Californians by developing and promoting consumer health education programs and activities developed by the members in an integrated fashion.

The function of the group is to develop and/or disseminate integrated public information campaigns on priority health topics identified by the partnership members. Other active members of the group are the Medical Board of California, the Food and Drug Administration, CPhA and California Retailers Association. For example, pharmacists, nurses, physicians will receive information from their respective regulatory boards or associations that will mesh with concurrent public outreach efforts.

There have been three major campaigns since the formation of the group about three years ago. The last major campaigns have focused on cancer screening, which aimed at educating the public about the need for and importance of breast cancer or prostate cancer screening. Outside funding from a private foundation enabled the use of a vendor that specializes in distributing prewritten consumer columns for small and typically weekly newspapers. There were also public service announcements intended for airing on radio. This greatly expands the exposure and reach of the campaign.

There has not been a meeting of the partnership in the last three months. The Center for Consumer Self Care reaffirmed its support for developing additional outreach campaigns in the future, and hope to find a means to finance them.

E. Update on *The Script*

FOR INFORMATION:

The January 2007 issue of *The Script* was published and mailed to pharmacies and wholesalers in January.

The next issue of the newsletter is being developed for publication for July 2007. It will focus on new regulations and implementation issues in Pharmacy Law.

E. New Board Web Page Under Development

In July 2006, the board completed its redesign of the board's Web page to conform to the parameters established by the Governor's Office. This completed a process started about a year before to redesign the Web page so it looked like those of other state agencies.

The Governor's Office recently developed requirements for a new look to state government's Web pages. So the board will redesign its Web page again to conform to the new look for state agency Web pages. The deadline for conversion to the new format is November 2007.

Staff has begun work on the new format, and should meet the November deadline. This time the board will be at the leading edge of the conversion, instead of being among the last to convert to the new format.

Attachment 5 contains the new format.

G. Development of New Consumer Brochures

FOR INFORMATION:

Since the arrival of a consumer outreach analyst, the board is moving ahead with new materials. An update of work underway is:

- *Board of Pharmacy Informational Brochures*
Ms. Abbe has revised two brochures about the board – one is an overview of the board, the other is information about filing a complaint with the board. These manuscripts will be converted into final brochures in the next quarter.

Currently under development are:

- *Prescription Drug Discount Program for Medicare Recipients*
The board has started revision of the "Prescription Drug Discount Program for Medicare Recipients" brochure that was developed in response to SB 393 (Speier, Chapter 946, Statutes of 1999). This state program allows Medicare recipients to obtain medications at the MediCal price if the patients pay out of pocket for the medication. The brochure needs to be

meshed with the Medicare Part D Plan benefits that became available to beneficiaries in 2006.

- Informational Fact Sheets for Applicants

While the following information is available to applicants who read the pharmacist examination application materials, some applicants do not read this information or retain it.

- Information about applying for the CPJE or a California intern pharmacist license specifically for pharmacists licensed in other states
- Information about how foreign graduate can qualify for a pharmacist license in California

Information on Preventing Prescription Errors

The staff will develop a section of its Web site into a resource on preventing medication errors. The board has been actively involved in a number of activities aimed at reducing errors, including the quality assurance program requirements mandating pharmacies to evaluate every prescription error. The Web site will include data such as that presented at the July 2006 Board Meeting on prescription error data identified by the board through investigations of consumer complaints. It will also include information from other sources, such as ways to prevent errors and frequently confused drug names. It will have links to Web sites and other material as well.

F. Update on Public Outreach Activities

FOR INFORMATION:

From January through April, 2007, the board provided six presentations to professional associations and meetings, and staffed a booth at two information fairs.

A detailed list of the board's public outreach activities this quarter is provided in **Attachment 6**.

G. Consumer Interest Articles in the Media

FOR INFORMATION:

Attachment 7 contains copies of articles of consumer interest that are not under review by one of the board's other strategic committees.

H. Meeting Summary

FOR INFORMATION:

A summary of the Communication and Public Education Committee Meeting held April 3, 2007, is provided in **Attachment A**.

Attachment 1

*Minutes of the February 1, 2007
Forum on Medicare Drug Benefit
Plans*

*(Held during the January 31 and
February 1, 2007 Board Meeting)*



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Public Forum on Medicare Part D Plans
Summary of the Meeting February 1, 2007
9:00 am – 11:35 a.m.

BOARD

MEMBERS PRESENT: William Powers, President
Stanley Goldenberg, RPh, Chairperson
Kenneth H. Schell, PharmD
Ruth M. Conroy, PharmD
D. Timothy Dazé
Clarence K. Hiura, PharmD
Henry Hough
Susan L. Ravan, PharmD
Robert E. Swart, PharmD
Andrea Zinder

STAFF

PRESENT: Virginia Herold, Executive Officer
Karen Cates, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Joan Coyne, Supervising Inspector
Judi Nurse, Supervising Inspector
Joshua Room, Deputy Attorney General
Anne Sodegren, Legislation and Regulation Manager
Gloria Schultz, Administrative Assistant

President William Powers opened the meeting at 9:00 a.m. Mr. Powers observed that the Medicare Drug Benefit Plan was one of the most important changes in the history of the Medicare program since its inception in the 1960s. The Board of Pharmacy believes that it is important to hold these public forums to allow stakeholders to discuss how the Medicare Drug Benefit program is operating, their concerns with the program and those issues impacting the quality of services being provided to California patients.

President Powers reported that the board's subcommittee on the Medicare Drug Benefit Plan has been meeting for about a year and that committee members have heard testimony from various stakeholders on the concerns, problems, and successes of the program. Chairperson Goldenberg then thanked the members in the audience for their attendance and stated that the board wants to bring resolution to some of the problems

brought before the subcommittee over the last year. He announced the meeting format of forum and that long term care representatives would make the first presentations.

Don Amorosi of Omnicare, Inc. thanked the board for holding the forum and stated that he and his colleague, Mary Lou Gradisek, will be presenting a PowerPoint presentation on the Medicare Part D challenges facing long term care (LTC). He provided a copy of LTC patient protections from Omnicare contracts with Part D plans, many of which were adopted by the Centers for Medicare and Medicaid Services (CMS) as part of its 2007 transition plan. He also provided copies of CMS memos concerning Part D transition of care policy and expectations for the 2007 contract year and "Best Available Data" policies for reconciling CMS low income subsidy status.

Mr. Amorosi's presentation centered around the Part D landscape in California and the challenges that face long term care under Medicare Part D in the areas of transition of care, long term care infusion therapy co-pays and subsidies, and recommended best practices. He included a brief overview of Omnicare's long-term care role in California, the shift in payer mix and the top five plans that service the institutionalized in California.

Mary Lou Gradisek then spoke on the CMS LTC transition policy changes for 2007 and the impact of these changes and the transition policy for LTC. She focused on emergency fills, multiple fills of non-formulary drugs and "refill too soon" limitations, prior authorization requirements for IV therapy medications, and best billing practices for IV therapy. Ms. Gradisek stated that the intent of the CMS transition policy is to make sure that the needs of a LTC patient are specifically addressed and that enrollees have enough time to receive the drugs that are prescribed by the physician and for those drugs that are not covered by the plan, that there is time available for an enrollee to acquire additional documentation, to change to a covered alternate or for the pharmacy to work with the physician to provide the documentation that justifies the medical need for those prescriptions.

Mr. Amorosi then provided a background on issues pharmacies are facing with co-payments and the inability of providing timely information to CMS and the plans regarding full subsidy eligibility for long term care patients. He stated that LTC patients have a combination of Medicaid and Medicare eligibility and are not subject to co-payments. However, there is a delay in getting that LTC eligibility information to CMS and the pharmacies are required by the plans to collect a co-payment before the medication is dispensed. Once a patient's dual eligibility is verified, the plans do not have a legitimate process in place, such as electronic submission capability, to retroactively update the system to reimburse pharmacies for the co-payments. Mr. Amorosi added that CMS has issued best available data guidelines for use at the point of dispensing to determine full-benefit dual eligibles and other low-income subsidy eligible individuals.

In summary, pharmacy liability for co-pays must be resolved, best practices include adoption of already defined industry standards and the continuity of LTC service models requires unique patient protections.

President Powers introduced Charlene Zettel, Director of the Department of Consumer Affairs. Director Zettel thanked the board members for their work and the contribution they make to the patients and consumers of California. She added that Governor Schwarzenegger is committed to increased access to health care and coverage for all Californians, and the Department of Consumer Affairs looks forward to working collaboratively with the board on outreach for the Medicare Drug Benefit Plans.

President Powers thanked the Director for her comments and invited the next presenter to the podium.

Kim Aksentijenic of Kyffin Pharmacy introduced herself and stated that her pharmacy serves Los Angeles County long-term care and assisted living patients. Ms. Aksentijenic clarified that the Part D program is a real time, point of sale process developed for ambulatory patients who can go to the pharmacy, get their prescriptions and the pharmacist processes a point of sale transaction and obtains a promise of payment from the Part D plan. The LTC environment however does not operate in real time and relies on the facility to provide information as to a patient's eligibility that oftentimes creates a rebilling issue due to erroneous information and the necessity of using clinical staff to resolve reimbursement issues.

Ms. Aksentijenic continued with the issues surrounding LTC prior authorizations and physician approval for prior authorizations. In the LTC environment, the facility, the consulting pharmacist, the dispensing pharmacist and the pharmacy all have the clinical information on a patient. The physician does not have the clinical data available to make a decision so it is a problem when the Part D plans require a physician to be the primary point person in the prior authorization process. Some physicians will not participate in the prior authorization process; this then may result in a LTC patient not getting the medication a physician has ordered. She added that compliance packaging has also proved to be an issue. LTC relies on compliance package to facilitate the patients receiving their medications correctly. A problem arises when a 31-day supply is dispensed, which results in a double co-pay for the patient.

Ms. Aksentijenic concluded by relaying incidents where LTC patients whose medications were previously approved under Part A were unable to receive medications due to Part D plans denying coverage. This denial prohibits a consistent treatment plan and the ability to properly control patient pain.

Chairperson Goldenberg questioned the time it takes to get prior authorizations signed. Ms. Aksentijenic explained the process and responded that she has an employee who processes prior authorizations full-time. She stated that some plans accept the form without a physician's signature and others contact the physician based on information provided on the form. She added that Kyffin is not notified of the approval or denial of a prior authorization. Her employee either has to call the Part D plan or submit a trial claim to determine approval. There is a lack of communication to the pharmacy as the actual provider and caregiver.

Ms. Aksentijenic agreed with Chairperson Goldenberg's comment that if the standardized form provided by CMS was available electronically and that the status of a prior authorization could be checked on-line, a significant amount of time would be saved.

David Solomon of Kyffin also thanked the board on the work they have been doing the past year on Part D and reported on the financial ramifications of Part D. He stated that Kyffin's personnel costs, delivery and receivables costs have increased but its overall business has not increased. He added that Kyffin is trying to deal with these changes while assuring that its clients experience the least amount of change in their daily medication routine. Kyffin has spent an enormous amount of time and money to ensure that prior authorizations are completed, that co-payments are collected and costs are not consistently absorbed. As with other pharmacy caregivers, Kyffin is not forcing the facilities to reimburse for the co-pays or for non-covered charges – especially when an eligibility status occurs retroactively. The pharmacies are absorbing these costs.

Mr. Solomon reported that since 2005 Kyffin Pharmacy has sponsored numerous education outreach programs to their facilities addressing what information is needed by Kyffin from the facilities in order to provide continuation of care to their LTC clients. He noted that there seems to be a lack of support from CMS in this education process.

Chairperson Goldenberg reported he has queried facilities asking what they would do when a pharmacy is faced with a situation where the drug is so expensive they cannot provide it but the doctor feels the care and the medication must continue. The majority of the facilities responded that they would transfer the patient to an acute care hospital, which then creates additional costs and an enormous amount of trauma to an elderly patient. He added that the care of patients is being compromised, the cost of care increases with the changes in Medicare coverage and reimbursement, and the frail elderly patient is subject to trauma if transferred out of the facility. The system has to be resolved so that the frail elderly are not placed in harm's way. He stated that because a response has not been received from the plans and CMS concerning the problems and frustrations the subcommittee has been discussing the last year, the issue is being brought before the full board to address this concern of harm to the frail elderly as it is now time to take action.

Mr. Hough stated that an electronic database, enabling the proper identification of a patient's eligibility status is a key issue towards resolving the points introduced by the speakers. This is an authority matter where direction must be given to mandate the establishment of such a database.

Chairperson Goldenberg introduced representatives of CMS and thanked them for attending the forum and expressed a hope that they would provide a response to these concerns.

Jeff Flick, Regional Administrator for the San Francisco office of CMS, stated he appreciated the opportunity to participate in this forum. He introduced Lucy Saldana, Region 9 pharmacist with CMS. Mr. Flick stated that the information learned in the forum is very beneficial. He added that he feels very good about the Part D Program. Although there is room for improvement; the program has come an incredible distance in one year. Today, in the State of California, 97 percent of the Medicare beneficiaries have comprehensive prescription drug coverage, whereas 14 months ago only about 55 percent of the Medicare beneficiaries enjoyed comprehensive prescription drug coverage. With regard to the LTC portion of the Part D plans, Mr. Flick will take the specific issues and problems discussed in today's forum back to their industry collaborative (ICE), a roundtable of stakeholders who work together to solve Part D problems. In the last year, this collaborative effort has resulted in several policy changes although there are still concerns and issues that are being addressed.

He stated that ICE can address many of the issues discussed here today and he is very interested in pursuing electronic data transmission, keeping in mind the necessity of data security. Mr. Flick added that there are positive aspects to the program such as medication therapy management, e-prescribing and prior authorizations, but the stakeholders must keep working together to realize these benefits without a negative impact. The encouraging aspect is that the entire health care stakeholder community has a history of being able to work together to solve problems and to continue to improve the program.

Mr. Flick acknowledged that it has been difficult getting dedicated physicians for LTC patients who can respond quickly when problems arise. He agreed that nursing homes do need the ability to engage physicians quickly and that perhaps CMS could assist in resolving that problem.

Mr. Goldenberg asked Mr. Flick whether CMS's authority to speak directly to the plans is limited. He added that the feedback that the board is getting from all the stakeholders is that CMS has very little authority over the plans. Mr. Goldenberg asked how the board could be assured that CMS is working with the plans to resolve problems and that plans will listen to CMS.

Mr. Flick responded that CMS works well with the plans through the ICE collaborative efforts. There are times when an issue cannot be resolved through collaboration and cooperation and at these times, CMS does talk with their central office to deal with the specifics. He stated that every plan signs a contract with CMS, the terms of these contracts are very specific and CMS does have a lot of authority over those contracts and will terminate a contract for serious noncompliances. However, CMS does work with a plan to ensure compliance with the Medicare program.

President Powers stated that from listening to the presenters, there are systemic problems in the system that will need to be resolved through the ICE collaborative.

Mr. Flick responded that most of the issues that were raised today could be resolved through ICE. As in the past, CMS has changed policies based on recommendations from the collaborative.

Mr. Goldenberg questioned whether it would be a fair expectation of the board that the ICE collaborative would be discussing problems heard in today's forum and the board could anticipate some timely action by the plans and CMS to remedy these problems and help California's seniors.

Mr. Flick answered that CMS's focus is to work with ICE as a collaborative effort in resolving issues. CMS is not purposely mandating directions and timeframes. He stated that it was important to understand the environment of this collaborative effort – that there are requests from all the stakeholders, including the plans for assistance with certain issues, and that it makes for a better process to have the stakeholders working together.

Dr. Saldana of CMS stated that e-prescribing should resolve many of the issues that were discussed today. E-prescribing is on a fast track and by 2008 the ability for e-prescribing should be in place. There was a question from the board as to whether the health insurance plans would use e-prescribing and electronic databases and if CMS could work towards a legislative mandate to require the use of electronic databases. Mr. Flick responded that CMS does not lobby for legislative change, but he agreed that CMS could communicate to legislators where change is needed. It was commented that if California took the lead in this area, it would assist the Medicare Part D program nationally.

Chairperson Goldenberg announced that Terry Miller of the Department of Health Services would speak next, followed by representatives of the plans.

Dr. Miller reported that as Chairperson Goldenberg stated, that prior to Part D, the pharmacists could submit a treatment authorization request via facsimile through the Medicare program. Currently, with CMS requirements related to Part D, the treatment request must be submitted from the physician which then puts the onus on the physician who is not used to routinely working with the plans. The former system whereby pharmacies pursued authorizations for drug coverage worked well with the Medicaid and Medi-Cal programs in California, and now it is a significant issue for prescribers.

Dr. Miller stated that with respect to emergency drug benefits, the California Legislature approved an emergency drug benefit to assist patients who could not get their medications via the Part D plan for one year. Although this benefit recently expired, the Department of Health Services has seen a significant decrease over the last year in the number of claims submitted to the emergency drug program. Ms. Miller indicated that this decrease indicates a significant improvement in the Part D program. However, she

agreed that there are still issues that need improvement, specifically in the arena of LTC and home infusion.

John Jones from Prescription Solutions stated that his organization serves two large prescription drug programs and that Prescription Solutions is a representative on the ICE collaborative. He stated that it is very difficult for ICE to address an issue on a conceptual basis. ICE works better responding to specific facts where they can develop mechanisms to prevent specific problems from reoccurring. ICE is committed to making the process better.

Mr. Jones stated that they are routinely communicating with CMS and notifying them of problems. He added that CMS does have authority over the plans and the plans performance is considered at the time of contract renewal. Customer service is important to Prescription Solutions, if there is a problem they need to know about it so they can fix it. These board forums and the ICE collaborative provide them with the opportunity to hear the issues. Mr. Jones agreed that e-prescribing would be very beneficial but many physicians are reluctant to go that route. However, by 2008 a financial leverage should be in place where electronic submissions by physicians will be required before payments are made.

Chairperson Goldenberg asked whether Mr. Jones's organization and its affiliates could address electronic connectivity now and not wait for the ICE collaborative. Mr. Jones responded that the Prescription Solutions has a system that is currently working. He added that e-prescribing will move the industry toward an electronic interface. If the board is looking at an interim solution before e-prescribing, Mr. Jones questioned whether that would be a good use of resources as Prescription Solutions has a system in place that is currently working.

Chairperson Goldenberg indicated that the board heard today that the system is not working effectively and there are issues that need to be resolved. Mr. Jones stated that when he is notified of a problem and given the specific details of that problem, he would facilitate a resolution. He added that he would continue to assist with the facilitation of communication at all levels so that ICE can be a meaningful process.

Timothy Cutler, assistant clinical professor at the UCSF School of Pharmacy highlighted specific Medicare Part D issues facing providers, pharmacists, and patients in California. He provided examples of patients' confusion with plan options, misinformation from brokers, brokers attempting to sell additional coverage to patients and patients being over insured. He emphasized the large amount of misinformation that patients receive from the plans and brokers. He stated that with the number of eligible patients, number of prescription drug plans and number of brokers, there are not enough educators to provide Part D outreach educational activities to the seniors of California. Mr. Cutler added that brokers are not subject to the same regulatory provisions that pharmacists are in terms of information that can be provided to patients. That is a problem and something should be done to protect beneficiaries from those brokers who are imparting misinformation to patients. He also spoke to the continuing

delays in coverage for the dual eligibles and provided patient examples of this gap in coverage.

Dr. Cutler then highlighted recommendations for improving the system such as the continued coordination of communication efforts between the plans and CMS to prevent gaps in coverage from occurring, and the communication must be easier between the patient, the health plan and the system. CMS should have one system in place, similar to Medi-Cal in terms of a safety net provided to patients and a standardized prior authorization process.

Michael Rigas of Crescent Healthcare, a home infusion company, reported on Crescent Healthcare's experience over the last twelve months with Medicare Part D program. He provided a PowerPoint handout and briefly summarized the highpoints from that handout. Crescent Healthcare serviced over 850 home IV patients in 2006. Very few of those patients were able to afford a co-pay unless they had assistance with a secondary plan or Medi-Cal and their costs to administer to those patients were two to three times the costs of other payment systems. The ability to manage these patients on an ongoing basis will become more difficult as processing gets more complicated. Dr. Rigas added that obtaining prior authorizations might take 5 to 7 business days for complex therapies. He provided a brief overview of special issues of importance to the home infusion industry that included billing issues with multiple ingredients – prescription billing is based on the most expensive first active ingredient only; concerns about the future stability of pricing structures and plans with specialty drug copays. Also, due to the 2007 changes made by the Part D Plans as a result of issues in 2006, Crescent Healthcare has to navigate through new copay policies that have a dramatic impact on their patients. Also many Part D Plans and MA-PDS have their own pharmacy out-of state, so when Crescent sends the prior authorization through, the prescription is filled by the plans' own pharmacies and the prescription arrives directly to the patient, with no items to mix it, no pump, no pharmacist or nurse, and no way to infuse it. He added, in response to a question from the board, that there is a delay in obtaining prior authorizations and once received, there is oftentimes a billing issue as a brand is approved, but not the generic.

Dr. Rigas then provided specific examples of home infusion patients who were having problems continuing to receive the treatment and medications that they had under previous coverage Part B coverage but can now not get under Part D. Dr. Rigas concluded that Part D does not provide adequate coverage for Home Infusion Therapy resulting in patients having to stay in a hospital, go to a skilled nursing facility, or having to pay large amounts of money out-of-pocket. He stated that there are definite benefits with Part D coverage, especially for patients who would have no coverage at all, but there are still significant issues relating to coverage and billing that need to be addressed.

Chairperson Goldenberg requested Jeff Flick and John Jones to provide their thoughts on today's presentations. Mr. Jones stated LTC and home infusion therapy are areas where the industry and CMS wants to work well but they were not areas that were

initially part of the Part D congressional discussions. He complimented CMS on their handling of these issues and their methods of working with them.

Chairperson Goldenberg stated that there are significant issues involved - the health and well being of the patient, the health and well being of an industry that exists that offers much better care, and there it is more than just an issue of lower costs – it is better care at home. He added that the board would continue to meet to hear the issues and assist in the resolution process. He thanked everyone for coming and requested that they send in their suggestions as to what the board can do legislatively to help.

President Powers also thanked everyone for their participation and announced that due to continuing interest and today's time constraints that did not allow all interested attendees to address the board, the board will hold another public forum on Medicare Part D Plans in March. He added that written testimony may be submitted to the board's Executive Officer, Virginia Herold who will ensure that it is distributed to all board members.

The forum ended at 11:35 a.m.

Attachment 2

*Minutes of the March 30, 2007
Forum on Medicare Drug Benefit
Plans*



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

**Communication and Public Education Committee
Subcommittee on Medicare Drug Benefit Plans
Public Forum on Medicare Part D Plans**

MEETING SUMMARY

Date: March 30, 2007

Location: Los Angeles International Airport
Samuel Greenberg Board Meeting Room
1 World Way
Los Angeles, California 90045

Board Members

Present: Bill Powers, Board President and Chairperson
Stan Goldenberg, RPh, Board Member
Clarence K. Hiura, PharmD, Board Member
D. Timothy Dazé, Board Member

Staff Present:

Virginia Herold, Executive Officer
Robert Ratcliff, Supervising Inspector
Karen Abbe, Public and Licensee Education Analyst

A. Call to Order and Introductions

Chairperson Powers called the meeting to order at 9:32 a.m.

Mr. Powers stated that this is the continuation of an open forum the board provided on February 1, 2007 on the Medicare Part D program. This is the 5th meeting in a series of meetings convened by the board since the Medicare Modernization Act's prescription drug plan benefit was rolled out. The board hosts these meetings so that those with unmet concerns with the program have an opportunity to voice their concerns and seek solutions. Hopefully these discussions have led to some improvement already.

Mr. Powers introduced Lucy Saldana, PharmD, a pharmacist with CMS Region 9, who participated via speakerphone. CMS Regional Administrator Jeff Flick became unable

to attend this meeting very recently, but agreed to join via telephone later in the afternoon.

B. Medicare Part D Implementation – Issues and Comments from Patient Advocates

Mr. Powers stated that the purpose of this forum is to continue the discussion among stakeholders and policy makers on issues impacting the quality of services provided to patients under the Medicare Modernization Act's Prescription Drug Plans for California patients. At the forum held on February 1, 2007 in San Diego, provider comments were predominant. At today's forum, he wanted advocates to have adequate time to state their concerns and ideas.

David Lipschutz introduced himself as Staff Attorney for California Health Advocates. He said he provides free and unbiased information to consumers about HICAP. He works with HICAP and speaks for them, saying what they cannot say and should not say. He identifies problems and troubleshoots to make the program better.

Mr. Lipschutz referenced an executive summary from the Center for Medicare Advocacy, Inc., dated January 16, 2007. He said the summary was an excellent resource, which outlines the issues surrounding the Medicare Part D Program after its first year, but today he wanted to focus on several broad issues.

- Medicare marketing and misconduct during sale of Medicare and Part D products

People are being enrolled in Medicare Advantage and Part D plans that they either did not intend to enroll in, or they enroll in plans that are not right for them. The private fee-for-service programs are particularly problematic. Since the Act was passed, there has been a mushrooming in the numbers and types of products, notably in Medicare Advantage plans. There is not enough corresponding oversight of those plans or the agents and brokers offering the plans. There is difficulty in changing into more suitable plans once a patient realizes he/she would be better served in another plan. Medicare beneficiaries do not have sufficient knowledge to make choices among the plans. There is a fundamental misunderstanding among agents and brokers about how these plans work.

Mr. Lipschutz stated that the system is ripe for abuse because high commissions are paid to agents when they enroll people in Medicare Advantage plans, higher than for stand-alone prescription plans. These high commissions result in "migration" where people sign up for Medicare Part D, then the agents try to enroll the same individuals in their more lucrative Medicare Advantage products.

Private fee-for-service plans have proliferated, but they are also the least understood. People who are dual-eligible in Medicare and Medi-Cal are being

targeted for private fee-for-service plans, which sometimes results in those consumers losing their chosen providers who are not part of the coverage.

Mr. Lipschutz stated that oversight of agents and brokers has been lax. There is conduct that is questionable, and in some cases, outright misconduct is occurring. Agents are participating in practices like going door to door in senior resident facilities, and doing mass enrollment of 40 or more people at a time. He said that on the California Health Advocates Web site, they have an Issue Brief entitled "After the Goldrush: The Marketing of Medicare Advantage and Part D Plans, Regulatory Oversight of Insurance Companies and Agents Inadequate to Protect People with Medicare." The brief reveals misconduct by agents that negatively impacts dual-eligible beneficiaries.

- Limited open Enrollment period, including open enrollment that starts Sunday April 1, 2007

Mr. Lipschutz stated that there is one choice per election period to get in or out of a plan, with restrictions. There's a limited open enrollment period set to go into effect on April 1, 2007. During this period, beneficiaries can make a "one way" movement into a Medicare plan. There are potentially serious consequences. For example, if an individual enrolls in an HMO or PPO and has stand-alone prescription drug coverage, they will lose their stand-alone prescription drug coverage for the year.

- Disenrollment of beneficiaries by Sierra RX Plus

Mr. Lipschutz stated that Sierra RX Plus provides brand name coverage in the gap (donut hole). Until just a few weeks ago, no Part D plan involuntarily disenrolled enrollees due to nonpayment of premiums. Suddenly there was a rise in involuntary disenrollments. Some people were disenrolled despite timely payments during a grace period to bring payments current. Sierra was kicking people out of their plans, and unwilling to let people back in to their plans even when payments were brought current. CMS ordered Sierra RX to reinstate their 90-day grace period during which enrollees can bring their premium payments up to date.

Mr. Lipschutz stated that Sierra RX informed their investors that they were losing money on the prescription plan, and accused another company of steering their most costly patients to enroll in Sierra's plan.

- Heroic efforts made by pharmacists

Some pharmacists have taken out lines of credit in order to provide prescription coverage to enrollees. Many pharmacists are still unaware of the WellPoint point-of-sale system for dual eligible people. It's a rough "safety net" for those not enrolled in a Part D plan, but all pharmacists do not use the system, and

some are refusing to use the system. CMS says they can't force pharmacists to use the system.

Mr. Lipschutz also stated that there are lags in data for the low-income subsidy. Some Part D enrollees can get assistance, reducing costs sometimes from \$5 down to \$1 for a co-pay. If the low-income subsidy beneficiary provides proof like a Medi-Cal card, some pharmacies are still refusing to apply the discount.

- Notices and/or posters at pharmacies

CMS rules require either a poster or notice handed to patients saying they can ask their plan to cover a certain drug or share in the cost. Pharmacists either don't have the notices, or put the poster out of view of customers. Mr. Lipschutz and his organization are calling for a more uniformed standard so that beneficiaries will know that they can contact their plans to and ask for coverage of certain medications.

Mr. Goldenberg asked Mr. Lipschutz to give this presentation at the April 18, 2007 full board meeting. He believed the information would be enlightening.

Mr. Lipschutz said he will be out of town on that date, but can send another representative of California Health Advocates.

Mr. Goldenberg asked if he had knowledge of challenges for long-term care and home infusion patients.

Mr. Lipschutz responded yes, but heard of these problems less frequently.

Mr. Goldenberg said the "plan side and provider side" were present, and he encouraged Mr. Lipschutz to stay for the full meeting so he could provide suggestions to solving these problems.

Mr. Lipschutz stated he has made recommendations to CMS Region 9, but the CMS policy office in Baltimore needs to approve the recommendations. He proposed that agent commission fees should be "flat," but unfortunately there must be some incentive to sell Medicare Part D products verses Medicare Advantage plans. An equal commission fee structure is facing strong industry resistance.

Mr. Goldenberg said it appeared there was cooperation from Region 9 in general, but policy changes must come through Baltimore. He asked if there were an entity in California assisting in oversight of these plans, would it facilitate the ability of seniors to get benefits or provide additional protection?

Mr. Lipschutz replied that from a beneficiary standpoint, California state agencies are prohibited from regulating Part D plans. The Department of Insurance has oversight of agents, so maybe they can weed out bad agents for misconduct. In one case that he

was aware of though, although there were reams of evidence showing misconduct by an agent in one plan, the agent just went to work for another plan.

Mr. Goldenberg said he wanted to make a personal statement that the board has not been having these subcommittee meetings for enjoyment. We want to protect seniors, and the dual eligibles. And it is even more difficult for those patients who are institutionalized.

Mr. Lipschutz stated that in one case of marketing misconduct in a long-term care setting, an agent went to the home of a sister who was the conservator for her brother. The sister enrolled her brother in a plan, and it turned out that the long-term care facility her brother was in did not do business with that plan. Later, the sister had to undue the damage caused by enrolling her brother into the wrong plan.

Dr. Saldana said she appreciated David Lipschutz bringing these problems to light. She wanted to mention that Sierra RX, as of March 23, 2007, had reinstated beneficiaries that were disenrolled. She invited people to contact her to ensure that everyone who should be reinstated does get reinstated.

Mr. Powers asked if Region 9 can play a part in resolving these problems, and whether there is oversight by CMS.

Dr. Saldana stated that she's been working with David Lipschutz and other advocates regarding some of these problems. In terms of regulations, many of those issues are controlled out of their central office.

Mr. Powers asked if there were any other representatives from other consumer groups who wanted to speak. There were none.

C. Issues Involving Specialized Settings (e.g., Long-Term Care, Infusion Pharmacies)

Mr. Powers asked if there was anyone who wanted to make a presentation regarding specialized settings such as long-term care or infusion pharmacies.

Sherri Cherman, Chief Operating Officer of Modern Health, said Modern Health has retail pharmacies that find meds for patients with chronic conditions like HIV and other high out-of-pocket costs. They also serve skilled nursing facilities and infusion services at home. Ms. Cherman said that in long-term care, costs are shifting in Part D plans, and the pharmacies are left with the financial risk if they provide medication before it is approved. Modern Health ends up taking the financial risk. They either pay for the medication or the long-term facility pays.

Mr. Goldenberg added that state and federal laws for timely administration of medications means that if a doctor orders a drug on a stat basis, it must be given to the

patient within one hour, and the majority of medications must be given within four hours. The facility is placed in an environment of having to provide medication timely, and pharmacies have been taking it on the chin as far as cost. Facilities state that when they can't provide an expensive medicine, they'll send the patient back to the acute hospital setting which can mean a \$3,000 a day environment just to get medicines in a timely manner. The board needs to shine a light on this problem so that people don't get hurt. When elderly patients are transferred between facilities, even just between rooms in a facility, it causes harm to the patient just because they are moved. Morbidity and mortality increase when patients have to be transferred, and we must protect these patients.

Ms. Cherman stated that Modern Health has been accepting the financial risk to aid patients in getting medicine more quickly, but they cannot continue taking this risk indefinitely. Additionally, securing approval for payment has required the addition of staff, just for this function.

Mr. Goldenberg stated there is minimum oversight of this government program. We must protect the most vulnerable frail and elderly, and other with significant diseases. People walking into pharmacies have more options than the most frail or sick patients.

Mr. Powers asked Dr. Saldana if CMS can offer responses as to how we can stop this elder abuse.

Dr. Saldana replied that if Mr. Powers meant that pharmacies are exposing themselves to financial risks in the current environment, she agrees with Sherri Cherman's assessment of the situation. She has heard that things have gotten better from pharmacies. While this is what she understands from the pharmacies that have contacted her, there are still problems. When pharmacists call her, she tries to connect them with the specific plan to get assistance. She agrees that issues need to be tweaked, but plans have been trying to address the problems.

Mr. Goldenberg stated that if there is improvement, he can't help but think about the situation starting at absurd, and now we're at unacceptable. He asked how we could prevent patients from being hurt.

Dr. Saldana replied that Region 9 has been passing these concerns to the central office during conference calls. She wishes there was an answer coming down the pipeline.

Mr. Powers asked if changes must be made in law by Congress.

Dr. Saldana replied that yes, Region 9 doesn't make laws, and you need to write to your congressman. Region 9 just puts the laws into effect.

Ms. Cherman stated that she believes the situation has actually gone from horrific to unacceptable. It has reached a plateau recently, with no improvement in the last six

months. It is very costly for pharmacists to continue to complain because it takes a lot of time on the phone to get through to someone who can help.

Mr. Goldenberg thanked everyone who spoke and who attended today.

Executive Officer Herold asked Ms. Cherman about the 3,000 patients they serve in skilled nursing, and how many of those patients had to be moved back into a care facility in order to get the medication coverage they needed.

Ms. Cherman estimated that over 100 patients with acute needs have had major disruptions to their care during the year, and had to be moved to a facility offering a higher level of care for medication coverage.

Mr. Goldenberg added that pharmacies can't continue to absorb costs, so that number of patients being transferred is going to grow.

Mr. Dazé stated that the economy is taking a hit in a lot of areas, and pharmacies may discontinue these carrying costs because they are responsible to shareholders. Publicly traded companies may not be able to continue to fill the prescriptions without payment.

Mr. Powers stated that long-term care costs government more than if they provided for this therapy at home.

Mr. Goldenberg emphasized the impact that the trauma of transfer causes to patients. There is a 25 percent mortality rate due to the transfers, not due to the underlying disease.

Mr. Powers invited the public to ask questions or give comments.

Eileen Goodis, from Walgreens, said that home infusion patients are staying in the hospital an extra one to four days because there's no prior authorization to continue the therapies at home. Plans require prior authorizations before authorizing medicines for patients who are sent home with the same therapy they received in a hospital. Ms. Goodis suggested that there be an automatic 10-day authorization to continue the medications upon discharge, to allow time for the plans to approve the ongoing therapy at home.

Ron Belville stated that he has worked in long-term care for a long time. He's been listening to agents and their marketing plans. He said information is not provided to help people make informed choices as to which plan would best fit their needs. He said people should not be steered towards certain plans due to financial incentives because other plans may be better suited for certain patients. He suggested that better information about the plans be provided.

Ira Halpern, President of Modern Health, stated that for 20 years, he has experienced that one size cannot fit all. Retail patients can be better served because they can walk away, but patients in facilities are different. One plan cannot work for all kinds of specialty needs. One mousetrap does not work for all mice, and different issues and different settings like long term care verses home care.

Michael Rigas, Senior Vice President, Crescent Healthcare, provided a presentation.

Dr. Rigas stated that pharmacies are absorbing financial costs to provide patient care. Part D does not provide adequate coverage for home infusion therapy. The result is patients have to stay in the hospital longer, or go into skilled nursing facilities, or pay large out of pocket amounts. The nuances between Medicare Parts B and D are problems for patients, providers and payers. Part D rules and exclusions are confusing to most patients, and changes to Part D rules result in higher co-pays to patients, less doughnut hole coverage, more restrictive formularies, and higher monthly premiums.

Dr. Rigas' outlined 12 suggested changes to correct the problems with Medicare Part D. Some of the suggested changes included reorganizing how Medicare Part B and Part D relate to each other in order to benefit patients, allowing Part D to pay an infusion per diem, relaxing home-bound regulations so that Part A nursing can pay for infusion nursing, controlling the number of plans available in a region, ensuring that authorizations are timely and accurately reflect patient's drug and disease state, and re-establishing the automatic 10-day authorization for drugs provided under Part A.

Dr. Rigas stated that there has been discussion on whether Crescent can continue offering Part D under the current rules.

Mr. Powers stated that a bill has been introduced federally to require a "report card" of Medicare Part D.

Mr. Goldenberg asked about the dispensing of vials. There are sterile compounding regulations, and out of state licensing regulations. Between those two regulations, vials are still being sent to patients who are supposed to admix their own. This should not be happening, but it is.

Ms. Herold clarified that anyone shipping drugs into California is required to be licensed by the Board of Pharmacy. If a product must be mixed and it is sent not mixed, it would be viewed as a prescription error. It's a quality of care issue.

Mr. Goldenberg stated that unless a patient complains that something wasn't mixed right, the board would not be aware there was a problem.

Mr. Powers thanked Dr. Rigas for his presentation. He asked if there were any other comments regarding specialized groups.

Molly Forest introduced herself as CEO and president of the Los Angeles Jewish Home. She stated that it is one of the largest nursing homes, and she can share the challenges that the Jewish Home has been experiencing.

Ms. Forest stated that while they are not the largest nursing home in California, they are the largest single source provider of welfare (Medi-Cal) recipients. She said that the Jewish Home operates community clinics and has their own medical group. They have several concerns.

The average age of their patients is 90. There are difficulties with the prescription drug benefit due to patient intolerances to the administration drug route and the drug that each patient would prefer. The paperwork is so cumbersome. Prior to part D, they spent \$200,000 on medicines that welfare would not cover, but now it's \$400,000 a year because their philosophy is to never put a patient in jeopardy.

Ms. Forest stated that they are concerned about formularies because of intestinal and absorption issues. Liquid vitamins are absorbed much better by the elderly. The Jewish Home provides these at their own cost because liquid vitamins are not covered. With the elderly, you must get them into the proper plan, then you get into formulary issues. She would like to see standards developed to address this.

California has a category called medically needy only (MNO). Those individuals are only allowed \$20 per month for incidentals, which is easily eaten up by clothing, toothpaste, and over the counter medications, a level that has not been increased for years.

Mr. Powers stated that the Jewish Home sent a 93 year old recipient to testify to Governor Davis on the matter of MNOs. Unfortunately, Governor Davis was recalled, and Governor Schwarzenegger has not addressed MNOs. There are only about 200,000 MNO beneficiaries.

Mr. Dazé asked if the Jewish Home had approached the Assembly, which is controlled by the Democratic Party, in order to introduce legislation.

Ms. Forest stated that they need the Board of Pharmacy to aid in getting legislation introduced.

Mr. Goldenberg asked about getting authorizations for nonformulary drugs. For example, if there are 800 patients and only four physicians, is there a number as to how many of these authorizations they're faced with.

Ms. Forest replied that there are about 100 authorization requests per week for 800 residents.

Mr. Goldenberg stated that long-term care physicians constantly move from one institution to another during the day, and they can receive sometimes 100-500 faxes per day. Prior to Part D, it was around 30 faxes per day.

D. Comments from Part D Plan Providers

Mr. Goldenberg invited other plan providers to come forward with their comments.

John Jones, United Health Care, stated that he would talk in general terms because they have a large plan with about 6,000,000 enrollees in Medicare. He said that they've made improvements, but Part D was never designed for long-term care or infusion care. He encouraged Lucy Saldana to chime in.

Dr. Saldana stated that CMS has had a lot to deal with during a short time period. Medicare and Medicaid are safety net programs, so money won't be thrown at the problems because there's a preservation of public dollars. The programs must run efficiently and economically to make people happy. They are working with Crescent and other providers to make things work better.

Richard Katz, CEO of Modern Health, said that he is beginning to see consolidation within third party plans. The future of pharmacies and taking care of seniors is going to be more difficult. Mr. Katz asked that the board protect the rights of patients in California, but he doesn't know what the recommendations should be. He sees the hurdles getting worse, and economic constraints getting tougher. He wants the board to voice what we can accept and cannot accept. He turns to the board as the leader to help solve these problems.

Jacqueline Ejuwa, Blue Shield of California, stated that she has worked in pharmacies in long-term care. She said she echoed the things that John Jones mentioned. The challenges of what's covered under Part B and Part D and prior authorizations are difficult, as well as an understanding of levels of care and patients moving in between and back and forth. She stated that Blue Shield will "override" lack of a prior authorization in order to ensure patients receive the same therapy they received in licensed facilities to provide emergency amounts of medications to patients when they are discharged.

Mr. Goldenberg asked if a resident comes to a nursing home on a drug therapy, is that a continuation of therapy and is the drug covered?

Ms. Ejuwa replied that yes, it is for 30 days, and most providers know that. For home infusion, she's not sure.

Ms. Herold asked whether they can get an override without authorization from the plan.

Ms. Ejuwa replied that yes, by following certain processes. They call the third party claims processor for a patient that needs a transition supply of medicine and is already stable on that same medication. They can call a claims processor 24 hours a day, 7 days a week. It usually takes about 5-10 minutes, but no longer than 15 minutes. After receiving the override code, they can provide the transition supply of medicine to the patient.

Mr. Goldenberg asked CMS if there was a way to get this encouraging news out to other plans, and whether the board can put it in our publication. He also asked whether CMS had other answers.

Dr. Saldana replied that she was encouraged that processes are in place to get the medications to patients. She wants to allow market forces to hear how this plan operates, and she has no problem if we put it in the board's newsletter.

Mr. Goldenberg stated that the long-term community has an open formulary for long-term care patients. Because they're responsible for the whole patient, they don't want patients getting expensive care in other settings unnecessarily.

Mr. Powers said there should be a system where information like this does not have to be provided by rumor.

Dr. Saldana stated that on the Medicare.gov Web site, they have performance standards, overviews about customer service, complaints, appeals, and so on. She noted that it's only a start, but the information is being posted on the web. Family members can get information by looking on the web at the statistics. As more data is provided, people should look at it again.

Mr. Goldenberg stated that with all due respect, a 90 year old patient will likely have a 70 year old son or daughter. The system of communication should be familiar to the clients. The Web site may not be feasible because people will have to fish through the technicalities that he himself finds hard to follow.

Dr. Saldana replied that he should go on Web site, highlight the good plans, and put them in the newsletter, but without promoting certain plans.

E. Open Discussion and Problem Solving on General Items of Interest

Dr. Hiura asked Ms. Ejuwa to clarify which plan she was with, and to share what she knows about authorizations for transition supplies.

Ms. Ejuwa stated that she manages the drug authorization process for Blue Shield of California, and that transition supplies are for patients that are already in care. She suggests that other plans should change their policies to reflect the needs of patients that are already in care.

Mr. Goldenberg stated that having a regulation without oversight is not good.

Ms. Ejuwa stated that Medicare Part D is so complex that information gets lost in translation. Her plan reminds people on the phone that these are patients that are already on therapy, so they just need a transition of that therapy.

Dr. Hiura shared a personal story of his mother in who is currently living in the Jewish Home on 4th and Boyle. His mother is 97 years old, is indigent, and in a wheelchair. He supplements her with money to buy over the counter medications. She is dual eligible. Dr. Hiura stated that fundraisers also chip in to help fill the gap for these patients.

Magda Gabali, Department of Health Services, stated that she hasn't looked at the CMS Web site for a while, and wanted to know if there are links to specific plans so that people can ask questions. She recalled the Web site only listed plans, but with no direct link for consumers to get to the plans' Web sites. She stated that it would be more helpful to provide links to the specific plans, and not just a list.

An unknown person from CMS spoke via speakerphone stating that getting transition authorization can be just as time consuming. Allowing a co-indicator would help.

Ms. Ejuwa said that she must call first, then do a computer override. That saves one to two days, but still costs around 15 minutes on the phone.

Mr. Jones said that Health Net implemented a code to allow for transitional authorization, and they broadcast that information to pharmacies.

Mr. Lipschutz said he wanted to speak to an earlier issue about steering people towards or away from any particular plans. He said HICAP is not allowed to steer people towards or away from particular plans. He stated that the CMS Web site is very confusing regarding prior authorization. You can't ask frail and ill people to navigate a 50-page Medicare Web site.

Mr. Powers thanked everyone for sharing their concerns and proposed solutions. He said these meetings have been held to give people a platform. Now we should go beyond, and publicize those concerns and possible solutions. We will also be looking to state and federal legislation, and will bring these ideas to the full board to see if we can expand. We must impress upon CMS and Congress to change these flaws in the program.

F. Adjournment

There being no additional business, Chairperson Powers adjourned the meeting at 12:05 p.m.

President Powers asked that we share this with you for discussion.

**FOR BOARD MEETING
DISCUSSION:**

Report on Medicare Part D Programs

Center for Medicare Advocacy, Inc.



MEDICARE PART D AFTER YEAR ONE: A REVIEW OF PROBLEMS, AND RECOMMENDATIONS FOR CHANGE

January 16, 2007

EXECUTIVE SUMMARY

After one year's experience with Medicare Part D, many people remain confused and frustrated by the complexity and limitations of the benefit. Problems are difficult to resolve because of system failures, complicated data-sharing requirements among multiple entities, lack of useful and standardized information about plan benefits and appeal processes, and regulatory limitations that are more stringent than required by law.

The beneficiary stories in this report are illustrative of the many beneficiaries who are experiencing problems and high costs due, in large part, to the lack of uniformity in Medicare Part D. The stories focus on particular aspects of Part D implementation – the failure of systems to ensure that low-income beneficiaries are enrolled in plans and receive their subsidies, the lack of useful information about benefit limitations to help beneficiaries plan, the failure of the system for withholding plan premiums from beneficiaries' Social Security checks, and the lack of uniform policies and procedures for seeking exceptions to formulary limitations.

Reflection on the issues underlying these problems confirms that beneficiaries would be better off with a redesigned benefit that is standardized, available throughout the country, and administered through the traditional Medicare program. Such a system would be more valuable for more beneficiaries and more cost-effective for taxpayers.

Accordingly, the Center for Medicare Advocacy continues to call for systemic changes to Part D. Our key recommendations include the following:

Recommendations for Congress:

1. Congress should redesign Medicare Part D to create a benefit that is standardized, available throughout the country, and administered through the traditional Medicare program. Such a system would be more valuable for more beneficiaries and more cost-effective for taxpayers.
2. Congress should eliminate the Donut Hole. If the Donut Hole is not eliminated, Congress should, at a minimum, authorize payments by AIDS Drug Assistance Programs (ADAPs) programs and pharmaceutical assistance program (PAPs) to count towards the beneficiary out-of-pocket spending limit.

3. Congress should require Part D plans to give deference to the opinion of the beneficiary's attending physician when making coverage decisions and should require CMS to delete the provision to the contrary in its regulations [42 CFR§ 423.578(f)].

4. Congress should authorize Part D coverage for off-label uses of drugs that are supported by peer-reviewed studies, are proven safe and effective over a substantial period of time, are covered by the beneficiary's state Medicaid program, or are listed in one of the three compendia currently included in the Medicare Act.

5. Congress should hold oversight hearings on the implementation of Part D. The hearings should include an inquiry into the special problems of dually eligible beneficiaries, the withholding of premiums by plans and Social Security, and CMS's role in setting and enforcing standards for plan participation.

6. Congress should require CMS to expeditiously establish a full system of real time data-sharing among all entities involved in Part D. Congress should require CMS to report on its strategies to resolve these problems effectively and within a specific time period, and should require periodic status reports from CMS.

Recommendations for the Centers for Medicare & Medicaid Services (CMS)

1. CMS should create a real time data-sharing system among all entities involved in Part D, and develop mandatory fail-safe systems to ensure that persons who are dually eligible for Medicare and Medicaid do not experience gaps in either their drug coverage or their low-income subsidy.

2. CMS should expand its point of service (POS) system to make its coverage available at the pharmacy for all dually eligible persons who experience plan enrollment and related drug dispensing problems at the pharmacy. Further, CMS should require pharmacies to use the POS system, and hold pharmacies harmless for good faith billings to the POS that turn out to be incorrect.

3. CMS and Part D plans should be required to provide beneficiaries with clear and accurate information about Part D, individual plan offerings, and in particular, about the Donut Hole coverage gap. This information should include the following:

- Materials from CMS and the enrollee's plan that explain how the initial coverage limitation and beneficiary out-of-pocket expenses, including Donut Hole payments, are calculated should be mailed to beneficiaries;
- Monthly statements that clearly indicate the total amount of payments that have been made that count towards the individual's initial coverage limit and beneficiary out-of-pocket responsibilities should be mailed to beneficiaries; and
- Monthly statements that indicate, after the initial coverage limit has been reached, all costs that continue to count towards the out-of-pocket limit in the Donut Hole and how much more is needed to reach catastrophic coverage should be mailed to beneficiaries.

4. CMS should require plans to provide a written coverage determination electronically at the pharmacy whenever a drug is not covered. The written coverage determination must explain why the plan will not pay for a drug, describe beneficiary appeal rights, and explain how to request the next level of review.
5. CMS should ensure that Part D plans comply with required appeals and grievance processes, that plan call centers respond appropriately to beneficiaries, and that Medicare “customer service” representatives provide accurate information and keep track of beneficiary complaints.
6. CMS should exercise its enforcement authority to take actions against Part D plans that do not provide adequate notice, fail to meet the regulatory time frames for deciding a coverage determination or an appeal, or fail to train their call center staff adequately.

INTRODUCTION

The Center for Medicare Advocacy has assisted thousands of Medicare beneficiaries and their helpers to understand and utilize the Part D system, plan options, and rules. In our conversations with Medicare beneficiaries, their advocates, and policy-makers, we hear repeatedly about beneficiaries having insufficient information to make sound decisions about which plan to choose, to understand what should be covered, and to know how they will fare during Part D’s various coverage gaps. They also report difficulty obtaining exceptions for drugs not on a plan’s formulary, for drugs with quantity limits, and for the off-label use of certain drugs. Similarly, we hear many complaints that the exceptions process is both complicated and vague. Beneficiaries who are dually eligible for Medicare and Medicaid are too often unable to obtain their medications due in large part to data-sharing problems among states, the Centers for Medicare & Medicaid Services (CMS), and Part D plans.

As we noted in our Six-Month Report (July 19, 2006), CMS, the agency that administers Medicare, continues to tout Part D as a resounding success, while characterizing what are persistent and systemic issues as small glitches in the system. Our experience continues to show otherwise. Systemic problems identified at the beginning of 2006 continued, and new problems developed during the course of the year. This report highlights some of the most glaring continuing problems:

- As currently designed, the Part D program is immensely complicated. The program’s complexities affect the ability of beneficiaries to understand the program, choose plans, pay premiums, benefit appropriately from the low-income subsidy, and utilize the exceptions and appeals process.
- CMS’s administration of the Low-Income Subsidy (LIS) lacks clarity and uniformity so that the subsidy too often fails to reach eligible beneficiaries.
- Beneficiaries do not have adequate information to allow them to make sound Part D plan choices or to properly prepare for the gap in coverage of necessary drugs during the “Donut Hole.”
- The Part D exceptions and appeals process is too complex and too varied from plan to plan to be adequately accessible to Medicare beneficiaries. Further, the standards for appeals are too vague and do not give adequate credence to the opinion of beneficiaries’ attending physicians.

PART D IS IMMENSELY COMPLICATED. THIS COMPLEXITY AFFECTS ALL ASPECTS OF THE PROGRAM.

1. The Complexity Of Part D Causes Special Problems For Low-Income Beneficiaries

One of the major changes made by Part D is the requirement that beneficiaries who are eligible for both Medicare and Medicaid (dually eligible beneficiaries) get their prescription drugs through Medicare Part D. On January 1, 2006, these people lost their eligibility for prescription drug coverage under Medicaid. Further, Medicaid beneficiaries who become newly eligible for Medicare lose their Medicaid drug coverage when their Medicare eligibility begins, even if they are not enrolled in a Medicare prescription drug plan. Such beneficiaries may experience drug coverage gaps when they are first eligible for Medicare due to time lags in the transmission of information about their new dual status, which must flow from the state to CMS. This change in drug coverage for low-income beneficiaries was the source of some of the most serious and significant problems when Part D began in 2006. Problems with Part D drug coverage for dually eligible people persisted throughout the year. For example:

Mrs. S, an SSI recipient who had been on MassHealth (Massachusetts Medicaid) and had a number of health problems, including bipolar disorder and diabetes, turned 65 on September 17th and became eligible for Medicare effective September 1, 2006. When she went to the pharmacy in early September, nine months after Part D began, she learned, when the pharmacist tried to bill MassHealth, that she no longer had Medicaid prescription drug coverage. The pharmacist was told that Medicare's records showed that the woman was in a Part D plan. However when he tried to bill that plan, he was unable to do so. Plan officials told both the pharmacist and the client's social worker that they had no record of her. The pharmacist then tried to bill Wellpoint/Anthem, the "Point of Service" (POS) option for dual eligibles who do not have a drug plan, but was unable to do so because Medicare records showed that she was already enrolled in a plan. She left the pharmacy without her medications.

Although CMS automatically enrolls dual-eligible beneficiaries into plans, effective the first day of the month in which they become dually eligible for both Medicare and Medicaid if they have not chosen a plan themselves, the enrollment may not, in fact, have been effectuated by the time they lose Medicaid coverage. Although they are entitled to reimbursement for out-of-pocket costs above the level of their subsidized co-payments, their low-income status may make it impossible for them to actually pay out-of-pocket. Those beneficiaries who choose a plan, rather than accept auto-enrollment, must affirmatively request through their plan that their enrollment be retroactive to the date they became dually eligible. The plan must submit the request to CMS.

As Mrs. S's story indicates, CMS has a point of service (POS) system that allows a newly dually eligible beneficiary for whom plan enrollment information is not available to receive drug coverage at the pharmacy (the "point of service") upon a showing of proof of Medicare and Medicaid enrollment. However, this system is not available to other dually eligible persons who experience difficulties at the pharmacy, including those for whom CMS's records show enrollment in a specific plan. Moreover, many pharmacists are unfamiliar with the POS system and, even if they know about the system, they are not obligated to use it. Further, if pharmacists use the POS system in error, the pharmacy is liable for the difference between the billed amount and the full cost-sharing due. Ironically, because Mrs. S was already enrolled in a plan that did

not acknowledge her enrollment, the POS option did not work for her and she was worse off than if she had not been enrolled in a Part D plan at all.

A. Information About Subsidy Status Is Also Often Delayed In Its Transmission To The Plan And The Pharmacy

Although dually eligible persons are entitled by law to change plans at any time, they do so at their peril. Considerable confusion often occurs when plan changes are made and it may be difficult to understand which plan is responsible to pay for a drug during a plan-change transition. For example:

Mr. B, a Medicare beneficiary who resides in the dementia unit in a nursing home, was enrolled by his daughter into a Part D drug plan in January 2006. In April 2006 he became eligible for Pennsylvania Medicaid.

It took five months, and 15+ phone calls to Medicare, the regional CMS office, Pennsylvania Department of Welfare, the local Medicaid office, the Part D plan and the nursing home just to get Medicare to update the beneficiary's status to dual-eligible so that he no longer had to pay monthly drug premiums, co-payments, or the full cost of his drugs. The Pennsylvania Department of Welfare had the wrong birth date for the beneficiary in its records, listed him as not being on Medicare at all, and delayed sending the updated information to the Medicare database. The drug plan also could not update its information until Medicare had updated its information. The nursing home kept reminding the daughter that her father's drug bills were going unpaid.

Medicare beneficiaries becoming newly eligible for Medicaid experience delays in getting access to their low-income subsidy. Data are transmitted by the states monthly; a beneficiary whose dual status is determined the day after the monthly transmission will not appear as a dual-eligible until the following month. Mr. B's story illustrates the complexities of the data-sharing that is required to ensure that dual-eligible beneficiaries do not experience coverage gaps or gaps in their entitlement to lower cost-sharing when they become dually eligible. It also illustrates the complexity of resolving such problems, because so many entities are involved and each may be required to take some action that depends on the prior actions of another agency.

B. Re-determinations Of Eligibility For Low-Income Subsidy Are Made Through Multiple Mechanisms, Leading to Confusion and Errors

Low-income beneficiaries must re-qualify for the Part D low-income subsidy (LIS) each year. Since several paths exist for re-qualification, the process is confusing, especially for those whose circumstances fluctuate over the course of a year. Medicare beneficiaries who are also enrolled in Medicaid, a Medicare Savings Program, or SSI are "deemed eligible" for LIS. If individuals were on the rolls in one of these programs in July of 2006, they were to be "re-deemed" eligible for the subsidy for 2007. As Mrs. M's story indicates, however, plans do not always have correct information about beneficiaries' subsidy-eligibility status:

Mrs. M, a dually eligible resident of Virginia who is deemed eligible for the low-income subsidy (LIS), was told that she needed to meet the Part D \$265

deductible when she went to get a prescription on January 2, 2007, although people entitled to the LIS do not have a deductible. The woman had no changes in her income, assets, or program eligibility for SSI, Medicaid, or Medicare. Her Medicaid eligibility worker called her drug plan and was told the woman had lost her low-income subsidy eligibility.

In December 2006, CMS sent a memorandum to Part D plans explaining that they must use the best available data to reconcile status when a beneficiary believes he or she is still eligible for the subsidy. The beneficiary may present proof of eligibility, such as a Medicaid card, at the pharmacy and the plan should follow up to collect the evidence. In Mrs. M's situation, however, the plan failed to explain to the pharmacist that the beneficiary could present documentation of her Medicaid eligibility at the pharmacy in order to continue receiving the subsidy, and her medications, until the issue was resolved.

Another example:

Mr. and Mrs. Y have developmental disabilities and qualified for Missouri Medicaid for a portion of 2005 after they "spent down" their excess income to meet medical expenses. Thus, they were deemed eligible for the full low-income subsidy in 2006. Because they allegedly had not met their "spend-down" amount in the second half of 2006, however, they were not deemed eligible for the low-income subsidy for 2007. The couple qualifies for a partial subsidy based on income, and so, in contrast to their experience in 2006, they will have to pay a deductible and premium for their drug coverage in 2007. They will also have to pay more for each prescription.

An advocate who was assisting the couple in choosing new drug coverage at the end of December 2006 discovered that the couple had hospital and medical bills that should have been sufficient to establish that they had met their "spend-down amount" (payment toward medical expenses, recognized by Medicaid, as reducing the applicant's income for purposes of qualifying for Medicaid) in October 2006. Had they submitted the medical bills to the state Medicaid agency, they would have been eligible for Medicaid and deemed eligible for LIS for all of 2007. Because they did not submit the medical documents on time, they will have to pay premiums and cost-sharing until their Medicaid is established retroactively. They will then be deemed eligible for full LIS retroactively, and they and their advocate will have to take steps to seek reimbursement for the premiums and other expenses they paid until information about their LIS-subsidy level is shared with their drug plan.

Individuals who were not on the Medicaid rolls at the time CMS made deemed status decisions were sent letters telling them that they were losing their subsidy because of the loss of their other benefit. The letter included an application to be mailed to the Social Security Administration. However, if the individual later regains eligibility for the other benefit, he or she will be re-deemed for the LIS, without further consideration of his or her SSA application. While this is a desirable outcome, beneficiaries are too often confused by the array of letters they receive regarding their changing status. Moreover, delays in the transmission of subsidy information between states, SSA, CMS, and plans may result in incorrect LIS status information being available at the pharmacy when a beneficiary arrives in 2007. As described above, this can result

in low-income people paying more than they should – and sometimes failing to obtain their medications.

When a Medicaid beneficiary loses eligibility for Medicaid benefits, states have an obligation under Medicaid law to determine if that person is eligible under another category of the state's program. For example, someone losing Medicaid eligibility might, nonetheless, still be eligible for a Medicare Savings Program, since these income and resource limits are higher than Medicaid in most states. If states routinely undertook these new determinations of eligibility for other Medicaid benefits before terminating people from the program, fewer LIS recipients would find themselves in the limbo of not knowing about their LIS status. Similarly, even for those individuals no longer eligible for any benefits under the state Medicaid program, the state or the Social Security Administration (SSA), whose income and resource limits are higher than those of most states' Medicaid programs, could undertake independently to determine their eligibility for the LIS.

SSA is required by law to redetermine eligibility of those individuals who applied for LIS through SSA within the first year after their initial enrollment. SSA used a largely "passive" redetermination process for 2007. It sent letters to beneficiaries who qualified for the LIS in 2006 asking them to contact SSA if their circumstances had changed. If the individual's circumstances had not changed, the beneficiary was not required to take any action. If they had, the process continued. Little information is available at this time on the effectiveness of this system.

After the first redetermination, the Commissioner of SSA has discretion to undertake redeterminations as necessary. Since most low-income Medicare beneficiaries do not have significant changes in income and resources, the Commissioner could exercise his discretion to minimize redeterminations.

Recommendations

Congress should hold oversight hearings on the implementation of Part D. The hearings should include an inquiry into the special problems of dually eligible beneficiaries and CMS's role in setting and enforcing standards for plan participation.

Congress should require CMS to create a plan to move expeditiously to a full system of real time data-sharing among all entities involved in Part D. Congress should require CMS to report on its strategies to resolve these problems effectively and within a specific time period, and should require periodic status reports from CMS.

CMS should require states to redetermine the eligibility of *anyone losing Medicaid* to determine if that individual qualifies for the low-income subsidy (LIS, also known as Extra Help) as a result of eligibility for other qualifying benefits. CMS should also require states to redetermine LIS eligibility for *anyone who lost his or her Extra Help due to losing their deemed status*. Further, CMS and SSA should explore which agencies should oversee such redeterminations.

CMS should create a real time data-sharing system among all entities involved in Part D, and develop mandatory fail-safe systems to ensure that persons who are dually eligible for Medicare and Medicaid do not experience gaps in either their drug coverage or their low-income subsidy.

CMS should expand its point of service (POS) system to make its coverage available at the pharmacy for all dually eligible persons who experience plan enrollment and related drug dispensing problems at the pharmacy. Further, CMS should require pharmacies to use the POS system, and hold pharmacies harmless for good faith billings to the POS that turn out to be incorrect.

2. Beneficiaries Are Confused By The Part D Benefit Structure, And In Particular By The Gap In Part D Coverage Known As The “Donut Hole”

The standard Part D prescription drug benefit includes a deductible and beneficiary cost-sharing up to an initial coverage limit. Once that limit is reached, beneficiaries enter a “coverage gap,” known as the “Donut Hole,” and are responsible for the full cost of their drugs unless and until they reach a catastrophic threshold. Cost-sharing is reduced for all beneficiaries who get out of the Donut Hole, including those who are eligible for the low-income subsidy (LIS), also known as “Extra Help.” Unfortunately, many beneficiaries do not understand the benefit structure and the implications of the Donut Hole. Thus, they were not adequately prepared when they had to pay the full cost for their prescriptions. For example:

In September 2006, Mrs. L, the wife of a Medicare beneficiary, was charged \$73.59 for one of her husband’s prescriptions instead of the \$28.00 that she had been paying since the beginning of the year. The pharmacy technician had “no idea” why the cost of the drug increased. The wife called the drug plan and was told about the Donut Hole. The woman said that when she signed her husband up for Part D, she did not understand how the Donut Hole might affect her family. Because her husband would not exit the Donut Hole by December 31, he paid the Part D premium as well as the full cost of his drugs for the rest of 2006. Since learning of the Donut Hole and its impact, the woman has been blaming herself. She remarked that she knows she needs to educate herself (her husband is not mentally capable of doing so). She said that she has to work, to take care of her husband, to pay the bills, and to figure out how best to manage all health care options, and she does not have enough time in the day to sort out health insurance issues. She wonders how a program could be designed with such flaws.

Information provided to beneficiaries by both CMS and by drug plans often does not clearly explain the Donut Hole coverage gap. Even beneficiaries who understood that they would experience a gap in coverage did not understand how the initial coverage limit is calculated (full cost of all formulary drugs) and how their out-of-pocket costs to reach the catastrophic limit are calculated (beneficiary cost-sharing for formulary drugs up to the coverage limit, plus full cost of formulary drugs purchased at network pharmacies while in the gap.) Further, because Part D allows the costs of prescriptions to vary throughout the year, beneficiaries who relied on the plan’s price for their drugs when they chose a Part D plan may have underestimated what they would spend for prescriptions when they entered the coverage gap.

A. Paying For Drugs In The Donut Hole Creates Problems For Many Beneficiaries

Some beneficiaries who enter the Donut Hole have difficulty figuring out how to pay for their prescriptions. For example:

A case worker complained to the Center for Medicare Advocacy that many of her clients cannot afford their medications once they enter the Donut Hole. Some individuals have been assisted through the local Adult Protective Services program and other social services agencies that will pay for at least one month of medications. A few patient assistance programs have provided free medications for individuals who have a statement from their plan that they have reached the gap in coverage. Unfortunately, the case worker had clients who were going without medications or were spending their savings to buy medications.

The Donut Hole problems are exacerbated by the fact that some previous methods of paying for prescription drugs may no longer be available to Medicare beneficiaries. Some pharmaceutical assistance programs (PAPs), sponsored by drug manufacturers, no longer provide assistance to people enrolled in Part D. Even if a PAP will assist a Part D enrollee, neither the PAP's contribution toward the drug nor the beneficiary's cost-sharing counts towards the out-of-pocket amount the beneficiary needs to spend in order to get out of the Donut Hole. Similarly, assistance provided by AIDS Drug Assistance Programs (ADAPs) does not count to get out of the Donut Hole.

CMS encourages beneficiaries to consider using generic drugs and to enroll in plans with enhanced drug coverage that includes coverage through the Donut Hole. However, changing to a generic drug is not always possible. Many people with cardiac problems, cancer, multiple sclerosis, and other ongoing conditions rely on new, brand-name drugs for which there are still no generic equivalents. Most plans that offer Donut Hole coverage only pay for generic drugs in the gap. A few plans provide gap coverage for brand-name drugs, but there are only a few such plans, they are costly, and they are not available in every state. Even fewer such plans are available in 2007 than in 2006.¹ Thus, these plans provide no assistance to beneficiaries for whom a generic drug is either not available or not medically indicated.

B. Lack Of Knowledge About How The Donut Hole Works Often Leaves Beneficiaries Unprepared For This Gap In Coverage

Beneficiaries often do not know when they are approaching the Donut Hole or if and when they will reach the catastrophic coverage amount. Part D plans are supposed to include information in the monthly summary of benefits they send to plan enrollees so that enrollees can calculate when they will reach the Donut Hole. As shown by Mrs. L's story, however, that information may not be provided at all or may not be provided in a manner understood by beneficiaries. Problems also occur when beneficiaries try to predict whether their drug costs are high enough to get them through the coverage gap. For example:

A Florida-based advocate worked all year with the CMS regional office on behalf of a dual-eligible beneficiary who experienced continuous enrollment and disenrollment problems. Because the beneficiary's drug costs are so high, the advocate believed that the beneficiary should have gotten through the Donut Hole and therefore not been charged any co-payments for her drugs. However, neither the plan nor CMS could tell the advocate when the beneficiary had reached the

¹ In 2006, 2.3% of PDPs offered coverage for generic and brand-name drugs during the coverage gap (Donut Hole). That number falls to 1.4% in 2007. J. Hoadley, E. Hargrave, K. Merrill, J. Cubanski, T. Neumann, "Benefit Design and Formularies of Medicare Drug Plans: A comparison of 2006 and 2007 Offerings – A First Look" (Kaiser Family Foundation, November 2006), at p. 16.

catastrophic threshold. The e-mail response from CMS seemed to indicate that the beneficiary would still be charged co-payments after she reached the catastrophic threshold, even though federal law states otherwise.

Beneficiaries cannot calculate their expenses if they do not know when they will have to start paying for their drug costs in full or when they have reached the catastrophic limit. Beneficiaries' plans and CMS must ensure that Part D enrollees have the information they need and that beneficiaries with very high drug costs get the full Part D benefit to which they are entitled.

Recommendations

Congress should eliminate the Donut Hole. If the Donut Hole is not eliminated, Congress should, at a minimum, authorize payments by AIDS Drug Assistance Programs (ADAPs) and pharmaceutical assistance programs (PAPs) to count towards the beneficiary out-of-pocket spending limit.

CMS and Part D plans should be required to provide beneficiaries with clear and accurate information about Part D, individual plan offerings, and in particular, about the Donut Hole coverage gap. This information should include the following:

- Materials from CMS and the enrollee's plan that explain how the initial coverage limitation and beneficiary out-of-pocket expenses, including Donut Hole payments, are calculated should be mailed to beneficiaries;
- Monthly statements that clearly indicate the total amount of payments that have been made that count towards the individual's initial coverage limit and beneficiary out-of-pocket responsibilities should be mailed to beneficiaries; and
- Monthly statements that indicate, after the initial coverage limit has been reached, all costs that continue to count towards the out-of-pocket limit in the Donut Hole and how much more is needed to reach catastrophic coverage should be mailed to beneficiaries.

3. Beneficiaries Cannot Be Guaranteed That Premiums Will Be Withheld From Their Social Security Checks As Requested, Or That The Premiums They Pay Will Reach The Part D Plan In Which They Are Enrolled

Paying premiums for the Part D plans they have chosen is a challenge for many beneficiaries. Many beneficiaries chose to have Part D premiums withheld from their Social Security checks and paid directly to their plans, as they are accustomed to doing with Part B premiums. For some, Social Security withholding was never implemented. For others, Social Security withholding was implemented incorrectly. Some beneficiaries received refunds of their withheld premiums that were not due them, while others who were due premium refunds waited months to receive the money that was owed them. For example:

Mrs. X received an incorrect premium refund in August and repaid the money by sending a personal check to her drug plan, rather than to CMS. She then received a bill from her drug plan for a total of three months' premiums, September, October, and November. These premiums had already been deducted from her Social Security benefit, two payments from her October benefit and one from her November benefit. An advocate contacted the drug plan on her behalf, with a representative of the Social Security Administration on the phone, to verify that the premiums had been deducted. The information was to be sent to the drug plan's finance department, but confusion about the three months' payment has not yet been resolved.

At the same time, the advocate learned that Mrs. X's account with her drug plan had been changed from Social Security withholding to direct pay. The advocate asked if this change was made because the beneficiary paid the "refund" with a personal check. The customer service representative could not answer; she did not have access to payment information. The client had not requested to have her payment method changed to direct pay. The drug plan representative could not talk about payment history.

Another example:

An advocate was concerned about finding a safe and effective course of action for Mrs. R, whose Part D premiums throughout 2006 had never been withheld from her Social Security check as she requested. Mrs. R. is understandably concerned about when and how the year's worth of premiums will be deducted from her Social Security check. In particular, she is worried that, with the press of obligations, she will not have the funds to make a lump-sum payment if requested; the payment issues have left her with a lack of confidence whether to use the Part D benefit at all.

These stories illustrate the complex and apparently intractable nature of premium-withholding problems. Whether Mrs. X's issue was resolved was impossible to confirm despite a three-way conversation with SSA, the plan, and the client and her advocate. Mrs. R's problem continued throughout 2006 and had not been resolved by the end of the year.

The Center for Medicare Advocacy hears regularly from advocates who generally advise clients to ask for direct billing from the plan, rather than premium-withholding, because the withholding system is so broken. While this recommendation is an effective short-term solution, it denies beneficiaries their right under the law to use the premium-withholding system so familiar to them from Medicare Part B, a system that, under Part D, has fallen victim to the complexities and inefficiencies of a program dependent on hundreds of private plans.

CMS has admitted that problems exist with its system of withholding the amount of the Part D premium from beneficiaries' Social Security checks and transmitting that amount to beneficiaries' Part D plans. In a hearing before the Senate Finance Committee in early September 2006, CMS acknowledged that the problem of premium-withholding had initially affected more than half a million beneficiaries. It claimed, at that time, that it had resolved most of the problems and that only about 150,000 remained to be addressed. Later in the fall of 2006,

however, with problems continuing, CMS changed the default setting for payment of premiums on its web-based Plan Finder, from premium-withholding to direct billing from the Social Security check. A beneficiary wishing to have premiums withheld from his or her Social Security check cannot choose that option on-line but “will be contacted” by CMS to make specific arrangements. The number of beneficiaries still experiencing problems with premium-withholding is unknown, but problems still persist for many:

- Premium withholding continues to occur without beneficiary authorization or continues after the beneficiary has disenrolled from the plan or is not stopped when a beneficiary so requests.
- Premiums are not withheld when a beneficiary has so requested. Some beneficiaries have had no withholding throughout 2006 and are understandably anxious that all the premiums will be taken from a single Social Security check, leaving them with little or no income for the month.
- Withheld premiums have been refunded to many beneficiaries, in some cases correctly and in others, incorrectly. When CMS sought to recover the incorrectly-refunded premiums, it failed to notify beneficiaries of their right to be excused from recovery.
- Plans have still not received payment from CMS or SSA of premiums apparently withheld.

Recommendations

Congress should hold oversight hearings to understand the issues that make premium withholding so unreliable and should require CMS to solve these problems.

CMS should notify all beneficiaries who received incorrect premium refunds in 2006, and all beneficiaries for whom premium withholding has been delayed, of their right to seek a waiver of the recovery of these funds.

CMS should ensure that all plans have been paid all premiums owed for beneficiaries who asked for premium withholding in 2006 (so that the burden is not left with individual beneficiaries to work out problems on their own with their plans).

4. The Process For Getting Coverage Of Drugs That Are Not On A Drug Plan's Formulary Is Confusing, Complicated, And Often Not Understood By Beneficiaries

In promoting Part D, CMS assured beneficiaries that they would have access to all of their medically necessary prescription drugs. What CMS failed to explain to beneficiaries is that they might have to file for a “coverage determination” and pursue an appeal if the drug they need is not on their plan's formulary or is subject to certain restrictions, such as a limitation on the number of dispensable pills (“quantity limits”) or the need to request the plan's permission before the drug is prescribed and paid for (“prior authorization”). The process for requesting a coverage determination and then an appeal is complicated, and most beneficiaries do not even understand this process, or the fact that they have the right to seek coverage for a drug not on their plan's formulary.

A. Beneficiaries Are Not Adequately Informed Of Their Right To Request A Coverage Determination And File An Appeal

The Part D appeals process cannot begin unless and until a beneficiary who is denied coverage for a drug at the pharmacy affirmatively requests a formal “coverage determination” from his or her Part D drug plan. A coverage determination can only be issued by the drug plan itself; the denial at the pharmacy counter has no legal effect. The formal coverage determination from the plan should explain why the plan will not pay for the drug and how to start the appeals process.

Most beneficiaries who are denied coverage for their prescribed medications need to request a special type of coverage determination known as an “Exception.” An Exception may include a request to cover a drug that is not on the formulary, a request to reduce the cost-sharing for a drug, a request to provide a larger dose of a drug than the formulary limit, or a request to receive the prescribed drug without first trying a less expensive drug (“step therapy”). An Exception may also include a request to provide a drug without first getting prior authorization from the drug plan.

Unfortunately, beneficiaries are not adequately informed of the need to request a coverage determination. As a consequence, they never contact their drug plan for a coverage determination and they never enter the appeals process. For example:

After waiting two weeks for her refill, Mrs. F, a Maryland Medicare beneficiary, called the mail-order pharmacy used by her plan, only to be told that her prescription could not be refilled without prior authorization from the drug plan. If she had not called the pharmacy, she would not have known that she needed to request prior authorization from the drug plan before it would cover her drug. Even after she called, the mail-order pharmacy never sent her the notice explaining her rights. Thus, she did not know that she had a right to request an Exception to the prior authorization requirement.

Advocates continue to report that pharmacies are not providing beneficiaries with the CMS-approved notice, “*Medicare Prescription Drugs and Your Rights*,” which explains in general the right to contact one’s plan to request an Exception or other coverage determination. In December, an advocate who saw that the notice was not posted at a large chain drug store in suburban Washington, DC, was told that the pharmacy tells beneficiaries to call their plan, without giving them anything in writing or posting the notice.

Medicare regulations require Part D plans to arrange with their network pharmacies either to post the generic “*Medicare Prescription Drugs and Your Rights*” or to hand the notice to a beneficiary whose prescription has been denied. Posting of the notice provides very little protection. The notice is often posted in a place that makes it difficult to read. Moreover, because the notice is generic, telling beneficiaries only of their right to request an exception and the need to contact the plan, beneficiaries do not know what information they will need to provide in order to get their prescription covered or exactly how to contact their plan.

Furthermore, neither CMS nor the plans take responsibility when advocates complain that beneficiaries are not being informed of their rights to ask for an Exception and then to appeal. CMS says the plans are required to ensure distribution of the generic notice; plans claim they have done their job in educating pharmacies.

B. Beneficiaries Lack Plan Information For Evaluating A Prior Authorization Request

Even if, as in the case of Mrs. F, the pharmacy tells a beneficiary that prior authorization from the plan is required before a drug will be covered, the beneficiary still does not have all the information he or she needs in order to take action to get his or her medication. Drug plans do not make available on their web site or through their customer service centers the criteria they use to evaluate a prior authorization request. Thus, beneficiaries, their doctors, and their advocates do not have the information they need to support a request for prior authorization or a request for an Exception to a prior authorization requirement.

C. The Part D Appeals Process Includes Conflicting Directives Concerning The Effect Of The Attending Physician's Opinion On An Exception Request And Appeal

A beneficiary must have the support of the prescribing physician in order to succeed with an exceptions request. Indeed, the Medicare statute makes the opinion of the attending physician concerning his or her patient's need for a non-preferred drug the controlling factor in determining coverage. However, the Part D regulation specifically downgrades the effect of the physician's opinion to such an extent that it is not clear whether any deference is given. Thus while beneficiaries must obtain a supporting document from their physician even to enter the appeals process, Part D plans are not required to respect the physician's opinion.

This is particularly problematic when the beneficiary and physician seek an Exception for approval of an "off-label" use of a drug approved by the Food and Drug Administration (FDA). The use of drugs "off-label" is legal in the United States and is governed by strict rules for marketing. In many situations, physicians and their patients have determined over time that certain drugs approved by the FDA for one purpose also help with a different medical problem. Yet Part D plans do not defer to the opinion of the treating physician, even when the off-label use is supported by scientific literature, proven safe and effective over a substantial amount of time, and covered by the beneficiary's state Medicaid program. For example:

In 1995 Mrs. B, a dually eligible beneficiary in Florida, was prescribed an off-label drug to treat her multiple sclerosis (MS). As a result of the drug, she remained symptom-free, and she experienced no side effects. As required, Mrs. B looked to Part D to cover this drug in 2006. She chose a Part D plan because the plan representative said the drug was on the formulary. However, in April 2006, the drug plan said it would no longer cover the drug. The woman requested an Exception, and the plan asked her physician and her attorney to provide two national and professional medical journals to show why the use of the drug was medically reasonable to treat MS. Despite the fact that the beneficiary's medical record established that the drug had been effective for 11 years, and despite the fact that four peer-reviewed medical journal articles were submitted, the plan denied coverage of the drug. An Administrative Law Judge ruled in December that the drug was safe and effective and medically necessary for the woman, and ordered the drug plan to cover the drug. However, because the woman stopped taking the drug at the end of March, her symptoms returned.

D. Part D Complaint Mechanisms Are Not Prompt Or Reliable, Making The Process More Difficult For Beneficiaries

CMS has established a number of mechanisms through which beneficiaries may seek redress of problems with their drug plan. Beneficiaries may seek a coverage determination and appeal if a drug is not covered, file a grievance with the drug plan if they have a complaint that does not involve drug coverage, and/or file a complaint by calling the Medicare hotline, 1(800)MEDICARE. As illustrated below, these mechanisms are ineffective.

Mr. S, a New York beneficiary, and his doctor requested an expedited (72 hour) appeal after his drug plan said it would no longer cover one of his drugs. When no response was received, the beneficiary called the plan three times. He waited each time for about 45 minutes, trying to speak to a plan call center supervisor, and was disconnected each time before speaking to a supervisor. Finally, the beneficiary was called by the plan and told that the drug in question was not covered. The telephone representative did not provide any further explanation or describe additional appeal rights. The beneficiary did not receive written notice of the denial. The beneficiary subsequently called 1(800)MEDICARE to complain about the process. CMS's customer service representative told the beneficiary that the Medicare Call Center has no control over appeals issues and that he should contact the drug plan.

Recommendations

Congress should redesign Medicare Part D to create a benefit that is standardized, available throughout the country, and administered through the traditional Medicare program. Such a system would be more valuable for more beneficiaries and more cost-effective for taxpayers.

Congress should require Part D plans to give deference to the opinion of the beneficiary's attending physician when making coverage decisions and should require CMS to delete the provision to the contrary in its regulations [42 CFR §423.578(f)].

Congress should authorize Part D coverage for off-label uses of drugs that are supported by peer-reviewed studies, are proven safe and effective over a substantial period of time, are covered by the beneficiary's state Medicaid program, or are listed in one of the three compendia currently included in the Medicare Act.

CMS should require plans to provide a written coverage determination electronically at the pharmacy whenever a drug is not covered. The written coverage determination must explain why the plan will not pay for a drug and describe beneficiary appeal rights and explain how to request the next level of review.

CMS should require Part D plans to include on their web site, through their customer service centers, and in their written materials, information about whether each drug on their formulary requires prior authorization or other utilization management tools, and the criteria used by the plan in determining whether the precondition to Part D coverage has been met.

CMS should ensure that Part D plans comply with required appeals and grievance processes, that plan call centers respond appropriately to beneficiaries, and that Medicare “customer service” representatives provide accurate information and keep track of beneficiary complaints.

CMS should exercise its enforcement authority to take actions against Part D plans that do not provide adequate notice, fail to meet the regulatory time frames for deciding a coverage determination or an appeal, or fail to train their call center staff adequately.

CONCLUSION AND RECOMMENDATIONS

The stories presented here illustrate a variety of problems that continue to affect Part D beneficiaries at the end of the first year of program implementation. While each of these problems could be remedied by certain changes in program operations, they all derive, in large part, from the lack of uniformity in Medicare Part D and its reliance on hundreds of private plans. Although some people are better off than they were prior to Medicare Part D, too many remain confused and frustrated with the complexities and limitations of the drug program. All beneficiaries would be better off with a redesigned benefit that is standardized, available throughout the country, and administered through the traditional Medicare program.

BASED ON OUR EXPERIENCE WITH MEDICARE BENEFICIARIES AND THEIR HELPERS, THE CENTER FOR MEDICARE ADVOCACY RECOMMENDS THE FOLLOWING.

THESE RECOMMENDATIONS WILL IMPROVE MEDICARE'S PRESCRIPTION DRUG BENEFIT, MAKING IT MORE VALUABLE FOR BENEFICIARIES AND MORE COST-EFFECTIVE FOR TAXPAYERS.

Recommendations for Congress:

1. Congress should redesign Medicare Part D to create a benefit that is standardized, available throughout the country, and administered through the traditional Medicare program. Such a system would be more valuable for more beneficiaries and more cost-effective for taxpayers.
2. Congress should eliminate the Donut Hole. If the Donut Hole is not eliminated, Congress should, at a minimum, authorize payments by AIDS Drug Assistance Programs (ADAPs) and pharmaceutical assistance programs (PAPs) to count towards the beneficiary out-of-pocket spending limit.
3. Congress should require Part D plans to give deference to the opinion of the beneficiary's attending physician when they make coverage decisions.
4. Congress should authorize Part D coverage for off-label uses of drugs that are supported by peer-reviewed studies, are proven safe and effective over a substantial period of time, are covered by the beneficiary's state Medicaid program, or are listed in one of the three compendia currently included in the Medicare Act.
5. Congress should hold oversight hearings on the implementation of Part D. The hearings should include an inquiry into the special problems of dually eligible beneficiaries, the withholding of premiums by plans and Social Security, and CMS's role in setting and enforcing standards for plan participation.

6. Congress should require CMS to expeditiously establish a full system of real time data-sharing among all entities involved in Part D. Congress should require CMS to report its plans to resolve these problems effectively and within a specific time period, and should require periodic status reports from CMS.

Recommendations for the Centers for Medicare & Medicaid Services (CMS)

1. CMS should require states to redetermine the eligibility of *anyone losing Medicaid* to determine if that individual qualifies for the low-income subsidy (LIS, also known as Extra Help) as a result of eligibility for other qualifying benefits. CMS should also require states to redetermine LIS eligibility for *anyone who lost his or her Extra Help due to losing their deemed status*. Further, CMS and SSA should explore which agencies should oversee such redeterminations.

2. CMS should create a real time data-sharing system among all entities involved in Part D, and develop mandatory fail-safe systems to ensure that persons who are dually eligible for Medicare and Medicaid do not experience gaps in either their drug coverage or their low-income subsidy.

3. CMS should expand its point of service (POS) system to make its coverage available at the pharmacy for all dually eligible persons who experience plan enrollment and related drug dispensing problems at the pharmacy. Further, CMS should require pharmacies to use the POS system, and hold pharmacies harmless for good faith billings to the POS that turn out to be incorrect.

4. CMS and Part D plans should be required to provide beneficiaries with clear and accurate information about Part D, individual plan offerings, and in particular, about the Donut Hole coverage gap. This information should include the following:

- Materials from CMS and the enrollee's plan that explain how the initial coverage limitation and beneficiary out-of-pocket expenses, including Donut Hole payments, are calculated should be mailed to beneficiaries;
- Monthly statements that clearly indicate the total amount of payments that have been made that count towards the individual's initial coverage limit and beneficiary out-of-pocket responsibilities should be mailed to beneficiaries; and
- Monthly statements that indicate, after the initial coverage limit has been reached, all costs that continue to count towards the out-of-pocket limit in the Donut Hole and how much more is needed to reach catastrophic coverage should be mailed to beneficiaries.

5. CMS should notify all beneficiaries who received incorrect premium refunds in 2006, and all beneficiaries for whom premium withholding has been delayed, of their right to seek a waiver of the recovery of these funds.

6. CMS should ensure that all plans have been paid all premiums owed for beneficiaries who asked for premium withholding in 2006 (so that the burden is not left with individual beneficiaries to work out problems on their own with their plans).
7. CMS should require plans to provide a written coverage determination electronically at the pharmacy whenever a drug is not covered. The written coverage determination must explain why the plan will not pay for a drug, describe beneficiary appeal rights, and explain how to request the next level of review.
8. CMS should require Part D plans to include on their web site, through their customer service centers, and in their written materials, information about whether each drug on their formulary requires prior authorization or other utilization management tools, and the criteria used by the plan in determining whether the precondition to Part D coverage has been met.
9. CMS should ensure that Part D plans comply with required appeals and grievance processes, that plan call centers respond appropriately to beneficiaries, and that Medicare "customer service" representatives provide accurate information and keep track of beneficiary complaints.
10. CMS should exercise its enforcement authority to take actions against Part D plans that do not provide adequate notice, fail to meet the regulatory time frames for deciding a coverage determination or an appeal, or fail to train their call center staff adequately.

THE CENTER FOR MEDICARE ADVOCACY

Founded in 1986, the Center for Medicare Advocacy is a national, non-profit, non-partisan organization that works to ensure fair access to Medicare and quality health care. The organization is headquartered in Connecticut, with offices in Washington, DC and throughout the country.

The Center responds to over 7,000 calls and emails annually from older people, people with disabilities, their families, and support networks. The Center provides in-person and web-based training throughout the United States. The organization is a partner in Connecticut's SHIP (State Health Insurance and Assistance Program, known in Connecticut as CHOICES), providing training, educational materials, and direct assistance with Medicare, Part D, and related programs. Since November 15, 2005, when beneficiaries could first enroll in Part D, through May 15, 2006, when enrollment closed, the Connecticut CHOICES program handled over 38,000 calls, more than two-thirds of which were about Part D. As the CHOICES legal support center, the Center for Medicare Advocacy handled, or provided guidance about, a significant portion of these calls.

As a result of a grant from a national foundation, the Center for Medicare Advocacy also provides advocacy, training, telephone and on-line assistance regarding Part D on behalf of beneficiaries and their advocates throughout the country. The Center hosts two web sites: www.medicareadvocacy.org and www.fairmedicare.org.

Attachment 3

Strategic Plan Update for 2007- 2008

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Goal 4: Provide relevant information to consumers and licensees.

Outcome: Improved consumer awareness and licensee knowledge.

Objective 4.1	Develop a minimum of 10 communication venues to the public by June 30, 2011.
Measure:	Number of communication venues developed to the public
Tasks:	<ol style="list-style-type: none"> 1. Assess the effectiveness of the board's educational materials and outreach: survey consumers to identify whether board-produced materials are valued and what new materials are desired. 2. Restructure the board's Web site to make it more user friendly. 3. Work with the California Health Communication Partnership on integrated public information campaigns on health-care topics. 4. Continue collaboration with UCSF's Center for Consumer Self Care for pharmacist interns to develop consumer fact sheets on health topics. 5. Develop a Notice to Consumers to comply with requirements of SB 2583 (Nation) on patients' rights to secure legitimately prescribed medication from pharmacies. 6. <u>Evaluate the practice of pill splitting.</u> 7. <u>Evaluate the SCR 49 Medication Errors Report for implementation.</u>
Objective 4.2	Develop 10 communication venues to licensees by June 30, 2011.
Measure:	Number of communication venues developed to licensees
Tasks:	<ol style="list-style-type: none"> 1. Publish <i>The Script</i> two times annually. 2. Develop board-sponsored continuing education programs in pharmacy law and coordinate presentation at local and annual professional association meetings throughout California. 3. Maintain important and timely licensee information on Web site.
Objective 4.3	Participate in 12 forums, conferences and public education events annually
Measure:	Number of forums participated
Tasks:	<ol style="list-style-type: none"> 1. Participate in forums, conferences and educational fairs.

Attachment 4

Background Information on Pill Splitting

Attachment 4

Background Information on Pill Splitting

EXCERPTS FROM THE DISCUSSION REGARDING
PILL SPLITTING FROM THE (DRAFT) MINUTES OF THE
JANUARY 31, 2007 BOARD MEETING

Chairperson Schell stated that during the Subcommittee on Medicare Drug Benefit Plans held on November 30, 2006, the committee was asked to consider the safety of pill splitting by patients.

Board member Stan Goldenberg serves as Chairperson of the Subcommittee.

Charles Phillips, M.D., an emergency room physician, attended the Subcommittee on Medicare Drug Benefits Plans Meeting held on November 30th, and stated that he was concerned about the practice of pill splitting. Subcommittee Chairperson Goldenberg asked Dr. Phillips to provide information on this topic at a future board meeting.

Chairperson Schell called on Dr. Phillips to make his presentation on the subject of pill splitting.

Dr. Phillips introduced himself as an emergency room physician, currently practicing in Corcoran, California. He stated that he regularly fine tunes proper dosage medication for patients, teaches medication administration, and is experienced in titrating medication.

Dr. Phillips presented a bottle containing cholesterol medication, as a visual display. The bottle contained fragments and crumbled residue of drug product at the bottom of the container. Dr. Phillips stated that the crumbled residue was a result of pill splitting. He stated that he has not seen any books on the subject of pill splitting or pill fragmentation, yet the practice is commonplace.

Dr. Phillips stated that he wrote a prescription for himself for a 20-milligram dosage of medicine, and later presented that prescription to a Kaiser pharmacy to fill. The prescription that was filled and provided to him, however, contained a 40-milligram dosage. The medication was provided to him from the Kaiser pharmacy, along with a pill splitter. Dr. Phillips stated that he did not write the prescription that way. He expected 20-milligram dosage medication. He stated that the explanation given at the Kaiser pharmacy window was that it is their policy to provide the higher dosage pill to the patient, along with a pill-splitter.

Dr. Phillips stated that the policy to pill-split is carried out throughout Kaiser pharmacies, V.A.s, and some Medi-Cal units. He stated the policy is carried out for fear of retaliation, peer reviews, and pressure to save costs and increase profits, and that physicians are afraid to speak out. He questioned whether it is ethical to ask patients to pill-halve when there is a standard pill in the lower dose, particularly for patients who are physically incapable of performing an accurate pill split. He provided an example of a specific patient who has cerebral palsy. Mr. F. can move only his head, not his arms or legs, yet he has been asked to pill-split, which he is incapable of doing. When Mr. F.'s attendant is unavailable to perform a pill-split, he cannot take the proper dosage when needed, and that results in muscle pain and other problems.

Dr. Phillips stated that even when a prescription for a lower dosage is presented to a pharmacy, the pharmacy technician or pharmacist hits a button resulting in a higher dose medication, along with instructions to the patient that the pills must be split. He said there is no physician orientation book for Kaiser physicians on this policy.

Dr. Phillips asked Kaiser for any research they have to support their policy of asking patients to split pills. He stated that no research was provided from Kaiser as a result of his request, but they stated that the VA started the practice, and Kaiser adopted it. He further stated that Kaiser enjoys a budget savings as a result of the practice, and the VA experiences around \$40,000,000 in cost savings with the practice of pill splitting. Dr. Phillips referred to a VA study of 442 reports of pill splitting, which resulted in 38 adverse medical events that were not therapeutic to patients. According to the survey, not all pills were split evenly. Inconsistent dosages resulted in medications causing higher reactions one day and lower reactions on other days, including bouncing cholesterol and blood pressure. He also referred to a study of 752 reports of pill splitting that showed 41 percent of the split pills deviated by more than the accepted weight standard.

Dr. Phillips recommended that the board take a stand on pill splitting and pill fragmentation. He stated that if the board is silent on this issue, it enables the problem. He considers the policy of asking seniors to pill-split is a form of patient abuse. Dr. Phillips referred to a case against Kaiser where the judge said he hadn't heard a lot of noise from regulatory bodies on the subject. He also referred to a 1997 NABP conference in Seattle that addressed the issue of informed consent regarding pill splitting and pill fragmentation. He believed that all 50 states participated in the conference.

Ms. Herold clarified that the California Board of Pharmacy was not a member of the NABP in 1997. The board has since joined, but was not a member at the time that Dr. Phillips stated.

Chairperson Schell opened the floor for questions or comments from the board and the public.

Mr. Goldenberg asked if any state's board had passed an informed consent rule regarding pill splitting.

Dr. Phillips stated that Kentucky's board came close, but only provided a general resolution on the subject of informed consent. He further stated that he has complained separately to California's Medical Board.

Dr. Hiura asked why physicians write these prescriptions when they are aware of the problems, especially when some manufacturers sell 10 milligrams for the same price as 20 milligrams or 40 milligrams.

Dr. Phillips responded that he does not write prescriptions that way, unless the patient specifically states that they cannot afford the medication and they must choose between the medication and food. In that case, Dr. Phillips will write the prescription and inform the patient as to the risks. He stated that Kaiser physicians cooperate with Oakland to become vested and retire, and Kaiser physicians shown the data would not pill-split without the policy.

Mr. Hough stated that he agreed with Dr. Phillips' concerns, and believed that the issue relates directly to the cost of health care.

Chairperson Schell asked if there were any other comments. Various comments were provided including reference to data from a study at Florida's College of Cardiology showing a safety efficacy window that was not affected by varying weights of split tablets. Dr. Ravnan said she believes the evidence supports a safe practice of pill splitting.

Steven Gray, Kaiser Permanente, provided a binder of printed documents for the board's review. The binder contained various news articles and scientific research on the subject of pill splitting. One of the documents was a copy of an on-line article about pill splitting from Consumer Reports. Dr. Gray stated that although Consumer Reports is not a scientific magazine, they base their recommendations on science. The article listed medications that can be safely split. Dr. Gray stated that physicians and scientists must make decisions on which medications are safe to split, and learn as we go, reversing decisions based on data as applicable. He said that pill splitting devices should be provided free of charge to patients to effectuate pill splitting which he said would be better than using a paring knife.

Dr. Gray further stated that pill splitting is performed nationally and internationally. The practice is encouraged by medical group committees. He stated that the program is voluntary.

Dr. Gray said that informed consent would have four types of mandates:

1. on patient
2. on physician
3. on pharmacist
4. on pharmacy

President Powers asked what happens if a patient tells his or her doctor that he or she does not want to split a pill.

Dr. Gray responded that patients would then get the dose they need in a non-split form. But he couldn't guarantee that that practice would be followed by every physician. And he couldn't guarantee that every patient would split a pill, even when asked to do so.

Mr. Dazé commented that there appears to be an educational process in a 3-person chain: patient, doctor, and pharmacist. Mr. Dazé asked if each patient should be informed that he or she does not have to accept a split pill prescription.

Dr. Gray responded that a doctor should inform the patient that he or she does not have to accept a split pill prescription. The patient has the right to request the proper dosage.

Anthony Morielli introduced himself as someone who works for the VA, but was not representing the VA. He's a pharmacist and researcher in this area. He stated that he believes the facts about pill fragmentation are being distorted by Dr. Phillips. There are differences in clinical effects of any pill, and that 15 percent variation up or down in any individual dose is acceptable. Dr. Morielli took scored tablets approved by FDA for splitting and matched them to unscored lower doses – he said results show same variation – only 2 percent did not meet standard, and none exceed 17 percent of variation the range. Dr. Morielli advocated health care system cost savings, but did agree that safeguards should be in place. Pill splitting has its

benefits, and has limited clinical adverse events. At the VA, no one is mandated to split. In their computer system, medication will show as a pill-split dose, so doctor gives the patient counseling along with a pill splitter. Most patients go along with the program. Dr. Morielli asked that the board recommend that doctors apply good science, and give patients options and informed consent.

John Jones introduced himself, stating he was from United Health Care and had 30 years practice in tablet splitting. He didn't recall any negatives, except for discarding some split pills. He provided a handout from United Health Care that indicates that pill splitting is a voluntary program. He further stated that he is on the IOM panel to review the VA drug management system. He suggested a public education program for patients to know when it's appropriate and when it's not appropriate. For example, mental acuity of a patient could affect whether the patient could perform a pill split with accuracy. Cost savings are important to vets, as well as avoiding the Medicare Part D donut hole. Out of pocket costs are reduced by pill splitting. Dr. Jones asked the board to preserve the pill splitting tool.

John Cronin introduced himself as a private pharmacist and attorney in San Diego. He said that a point not raised is that this practice is driven by dollars. The issue belongs in public education. He further stated that Consumer Report articles end up in broadcasts, even on UCSF student fact sheets. Pill splitting can be safe, but the problem is that many consumers start wanting to split everything, including odd-shaped tablets like Lipitor, which are expensive. Dr. Cronin asked the board to keep the matter of informed consent in the Public Education Committee.

President Powers said he has tried splitting a soft small pill that falls apart when he tries to split it. He said there is evidence of problems with pill splitting, and that he will refer the matter to both committees (Public Education and Enforcement) for further recommendation.



IOM Report Addresses Medical Errors

A report released in late 1999 by the Institute of Medicine (IOM) of the National Academy of Science's Committee on Quality of Health Care in America concluded that rigorous changes throughout the health care system, including mandatory reporting requirements, are necessary to reduce medical errors and create a safer health care system.

Citing recent studies that place mortality estimates from medical errors between 44,000 and 98,000 annually, the Committee outlined a plan for government, industry, consumers, and health providers to reduce medical errors; called on Congress to form a national patient safety center to develop new systems that can address persistent problems; and set as a minimum goal a 50% reduction in errors over the next five years.

"Our recommendations are intended to encourage the health care system to take the actions necessary to improve safety," said William Richardson, chief executive officer of the W.K. Kellogg Foundation, Battle Creek, Mich, and chair of the Committee. "We must have a health care system that makes it easy to do things right, and hard to do them wrong."

The report, entitled "To Err Is Human: Building a Safer Health System," is available for a fee by calling 800/624-6242. The IOM is a private, nonprofit institution that provides health policy advice under a congressional charter granted to the National Academy of Sciences.

FDA Issues Final Dietary Supplement Labeling Rules

In the January 6, 2000 *Federal Register*, the US Food and Drug Administration (FDA) published final regulations that define the types of statements that can be made concerning the effects a dietary supplement has on the structure and function of the human body pursuant to the Dietary Supplement Health and Education Act of 1994 (DSHEA). The regulations are intended to clarify the types of claims that may be made for dietary supplements without prior review by the FDA, as well as the types of claims that require prior authorization through the establishment of criteria for determining when a statement about a dietary supplement is a disease claim.

Under DSHEA, dietary supplements may, without prior FDA review, carry "structure/function" claims (ie, claims that a product may affect the structure or function of the body), but may not, without prior FDA review, carry express or implied claims that they can treat, diagnose, cure, or prevent disease (disease claims). For example, the express disease claim "prevents osteoporosis" and the implied disease claim "prevents bone fragility in postmenopausal women" would be prohibited without prior FDA review. The rule clarifies that express and implied disease claims made through the

name of the product (ie, Carpalum, CircuCure); through a statement about the formulation of a product (ie, contains aspirin); or thorough the use of pictures, vignettes, or symbols (ie, electrocardiogram tracings) can be made. It also permits claims that do not relate to disease, such as health maintenance claims ("maintains a healthy circulatory system"); other non-disease claims ("for muscle enhancement"); and claims made for common, minor symptoms associated with life stages ("for common symptoms of PMS," "for hot flashes").

Under DSHEA and existing regulations, dietary supplement manufacturers are already required to maintain documentation substantiating structure/function claims and must include a disclaimer on their labels that their products are not drugs and receive no FDA pre-market approval. They must also notify the FDA of the claims they are making within 30 days of marketing.

The final rule became effective February 7, 2000. For further information contact Ann Marlin Witt, Office of Policy, Planning, and Legislation (HF-11), FDA, 5600 Fishers Lane, Rockville, MD 20857, 301/827-0084.

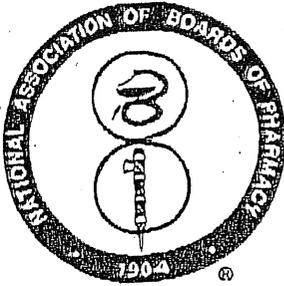
Tablet-Splitting Policies Raise Concern

Some state boards of pharmacy are concerned about the cost-saving initiatives of certain health care plans that encourage or mandate the practice of dispensing higher doses of certain medications so that patients must split the tablet to obtain the appropriate dose. Targeted are those high-cost drugs that are available in similarly priced higher- and lower-dose tablets, such as Zoloft[®], which has 50 mg and 100 mg dosages selling for about the same price. Medical insurance plans favoring this method of cost cutting provide pill-cutters to enrollees and instruct physicians to prescribe the higher dosage tablets.

Inaccuracies in tablet splitting, the lack of testing on the effectiveness of split pills, and the potential for overdosing are the primary issues of concern. "As a cost-saving measure, tablet splitting may be considered in certain situations; however, health care insurers should not mandate such practices for financial gain without regard to patient safety," says NABP President Dyke F. Anderson. "The pharmacist is ultimately responsible for providing adequate patient counseling, and for assuring that tablet-splitting is safe and appropriate for the patient."

FDA Targets Illegal Internet Prescription Sales

The US Food and Drug Administration (FDA) is furthering its efforts to combat illegal Internet prescription drug and device sales. The agency recently announced that it has issued, via the Internet, warning letters to a dozen foreign-based Internet



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RESOLUTION NO. 97-4-01

TITLE: Opposition to Mandated Tablet Splitting

Whereas, insurance companies and pharmacy benefit managers are advocating and mandating that practitioners prescribe and pharmacists dispense dosages of medications that may require the patient to physically split the medication; and

Whereas, the precise splitting of tablets may be difficult for patients, resulting in under- or overdosing and endangering patients' health; and

Whereas, the tablet splitting practices advocated and mandated by insurance companies and pharmacy benefit managers do not appear to be in the best interest of the patient but, rather, monetarily driven;

THEREFORE BE IT RESOLVED that NABP oppose this mandate by working with other national associations and government agencies to stop this potentially dangerous practice.

(Resolution passed at NABP's 97th Annual Meeting, Seattle, WA)

Half Tablet Program – Effective August 15, 2006
FREQUENTLY ASKED QUESTIONS

Q1: What medications are available for tablet splitting in the Half Tablet Program?

The list of medications available for tablet splitting includes:

Category	Medications	Dosage
ACE inhibitors	Aceon	2mg, 4mg
	Mavik	1mg, 2mg
	Univasc	7.5mg
Angiotensin Receptor Blockers (ARBs)	Atacand	4mg, 8mg, 16mg
	Avapro	75mg, 150mg
	Benicar	20mg
	Cozaar	25mg, 50mg
	Diovan	40mg, 80mg, 150mg
Antidepressants	Lexapro	25mg, 50mg
	Pexeva	10mg, 20mg
	Zoloft*	5mg, 10mg
Lipid-lowering medications	Crestor	5mg, 10mg, 20mg
	Lipitor	10mg, 20mg, 40mg
	Pravachol*	5mg, 10mg, 20mg, 40mg
	Zocor*	
Antivirals	Valtrex	500mg

* Half Tablet Program applies to the generic equivalents to these brands.

The list of medications available for tablet splitting does not include all medications within a therapeutic class; only those medications determined to be appropriate for splitting are included.

Some of the tablets included in this program are not scored or designed specifically to be split. However, with the use of a tablet splitter, these medications may be appropriately divided. As is true with all medical decisions, you and your doctor will need to determine if the Half Tablet Program is right for you. Medications in the program will be reviewed periodically; additional medications may be included as appropriate.

Q2: What are the criteria for determining which medications are included in the program?

The UnitedHealthcare National Pharmacy and Therapeutic (P&T) Committee approved the following clinical criteria to determine prescription product inclusion in the Half Tablet Program.

- Medications with a wide margin of safety so that minimal differences in tablet sizes will not result in either underdosing or overdosing
- Tablets that can be split relatively evenly without crumbling
- Medications that will remain stable after splitting

In addition, the medication must be available in "double" dosage strengths that are comparably priced.

The National P&T Committee approved the following criteria for exclusion of medications from the program.

- Enteric-coated tablets
- Capsules, liquids, topical medications
- Unscored extended-release tablets
- Combination tablets in which the amount of one active ingredient changes from one tablet to the next, but the amount of the other ingredient does not

Q3: How do I get my free tablet splitter?

You can call 1-877-471-1860 or visit www.halftablet.com to order your free tablet splitter and to view Frequently Asked Questions regarding the Half Tablet Program. Notification letters will contain a Participant Code which is required when ordering the tablet splitter.

Q4: How long does it take for my splitter to arrive?

Your splitter should arrive within 10 business days. Please do not call to check on the status of your tablet splitter until at least 10 business days. If you do not receive your splitter after 10 business days you may call 1-877-471-1860 for more information.

Q5: Can I still get a free tablet splitter if I don't have a Participant Code?

If you haven't received a letter, lost your letter, or do not have a Participant Code you can still receive one free tablet splitter by calling 1-877-471-1860. You will be asked to provide your UnitedHealthcare member number and your eligibility in the program will be verified. Not having a Participant Code may cause a delay in receiving your free tablet splitter.

Q6: What if I lose my tablet splitter? What if it breaks or wears out?

Tablet splitters are available for purchase at most pharmacies. UnitedHealthcare will provide you with one free tablet splitter.

Q7: How does the program work?

If you fill a prescription for a medication included in the Half Tablet Program you will:

- Receive a notification letter in the mail informing you of the Half-Tablet Program.
- Discuss the Half Tablet Program with your doctor. You and your doctor decide together if the program is appropriate for you. If yes, your doctor writes a new prescription for the higher-strength dosage with instructions to take one-half tablet.
- Fill your prescription at a participating retail pharmacy.
- Receive an appropriate quantity (15 tablets to meet 30-day supply, 16 tablets to meet 32-day supply, or 17 tablets to meet 34-day supply) with instructions for using half a tablet.
- Follow instructions included in member notification letter for obtaining free tablet splitter or purchase one at a retail pharmacy.

Q8: How does the Half Tablet Program work at mail order?

You will receive 45 tablets to meet a 90-day supply at mail order. Because prescriptions are dispensed as written through mail order, you must obtain an appropriately written prescription for participation. The mail order pharmacy will not make outbound patient or doctor calls to initiate program participation.

Q9: What if I don't want to participate in the program?

Participation in the program is entirely voluntary. If you do not wish to participate in the program, you may simply continue to fill your prescription as usual, taking the same strength dosage. No action is required if you choose not to participate. If you try the Half Tablet Program and decide that it is not right for you, you may have your doctor write a new prescription for the old dosage level and go back to your usual copy.

Q10: Have any studies been done on the safety and effectiveness of tablet splitting?

A number of clinical studies have been conducted on the safety and effectiveness of tablet splitting. These studies, published in peer reviewed medical literature, conclude that when appropriate medications are selected, tablet splitting delivers a safe and effective dose of medication. The following sections summarize two of the studies that have been conducted (please be advised the descriptions below are very clinical in nature).

Parra D et al. Effect of splitting simvastatin tablets for control of low-density lipoprotein cholesterol. American Journal of Cardiology 2005;95:1481-1483.

This is a retrospective evaluation of a voluntary simvastatin tablet splitting program in 6 VA medical centers. A total of 1,331 patients who were converted to split tablets and 2099 who were not converted were included in the analysis. Patients were converted from whole to split simvastatin tablets at the same total daily dose and issued a pill splitter and instructions about the conversion. Patients who had visual limitations or other disabilities were exempted from the conversion as were patients whose health care provider or pharmacist deemed them unable to perform the tablet splitting. Primary endpoints were the average final LDL-cholesterol value and the average change from baseline between the split group and the whole tablet group. Secondary endpoints included comparison of total yearly simvastatin costs between groups, incidence of transaminase increases greater than 2 to 3 times the upper limit of normal and assessment of compliance. Baseline and final LDL-cholesterol levels and average change from baseline were not significantly different between

groups ($P>0.05$), nor were the incidences of transaminase increases or measurements of patient compliance.

Gee M, Hasson NK, Hahn T, and Ryono R. Effects of a tablet-splitting program in patients taking HMG-CoA reductase inhibitors: analysis of clinical effects, patient satisfaction, compliance, and cost avoidance. *Journal of Managed Care Pharmacy*. 2002(8)6:453-58.

The primary objective of this study was to determine the effect of splitting atorvastatin, lovastatin, and simvastatin tablets on laboratory outcomes (lipid panel and liver enzyme tests). Other objectives were to assess patient compliance and satisfaction with splitting tablets and to measure the reduction in drug acquisition cost. Before entering the program, patients were evaluated by a prescribing physician or pharmacist for cognitive or physical barriers to assess whether or not they were able to effectively split tablets. If patients agreed to participate, prescriptions were automatically converted by a pharmacist. A tablet splitter and instructions for use were provided free of charge to patients. A total of 2,019 patients were included in the trial conducted by a Veterans Affairs Health Care System facility. A total of 512 patients were eligible for the laboratory analysis. There was no difference between preintervention and postintervention laboratory values for total cholesterol and triglycerides. There was a statistically significant, but not clinically significant decrease in LDL (102 vs. 97, $p<0.001$) and increase in HDL (46 vs. 48, $p<0.001$), AST (26 vs. 28, $p<0.001$) and ALT (24 vs. 26, $p<0.006$) after the initiation of tablet splitting. A total of 454 patients responses to a mailed questionnaire (50%). Results showed that 84% believed that the tablet splitter was not difficult to use, 85% stated that split tablets were not harder to take compared to whole tablets, and 74% agreed that the tablet splitter was not too time-consuming or bothersome; 46% believed that it was easier to take medications when they did not have to split the tablets. Only 7% of the patients stated that tablet splitting had an effect on their willingness to take medications, and 7% stated that they missed more doses in a month while tablet splitting.

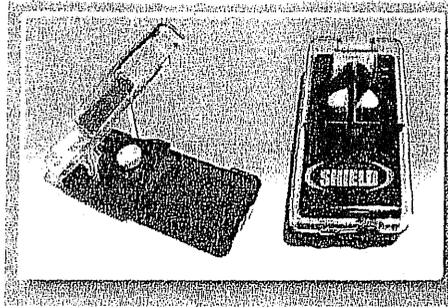
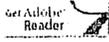
Other studies on tablet splitting include:

1. MA Veronin and B Youan. Magic bullet gone astray: medications and the internet. *Science* 2004; 305:481.
2. JM Rosenbergy et al. Weight variability of pharmacist-dispensed split tablets. *J Am Pharm Assoc* 2002; 42:200.
3. J Teng et al. Lack of medication dose uniformity in commonly split tablets. *J Am Pharm Assoc* 2002; 42:195.
4. JE Polli et al. Weight uniformity of split tablets required by a Veterans Affairs policy. *J Manag Care Pharm* 2003; 9:401
5. TJ Cook et al. Variability in tablet fragment weights when splitting unscored cyclobenzaprine 10 mg tablets. *J Am Pharm Assoc* 2004; 44:583
6. BT Peek et al. Accuracy of tablet splitting by elderly patients. *JAMA* 2002; 288:451
7. MC Duncan et al. Effect of tablet splitting on serum cholesterol concentrations. *AM Pharmacother* 2002; 36:205.
8. M Gee et al. Effects of a tablet-splitting program in patients taking HMG-CoA reductase inhibitors: analysis of clinical effects, patient satisfaction, compliance, and cost avoidance. *J Managed Care Pharm* 2002; 6:453.
9. JP Rindone. Evaluation of tablet-splitting in patients taking lisinopril for hypertension. *JCOM* 2000; 7:22.
10. RS Staffor and DC Radley. The potential of pill splitting to achieve cost savings. *Am J Manag Care* 2002; 8:706.
11. P Gupta and K Gupta. Broken Tablets: does the sum of the parts equal the whole? *Am J Hosp Pharm* 1988; 45:1498.
12. JT McDevitt et al. Accuracy of tablet splitting. *Pharmacotherapy* 1998; 18:193.



View a list of Frequently Asked Questions for UnitedHealthcare's Half Tablet Program

You need Adobe Reader installed on your computer in order to view the Frequently Asked Questions. If you do not have it, you may click below for a free download.



To order your FREE tablet splitter as part of the UnitedHealthcare Half Tablet Program simply type in the Participant Code and your name as it appears on your Half Tablet Program notification letter and click submit. Only one tablet splitter per participant.

Participant Code First Name Last Name

Input fields for Participant Code, First Name, and Last Name



I have read and acknowledge the statement below

United Healthcare Services, Inc ("United") is providing this free tablet splitter to you at your request. By ordering this tablet splitter, you acknowledge and agree that you will only use it to split tablets that your doctor has approved for splitting.

To help maintain the effectiveness of your medication, do not split all of your tablets at one time. Split one tablet and take one half. Take the second half for your next scheduled dose. Repeat the process until you have taken all of your medication.

This tablet splitter is not manufactured by United or any of its affiliates. United makes no warranty as to the reliability of the tablet splitter, nor does United guarantee or warrant the performance of the tablet splitter, including the tablet splitter's conformity to any law, rule, regulation or policy. You assume full responsibility for using the tablet splitter for its intended use in accordance with the manufacturer's instructions. United is not responsible for any direct, indirect incidental, consequential or punitive damages arising out of your use of this tablet splitter.

Con Pill Splitting

Com

(Charles Phillips, MD, FACEP, 2216 E. Los Altos Ave. Fresno, CA 93710

Cphil49401@aol.com Cell – 559-917-8997 (after 10 AM)

PRESENTATION ON 4/3/07 TO
THE CALIFORNIA BOARD OF PHARMACH
ON PILL FRAGMENTATION -
REBUTTAL OF SAN DIEGO PUBLIC TESTIMONY –

Subcommittee on Communication and Public Education Meetings

Once again, thank you for letting me come to the microphone, this time for the focus of what might be the correct patient information that should be published about pill splitting (never to allowed to be called Pill Halving or Half Pill Program because of the rarity of a half and the high likelihood of very uneven fragments). This right for clear information to bring the patient to the level of the provider as much as possible and to empower the patient to have real choices is the principle of “autonomy.” Paternalistic medicine by those with white coats is gone forever (except in Singapore) and that patients must actually make their own decision. That is where we get INFORMED consent. It is echoed on the wall of every accredited hospital⁹, in the Board of Pharmacy “Patient’s Bill of Rights”¹⁰ (Exhibit #5), and the VA’s “Patient and Nursing Home Resident Rights and Responsibilities”¹¹.

⁹ In Kaiser Fresno this paper is behind a patient waiting chair in x-ray such that other patients would be highly unlikely to read it. Two miles away at Saint Agnes Hospital the same paper is next to the public’s coffee machine in the registration area where most patients and/or families will see it. The Joint Commission has as their first chapter in accreditation Patient Rights.

¹⁰ I would like to see these rights print out easily in portrait rather than landscape form so patients can actually read them easily as they come to a pharmacy window and have their high trust interaction.

¹¹ Hippocrates did not seem to have to trade the gift of a professional oath (this world) and covenant (the next world) for patients having to perform in any way; now it is phrased as some even trade between business associates. Patients do not join practices, practitioners join families.

I will try to improve on the two best examples of patient education on pill splitting that I could find on many hours of computer research: the VA's approach in Indiana VA and the Benefits Office of the University of Michigan. Using those two fine examples of trying to get it right – both specifying the sequential use of split fragments – I have tried to create my own consent requirements:

1. Your prescription has the option of being filled by pills that are split into usually unequal pieces for the saving of health system moneys; you have a right to know where this money goes since you are taking on the disease risk of uneven dosing;¹²
2. after reading all of these notes you can chose to have the split of the double size pill approach or the unsplit whole pill without any pressure, influence, criticism, fear of reprisal, or thought that your caregiver might even be annoyed (in case he or she is tracked for pharmacy costs of his or her patients);
3. The research on this topic involved patients who split their pills every day and took the large and small fragments within two days, thus balancing out the dosage; these were on pills that stick around a long time so it has been presumed safe.
4. If you are being asked to split pills in large numbers all at once, there is no research to say that is safe and, in fact, it would be most likely unsafe¹³; bouncing cholesterol, blood pressure, diabetes, etc. has no likelihood of being safe and is most likely to accelerate your disease process;
5. The most common problem surfacing in pill splitting - as discovered by NASA in the contract review of VA practices – is the doubling of pills, and this commonly occurs to about 9% of the splitters about three times a month; your physician and pharmacist need to be sure that a double dose is safe for you on occasion (too tired to split a pill some sleepy morning);
6. There is also no science that says that if you split 200 days of medication that the exposed surfaces of the pills will not add oxygen or water in a way that changes their effect, since pill splitting was never part of the animal or human studies on the way to this after sale practice of dispensing; there have been warnings about this;

¹² This would be the place where an HMO could explain the vast savings that accrue and the split of profits with the physicians. Perhaps the accumulation of \$1 billion by CEO Dr. William Mc Guire while making these decisions might suggest that his decisions involved a hand in the cookie jar. I once tried to talk him out of pill splitting; but he continued undaunted.

¹³ Note Kaiser has offered up no research of its own, although a surprising number of investigators on this topic have ended up Kaiser-financed-related before the day of publication – two pharmacists and one “pharmaco-economist.” It is unclear to me whether or not Dr. Stafford, the pharmaco-economist - who did not study safety in pill splitting beyond the theoretical – ever gave out one pill in his life. His supposed ties to Harvard, Yale, and Stanford did not seem to change the practice – almost no pill splitting – of any of them.

7. The newest pill splitters – which you need to request – have child safety plastics that prevent fingers from being cut; but no splitter is child proof to be opened so that any pills or fragments left in the pill splitter can be of harm to your children, grandchildren, or young visitors;
8. You need to replace the one or several pill fragments back into your pill bottle but be able to find them before they migrate down to the bottom; ask your pharmacist how to do this safely;
9. The average time calculated in the US and Canada for safe counseling on pill splitters by pharmacy students or pharmacists is considerable¹⁴; expect that counseling to be needed on the first few refills and twice a year so that you do not fall into several common error patterns;
10. The California Board of Pharmacy would like to hear about any errors that occur in pill splitting as this largest of states at phone number 916-____-_____.

Please sign that you have read this safety sheet - _____.

END OF SECOND PRESENTATION - CP

¹⁴ Canada decided that the time needed to do this safely ate up any profit expected.

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PRESENTATION ON 4/3/07 TO
THE CALIFORNIA BOARD OF PHARMACY
ON PILL FRAGMENTATION -
REBUTTAL OF SAN DIEGO PUBLIC TESTIMONY –
Subcommittee on Legislation and Regulation

Members of the Pharmacy Board, the Board staff, the audience, and the public served by this consumer protection activity, thank you for letting me come to the microphone again on the topic of the safety of pill handling between pharmacist and the moment of patient swallowing. This is my third appearance which represents your appropriate focus on what is a major source of abuse to seniors and the disabled, if not all patients participating. I do not mind the driving effort from Fresno; I have spent more time on this topic than any other physician in the country (when the AMA is asked about this topic, they refer the reporters to me).

Pill splitting – more accurately **pill fragmenting** – appears today on **two** Pharmacy Board subcommittees. This is appropriate because there is a need to first review real **patient safety**¹

¹ Last Friday I received an Email alert from Maggie Dee – San Francisco radio show host – that “20-20” was going to have a long segment that night on frontline pharmacy safety. I thought the show was accurate as well as scary. While states were not mentioned, I have personally witnessed many of the allegations in California. I particularly noticed that the problem was often related to the pharmacy business managers just above the frontline professionals - in which the pharmacy tasks cannot be done safely simply by pure volume of prescriptions to be filled. There appears to be a dark-hole vacuum of responsibility above the frontline, so that the manipulators of pharmacy “benefits” and the bosses of the frontline providers keep the license boards aimed at the moments of error rather than the systems that made it inevitable. **As long as we search only for rotten apples, we will miss the obvious rotten barrels that populate this universe of care.**

The pharmacist – like the physician – in managed care is turned into a “profit center” and the patients are only “external customers.” The professional who get ahead are those who put all the risk on the patient by delegating the care to those least trained and thus least expensive. This is the same ethic as that is pictured by one pharmacy chain outlet Kaiser (on the internally developed Permanente Medicine Map) as the “group ethic” which is the “wind” of the Permanente Fleet. The goal is to replace the frontline Hippocratic Oath relationship with the ethic-challenge approach called the “Permanente-Patient relationship.” Frontline providers are only hourly-paid cassette tapes moved around as spaces open up. Unfortunately, the Board will be

and then to see if this delivery strategy – if still standing in some form after such an evaluation – can be communicated through educational means in some way respectful to **a patient's rights to know the risk and benefit of any medical treatment.** The Western patient has – since the Nuremberg Trials showed how easily physicians can stray from care to harm – appropriately demanded and obtained the principle of “autonomy” to actually make decisions once fully and honestly informed.

For this Legislation/Regulation Committee then, I will focus on the lack of safety with pill splitting – keeping my comments brief, without repetition of early material, and responding mostly in rebuttal. I will also include summarizing some recent email interactions I have had with VA research personnel, patients who are splitting in various states and clinical settings, and Dr. Mark Aramowicz, the three decade Editor of The Medical Letter.

As Kaiser has deposed me on this topic with some two days of video-taped interview under penalty of perjury and thereafter to risk to my license if speaking any untruth, I would like to state that the comments I make here today will be given as if under oath - so that the Board is not lead astray. **I would ask that the others speaking on this topic also hold themselves to the same oath and license standard.** We are practicing medicine and pharmacy whether we are at the front doors of care or in far away cities stating in testimony to what is safe and unsafe. The AMA, in fact, would like to see all those in managed care be viewed as practicing medicine, particularly when care is rationed, modified off standard, or otherwise curtailed.²

First of all, pill splitting was depicted by Mr. Steven Gray of Kaiser³ at your last meeting as safe. The pictorial held up was that of the Consumer Reports magazine which does, in fact, say “Pill-Splitting – It's safe and can save you lots of money.” [See exhibit #1]. So I E-mailed the Consumer Union and found that they had leaned heavy for their anonymous article on another non-profit foundation that they claim to have initiated – The Medical Letter. After much search I found the anonymous 2004 article (Exhibit #2). And after further search I reached the Editor for the last 30 years – Dr. Arbramowicz of New York. We exchanged some E-mail. I told him that the article was fair in the sense that it described accurately the great difference in split pill sizes – **51% falling outside the USP limits on generics of 85% to 115% and that physicians and pharmacists were to make sure pills were split one at a time so that the low dose would**

encouraged to have pharmacy students with new and fragile ethics spend more time with the manipulators of the game rather than those struggling in offices, emergency rooms, and pharmacies to do the job the way they were trained and within the White Coat mantel.

² When I had a private office, I would often find myself fighting for a patient to get the correct medicine and after listening to country music getting a pharmacy tech in Iowa who would read me the rules of some HMO. I always won the issue, but lost the time and finally closed my office.

³ Background unknown to me so far.

match the next day's high dose. (The Consumer Reports said the same – far into the article).

He said The Medical Letter will be drafting another article on pill splitting after my interactions this last month, this time – I believe after studying the 422 errors in the VA over 3 years – he will probably be even more insistent that **should there be a pill split, the first day's fragment must be followed the second day by the other fragment. And with the high rate of pill doubling going on, there must be much more attention to slow implementation to person by person with a lot of education and close follow up.**

I think that when the Hippocratic Oath is reapplied to this practice, the time needed to do this right will – as well explained in the Canadian article in your attachments by staff – be so excessive in teaching that all economic gains are lost. It will be even more clear than it is now, that the Kaiser approach of giving patients 100 pills to be split into 200 uneven pieces with no careful instruction, no safety paper⁴ does not match either the Consumer Report (or the Medical Letter article) though advanced before this Board as a form of validation for what this for profit HMO does.

As to the idea that pill splitting is “voluntary,” that totally ignores both the fact that the patient is given no information about risks and benefits and the enormous unwillingness of patients to question professionals in the absence of such information. I have never had a patient agree to splitting after hearing the real risks and benefits of bouncing medication. None of the Kaiser patients in Timmis v. Kaiser (Exhibit #3) thought that they had any choice.⁵ And in the case of Nicholas I mentioned in Sacramento testimony, he was expressly lied to that Kaiser did not have his pill in the two milligram size; it is present in every Kaiser hospital formulary since nurses would refuse this silliness.

I do agree with Mr. Gray that the practice is endorsed by the Permanente committees (aka the Permanente Federation members that dominate the P+T Committee where pharmacists do not even vote). But that has more to do with their split of profits and plush retirements than with any science that could stand the light of day. And the Pharmacy Board does have the consumer protection role to judge if this is safe, physician partnership for profit ruling or not. Actually, Kaiser is not even following the guidance of the Academy of Managed Care Pharmacy on this issue – they have published that pills must be split one at a time.

⁴ The Kaiser explanation paper presented as handed out to all patients – advanced during the court battle on splitting called Timmis v. Kaiser as part of the safety system – can no longer be located if a patient or physician so requests (as I did again yesterday in a Kaiser pharmacy). I have verified this at several locations. There are simply splitters and pills. And the average training of those assisting the pharmacist needs to be rechecked; the 20-20 suggestion of students in training in frontline pharmacies is highly accurate for many.

⁵ Audrey Timmis had no choice because Kaiser only ordered the high dosed Mazide for outpatient use; the normal dose for seniors reserved for hospital use only.

Dr. Anthony Morielli – who next spoke to you - was a bit humble about his many titles as he spoke for the benefits managers point of view in the VA. He is the West Coast head of benefits as well as the chief pharmacy of the VA in San Diego. The idea that he simply “works for the VA” in your minutes is an understatement. Of course, he cannot represent the VA in calling the practice safe because **the VA has not endorsed it after all their “research.”** Their Technical Advisory Committee in Massachusetts will not let them! Dr. Morielli started pill splitting, research following practice, though wondering by Email to me who told me (no denial mentioned)⁶; he bears great responsibility if it unsafe.

I have been in communication with a VA pill splitting researcher (Exhibit #4) who said very clearly that the VA in the largest splitting area – Tampa – has made sure that pills are split one at a time due to unequal weight. I asked him why this was not explained very often in their research; HMOs never using this safety step. He was not sure and new that it was explained in oral presentations. Research that does not clarify methodology is not valid research.

A careful reading of the VA articles show that the vets are compliant, that the pills are very unequal in size, that pill doubling is a big problem, and that there has to be a matching of fragment sizes.

This leads me to my poster review of the problem as I head toward my conclusion:

1. (Poster One) Pill splitting is inherently unequal, going beyond the safe limits whether or not there is a split line; the only even split is that envisioned in a new product (Poster Two);
2. (Poster Three) HMOs who have taken the VA research and dropped out the safety steps need to be held responsible – I pity the frontline pharmacists and wish the Board to look more closely at the high-rises of power;
3. (Poster Four) The loose science involved creates a house of cards⁷ in which there is really no proof of any safety and clear likelihood of danger in the methods used in HMOs to give medications to seniors; these are often blood pressure pills, diabetic pills⁸, etc.
4. (Poster Five) The judges in Timmis v. Kaiser have handed the responsibility back to the Boards; it is up to you to represent the people;

⁶ “How did you know that pill splitting was first tried successfully by me at the VA San Diego?” – 1/31/07

⁷ This is a term I am borrowing from a book by about the same title describing the HMOs in Guam, where I set up the paramedic system.

⁸ Tolazamide (Tolinase) has been one of Kaiser’s favorite splits – read in the PDR about the warnings to seniors for hypoglycemia at night. Stanford considers this a museum pill.

5. (Poster Six) This will be my summary – watch as we go from Brand, to generic, to VA research split with common doubling, to HMO split with steady decrease of pill dosage and or bouncing effect.

Conclusion

This is patient abuse. It is most dangerous for seniors or those with disabilities. I recognized it in 1998. With one surprise visit, any of you could see for your own eyes what is in those pill bottles called medication.

Pill splitting was invented for financial and not clinical reasons. The managers have ignored the safety precautions. Many have already been harmed in the silent processes of hypertension, diabetes, arteriosclerosis, etc. What looked like a way to save money will cost patients billions of dollars.

There are probably 1 million pills a day split in California alone. Any delay in Board decision will cost those involved the predictable harm of uneven dosing. I ask you to act – for Audrey Timmis, Mary O'Donnell, Maggie Dee, Nicholas Feldman, and many others.

END OF FIRST PRESENTATION – CP

11/04

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IN THIS ISSUE

Tablet Splitting

SUMMARY – Depending on the patient and the tablet, splitting tablets into 2 halves could be worthwhile. It may not be highly accurate, but for long-acting drugs and those that have a wide margin of safety and a flat dose-response curve, accuracy may not be critical. With scored tablets, FDA approval of splitting can be inferred. Some health care systems have used this practice to save on drug costs.

• Not necessarily a bad idea, especially if the 2 halves are taken as consecutive doses. PAGE 89

Tablet Splitting

Breaking drug tablets in half is a common practice. In some cases, a lower drug dose may be as effective as a higher one, with fewer adverse effects. Sometimes tablets are split to achieve an intermediate dose between marketed strengths. When 2 tablet sizes cost the same, as they often do, splitting the larger size saves money. Is this a reasonable practice?

DOSAGE UNIFORMITY — The distribution of active drug in a whole tablet, or its potential for crumbling or breaking unevenly, is related to drug manufacturing quality assurance standards. In one study, using near-infrared spectroscopic imaging, large clumps of active ingredient were found in simvastatin tablets manufactured in 4 countries by secondary manufacturers, but not in tablets manufactured by Merck in the US.¹

STUDIES — In 3 studies that included more than 22 US-manufactured scored and unscored tablets that were split by pharmacy technicians, split tablets were considered to contain half the dose if they weighed 85-115% of half the mean weight of the whole tablet. Homogeneous distribution of the drug throughout the tablet was assumed. Weight uniformity requirements

were met by 7 (32%) of 22,² 3 (27%) of 11,³ and 8 (67%) of 12 drugs tested.⁴ Even some scored tablets did not split evenly.

In another study, a licensed pharmacist and two Pharm.D. students split unscored generic cyclobenzaprine 10-mg tablets. The study was sponsored by the manufacturer of the brand name equivalent, *Flexeril*, which is available as a 5-mg tablet (the generic is not). After splitting the tablets with a pill cutter, the weights of the tablet halves ranged from 69% to 130% of the expected weight, corresponding to an estimated drug content of 3.5-6.5 mg per half tablet, assuming uniform distribution of active ingredient within the tablet. Use of a kitchen knife resulted in tablet halves weighing 50-150% of the expected weight, with an estimated drug content of 2.5-7.5 mg per half tablet.⁵

A study assessing the ability of elderly patients to split warfarin (*Coumadin*, and others), simvastatin (*Zocor*), metoprolol (*Lopressor*, and others) and lisinopril (*Zestril*, *Prinivil*, and others) found that the weights of the half tablets deviated by 9-37% from the expected weight.⁶

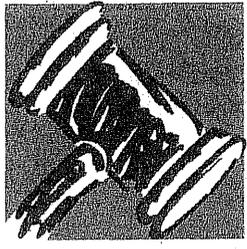
CLINICAL OUTCOMES — Two clinical studies enrolling a total of 2,128 patients taking statins described the effects of tablet-splitting programs conducted by two VA health care systems. No undesirable changes in cholesterol levels were detected in patients who took half tablets for six weeks or more.^{7,8}

In a crossover study, 29 patients taking a stable dose of lisinopril for hypertension were randomized to receive either a whole or split tablet once daily for two weeks; no statistically significant differences in systolic or diastolic blood pressure were found between treatment groups.⁹

COST EFFECTIVENESS — Tablet splitting can reduce prescription costs by as much as 50% because many drugs cost the same regardless of tablet strength.¹⁰ In separate studies of two VA health care systems, one reported a savings of \$138,108 (39%) over one year from a tablet-splitting program with atorvastatin, lovastatin and simvas-

The quarterly newsletter of The TLPJ Foundation

PUBLIC JUSTICE



Winter 2001

TLPJ Files Class Action against Kaiser Permanente for Forcing HMO Members to Split Pills

Mandatory Pill-Splitting Policy Values Profits Over Patients' Health

Trial Lawyers for Public Justice filed a class action lawsuit on December 6, charging that the country's largest HMO, Kaiser Permanente, is violating California law by forcing its members to split prescription pills. The suit contends that Kaiser's mandatory pill-splitting policy endangers patients' health solely to enhance the HMO's profits. It seeks a court order barring Kaiser from forcing its members to split pills and requiring the HMO to disgorge all profits made from this dangerous policy.

"Kaiser's mandatory pill-splitting policy is an outrageous example of an HMO valuing its profits over its members' health and safety," said TLPJ lead co-counsel Sharon J. Arkin of Robinson, Calcagnie & Robinson in

Newport Beach, California. "It makes Kaiser millions, but it has no possible therapeutic value and it puts patients' health at risk."

Kaiser adopted its pill-splitting policy because it allows Kaiser to profit from the fact that smaller dose versions of most prescription pills cost Kaiser almost as much as larger dose versions of the same pills. So, Kaiser forces patients prescribed the smaller dose pills to accept and split the larger dose pills – and pockets the enormous cost difference. For example, 50-milligram tablets of Zoloft, a commonly used anti-depressant, cost approximately \$227 per 100 pills, so it would ordinarily cost Kaiser \$454 to provide a patient prescribed 50 milligrams per day with 200

See Pill-splitting, page 10.



Photo by Xiang Zhou

Plaintiff Audrey Timmis

Project ACCESS Battles Secrecy in Goodyear Tire Safety Case

Despite Death Toll, Key Documents Remain Secret

Trial Lawyers for Public Justice and Consumers for Auto Reliability and Safety (CARS) are seeking public access to key documents and testimony about the dangers of Goodyear 16-inch Load Range E light truck tires. Press reports have disclosed a growing number of deaths and injuries involving these tires, but the documents and testimony about the tires' dangers remain under seal in a New Jersey case. The case was filed after three U.S. Air Force personnel riding in a General Motors Suburban were killed and three others were injured when a Goodyear

tire came apart and their vehicle rolled over.

TLPJ and CARS moved to unseal the documents because of their concern for public safety. The challenge to secrecy in the case was filed as part of Project ACCESS, TLPJ's 12-year-old nationwide campaign against unnecessary secrecy in the courts.

"Court secrecy should not be used to hide potential dangers from the public," said TLPJ Foundation President Peter Perlman of the Peter Perlman Law Offices in Lexington, Kentucky. "Dozens of people were killed or maimed before

See Frankl, page 8.

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Conference, San Antonio, Tx, November 2002

-----Original Message-----

From: CPhil49401@aol.com [mailto:CPhil49401@aol.com]
Sent: Sunday, April 01, 2007 10:39 AM
To: Coblio, Nicholas A.
Subject: Re: Tablet Splitting

Nick,

Why is this single pill splitting not mentioned in the VA research articles? Others copy pill splitting without this fundamental precaution.

Did you save the application to do research and the patient consent sheet? Do you have a safety paper to hand out now? (My home fax is 559-322-5307.)

Tampa must be the center of the largest of the VISN groups. Did Dr. Parra have his group use the same daily split to create a two day supply?

Do you think that the common pill doubling is much of a problem as the patient runs out of time to split for the day and tries to cover the dosing with one pill for two days? I seen the 2006 TIPS article where there have been 442 errors so far, mostly the double dose. One hospitalization /no death so far.

Chuck

In a message dated 4/1/2007 7:00:37 A.M. Pacific Daylight Time, Nicholas.Coblio@va.gov writes:

Hello:

Yes, the recommended procedure was, and still is, to split only one tablet at a time and take the next dose from the remains of the first split tablet. We use this procedure for any split doses.

Regards

-Nick

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-----Original Message-----

From: cphil49401@aol.com [mailto:cphil49401@aol.com]
Sent: Friday, March 30, 2007 9:08 PM
To: Coblio, Nicholas A.
Subject: Tablet Splitting

Dr. Coblio,

I have recently read the 2004 article "Using a Data Warehouse to Monitor

Clinical Outcomes Associated with Simvastating Tablet Splitting."

I am

wondering if during the research you used the approach recommended by

the Medical Letter (2004) of having the veteran split the tablet every

VA
Florida

in
Can

“Pill Fragmenting Program” -

Presentation by Charles Phillips, MD of Fresno, California
On Invitation to Speak at the California Board of Pharmacy
San Diego Meeting on January 31, 2007

INTRODUCTION

I would like to thank the Pharmacy Board's Subcommittee on Medicare Drug Benefits Plan for inviting me,¹ a physician, to discuss pill fragmentation before the full Board today. It is appropriate that this presentation be in San Diego for it is here that pill splitting got its start² and, perhaps, where it should as massive programs be stopped.

I also have to thank Maggie Dee for helping me to understand this problem through the disabled patient point of view as well. One patient she helped me to meet by Email is Mr. Nick Feldman, who due to cerebral palsy can only move his head. Yet he has graduated from UC Berkeley. He has been forced by Kaiser to split pills – Zanaflex 4 mg into two pieces that are supposed to simulate the 2 mg tablet. He saw the fragments created by his attendant's best efforts and stopped the splitting. He takes the whole dose in the morning to avoid the humiliation of medication fragmenting. This means he is over sedated in the morning and has muscle cramps in the afternoon. He has asked – through an Email to me – that you listen to me today and take action soon; he knows what is going on and wants it to be stopped.³

I believe large scale “pill splitting” to be a form of general patient abuse; it is particularly obnoxious to force onto the disabled. It is a form of **senior abuse**.⁴ It is also - in its

¹ My friends would find me well qualified to talk about HMOs and medications – as I have written a whole chapter of one of my textbooks on “Medication Administration” [Exhibit #1]. I have taught the same topic to nurses and paramedics as well. My enemies would try to destroy me as a messenger by pointing to a tattoo on my medical license around not catching a physician assistant's poor evaluation on a child in 1999. Luckily all peer reviews of that incident have been in my favor, and I never lost being Board Certified in Emergency Medicine – now for my 25th year.

² Pill splitting began with Dr. Anthony Morreale at the VA in San Diego. Later he became the “Pharmacist Benefit Manager” for VISN 22 – the whole West Coast as pill splitting spread to the VA in Long Beach. Then it spread to Kaiser through Dr. Fawell who moved from the VA in Long Beach to Kaiser Vallejo. The VA has conceded that the pills split unevenly. Thus many have the vets split one pill every two days so that big and little fragments might be matched up (e.g. Tampa, Florida VA).

³ One of the tricks used by Kaiser is to use two formularies – one for outpatient care that shows only one size for many medications – like Zanaflex 4 mg, Maxzide full strength, etc. The other one is seen by very few eyes but is built into the in-hospital dispensing systems with variable doses so that nurses are almost never asked to split pills. Zanaflex 2 mg is available in the Kaiser Hospitals. The traveling nurses – with no dental benefits – would be the first to turn Kaiser in for pill chopping if it occurred in the hospital. So if it is not safe for a nurse, how does that make it safe for a patient?

⁴ Naturally, I do not object to the few cases where pill splitting is necessary – titration on the way to the correct dose, getting a patient through a weekend when a pharmacy is out of a medication, or helping a

HMO form - the illegal corporate practice of medicine by the top hierarchy⁵ of the for-profit physician partnership⁶ called the Permanente Federation.

Pill fragmentation or chopping results in **uneven fragments producing uneven treatment**.⁷ In the case of the Kaiser HMO called "Kaiser Permanente"⁸ this puts the risk of accelerating cardiovascular and depression illnesses onto the patients – opposite to the \$45 million a year ad campaign with its "Thrive" message [Exhibit #4]. And nowhere in Kaiser's ads or website are seniors – the most vulnerable - warned that they might be funneled⁹ into pill splitting schemes or just what uneven pill fragments mean.

patient (like a child) achieve a correct medication dosage where there is no manufactured alternative. Pill scores were never meant to be invitations for massive pill fragmentation and is not condoned by the manufacturers, the FDA, the surgeon general, CMS, the AMA, pharmaceutical malpractice insurers, and many others.

In fact, the California Medical Board did vote with the other medical boards [the National Association of Boards of Pharmacy (NABP) in Seattle in No. 97-4-01 voted on in 1998 – "Whereas, insurance companies and pharmacy benefit managers are advocating and mandating that practitioners prescribe and pharmacists dispense dosages of medications that may require the patient to physically split the medications ... [programs that are] monetarily driven; therefore it be resolved that NABP oppose this mandate by working with] other national associations and government agencies to stop this potentially dangerous practice" [See Exhibit #2]

⁵ Kaiser HMO, its hospitals, and the very profitable Permanente Medical Groups (the Federation) are run out of the Ordway building [pictured in Exhibit #3] – Mr. George Halverson and Dr. Francis Crosson being co-chairman of the top executive committee. They each have an office on the 27th floor – thus only a few doors down the hall from one another. They each hope to be aloof to these decisions that tie the hands of doctors at the frontline. Those physicians and pharmacists who complain are deemed "not manage care suitable" and expelled. Many physicians don't even know that their prescriptions result in double doses and pill splitters – as a ER physician I did not catch on for one year. These decisions lead to the Sustainable Future of the partners – see the Permanente Map in the same Exhibit – not the patients. In fact, the unethical "group ethic" and the illegal "Permanente-patient relationship" are included on the greed map. This is "corporateering" at its worst.

⁶ As the HMO Act of 1973 created federal enhancement of prepaid health plans like Kaiser (the mother or grandfather of HMOs), it also required "independent physician groups" be put at financial risk. Such IPAs – like the Permanente group – do take risk for profit but pass that risk on to patients as rationed and often dangerous care. The patient carries the risk of illness; the physician carries the likelihood of profit – million dollar plus pension plans creating \$15,000 a month as the MDs turn senior.

⁷ In fact, the topic should never be called "pill halving" [which rarely occurs] or even "pill splitting" [still sounds sort of even], but rather **pill fragmentation**, which is really what happens.

⁸ The Kaiser lawyers are the first to point out that "Kaiser Permanente" does not exist as a legal entity. There are only three organizations who use a common strategy of care.

⁹ I use the word funneling because Kaiser can achieve 98% uniformity of prescription for hypertension, diabetes, high cholesterol, etc. using the following tools: pocket reminders, EPIC program computer pop-ups, peer pressure, medication utilization tracking, pay check reminders, one on one talks, our-way-or-the-highway, etc. And the funneling is toward split pills – Tolinase, lisinopril, statin of the year, Paxil, Zolof, Maxide, etc. The physician has little choice, so the patient has little choice. Pharmacists who complain are not encouraged to stay.

Time for Transparency

Transparency in health care is the only way to give back to seniors what has been so often stolen from them – the true information on which to base real consent. There can never be “informed consent” without the person being first fully informed.

And as this month is part of the-health-plan-switching period of time in Medicare, this is a good time for extra honesty. Either pill fragmenting is a way for the world to save \$15 billion in pharmaceutical expense or a way to cost patients some \$60 billion in early illness from uneven dosing.¹⁰

I originally sent you a formal complaint in 1998 - (#C1-98-17552). The silence of the previous Pharmacy Boards up until now – except for a quiet vote in Seattle [Exhibit #2] – has made the previous boards co-enablers of pill fragmenting in California. I ask that you transform your vote in Seattle to action in California. Further silence will simply endorse the status quo – massive pill splitting by the uniformed.

The Weighing Data

Is this “pill halving” or is it “pill fragmenting.” The classic study of J.T. McDevitt in 1998 published in Pharmacotherapy [Exhibit #5] is quoted both by Kaiser and the VA as well as all experts on the topic of pill fragmenting. No one has ever proved him wrong. And these were volunteers from a newspaper ad, not sick patients.

Exactly 1752 pills were split by 94 healthy volunteers, the latter recruited from a newspaper ad. “Some 41.3% deviated from ideal weight by more than 10% and 12.4% deviated by more than 20%.” Amazingly it did not matter if the pill had a score line or if the pill was split by hand or a pill splitter from Rite-Aid¹¹. “Given the choice, 96.8% of volunteers stated that they would rather not split a tablet if a lower-dose formulation was available.”:

And what we find in the general practice of pill splitting is that dependent patients are compliant with the general funneling system toward one product. But they are uniformed of true risks. White coats give patients the impression that it is perfectly safe. The very labels used by the HMOs – Kaiser and United HealthCare¹² of the “Pill Halving” programs is 100% deceptive since halves are not produced.

The VA has tried some weighing experiments even using a trained pharmacy student, and still the fragments were often greater than 10 percent of the hope for a half weight. In that study, the article suggested that lisinopril not be split; Kaiser does still split it. Those

¹⁰ Since most strokes are often sent home after Kaiser ER evaluation, the cost of care falls back to the family and not to the HMO.

¹¹ Rite Aid, Walmart, Walgreens, private pharmacists, Stanford, Harvard, Yale, etc. are not into pill fragmentation. It takes a dependent population who have prepaid benefits, a difficult path for legal suit, and the co-enabling by government - to pull of pill fragmentation.

¹² Dr. William W. McGuire who helped to okay pill splitting at United GroupHealth received an average compensation of \$57,843,000 per year for his last six years.

VA areas with at least partial ethics had their patients split pills every other day – so big pieces would be matched with small pieces. They did not mention this in most of their articles; and Kaiser leans on VA “research” as its backup.

No one has done this weighing study with seniors who have the usual co-morbidities of arthritis, hypertension, high cholesterol, acid reflux, and occasional depression. This weighing experiment could be done easily and quickly.

Seniors can be on three Kaiser splits at one time – like Mary O’Donnell of Corcoran California who has now passed away. A page from her medication diary [Exhibit #6] and Kaiser medication records show the splitting of her blood pressure pill, her anti-cholesterol pill, and her anti-depression pill¹³ all at the same time.

Or what about Audrey Timmis, an oxygen dependent patient who was asked to split Maxzide. Kaiser did not even order the smaller, senior dose for their formulary – regular dyazide (capsule) or Maxzide-25 – because the national goal in Kaiser pharmacy procurement in the Oakland highrise [See Exhibit #3] was to set up massive pill splitting and no choice. It saved money to order millions of Maxzide pills and have them rebundled into 100 pill bottles in Livermore. That translated for Audrey to have pieces – she called “tiddley winks” – flying all over her kitchen, even with her husband helping.¹⁴ For goals spelled out in Kaiser-eeze in the Recovery Plan by 2001 – Audrey did not matter; profit mattered.

Kaiser’s top profit year was 2004; the profit was \$2 billion – half going to the physicians. And pill fragmenting contributed to the profit. That is blood money in my book. How many strokes and heart attacks we will never know – the evidence is swallowed. It is almost the perfect crime. But it lacks professional ethics. And that is why we have professional boards – to foster ethics and protect patients.

Am I Alone?

I am sometimes viewed as a Lone Ranger type in health care. However, my position against pill splitting is supported by:

1. the manufacturers [letter available from Merck];
2. the FDA safety committee;

¹³ By the way, I was in Mary O’Donnell’s house the day ABC News investigated pill splitting. She never felt she had Informed Consent or any choice. She was part of the law suit against Kaiser whereby after Kaiser’s \$1 million plus defense effort, the judges ruled that Kaiser was right – this issue belongs before the California Board of Pharmacy and the California Department of Managed Health Care. In fact, your ongoing “investigation” became their defense that they should not have to defend the same issue on more than one “front.” They also admitted what I have long maintained, that “Kaiser Permanente” really does not exist. Kaiser maintains that they won this suit were embarrassed into dropping their splits from thirty-eight before the suit - including heart rhythm medication and seizure medication – down to about ten.

¹⁴ Another reliable patient has called these type of pieces “grenade fragments.”

3. the American Society of Pharmacy Consultants – same policy for years;
4. most malpractice carriers for pharmacists;
5. increasingly seniors who start to understand pharmacy science;
6. veterans who wonder why the VA has never declared splitting safe by their Technical Advisory Committee;

Those who are against large splitting programs coming down from those who would be less responsible – like “Medical Directors” of HMOs – include:

1. the Surgeon General;
2. the FDA;
3. the National Boards of Pharmacy in Seattle;
4. the American Medical Association;
5. most of the physicians and pharmacists on the frontline of Kaiser who actually complement me privately for reducing the corporate pressure coming down from Oakland.¹⁵

Those who seem to like splitting include:

1. Top MDs and administrators at HMOs like Kaiser and United HealthCare with a focus on seniors (and great retirement programs for top management);
2. the VA regional programs who compete with each other for limited funds – really a federal HMO the same size as Kaiser;
3. “Pharmacy Benefit Managers” like those in Wisconsin and Michigan;
4. the “outcome centers” supported by the federal government and often a Kaiser Family endowed chair – like Stanford; though Stanford pharmacists have not joined this practice;
5. Medicaid wherever Pharmacy Boards are lax;
6. some newspapers who think that medications cost too much and do not have an independent pharmacist on staff to really explain the risk vs. benefit of uneven dosing;
7. pill splitter companies.

I admire those pharmacists in Kaiser who split the pills for the patients who need half pills because of no available size on the market – as in pediatrics. I do not admire those physicians and pharmacists who have decided to go along with this approach so as to achieve personal “vesting” goals for golden retirements. One group of future seniors should not get to the Golden Pond on the pain and suffering of other seniors.

¹⁵ One ex-Kaiser pharmacist might be willing to privately testify to a Board investigator. But the risk of going against Kaiser is to have one’s career ruined. As with “The Firm,” getting out of Kaiser without being damaged on the way out is very difficult. Those out of Kaiser can also be damaged by sympathetic IPAs and hospital “risk management” offices that can change alter medical records without a flit of conscience.

Kaiser would easily spend \$5 million wining and dining all of the politicians possibly involved up through the Governor¹⁶ to keep pill fragmentation programs humming along and to cast me as an outlier. Usually physicians like me are pictured as eagles soaring over the canyons of the past (like Dr. Welby) who had no real sense to know that it is either HMO medicine [called “private health plans”] or government medicine.

I hope to hear of the new investigations that this presentation should set off. But either way history will take note of what California allowed on each and every consumer board watch. And it will also conclude that a Board vote of each individual professional is as much a licensed decision as the handing over of a pill bottle¹⁷ to a specific patient.

Conclusions

Of the two \$35 billion a year budget organizations who split pills, the group over which you have authority to protect the public is Kaiser with 800,000 enrolled seniors¹⁸ involved with Medicare D. As 75% of Kaiser has always been in California,¹⁹ that is 600,000 vulnerable California seniors who will only learn about who “Thrives” when they get sick or need medication.

What is needed now by the Pharmacy Board is a rapid investigation that goes way beyond asking for another letter from Kaiser. It is time to show up unannounced at the frontlines of Kaiser care and to see what senior splits really look like. That means looking into the brown bags. Your eyes will tell you – as they did mine in 1998 – that there is no need to even have another weighing of fragments; this is really about pill destruction for high profit.

Too many many people are starting to call California “Kaiser-fornia.” It is important that you do not let the tail wag the dog.

Don’t take action for me. Do it for Maggie Dee, for Nick Feldman, and for the memory of Mary O’Donnell.

¹⁶ The style is for the Kaiser Plan to give the Permanente Physicians money that is then sent on to the governor. Or one of his pet projects is enhanced – like health care built on the magnification of HMOs.

¹⁷ I briefly worked in a job with the Hmong community of Fresno that gave me only one choice for a medical plan – Kaiser. I joined so as to be a patient witness to what they do and what kind of misery it is to call into the system. They also managed to print one of my prescriptions in Spanish. I know Kaiser both as a former

¹⁸ This may be found in the internal, 2006, year end summary written by Mr. George Halverson, CEO, Chairman of the Board, and President of the Kaiser Plan, Inc., and Kaiser Hospitals, Inc. – both using the same board. Identical boards allow money to travel down from the Plan to the for profit doctors and the for bonus hospitals and then travel back up through the hospitals to become bonuses at the top.

¹⁹ Kaiser has withdrawn from many states in its history – New York, New Jersey, North Carolina, Texas, Missouri, Utah, etc – and has not ventured into a new state since developing its money losing plan in Washington, DC where it bought into Humana as the latter left. The Missouri Kaiser attempt folded because it had to send \$4 million excess each year to prop up the DC unit – see court papers.

And do it for the Class of 2010 (see inside of your notebook); don't let them graduate into a world of challenged ethics. The Hippocratic Oath is both a Oath and a Covenant invoking upon anyone who would misuse these talents misery in this life and the next.

1

My CV and Textbook

2

NABP Resolution Against
Large Scale Pill Splitting

3

Kaiser CEO + Top Physician -
and the Permanente Map

4

California - 49% HMO
Thrive Ads (Splitting Not mentioned)

5

McDevitt's Classic Study of
Pill Fragmentation

6

Mary O'Donnell's Pill Diary -
Three Splits at One Time

7

VA "SPOT" Harm Reports
> 400

8

Nicholas Feldman and the
Zanaflex fragments



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1: [Pharmacotherapy](#). 1998 Jan-Feb;18(1):193-7.

Related Articles Link

Accuracy of tablet splitting.

[McDevitt JL](#), [Gurst AH](#), [Chen Y](#).

MEDEX Clinical Trial Services, Inc., Ardmore, Pennsylvania 19003, USA.

We attempted to determine the accuracy of manually splitting hydrochlorothiazide tablets. Ninety-four healthy volunteers each split ten 25-mg hydrochlorothiazide tablets, which were then weighed using an analytical balance. Demographics, grip and pinch strength, digit circumference, and tablet-splitting experience were documented. Subjects were also surveyed regarding their willingness to pay a premium for commercially available, lower-dose tablets. Of 1752 manually split tablet portions, 41.3% deviated from ideal weight by more than 10% and 12.4% deviated by more than 20%. Gender, age, education, and tablet-splitting experience were not predictive of variability. Most subjects (96.8%) stated a preference for commercially produced, lower-dose tablets, and 77.2% were willing to pay more for them. For drugs with steep dose-response curves or narrow therapeutic windows, the differences we recorded could be clinically relevant.

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DRUG USE INSIGHTS

Accuracy of Tablet Splitting

Joseph T. McDevitt, B.S., Andrea H. Gurst, B.S.N., and Yinshuo Chen, Ph.D.

We attempted to determine the accuracy of manually splitting hydrochlorothiazide tablets. Ninety-four healthy volunteers each split ten 25-mg hydrochlorothiazide tablets, which were then weighed using an analytical balance. Demographics, grip and pinch strength, digit circumference, and tablet-splitting experience were documented. Subjects were also surveyed regarding their willingness to pay a premium for commercially available, lower-dose tablets. Of 1752 manually split tablet portions, 41.3% deviated from ideal weight by more than 10% and 12.4% deviated by more than 20%. Gender, age, education, and tablet-splitting experience were not predictive of variability. Most subjects (96.8%) stated a preference for commercially produced, lower-dose tablets, and 77.2% were willing to pay more for them. For drugs with steep dose-response curves or narrow therapeutic windows, the differences we recorded could be clinically relevant.

(Pharmacotherapy 1998;18(1):193-197)

Tablet splitting is a frequent method of obtaining the prescribed dose of a drug. Physicians prescribe doses depending on a patient's disease and level of drug tolerance; however, drugs do not always come in the appropriate strength, in which case tablets must be broken into portions. When patients are instructed to split tablets that are not intended to be split, the potential for dosing errors is introduced.

It is a violation of pharmacy law in most states for a pharmacist to dispense split tablets. Recognition that dosing flexibility is required to treat patients accurately led certain pharmaceutical manufacturers to introduce tablets specifically intended for splitting (Glynase PresTab, Upjohn, Kalamazoo, MI; Tagamet TiltTab, SmithKline Beecham, Philadelphia, PA; etc.).

Relatively few controlled studies have been performed to evaluate the accuracy of splitting tablets. In one study, 10-mm oval tablets scored on both sides had the least variability in weight

between portions when broken manually.¹ Large round tablets that were scored on one side tended to break unevenly, with large variability in weight between sides. Small (7-mm) round tablets were the most difficult to break accurately, with 44% of portions deviating from ideal weight by more than 20%. In addition, active drug was lost due to fragmentation and powdering during splitting. Some tablets have a protective coating that interferes with splitting, and others are specifically not intended to be split (e.g., enteric-coated tablets). Use of a tablet-splitting device resulted in findings similar to manual splitting.²

Currently, the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure recommends that the lowest effective dosage of a diuretic or β -blocker be first-line therapy for hypertension after a trial of lifestyle modifications.³ Hydrochlorothiazide is frequently prescribed in this circumstance. A large body of evidence suggests that a low dosage (12.5 mg/day) is both effective and safe,⁴⁻¹¹ but dosages of 6.25 mg/day were not consistently effective in controlling hypertension.¹²⁻¹⁴ At 12.5 mg/day, blood pressure reductions are generally similar to those with 25 mg/day, although with

From MEDEX Clinical Trial Services, Inc., Ardmore, Pennsylvania (all authors).

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fewer metabolic adverse effects. Increasing the dosage beyond 50 mg/day generally does not improve blood pressure control.

Until recently, the agent was available only as a relatively small (6-mm diameter), 25-mg, round, scored tablet. It was therefore necessary to split the tablet to approximate a 12.5-mg dose. A 12.5-mg formulation of the agent (Microzide capsules; Watson Laboratories, Corona, CA) has been approved for marketing in the United States.

Methods

Ninety-four volunteers were recruited from a suburban Philadelphia neighborhood through a newspaper advertisement. Adult men and women were eligible to participate without regard to race, religion, or socioeconomic background. Subjects reporting severe vision impairment, missing arms or digits, or disabling arthritis were excluded. Demographic and survey information was collected from each volunteer (Table 1, Figure 1).

Measurements

Each subject's grip strength was measured using a hydraulic hand dynamometer (JAMAR, Jackson, MI) before splitting. The subject sat with arms resting on a table and palms facing medially. The dynamometer was set at level 1 with the indicator at zero. The subject was instructed to squeeze the dynamometer as hard as possible using one hand and a slow, steady grip. This procedure was repeated 3 times for each hand, and the subject's mean grip strength was calculated.

Pinch strength was documented using a standard pinch test gauge (B&L Engineering, Santa Fe Springs, CA). The subject sat at a table with arms pronated. The indicator on the pinch test gauge was set to zero. The gauge was placed between the subject's thumb and distal phalanx of the index finger. The subject slowly compressed the pinch tester, and the maximum value was recorded. This procedure was repeated 3 times for each hand, and the subject's mean pinch strength was calculated.

The circumferences of the distal phalanges of the right and left index fingers were measured using a standard ring gauge. The ring that slid on and off the fingers easily, but allowed no additional room, was judged to be the appropriate size. The size of the thumb of each hand just above the first joint was measured and documented using the same procedure. Finally, the length of the subject's fingernails was noted. Long and short

Table 1. Demographic Information

Variable	Mean (SD)	Range
Age (yrs)	42.6 (14.8)	20-77
Weight (kg)	74.38 (17.27)	45.4-136.2
M/F	39/55	
High school education (no.)	16	
College education (no.)	78	
Fingernail length	36 long, 58 short	
Tablet-splitting experience, yes/no (%)	35.1/64.9	

fingernails were defined as those that did and did not extend beyond the digit, respectively.

Splitting Test

Each subject was provided with 10 tablets of hydrochlorothiazide (HydroDIURIL; Merck & Co., West Point, PA) that were randomly selected from a commercial supply bottle. Each tablet was weighed in milligrams on an electronic scale (Sartorius, Goettingen, Germany) before splitting. This scale had a minimum sensitivity of 0.001 mg. Subjects sat with forearms resting on a table and were instructed to split each of the tablets evenly by grasping and applying pressure to each side of the tablet with the thumbs and forefingers. If successful, subjects placed the tablet fragments from their right and left hands into appropriately marked containers, and the two portions were weighed in milligrams. This sequence was repeated until each subject had divided all 10 tablets.

In the event that a subject was unable to apply enough pressure to break a tablet manually, he or she was allowed to follow the same procedure using a commercial tablet splitter (Rite-Aid). Subjects who began splitting tablets manually but were unable to complete the process on all 10 tablets were allowed to divide the remaining tablets using the tablet splitter.

Statistical Analyses

Statistical tests of significance of preexisting conditions (age, gender, grip and finger pinch strength, finger size) on results of tablet splitting

1. Would you see a distinct benefit not to have to split tablets? (Yes/No)
2. Would you be willing to spend a little extra money for the convenience of not having to split tablets? (Yes/No)
3. How much would you be willing to spend if a 1-month prescription originally cost \$5, \$10, \$20, \$50?

Figure 1. Survey.

Table 2. Results of Manual Tablet Splitting

	No.	Mean (SD)	Range
Whole tablet weight (mg)	876	108.6 (1.55)	104.0-114.0
Loss in splitting (mg)	1752	1.16 (1.78)	0-21.0
Loss in splitting (%)	1752	1.06 (1.63)	0-19.4
Tablet portion weight (mg)	1752	53.7 (7.26)	25.0-80.0
Variation of tablet portion from ideal*	1752	10.2 (8.7)	0-54.9

*Ideal weight 54.3 mg.

ere conducted with χ^2 tests for categorical data and F test of analysis of variance for numerical data. Calculations of descriptive statistics and all statistical tests were conducted using SAS software (version 6.11).

Results

Ninety-four volunteers (55 women, 39 men) participated. A broad distribution of ages was represented: 34 volunteers were less than 35 years of age, 36 were age 35-44 years, and 24 were older than 55 years. All had completed high school and 83% had attended college. Most (85.1%) were right-handed and one was a left-handed. Sixty-two percent of volunteers had long fingernails. Men had larger hands, on average, than women, as well as correspondingly stronger pinch and grip strengths. Slightly more than one-third of volunteers (35.1%) had experience splitting tablets.

A total of 876 tablets were manually split into 1752 portions and 51 were split into 102 portions with a commercial splitter (Table 2). The mean variation from ideal weight of manually split tablet portions was 10.9%, with approximately 1.1% of a tablet's weight being lost in splitting.

Slightly more than one-third of split tablet portions were within 5% of ideal weight; however, 41.3% deviated from ideal weight by more than 10%, 23.5% by more than 15%, and 12.4% by more than 20% (Figure 2). Similar results were found with the tablet splitter: 40.2% of portions were within 5% of ideal weight, and 37.3% deviated from ideal weight by more than 10%.

Analysis of variance (ANOVA) of the effect of gender, age, education, tablet-splitting experience, and presence of long fingernails failed to identify particular factor that predicted difficulty splitting tablets accurately. Firm grip strength in men was, however, inversely associated with the ability to split tablets accurately ($p=0.0001$). This factor was not identified as significant for

women ($p=0.1569$). When failure to split a tablet within 15% or 20% of ideal weight was considered as an outcome, none of the demographic factors predicted failure; however, firm grip strength in men was identified by ANOVA to be significantly associated with increased failure at both the 15% and 20% levels. When drug lost in tablet splitting was measured, no patterns were identified that predicted increased loss, except that younger and older volunteers were slightly more likely to cause loss than middle-age volunteers (younger volunteers 1.22 mg lost, middle-age 0.86 mg lost, older 1.17 mg lost; $p=0.0082$, ANOVA).

Given the choice, 96.8% of volunteers stated that they would rather not split a tablet if a lower-dose formulation was available. Over three-fourths (77.2%) stated that they would be willing to pay more for a lower dosage strength, with the median amount being 20% over the original price of the prescription.

Discussion

Extensive analysis of the ability to split a 25-mg hydrochlorothiazide tablet accurately by 94 volunteers found that the average tablet portion

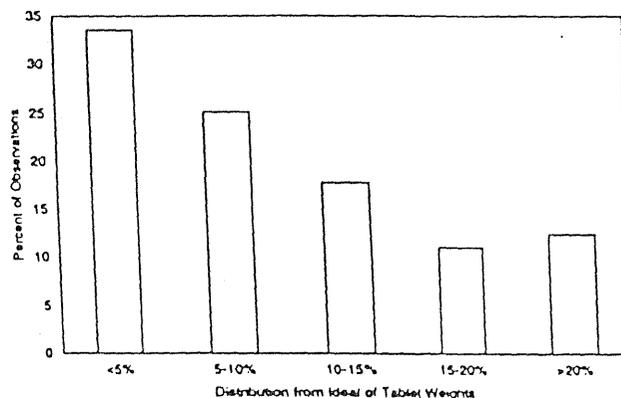


Figure 2. Distribution from ideal of manually split tablet portions.

varied from ideal weight by slightly greater than 10%, and that approximately 1.1% of the weight was lost in the splitting process. In addition, over 40% of portions deviated from ideal weight by greater than 10%, with almost 25% deviating by greater than 15% and over 12% by more than 20%. The use of a tablet splitter did not improve the accuracy of splitting.

Demographic and volunteer-specific data were captured to determine whether certain factors were predictive of inaccurate tablet splitting. Gender, age, education, and tablet-splitting experience were consistently found not to be predictive of accuracy. Only firm grip strength in men was a significant factor in predicting variation of tablet portion weight from ideal; grip strength was not predictive in women. No subpopulation existed that was consistently able to split tablets accurately. Thus, stereotypes regarding which patients might be "expected" to be able to perform this seemingly simple task should be discarded.

In rare circumstances (1.2%), the two tablet portions weighed more than the original whole tablet. This can best be explained by the transfer of finger oils from the subject to the tablet during splitting, and as a result, deviations from ideal may underestimate the true deviation from ideal. Such bias could be avoided with the use of unlubricated latex gloves, but that could have interfered with subjects' ability to split tablets accurately.

Several tablets were evaluated with respect to the percentage variation from ideal when split manually.¹ More than 87% of portions of oval 10-mm tablets with deep scores on both sides were within 10% of ideal weight. In contrast, smaller round tablets were more likely to yield inaccurate segment weights. Only 45% of round 8- or 9-mm tablet portions were within 10% of ideal weight, and 44% of round 7-mm tablet portions deviated from ideal by more than 20%.

The accuracy of a tablet-splitting device was assessed on 13 different agents available in tablet form.² The tablets differed in size, shape, and coating. Twenty tablets of each drug were split and the number of 40 resulting portions that were within 15% of ideal weight was determined. The best results were seen with larger tablets (> 600 mg) that were coated, and had an oblong (but not pointed) shape and flat edges. The smallest tablet tested was phenobarbital (4.1 mm, 30 mg), and this was among those with the highest percentage error.

Certain difficulties were observed with the

tablet splitter, primarily with placing tablets in the correct position. Hazards associated with the device included potential injury due to the sharp steel blade attached to the lid, and the possibility of combining the present drug with powder or fragments of previously split ones.

As cost containment has become increasingly important, it is apparent that many physicians are responding by prescribing larger dosages of drugs and then instructing patients to split the tablets to receive the correct dose.¹⁵ Some health maintenance organizations are providing tablet splitters to patients while dispensing larger than prescribed tablet sizes. Although this may be less expensive in the short run, it has not been proved to be financially or medically effective. Patients may be reluctant to split the tablets and decide to take double the dose at twice the dosing interval, thus leading to wide swings in blood concentrations. Alternatively, with polypharmacy common in many older patients, instructions regarding which drug to split may not be remembered between the time a prescription is received and the time the agent is taken, thus exposing the patient to unnecessary toxicity.

These results are applicable to other areas of therapy besides antihypertensives. In pediatrics, it is frequently necessary to split tablets, often into thirds or fourths. Although this was not the focus of the present study, it is reasonable to postulate that even greater errors would occur under these conditions. Because of the need to dose many drugs in children on a milligram per kilogram basis, these errors may be more important than in adults.

Our results may underestimate the variation from ideal in tablet portions. Tablets split by a patient in advance and returned to the pill bottle may be additionally subject to increased friability and fragmentation, hygroscopic absorption of water, and altered shelf life due to a break in the tablet's protective coating.

The *United States Pharmacopeia* specifies that a dosage formulation should be within $\pm 10\%$ of its stated value. For most drugs, a variation of more than 10% probably would not influence therapeutic outcomes. Errors could be of concern for those with narrow therapeutic indexes (e.g. digoxin, warfarin), capacity-limited metabolists (e.g., phenytoin), or steep dose-response curves (e.g., hydrochlorothiazide).

Possible future areas of study could be comparative bioequivalence trial of manual split tablets versus a commercially available formulation to determine if the accept

ness for establishing bioequivalence are

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Medication
Diary of Kaiser
Patient -
Elderly and on Oxygen
- three splits
at the same
time

MONDAY MAY 24, 1999

FLOVENT 3 PUFFS 2X DAY 6:00

COMBIVENT 3 PUFFS 3 TIMES DAY

ZESTRIL 1/2 PILL

PRILORGE 1 PILL

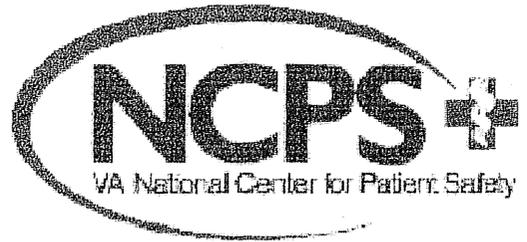
LABET 1/2 PILL

MELNIX 1 PILL

WELLBUTRIN 1/2 PILL

HHH 7:30-

TIPS



Volume 6, Issue 3

Topics In Patient Safety

May/June 2006

Tablet Splitting

By Mariscelle M. Sales, Pharm.D., and Francesca E. Cunningham, Pharm.D.

Background

TABLET SPLITTING is a common practice often recommended by providers and implemented by healthcare systems. Splitting a tablet allows for a lower dose than that manufactured by the pharmaceutical industries, can facilitate administration of large tablets that patients may find difficult to swallow whole, and can give patients access to more expensive medications.

Tablet splitting has many benefits, and consideration of both drug and patient characteristics ensures safe and appropriate use.

Certain physicochemical properties of a drug influence the decision to split. For example, drugs with enteric coatings, extended-release formulations, and some combination products can cause adverse outcomes if split.¹⁻³

In one study, elongated tablets scored deeply on both sides broke easily when manually split.⁴ Tablet splitting devices were shown to perform best with larger tablets, tablets with flat edges, and oblong tablets without pointed ends.⁵

Drugs with narrow therapeutic windows should only be split if the physicochemical properties are adequate and if the optimal therapeutic response depends on the dose being halved. Also, patients with severe physical or visual impairments may hinder precision in pill splitting.

Tablets come in all shapes and sizes and require sharp instruments to divide them. Patients or their caregivers must have good vision, manual dexterity, and the mental capacity to accurately split a tablet. Accuracy of tablet splitting also depends on one's technique or device.

An optimal tablet-splitting device should have a hard, steel blade that goes all the way into the base when the lid is depressed. This will ensure a clean cut without leaving unusable fragments or crumbs that break off from the tablet. Additional benefits are provided when using a non-slip surface with adjustable grips to firmly hold the tablet steady and an optional magnifying attachment to enlarge the view of small tablets.

Any alteration of a medication may result in an adverse event or close call; hence, tablet splitting may cause problems in the medication use process. Using a good tablet-splitting device, unambiguous directions listed on the prescription, and identification/recognition of non-splittable medications comprise steps that can help to prevent problems from developing.

VA NCPS and the VA Center for Medication Safety Patient Safety Center of Inquiry (PSCI) embarked on an effort to evaluate potential medication problems caused by tablet splitting. Data on tablet-splitting events were evaluated using the NCPS Patient Safety Information System database (nicknamed "SPOT"). This article describes the results of that analysis.

Analyzing SPOT Data

Methods:

NCPS identified tablet splitting entries by querying the SPOT database for all RCA and safety reports involving tablet splitting from January 2001 to April 2005, forwarding the results to our Patient Safety Center of Inquiry for analysis. Search terms included: pill splitting, tablet splitting, half tablet, quarter tablet, 1/2 tab, and 1/4 tab.

Data provided for each event included an anonymized case ID; date (year); free text description of event details; and record type (aggregate, safety report, RCA).

A complete evaluation of reports was conducted. Analysis of each individual case determined:

- ◆ Type of event (actual adverse event, close call, not enough information, or "other")
- ◆ Location of occurrence (inpatient or outpatient)
- ◆ Error type (overdose, underdose, incorrect directions, incorrect quantity, incorrect day supply, and incorrect strength dispensed)
- ◆ Medication characteristics (correct physicochemical properties, to include: non-extended release, no enteric coating and symmetric in shape; commercially available strengths; and high alert medications⁶)
- ◆ Documented patient outcomes (no harm, minor harm, hospitalization, and/or permanent harm/death)

Results:

We found 442 reports in SPOT related to pill splitting. Below are selected, notable statistics from these events:

- ◆ 38% were adverse events
- ◆ 66% of the adverse events involved patients receiving more than their intended dose
- ◆ 65% of the adverse events occurred in outpatient settings
- ◆ 51% of the adverse events involved medications that came in commercially available strengths
- ◆ 28% of the medications were high alert
- ◆ 9% of the adverse events resulted in causing harm to a patient, but only 2% required hospitalization; no deaths were reported

Discussion

Limited literature suggests that manually or mechanically splitting tablets does not always produce equal portions.⁷⁻¹⁵ The current evaluation of tablet splitting events within the VA revealed no problems regarding accuracy in splitting tablets to produce equal halves.

However, a potential source for problems was found in a number of areas: ordering, verifying, filling, and administering medications that require splitting.

continued on back page

Subj: **Re: questions about details of pill splitting**
Date: 1/28/2007 1:40:51 P.M. Pacific Standard Time
From: daretodream94704@yahoo.com
To: CPhil49401@aol.com

yes and here is my picture
CPhil49401@aol.com wrote:

So you get to sleepy once a day and no relief once a day because they will not supply you with the 2mg tablet to take twice a day.

In a message dated 1/27/2007 9:27:57 P.M. Pacific Standard Time, daretodream94704@yahoo.com writes:

The Baclofen did not work , It made me fall asleep .
You right about the 4mg . I was supposed to take it twice a day ,and now I take it just once.
thanks

Nicholas Feldman
Dare to Dream Attendant Services, LLC
275 5th St. #203
San Francisco, CA 94102
(800)988-9927
Fax: (415)541-8590
website: www.daretodreamattendantservices.com
blog: <http://mydreamweaver.blogspot.com/>
(Assistant may answer the phone)



Subj: **Re: questions about details of pill splitting**
 Date: 1/27/2007 9:27:57 P.M. Pacific Standard Time
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 To: cphil49401@aol.com

The Baclofen did not work , It made me fall asleep .
 You right about the 4mg . I was supposed to take it twice a day ,and now I take it just once.
 thanks

cphil49401@aol.com wrote:

My pocket book of medications that I carry as an emergency physician states:

"tizanidine (Zanaflex): muscle spaticity due to MS or spinal cord injury: 4-8 mg PO q 6-8 pm, max 36 mg/d. [Generic/Trade: Tabs 2 & 4 mg, scored. Trade 6 mg.] \$\$\$\$"

I'm thinking you are being asked to split the 4 mg. How often were you supposed to take it? Did you try Baclofen and compare? Dr. Phillips

-----Original Message-----

From: daretodream94704@yahoo.com
 To: cphil49401@aol.com
 Sent: Sat, 27 Jan 2007 4:21 PM
 Subject: Re: questions about details of pill splitting

2.5 miligrams

cphil49401@aol.com wrote:

Now I need the strength of the pill to verify that the half dose size was available as a full size pill either on the Kaiser formulary or to be bought. Dr. Phillips

-----Original Message-----

From: daretodream94704@yahoo.com
 To: CPhil49401@aol.com
 Sent: Sat, 27 Jan 2007 2:04 PM
 Subject: Re: questions about details of pill splitting

Dear Dr. Phillips,

The answers are below in italics. I really hope this makes a difference, and that the pharmacy board really does something. We need more advocates like you.

Thanks,
 Nick Feldman

CPhil49401@aol.com wrote:

1. Tell me about your general health and whether you could be expected by dexterity to split pills. *I have cerebal palsy in all of my limbs. Kaiser wanted me to split my Zanaflex to help reduce my spasticity.*

2. Tell me if your physician explained that you would be asked to split pills or whether it happened at the pharmacy window. *The woman at the pharmacy counter very casually told me that I can split the pill to help spread it out longer.*

3. Tell me the name of the pill and how long the splitting lasted. *Zanaflex...indefinitely*

4. Tell me if you gave up on splitting and simply take the whole dose every other day. *I gave up because I was not comfortable with my assistants having to split the pills. I also was never given a pill splitter, so determining what half the pill really is is really hard.*

5. Tell me if you have explained this to your physician or the pharmacist. Was any action taken? *Yes. No action was taken.*

6. Did you get any pill safety handout? *No*

7. Do you experience any side effects with the whole pill? *Yes. Drowsiness.*

8. Would you rather have the right dose in a smaller pill? *Yes*

9. Can I share your answers with the California Board of Pharmacy and thus the public? *Yes*

10. Where do you live? Where do you get your care from Kaiser? *I live in downtown San Francisco, and I am seen at the Kaiser on Divisadero, and also at the French campus.*

Dr. Phillips

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blog: <http://mydreamweaver.blogspot.com/>
(Assistant may answer the phone)

Check out the new AOL. Most comprehensive set of free safety and security tools, free access to millions of high-quality videos from across the web, free AOL Mail and more.

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(Assistant may answer the phone)

TIOPRONIN

Timolol [MC] (Continued)

vomiting, stomach discomfort, numbness in toes and fingers, dry sore eyes

Usual Dosage Children and Adults: Ophthalmic: Initial: 0.25% solution, instill 1 drop twice daily; increase to 0.5% solution if response not adequate; decrease to 1 drop/day if controlled; do not exceed 1 drop twice daily of 0.5% solution

Dosage Forms

Solution, as hemihydrate, ophthalmic (Betimol®) [\$\$\$]: 0.25% (5 mL, 10 mL, 15 mL); 0.5% (5 mL, 10 mL, 15 mL)
 Solution, as maleate ophthalmic (generic Timoptic®) [\$\$]: 0.25% (5 mL, 10 mL, 15 mL); 0.5% (5 mL, 10 mL, 15 mL)
 Solution, as maleate, ophthalmic, preservative free, single use (Timoptic® OcuDose®) [\$\$\$\$\$]: 0.25%, 0.5%

Recommended Alternative Levobunolol is the preferred ophthalmic beta-blocker

Generic Available No

- ♦ Timoptic® see Timolol [MC] on page 743
- ♦ Tioguanine see Thioguanine [MC] on page 735

Tiopronin

Brand Names Thioia™

Therapeutic Class 60:15 Resins & Chelating Agents

Use Prevention of kidney stone (cystine) formation in patients with severe homozygous cystinuria who have urinary cystine >500 mg/day who are resistant to treatment with high fluid intake, alkali, and diet modification, or who have had adverse reactions to penicillamine

Usual Dosage Adults: Initial dose is 800 mg/day, average dose is 1000 mg/day

Dosage Forms Tablet, 100 mg

Generic Available No

- ♦ Tiotixene see Thiothixene [MC] \$S on page 739
- ♦ Tissue Plasminogen Activator, Recombinant see Alteplase, Recombinant on page 106

Tizanidine \$\$\$\$\$

Brand Names Zanaflex®

Synonyms Sirdalud™

Therapeutic Class 30:40.15 Skeletal Muscle Relaxants, Centrally-Acting Agents

Use Skeletal muscle relaxant used for the acute and intermittent management of increased muscle tone associated with spasticity

Contraindications Previous hypersensitivity to tizanidine

Warnings Reduce dose in patients with liver or renal disease; use with caution in patients with hypotension or cardiac disease. Use with caution in patients receiving antihypertensives. Do not use tizanidine in patients receiving alpha₂-adrenergic agonists.

Adverse Reactions

>10%: Hypotension, sedation, daytime drowsiness, somnolence, xerostomia
 1% to 10%: Bradycardia, syncope, fatigue, dizziness, anxiety, nervousness, insomnia, pruritus, skin rash, nausea, vomiting, dyspepsia,

Kaiser

TOBRAMYCIN

constipation, diarrhea, elevation of liver enzymes, muscle weakness, tremor

<1%: Palpitations, ventricular extrasystoles, psychotic-like symptoms, visual hallucinations, delusions, hepatic failure

Drug Interactions

Oral contraceptives decrease tizanidine clearance.
 Increased toxicity: Additive hypotensive effects may be seen with diuretics, other alpha adrenergic agonists, or antihypertensives; CNS depression with alcohol, baclofen or other CNS depressants

Usual Dosage

Adults: 2-4 mg 3 times/day
 Usual initial dose: 4 mg, may increase by 2-4 mg as needed for satisfactory reduction of muscle tone every 6-8 hours to a maximum of three doses in any 24 hour period
 Maximum dose: 36 mg/day

Renal/hepatic impairment: Reduce dosage

Monitoring Parameters Monitor liver function (aminotransferases) at baseline, 1, 3, 6 months and then periodically thereafter

Additional Information Tizanidine is a centrally-acting alpha₂-adrenergic agonist with dose-dependent effects and is pharmacologically similar to clonidine. Patients should be counseled regarding the possibility of hypotension after the first dose. During trials the reduction in blood pressure was seen within 1 hour after dosing, and peaked at 2-3 hours after the dose. At times the hypotension was associated with bradycardia, orthostatic hypotension, lightheadedness, dizziness, and syncope (rare). Clinical trial data suggests that tizanidine is not associated with muscle weakness like baclofen. However, this finding also did not lead to any consistent advantage as measured by activities of daily living. Data on the long-term administration of tizanidine are limited. No rebound hypertension was seen during clinical trials when tizanidine was tapered over 7 days.

Dosage Forms Tablet, 4 mg

Generic Available No

- ♦ TNKase™ see Tenecteplase [FG] \$\$\$\$\$ on page 725
- ♦ TOBI™ Inhalation Solution [FR] see Tobramycin [FR] [MC] on page 745

Tobramycin [FR] [MC]

Brand Names Nebcin® Injection; TOBI™ Inhalation Solution [FR]; Tobrex® Ophthalmic

Therapeutic Class 05:05.05 Aminoglycosides; 75:25.05 Anti-Infectives, Ophthalmic

Use Treatment of documented or suspected *Pseudomonas aeruginosa* infection; infection with a nonpseudomonal enteric bacillus which is more sensitive to tobramycin than gentamicin based on susceptibility tests; susceptible organisms in lower respiratory tract infections, CNS infections, intra-abdominal, skin, bone, and urinary tract infections; empiric therapy in cystic fibrosis and immunocompromised patients; topically used to treat superficial ophthalmic infections caused by susceptible bacteria

Restrictions *Formulary.* Tobramycin solution for inhalation (TOBI™) is restricted to prescribing CF Subspecialists, Pediatric and Adult Pulmonology

Pregnancy Risk Factor D
 (Continued)

AT Journal

The Latest News & Resources in Assistive Technology

Vol. 97, May 15, 2004

A Personal Perspective...

By Nicholas W. Feldman

I can remember being 5 years old and my family all clustered around me, watching as I played my first video game using a chin control as I shot at the spaceships on the screen. It was 1980 and the Apple 2 + was all the rage. I had no idea what a significant role technology would play in my life as I grew up with Cerebral Palsy (CP).

Like a lot of children with CP, I went from school to school trying to find that, "equal education" that creates the integrated environment and allows the student with the disability to soar to their full potential. I sat in a special education kindergarten class where they told me about single input scanning. This is where you press a switch, using any part of the body (within reason) and it is connected to the CPU by a box. This then displays a row of letters, numbers, punctuation and a few very select groups of menu commands. The highlighted areas were divided into sections and if you pressed the switch in the right section, it would break down the individual letters, numbers and other symbols and when it would finally land on the right key, you would press the switch again and it would type it on the screen.

I am very verbal and my friend sitting next to me in that special education class was non-verbal and a lot was assumed for her. She was constantly told what to eat, what to wear, what to do and where she would go, via the request of our teacher to the classroom assistant. Then, one fine day, the teacher came to me and asked if I would empower my friend who was learning to do single input scanning, not on a computer per say, but a large board with different color lights with signs that said words like yes, no, bathroom, I want to eat, etc. My friend was very shy until that special board came along. The school had no idea what they were in for. Suddenly, questions that were once assumed now had different color lights and a whole personality to follow. I soon moved away and never really knew, but had a good imagination about my shy friend who, at age 6, finally got the opportunity to start making her own choices.

As I moved to different schools, with different levels of academic demand, I was still struggling with my single input scanning. I used a switch that was connected to a pillow on my headrest. I was doing this, but I had my sites set on bigger things like

being mobile with a power wheelchair. The technology had to allow me the ability to use my head to control a wheelchair. There was a company in Ohio, which had technology very similar to what I was using to activate the computer.

The wheelchair worked with a switch that was fastened to my headrest and when it was pushed, lights would flash on different arrows labeled "forward", "right", "left", "back" and all of the diagonal directions. To stop, the switch would need to be pushed again. By this time frame, it was the late 1980's and very early '90s. I was beginning to hear about not only portable computers, but I was fantasizing about sending an email to a friend in my car pool. Slowly, the Internet began to evolve and our family got its first subscription to an online service called Prodigy. I remember the first email I sent, was to my cousin who was serving in the military during the first invasion of Iraq.

Simultaneously, I was entering high school and was given a laptop computer and a new single input scanning system called words plus. This system had a feature called word prediction, which allows a slow type such as myself to have a list of possible words to choose from as you are typing. This vocabulary is primarily built by the words that it will remember after you type the word along with its own 68,000-word vocabulary. This made all the difference in the world especially when it came to book reports, essays, poetry, and letters that you weren't going to let your folks read.

The Internet was still in the first phase of the "web" and I was going into my junior year of high school. Someone with CP came down and demonstrated a voice activated program known as DragonDictate. This program, I had an opportunity to try out through a local computer access center which I was then affiliated with on an after school/volunteer basis. I became aware of some of the power in the Internet and through assistive technology such as the head master which has an infrared connection with a band that the user places around their forehead which emulates the mouse and a straw that the user uses to click and drag the mouse. There were now keyboards that would speak and new advancements in technology, which seemed to happen every millisecond.

I was just about to graduate from high school when I got a new type of wheelchair that had 3 switches that meant that with a new feature called "Cruise Control"; I could drive my wheelchair easier by pressing switches located on the sides of my headrest and one accelerator/brake. These features allowed me to drive and turn at the same time.

UC Berkeley was waiting for me with a big dose of Independent Living and much more of the Internet and disability culture. As I sit here speaking into my DragonDictate Classic controller along with a wheelchair, which I operate with my chin, I can function a lot more independently. I have worked with a lot of different access centers and independent living centers as well as the Department of Rehabilitation in order to fund all of this technology, which I had never dreamed of. I

even have a door opener that I can use with my headrest and a voice activated cell phone.

As an individual, my cerebral palsy has created some societal barriers, which the Internet breaks down. With a video camera and a microphone, everyone who I am in contact with is not always aware that I have a disability. Through all of my years, assistive technology has played an intricate role in so many areas of my life that includes: social (I, after 26 years, have a girlfriend, thank you messenger service), educational (typed and edited many college papers), housing (search through housing websites), and employment where I have had past jobs (dispatcher, independent living skills program coordinator, interim executive director of a non profit) and I currently work as the Oakland Center for Independent living as a Systems Change Advocate. As I go into the post education and job world, I continue to rely on assistive technology to help be my office for whatever opportunities await me. There is also the expectation that technology will continue to allow me the advancement and growth to continue affording me the opportunities that life with and without a disability has to offer and enjoy. I am hoping that the day will arrive when I say "get me up", a robot will be able to make my breakfast, program driving directions into my van, read me the latest email and news, walk my dog and vacuum the floor.

[AT JOURNAL | JOURNAL INDEX]

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Pro Pill Splitting

Half Tablet Program – Effective August 15, 2006
FREQUENTLY ASKED QUESTIONS

Q1: What medications are available for tablet splitting in the Half Tablet Program?

The list of medications available for tablet splitting includes:

Category	Medications	Dosage
ACE inhibitors	Aceon Mavik Univasc	2mg, 4mg 1mg, 2mg 7.5mg
Angiotensin Receptor Blockers (ARBs)	Atacand Avapro Benicar Cozaar Diovan	4mg, 8mg, 16mg 75mg, 150mg 20mg 25mg, 50mg 40mg, 80mg, 150mg
Antidepressants	Lexapro Pexeva Zoloft*	25mg, 50mg 10mg, 20mg 5mg, 10mg
Lipid-lowering medications	Crestor Lipitor Pravachol* Zocor*	5mg, 10mg, 20mg 10mg, 20mg, 40mg 5mg, 10mg, 20mg, 40mg
Antivirals	Valtrex	500mg

* Half Tablet Program applies to the generic equivalents to these brands.

The list of medications available for tablet splitting does not include all medications within a therapeutic class; only those medications determined to be appropriate for splitting are included.

Some of the tablets included in this program are not scored or designed specifically to be split. However, with the use of a tablet splitter, these medications may be appropriately divided. As is true with all medical decisions, you and your doctor will need to determine if the Half Tablet Program is right for you. Medications in the program will be reviewed periodically; additional medications may be included as appropriate.

Q2: What are the criteria for determining which medications are included in the program?

The UnitedHealthcare National Pharmacy and Therapeutic (P&T) Committee approved the following clinical criteria to determine prescription product inclusion in the Half Tablet Program.

- Medications with a wide margin of safety so that minimal differences in tablet sizes will not result in either underdosing or overdosing
- Tablets that can be split relatively evenly without crumbling
- Medications that will remain stable after splitting

In addition, the medication must be available in "double" dosage strengths that are comparably priced.

The National P&T Committee approved the following criteria for exclusion of medications from the program.

- Enteric-coated tablets
- Capsules, liquids, topical medications
- Unscored extended-release tablets
- Combination tablets in which the amount of one active ingredient changes from one tablet to the next, but the amount of the other ingredient does not

Q3: How do I get my free tablet splitter?

You can call 1-877-471-1860 or visit www.halftablet.com to order your free tablet splitter and to view Frequently Asked Questions regarding the Half Tablet Program. Notification letters will contain a Participant Code which is required when ordering the tablet splitter.

Q4: How long does it take for my splitter to arrive?

Your splitter should arrive within 10 business days. Please do not call to check on the status of your tablet splitter until at least 10 business days. If you do not receive your splitter after 10 business days you may call 1-877-471-1860 for more information.

Q5: Can I still get a free tablet splitter if I don't have a Participant Code?

If you haven't received a letter, lost your letter, or do not have a Participant Code you can still receive one free tablet splitter by calling 1-877-471-1860. You will be asked to provide your UnitedHealthcare member number and your eligibility in the program will be verified. Not having a Participant Code may cause a delay in receiving your free tablet splitter.

Q6: What if I lose my tablet splitter? What if it breaks or wears out?

Tablet splitters are available for purchase at most pharmacies. UnitedHealthcare will provide you with one free tablet splitter.

Q7: How does the program work?

If you fill a prescription for a medication included in the Half Tablet Program you will:

- Receive a notification letter in the mail informing you of the Half Tablet Program.
- Discuss the Half Tablet Program with your doctor. You and your doctor decide together if the program is appropriate for you. If yes, your doctor writes a new prescription for the higher-strength dosage with instructions to take one-half tablet.
- Fill your prescription at a participating retail pharmacy.
- Receive an appropriate quantity (15 tablets to meet 30-day supply, 16 tablets to meet 32-day supply, or 17 tablets to meet 34-day supply) with instructions for using half a tablet.
- Follow instructions included in member notification letter for obtaining free tablet splitter or purchase one at a retail pharmacy.

Q8: How does the Half Tablet Program work at mail order?

You will receive 45 tablets to meet a 90-day supply at mail order. Because prescriptions are dispensed as written through mail order, you must obtain an appropriately written prescription for participation. The mail order pharmacy will not make outbound patient or doctor calls to initiate program participation.

Q9: What if I don't want to participate in the program?

Participation in the program is entirely voluntary. If you do not wish to participate in the program, you may simply continue to fill your prescription as usual, taking the same strength dosage. No action is required if you choose not to participate. If you try the Half Tablet Program and decide that it is not right for you, you may have your doctor write a new prescription for the old dosage level and go back to your usual copy.

Q10: Have any studies been done on the safety and effectiveness of tablet splitting?

A number of clinical studies have been conducted on the safety and effectiveness of tablet splitting. These studies, published in peer reviewed medical literature, conclude that when appropriate medications are selected, tablet splitting delivers a safe and effective dose of medication. The following sections summarize two of the studies that have been conducted (please be advised the descriptions below are very clinical in nature).

Parra D et al. Effect of splitting simvastatin tablets for control of low-density lipoprotein cholesterol. American Journal of Cardiology 2005;95:1481-1483.

This is a retrospective evaluation of a voluntary simvastatin tablet splitting program in 6 VA medical centers. A total of 1,331 patients who were converted to split tablets and 2099 who were not converted were included in the analysis. Patients were converted from whole to split simvastatin tablets at the same total daily dose and issued a pill splitter and instructions about the conversion. Patients who had visual limitations or other disabilities were exempted from the conversion as were patients whose health care provider or pharmacist deemed them unable to perform the tablet splitting. Primary endpoints were the average final LDL-cholesterol value and the average change from baseline between the split group and the whole tablet group. Secondary endpoints included comparison of total yearly simvastatin costs between groups, incidence of transaminase increases greater than 2 to 3 times the upper limit of normal and assessment of compliance. Baseline and final LDL-cholesterol levels and average change from baseline were not significantly different between

groups ($P>0.05$), nor were the incidences of transaminase increases or measurements of patient compliance.

Gee M, Hasson NK, Hahn T, and Ryono R. Effects of a tablet-splitting program in patients taking HMG-CoA reductase inhibitors: analysis of clinical effects, patient satisfaction, compliance, and cost avoidance. Journal of Managed Care Pharmacy. 2002(8)6:453-58.

The primary objective of this study was to determine the effect of splitting atorvastatin, lovastatin, and simvastatin tablets on laboratory outcomes (lipid panel and liver enzyme tests). Other objectives were to assess patient compliance and satisfaction with splitting tablets and to measure the reduction in drug acquisition cost. Before entering the program, patients were evaluated by a prescribing physician or pharmacist for cognitive or physical barriers to assess whether or not they were able to effectively split tablets. If patients agreed to participate, prescriptions were automatically converted by a pharmacist. A tablet splitter and instructions for use were provided free of charge to patients. A total of 2,019 patients were included in the trial conducted by a Veterans Affairs Health Care System facility. A total of 512 patients were eligible for the laboratory analysis. There was no difference between preintervention and postintervention laboratory values for total cholesterol and triglycerides. There was a statistically significant, but not clinically significant decrease in LDL (102 vs. 97, $p<0.001$) and increase in HDL (46 vs. 48, $p<0.001$), AST (26 vs. 28, $p<0.001$) and ALT (24 vs. 26, $p<0.006$) after the initiation of tablet splitting. A total of 454 patients responses to a mailed questionnaire (50%). Results showed that 84% believed that the tablet splitter was not difficult to use, 85% stated that split tablets were not harder to take compared to whole tablets, and 74% agreed that the tablet splitter was not too time-consuming or bothersome; 46% believed that it was easier to take medications when they did not have to split the tablets. Only 7% of the patients stated that tablet splitting had an effect on their willingness to take medications, and 7% stated that they missed more doses in a month while tablet splitting.

Other studies on tablet splitting include:

1. MA Veronin and B Youan. Magic bullet gone astray: medications and the internet. *Science* 2004; 305:481.
2. JM Rosenbergy et al. Weight variability of pharmacist-dispensed split tablets. *J Am Pharm Assoc* 2002; 42:200.
3. J Teng et al. Lack of medication dose uniformity in commonly split tablets. *J Am Pharm Assoc* 2002; 42:195.
4. JE Polli et al. Weight uniformity of split tablets required by a Veterans Affairs policy. *J Manag Care Pharm* 2003; 9:401
5. TJ Cook et al. Variability in tablet fragment weights when splitting unscored cyclobenzaprine 10 mg tablets. *J Am Pharm Assoc* 2004; 44:583
6. BT Peek et al. Accuracy of tablet splitting by elderly patients. *JAMA* 2002; 288:451
7. MC Duncan et al. Effect of tablet splitting on serum cholesterol concentrations. *AM Pharmacother* 2002; 36:205.
8. M Gee et al. Effects of a tablet-splitting program in patients taking HMG-CoA reductase inhibitors: analysis of clinical effects, patient satisfaction, compliance, and cost avoidance. *J Managed Care Pharm* 2002; 6:453.
9. JP Rindone. Evaluation of tablet-splitting in patients taking lisinopril for hypertension. *JCOM* 2000; 7:22.
10. RS Staffor and DC Radley. The potential of pill splitting to achieve cost savings. *Am J Manag Care* 2002; 8:706.
11. P Gupta and K Gupta. Broken Tablets: does the sum of the parts equal the whole? *Am J Hosp Pharm* 1988; 45:1498.
12. JT McDevitt et al. Accuracy of tablet splitting. *Pharmacotherapy* 1998; 18:193.



View a list of Frequently Asked Questions for UnitedHealthcare's Half Tablet Program

You need Adobe Reader installed on your computer in order to view the Frequently Asked Questions. If you do not have it, you may click below for a free download.



To order your FREE tablet splitter as part of the UnitedHealthcare Half Tablet Program simply type in the Participant Code and your name as it appears on your Half Tablet Program notification letter and click submit. Only one tablet splitter per participant.

Participant Code First Name Last Name

Input fields for Participant Code, First Name, and Last Name



I have read and acknowledge the statement below

United Healthcare Services, Inc. ("United") is providing this free tablet splitter to you at your request. By ordering this tablet splitter, you acknowledge and agree that you will only use it to split tablets that your doctor has approved for splitting.

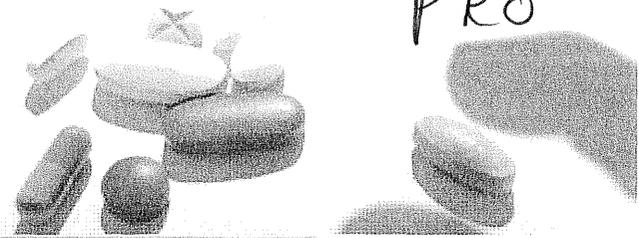
To help maintain the effectiveness of your medication, do not split all of your tablets at one time. Split one tablet and take one half. Take the second half for your next scheduled dose. Repeat the process until you have taken all of your medication.

This tablet splitter is not manufactured by United or any of its affiliates. United makes no warranty as to the reliability of the tablet splitter, nor does United guarantee or warrant the performance of the tablet splitter, including the tablet splitter's conformity to any law, rule, regulation or policy. You assume full responsibility for using the tablet splitter for its intended use in accordance with the manufacturer's instructions. United is not responsible for any direct, indirect, incidental, consequential or punitive damages arising out of your use of this tablet splitter.

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Pill-Splitting

It's safe and can save you lots of money

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Pill Splitting

If you take prescription drugs to treat a chronic illness, you could save money by splitting your pills — literally cutting them in half. Not all pills can be split, so pill splitting cannot be used in the treatment of every chronic disease. But in the face of mounting costs for prescription drugs, many doctors and health authorities are advising this strategy with more and more medicines. Most notably, all the cholesterol-lowering drugs known as statins can be split as can many of the drugs used to treat high blood pressure and depression.

Essentially, pill splitting allows you to buy two doses of medicine for the price of one — or get two months' worth of medicine for the price of one month. There is no danger in splitting pills as long as your doctor agrees that it's a good idea for you, you learn how to do it properly, and you split only pills that can be split. Simple pill splitting devices are now widely available.

BACKGROUND

Doctors have long counseled patients to split their pills. Initially, this was not to save money. Instead, it was to enable people to take a dose of medicine not readily available from a pharmacist. That's because drug companies make only a few fixed doses of any given medication. But many doctors prefer to tailor the dose of a medicine to a patient's exact needs, or to lower the risk of side effects. For example, a doctor may want to prescribe less of a drug (say, 10mg) than the lowest dose available (say, 20mg).

A common example of pill splitting these days involves good old aspirin. Health authorities now urge anyone at risk for heart disease to take half an adult aspirin tablet a day. A regular aspirin tablet contains 325mg, but studies show that 160mg or less is just as good at lowering the risk of a heart attack or stroke — and safer. Some companies now make half-dose aspirin tablets and children's aspirin comes in lower doses (generally 81mg). But often the least expensive alternative is

to buy a large bottle of generic aspirin and split the pills in half.

Pill-splitting saves money because pharmaceutical companies and pharmacies often charge nearly the same amount for a particular medicine regardless of its dose. For example, a once-a-day drug may cost \$100 for a month's supply of both a 100mg dose and a 50mg dose. Thus, if your doctor prescribes the 50mg pill, it'll cost you \$100. But if he prescribes the 100mg pill and instructs you to cut it in half, \$100 will buy you two months worth of medicine. If you take several medicines, that kind of savings can mount up.

Not surprisingly, many insurance companies are in favor of pill-splitting because it saves them money, too. Your employer may like the idea for the same reason. Some insurance companies now provide you with a list of approved drugs to split. And a few are even requiring pill-splitting by not covering the cost of some lower-dose drugs. This forces people to buy higher-dose pills and split them. The American Medical Association and the

American Pharmacists Association oppose this practice. But these organizations acknowledge that many pills can be safely split if done correctly. The Department of Veteran's Affairs allows pill splitting at a number of VA facilities, though it does not formally endorse the practice.

Most drug companies oppose pill-splitting. They say it can be dangerous. But studies to date have not shown any adverse impact on health. In addition, by reducing the cost of prescription medicines, pill splitting could improve

SOME MEDICINES THAT CAN BE SAFELY SPLIT

Amlodipine (Norvasc)
Atenolol (Tenormin)
Atorvastatin (Lipitor)
Citalopram (Celexa)
Clonazepam (Klonopin)
Doxazosin (Cardura)
Finasteride (Proscar)
Levothyroxine (Synthroid)
Lisinopril (Zestril)
Lovastatin (Mevacor)
Metformin (Glucophage)
Metoprolol (Toprol)
Nefazodone (Serzone)
Olanzapine (Zyprexa)
Paroxetine (Paxil)
Pravastatin (Pravachol)
Quinapril (Accupril)
Rosuvastatin (Crestor)
Sertraline (Zoloft)
Sildenafil (Viagra)
Simvastatin (Zocor)
Tadalafil (Cialis)
Vardenafil (Levitra)

health outcomes by helping people afford the drugs they need and comply with the drug regimens their doctors recommend.

PRACTICAL ADVICE

Consult your doctor about pill splitting. The dose you take of most medicines is very important. If you don't get the right dose, the effect of the drug may be substantially reduced. Your doctor should know which drugs can be split and which cannot. You can consult a pharmacist, too, who may be willing to show you how to split your pills.

Pills are only safely split in half and never into smaller portions, such as into thirds or quarters.

There is no official, complete list of medicines that can be split, and some drugs are dangerous to split. That makes it doubly important to consult a doctor or pharmacist. Generally the following kinds of pills should *not* be split:

- Chemotherapy drugs
- Anti-seizure medicines
- Birth control pills
- Blood thinners (Coumadin, warfarin)
- Capsules of any kind that contain powders or gels
- Pills with a hard outside coating

PILL SPLITTING SAVINGS – SOME EXAMPLES

Medicine and Daily Dose	Average Monthly Cost ¹	Potential Monthly Savings if Larger Dose Split in Half ²	Resulting Average Monthly Cost with Split Pills
Lovastatin (Mevacor) 10mg	\$33	\$14.50	\$18.50
Atorvastatin (Lipitor) 40mg	\$124	\$62.50	\$61.50
Amlodipine (Norvasc) 5mg	\$55	\$18.50	\$36.50
Sertraline (Zoloft) 50mg	\$98	\$49	\$49
Metoprolol (Toprol XL) 200mg	\$69	\$9.50	\$34.50

(1) Prices are nationwide retail averages; information derived by Consumer Reports Best Buy Drugs from data provided by Wolters Kluwer Health. (2) Dose used for calculation is double the dose listed in first column. Price of that dose is not given here.

- Pills designed to release the medication over time in your body
- Pills that are coated to protect your stomach
- Pills that provide drug release throughout the day
- Pills that crumble easily, irritate your mouth, taste bitter, or contain strong dyes that could stain your teeth and your mouth.

Examples of medicines that cannot be split include oxycodone (OxyContin) for pain, omeprazole (Prilosec) for heartburn, and cetirizine (Zyrtec) for allergies.

Some pills may deteriorate when exposed to air and moisture for long periods after being split. Therefore, you

should not split your pills in advance. Instead, do it on the day you are taking the first half. Then take the remaining half on the second day.

Don't split your pills with a knife. This can be dangerous and generally is imprecise. That is, it leads to unequal halves too often, studies show. Instead, purchase a pill splitter. They cost from \$3 to \$10 and are available at most pharmacies and large discount stores. A device for splitting oddly shaped pills may cost more, up to \$25. Some insurers will send you a pill splitter for free so check with your health plan.

If you have poor eyesight, or if you have an ailment like arthritis or Parkinson's disease, it might be difficult for you to split your pills. You should talk with your doctor about whether it might be too much of a burden. Likewise, people with memory problems or impaired thinking are not good candidates to split their pills.

The easiest pills to split are relatively flat round ones with a scored center. That's a slightly indented line that runs across the center of the pill. However, not every pill that has a scored center is meant to be split. Again, consult your doctor or pharmacist.

THE SHOPPER'S GUIDE TO PRESCRIPTION DRUGS SERIES

This series is produced by Consumers Union and *Consumer Reports Best Buy Drugs*, a public information project supported by grants from the Engelberg Foundation and the National Library of Medicine of the National Institutes of Health. The project's free Web site is www.CRBESTBUYDRUGS.ORG.

This brief should not be viewed as a substitute for a consultation with a medical or health professional. It is provided to enhance communication with your doctor, not replace it. Neither the National Library of Medicine nor the National Institutes of Health are responsible for the content or advice herein.

PHARMACOECONOMICS

Tablet Splitting

continued from page 16

Others view tablet splitting as a temporary escape from the larger issue of rising drug prices. "I'm glad that [Dr. Parra's] results were positive ... but it's not a solution, it's a Band-Aid," said Daniel Hussar, PhD, Remington Professor of Pharmacy, Philadelphia College of Pharmacy. "The issue that needs to be

addressed full force is prices."

Even as a temporary solution, tablet splitting remain risky and underresearched, according to some. The American Society of Consultant Pharmacists' (ASCP) policy statement on mandatory tablet splitting (available at www.ascp.com/public/pr/policy/tabsplit.shtml) warns of forcing extra medication-handling procedures on patients with physical or mental limitations such as arthritis or parkinsonism. ASCP

'Who's saving the money [via tablet-splitting]? Is it the patient? The hospital? Pharmacists will spend more time talking to their patients but pharmacy benefits managers aren't going to agree to higher dispensing fees.'

—Daniel Hussar, PhD

TarcevaTM erlotinib tablets

TARCEVATM (erlotinib) TABLETS BRIEF SUMMARY

INDICATIONS AND USAGE

TARCEVA is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of at least one prior chemotherapy regimen.

Results from two, multicenter, placebo-controlled, randomized, Phase 3 trials conducted in first-line patients with locally advanced or metastatic NSCLC showed no clinical benefit with the concurrent administration of TARCEVA with platinum-based chemotherapy (carboplatin and paclitaxel or gemtacin and cisplatin) and its use is not recommended in that setting.

CONTRAINDICATIONS

None.

WARNINGS

Pulmonary Toxicity

There have been infrequent reports of serious interstitial lung disease (ILD), including fatalities, in patients receiving TARCEVA for treatment of NSCLC or other advanced solid tumors. In the randomized single-agent study (see CLINICAL STUDIES section of full prescribing information), the incidence of ILD (0.8%) was the same in both the placebo and TARCEVA groups. The overall incidence in TARCEVA-treated patients from all studies including uncontrolled studies and studies with concurrent chemotherapy was approximately 0.6%. Reported diagnoses in patients suspected of having ILD included pneumonitis, interstitial pneumonia, interstitial lung disease, obliterative bronchiolitis, pulmonary fibrosis, Acute Respiratory Distress Syndrome and lung infarction. Symptoms started from 5 days to more than 9 months (median 47 days) after initiating TARCEVA therapy. Most of the cases were associated with confounding or contributing factors such as concomitant/prior chemotherapy, prior radiotherapy, pre-existing parenchymal lung disease, metastatic lung disease, or pulmonary infections. In the event of acute onset of new or progressive, unexplained pulmonary symptoms such as dyspnea, cough, and fever, TARCEVA therapy should be interrupted pending diagnostic evaluation. If ILD is diagnosed, TARCEVA should be discontinued and appropriate treatment instituted as necessary (see ADVERSE REACTIONS and DOSAGE AND ADMINISTRATION - Dose Modifications sections).

Pregnancy Category D

Erlotinib has been shown to cause maternal toxicity with associated embryofetal lethality and abortion in rabbits when given at doses that result in plasma drug concentrations of approximately 5 times those in humans (AUC₀₋₂₄ at 150 mg daily dose). When given during the period of organogenesis to achieve plasma drug concentrations approximately equal to those in humans, based on AUC, there was no increased incidence of embryofetal lethality or abortion in rabbits or rats. However, female rats treated with 30 mg/mg/day or 60 mg/mg/day (0.3 or 0.7 times the clinical dose, on a mg/m² basis) of erlotinib prior to mating through the first week of pregnancy had an increase in early resorptions which resulted in a decrease in the number of live fetuses.

No teratogenic effects were observed in rabbits or rats.

There are no adequate and well-controlled studies in pregnant women using TARCEVA. Women of childbearing potential should be advised to avoid pregnancy while on TARCEVA. Adequate contraceptive methods should be used during therapy, and for at least 2 weeks after completing therapy. Treatment should only be continued in pregnant women if the potential benefit to the mother outweighs the risk to the fetus. If TARCEVA is used during pregnancy, the patient should be apprised of the potential hazard to the fetus or potential risk for loss of the pregnancy.

PRECAUTIONS

Drug Interactions

Co-treatment with the potent CYP3A4 inhibitor ketoconazole increases erlotinib AUC by 2/3. Caution should be used when administering or taking TARCEVA with ketoconazole and other strong CYP3A4 inhibitors such as itraconazole, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin, toleandomycin (TAO), and voriconazole (see DOSAGE AND ADMINISTRATION - Dose Modifications section). Pre-treatment with the CYP3A4 inducer rifampin decreased erlotinib AUC by about 2/3. Alternate treatments lacking CYP3A4 inducing activity should be considered. If an alternative treatment is unavailable, a TARCEVA dose greater than 150 mg should be considered. If the TARCEVA dose is adjusted upward, the dose will need to be reduced upon discontinuation of rifampin or other inducers. Other CYP3A4 inducers include rifabutin, rifapentin, phenyltoin, carbamazepine, phenoxodolone and St. John's Wort. These too should be avoided if possible (see PRECAUTIONS - Drug Interactions section).

Hepatotoxicity

Asymptomatic increases in liver transaminases have been observed in TARCEVA treated patients; therefore, periodic liver function testing (transaminases, bilirubin, and alkaline phosphatase) should be considered. Dose reduction or interruption of TARCEVA should be considered if changes in liver function are severe (see ADVERSE REACTIONS section).

Patients with Hepatic Impairment

In vitro and in vivo evidence suggest that erlotinib is cleared primarily by the liver. Therefore, erlotinib exposure may be increased in patients with hepatic dysfunction (see CLINICAL PHARMACOLOGY - Special Populations - Patients with Hepatic Impairment section of full prescribing information and DOSAGE AND ADMINISTRATION - Dose Modification section).

TARCEVATM (erlotinib)

Elevated International Normalized Ratio and Potential Bleeding
 International Normalized Ratio (INR) elevations, and infrequent reports of bleeding events including gastrointestinal bleeding have been reported in clinical studies, some associated with concomitant warfarin administration. Patients taking warfarin or other coumatin-derivative anticoagulants should be monitored regularly for changes in prothrombin time or INR (see ADVERSE REACTIONS section).

Carcinogenesis, Mutagenesis, Impairment of Fertility

Erlotinib has not been tested for carcinogenicity. Erlotinib has been tested for genotoxicity in a series of *in vitro* assays (bacterial mutation, human lymphocyte chromosome aberration, and mammalian cell mutation) and an *in vivo* mouse bone marrow micronucleus test and did not cause genetic damage. Erlotinib did not impair fertility in either male or female rats.

Pregnancy

Pregnancy Category D (see WARNINGS and PRECAUTIONS - Information for Patients sections).

Nursing Mothers

It is not known whether erlotinib is excreted in human milk. Because many drugs are excreted in human milk and because the effects of TARCEVA on infants have not been studied, women should be advised against breastfeeding while receiving TARCEVA therapy.

Pediatric Use

The safety and effectiveness of TARCEVA in pediatric patients have not been studied.

Geriatric Use

Of the total number of patients participating in the randomized trial, 62% were less than 65 years of age, and 33% of patients were aged 65 years or older. The survival benefit was maintained across both age groups (see CLINICAL STUDIES section of full prescribing information). No meaningful differences in safety or pharmacokinetics were observed between younger and older patients. Therefore, no dosage adjustments are recommended in elderly patients.

Information for Patients

If the following signs or symptoms occur, patients should seek medical advice promptly (see WARNINGS, ADVERSE REACTIONS and DOSAGE AND ADMINISTRATION - Dose Modification sections):

- Severe or persistent diarrhea, nausea, anorexia, or vomiting
- Onset or worsening of unexplained shortness of breath or cough
- Eye irritation

Women of childbearing potential should be advised to avoid becoming pregnant while taking TARCEVA (see WARNINGS - Pregnancy Category D section).

ADVERSE REACTIONS

Safety evaluation of TARCEVA is based on 856 cancer patients who received TARCEVA as monotherapy and 1228 patients who received TARCEVA concurrently with chemotherapy. Adverse events, regardless of causality, that occurred in at least 10% of patients treated with TARCEVA and at least 3% more often than in the placebo group in the randomized trial are summarized by NCI CTC (version 2.0) Grade in Table 1.

There have been reports of serious ILD, including fatalities, in patients receiving TARCEVA for treatment of NSCLC or other advanced solid tumors (see WARNINGS - Pulmonary Toxicity, and DOSAGE AND ADMINISTRATION - Dose Modifications sections).

The most common adverse reactions in patients receiving TARCEVA were rash and diarrhea. Grade 3/4 rash and diarrhea occurred in 9% and 6%, respectively, in TARCEVA-treated patients. Rash and diarrhea each resulted in study discontinuation in 1% of TARCEVA-treated patients. Six percent and 1% of patients needed dose reduction for rash and diarrhea, respectively. The median time to onset of rash was 8 days, and the median time to onset of diarrhea was 12 days.

Table 1: Adverse Events Occurring in ≥10% of TARCEVA-treated Patients (2:1 Randomization of TARCEVA to Placebo)

NCI CTC Grade	TARCEVA N=485		Placebo N=242	
	Any Grade	Grade 3-4	Any Grade	Grade 3-4
MedDRA Preferred Term	%	%	%	%
Rash	75	8	<1	17
Diarrhea	54	6	<1	18
Anorexia	52	8	1	38
Fatigue	52	14	4	45
Dyspnea	41	17	11	35
Cough	33	4	0	29
Nausea	33	3	0	24
Infection	24	4	0	15
Vomiting	23	2	<1	19
Stomatitis	17	<1	0	3
Pruritus	13	<1	0	5
Dry skin	12	0	0	4
Conjunctivitis	12	<1	0	<1
Keratocconjunctivitis sicca	12	0	0	3
Abdominal pain	11	2	<1	7

Liver function test abnormalities (including elevated alanine aminotransferase (ALT), aspartate aminotransferase (AST) and bilirubin) have been observed. These elevations were many transient or associated with liver metastases. Grade 2 (>2.5 - 5.0 x ULN) ALT elevations occurred in 4% and <1%

TARCEVATM (erlotinib)

TARCEVA and placebo treated patients, respectively. Grade 3 (> 5.0 - 20.0 x ULN) elevations were not observed in TARCEVA-treated patients. Dose reduction or interruption of TARCEVA should be considered if changes in liver function are severe (see DOSAGE AND ADMINISTRATION - Dose Modification section).

Infrequent cases of gastrointestinal bleeding have been reported in clinical studies, some associated with concomitant warfarin administration (see PRECAUTIONS - Elevated International Normalized Ratio and Potential Bleeding section) and some with concomitant NSAID administration.

NCI CTC grade 3 conjunctivitis and keratitis have been reported infrequently in patients receiving TARCEVA therapy. Corneal ulcerations may also occur (see PRECAUTIONS - Information for Patients section).

In general, no notable differences in the safety of TARCEVA could be discerned between females or males and between patients younger or older than the age of 65 years. The safety of TARCEVA appears similar in Caucasian and Asian patients (see PRECAUTIONS - Geriatric Use section).

OVERDOSAGE

Single oral doses of TARCEVA up to 1,000 mg in healthy subjects, and up to 1,500 mg in cancer patients have been tolerated. Repeated twice-daily doses of 200 mg in healthy subjects were poorly tolerated after only a few days of dosing. Based on the data from these studies, an unacceptable incidence of severe adverse events, such as diarrhea, rash, and liver transaminase elevation, may occur above the recommended dose of 150 mg daily. In case of suspected overdose, TARCEVA should be withheld and symptomatic treatment instituted.

DOSAGE AND ADMINISTRATION

The recommended daily dose of TARCEVA is 150 mg taken at least one hour before or two hours after the ingestion of food. Treatment should continue until disease progression or unacceptable toxicity occurs. There is no evidence that treatment beyond progression is beneficial.

Dose Modifications

In patients who develop an acute onset of new or progressive pulmonary symptoms, such as dyspnea, cough or fever, treatment with TARCEVA should be interrupted pending diagnostic evaluation. If ILD is diagnosed, TARCEVA should be discontinued and appropriate treatment instituted as necessary (see WARNINGS - Pulmonary Toxicity section).

Diarrhea can usually be managed with loperamide. Patients with severe diarrhea who are unresponsive to loperamide or who become dehydrated may require dose reduction or temporary interruption of therapy. Patients with severe skin reactions may also require dose reduction or temporary interruption of therapy.

When dose reduction is necessary, the TARCEVA dose should be reduced in 50 mg decrements.

In patients who are being concomitantly treated with a strong CYP3A4 inhibitor such as itraconazole, clarithromycin, indinavir, itraconazole, ketoconazole, nefazodone, nelfinavir, montelukast, saquinavir, telithromycin, toleandomycin (TAO), or voriconazole, a dose reduction should be considered should severe adverse reactions occur.

Pre-treatment with the CYP3A4 inducer rifampin decreased erlotinib AUC by about 2/3. Alternate treatments lacking CYP3A4 inducing activity should be considered. If an alternative treatment is unavailable, a TARCEVA dose greater than 150 mg should be considered. If the TARCEVA dose is adjusted upward, the dose will need to be reduced upon discontinuation of rifampin or other inducers. Other CYP3A4 inducers include rifabutin, rifapentin, phenyltoin, carbamazepine, phenoxodolone and St. John's Wort. These too should be avoided if possible (see PRECAUTIONS - Drug Interactions section).

Erlotinib is eliminated by hepatic metabolism and biliary excretion. Therefore, caution should be used when administering TARCEVA to patients with hepatic impairment. Dose reduction or interruption of TARCEVA should be considered should severe adverse reactions occur (see CLINICAL PHARMACOLOGY - Special Populations - Patients with Hepatic Impairment section of full prescribing information, PRECAUTIONS - Patients with Hepatic Impairment, and ADVERSE REACTIONS sections).

HOW SUPPLIED

The 25 mg, 100 mg and 150 mg strengths are supplied as white film-coated tablets for daily oral administration.

TARCEVA (erlotinib) Tablets, 25 mg: Round, beconvex face and straight sides, white film-coated, printed in orange with a "T" and "25" on one side and plain on the other side. Supplied in bottles of 30 tablets (NDC 50242-062-01).

TARCEVA (erlotinib) Tablets, 100 mg: Round, beconvex face and straight sides, white film-coated, printed in gray with "T" and "100" on one side and plain on the other side. Supplied in bottles of 30 tablets (NDC 50242-063-01).

TARCEVA (erlotinib) Tablets, 150 mg: Round, beconvex face and straight sides, white film-coated, printed in maroon with "T" and "150" on one side and plain on the other side. Supplied in bottles of 30 tablets (NDC 50242-064-01).

STORAGE

Store at 25°C (77°F), excursions permitted to 15° - 30°C (59° - 86°F). See USP Controlled Room Temperature.

Manufactured for: OSI Pharmaceuticals Inc., Melville, NY 11747

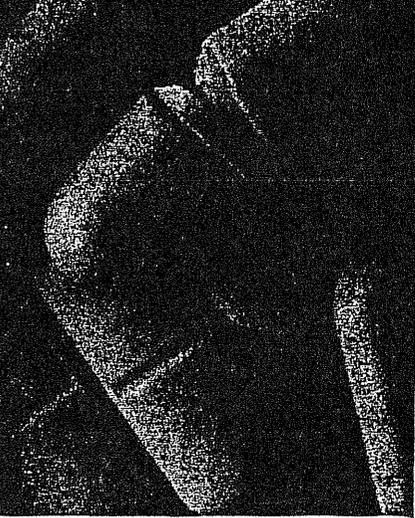
Manufactured by: Schwarz Pharma Manufacturing, Seymour, IN 47274

Distributed by: Genentech Inc., 1 DNA Way South San Francisco, CA 94080-4990

For further information please call 1-877-TARCEVA (1-877-627-2382) or visit our website at www.tarceva.com.

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Director of Policy and Advocacy Tom Clark, RPh, MHS, told *Pharmacy Practice News*, "Tablet splitting has been done clinically for many years, usually in cases where the patient needs a lower dose than is commercially available. But we don't want this to become widespread. Patients must be carefully selected and educated."

Both Dr. Hussar and Mr. Clark brought up practical questions involved in tablet-splitting programs. Considering long-term care facilities, Mr. Clark wondered whether already overextended nursing staff would be responsible for splitting tablets and where half-tablets would be stored. Having the pharmacist precut all tablets in a prescription poses its own problems, he noted. "Once a tablet's coating is breached, air and moisture can affect it. Is a half-tablet going to be stable for 30 days?"

Dr. Hussar raised issues regarding patient-pharmacist communications. "If the physician says one pill and the pharmacist says half a pill, who does the patient follow? What if the pharmacist splits the tablet and the patient thinks it still needs to be split?"

The bottom line on tablet splitting for Dr. Hussar remains the bottom line. "Who's saving the money? Is it the patient? The hospital? Pharmacists will spend more time talking to their patients but pharmacy benefits managers aren't going to agree to higher dispensing fees."

However, Dr. Parra noted a recent study showing that statins were the drug most likely to be discontinued by Medicare recipients because of cost. He added: "Although tablet splitting statins is not the solution for rising drug costs, it surely can have a role."

—Shayna B. Kravetz, BSc

PHARMACOECONOMICS

Tablet Splitting

continued from page 1

Participation in the Florida program was voluntary. Tablet splitting eventually became the default for electronic orders of eligible prescriptions, although prescribers, patients or pharmacists could still opt for whole-tablet regimens. During 1999, 3,787 patients received daily doses of simvastatin at 5, 10, 20 or 40 mg. The patients

were divided into two groups depending on whether they agreed to undergo voluntary conversion from whole simvastatin tablets to split tablets. Patients' low-density lipoprotein cholesterol (LDL-C) levels were followed through conversion to tablet splitting or, for patients who still received whole-tablet dosages, for at least 45 days.

With data for 1,098 patients in each group, 76.3% of patients in the tablet-splitting group achieved final LDL-C lev-

els <130 mg/dL, versus 73.6% of those receiving whole tablets (P=0.14). The two groups also showed similar changes in LDL-C levels from baseline, and average final LDL-C values overall; patients in the tablet-splitting group averaged 110.9±29.6 mg/dL and patients who received whole tablets averaged 112.1±32.4 mg/dL (P=0.304). Patients' adherence to each regimen, as tracked by prescription refills, and transaminase levels did not differ signifi-

cantly between the two groups.

The Pros and Cons

One benefit of tablet splitting is that some patients can save money. In a 2004 pilot program for Nebraska government employees, patients were offered \$10 off each refill's copay if they split tablets for their prescriptions of sertraline (Zoloft, Pfizer), citalopram (Celexa, Forest), escitalopram (Lexapro, Forest), and atorvastatin (Lipitor, Pfizer). Participants received a tablet splitter and brochure directly from their health plan. In 2004's first quarter, 113 patients saved \$2,360 and the state health plan saved \$7,300, after paying administrative costs of \$4,500, said Nina Homan, PharmD, Director of Pharmacy Programs, Prime Therapeutics, a pharmacy benefits solutions company based in Eagan, Minn.

see Tablet Splitting, page 18

LidoSite™ Topical System

Composed of LidoSite™ Patch (Lidocaine HCl/Epinephrine Topical Anesthetic Patch) 10%/0.1% and LidoSite™ Controllor

Summary (For full Prescribing Information, refer to package insert.)

INDICATIONS AND USAGE. LidoSite™ System is a topical local anesthetic delivery system indicated for use on intact skin to provide local analgesia for superficial dermatological procedures such as venipuncture, intra-vascular cannulation, and laser ablation of superficial skin lesions. LidoSite™ System is indicated for use on patients up to age 65 years of age.

CONTRAINDICATIONS. LidoSite™ System is contraindicated in patients with a known history of hypersensitivity to local anesthetics of the amide type, sulfites, or to any other component of the product. (See **WARNINGS** and **CAUTIONS** sections). LidoSite™ System is contraindicated for use in patients with electrically-sensitive devices (e.g., pacemakers).

WARNINGS - Rx Only. DANGER-EXPLOSIVE HAZARD: This product could serve as an ignition source and should be used in the presence of flammable anesthetics. Accidental Exposure in Children: Even a used LidoSite™ System contains a large amount of lidocaine (up to 100 mg). The potential exists for a small child to suffer serious effects from chewing or ingesting a new or used LidoSite™ Patch. Children should be closely observed if treated with the LidoSite™ System, and LidoSite™ Patches should be stored and disposed of in the proper manner. **Skin Reaction:** Lontophoresis can cause skin irritation, burning sensation and/or burns. Patients should be alerted of the possibilities and alerted to early signs such as itching or warmth. Patients should be instructed to notify appropriate personnel as soon as symptoms are detected. Longer than recommended durations of application, repeat applications or continued application after the occurrence of symptoms may increase the risk of local irritation or injury. Lontophoresis with the LidoSite™ Patch may cause transient, local blanching or erythema of the skin under the patch. The redness under the elongated reservoir is normally uniform in color, while under circular reservoir the color may be mottled. **Sulfite Allergy:** LidoSite™ Patch contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms, and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic people.

CONTRAINDICATIONS Related to Epinephrine: Since the LidoSite™ Patch contains a vasoconstrictor, it should not be used on areas of the body supplied by bare arteries or having otherwise compromised blood supply. Repeated applications should not be made to the same site. Patients with peripheral vascular disease and those with hypertensive vascular disease may exhibit an exaggerated vasoconstrictor response. LidoSite™ System should be used with caution in patients with severe coronary artery disease, hypertension or cardiac dysrhythmias or in patients who are currently taking monoamine oxidase (MAO) inhibitors or tricyclic antidepressants.

CAUTIONS. General: Since amide-type local anesthetics are metabolized by the liver, LidoSite™ System should be used with caution in patients with hepatic disease. Patients with severe hepatic disease normally are at greater risk of developing toxic plasma concentrations. LidoSite™ System should be used with caution in persons with known drug sensitivities. Patients allergic to para-ortho-benzic acid derivatives (procaine, tetracaine, cocaine, etc.) have not shown cross sensitivity to lidocaine. Nevertheless, LidoSite™ System should be used with caution in patients with a history of drug sensitivities, especially if the etiologic agent is uncertain. Lidocaine epinephrine should be used with caution in patients with impaired cardiovascular function since they may be unable to compensate for changes in cardiac conduction, contractility, and oxygen demand that may be caused by systemic exposure to these drugs. LidoSite™ System should be applied only by a health care practitioner in a clinical care setting. Resuscitative equipment, oxygen, and other resuscitative drugs should be available for immediate use when LidoSite™ System is administered. (See **WARNINGS** and **ADVERSE REACTIONS**). The intended treatment site should not be covered with excessive heat, as that may affect patch adhesion. The LidoSite™ System is not tested for safety or effectiveness in the head and neck areas, over damaged or denuded skin, or on mucous membranes. The safety of LidoSite™ System has not been tested in patients who have received long-term treatment with corticosteroids. Clinical judgment should be exercised when considering the use of LidoSite™ System in these patients, as they may be more susceptible to skin injury from LidoSite™ System. The LidoSite™ System reservoirs may remain in complete contact with the skin during treatment. Therefore, restricting motion is recommended for those application sites where movement could release the patch from the skin. Following iontophoresis and patch removal, the treatment site should be cleansed according to standard practice prior to starting medical procedure. Non-intact skin: Application to broken or inflamed skin, may result in local tissue injury and higher blood concentrations of lidocaine from increased absorption. LidoSite™ System is only recommended use on intact skin. **Eye exposure:** The contact of LidoSite™ Patch with eyes, should be avoided based on the signs of severe eye irritation with the use of similar products in animals. If eye contact occurs, immediately flush out the eye with water or saline and protect the eye until sensation returns.

Application: LidoSite™ System may increase blood levels of lidocaine. LidoSite™ System should be used with caution in patients who may be more sensitive to the systemic effects of lidocaine, including acutely ill, debilitated, or elderly patients. Lidocaine has been shown to inhibit viral and bacterial growth. The effect of LidoSite™ Patch on intradermal injections of live vaccines has not been determined.

Precautions For Patients: When LidoSite™ System is used, the patient should be aware that block of all sensation in the treated skin may occur. For this reason, the patient should avoid inadvertent trauma to the treated area, scratching, rubbing or exposure to extreme hot or cold temperatures until complete sensation has returned. Numbness sensation may persist for an hour or more (See **PHARMACODYNAMICS**). Patients should be advised to monitor the treated area for the return of sensation. The appearance of the treated area may appear to be itchy or red which are normal reactions and usually disappear within 24 hours. Patients should be instructed to monitor the site and report persistent pain, redness and other skin abnormalities based upon directions provided by the health care professional.

CLINICALLY SIGNIFICANT DRUG INTERACTIONS. Monoamine Oxidase Inhibitors: The administration of local anesthetics containing epinephrine to patients receiving monoamine oxidase inhibitors or tricyclic antidepressants may produce severe prolonged hypertension. Antiarhythmic drugs: LidoSite™ System should be used with caution in patients receiving Class I antiarrhythmic drugs (such as tocaine and mexiletine) since the systemic toxic effects are thought to be additive and potentially synergistic. **Local Anesthetics:** When LidoSite™ System is used concomitantly with other products containing local anesthetic agents, the systemic exposure from all formulations must be considered.

GENOTOXICITY, MUTAGENESIS AND IMPAIRMENT OF FERTILITY. Carcinogenesis: Long-term studies to evaluate the carcinogenic potential of lidocaine in animals have not been conducted. **Mutagenesis:** The mutagenic potential of lidocaine HCl has been tested in the Ames Salmonella/Mammalian Microsome Test, by analysis of structural chromosome aberrations in human lymphocytes *in vitro*, and by the mouse micronucleus test *in vivo* were not indicative of any mutagenic effects in these tests. **Impairment of Fertility:** Studies to evaluate the effects of lidocaine on fertility in animals have not been conducted. **Use in Pregnancy:** Teratogenic effects:regnancy Category B. Reproduction studies have been performed in rats at doses up to 500 mg/kg/day, s.c. (5.6 times the human injected dose) via mini-osmotic pumps and have revealed no significant adverse reproductive or teratogenic effects attributable to lidocaine. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. **Nursing Mothers:** Lidocaine is excreted in human milk. The milk/plasma ratio of systemically administered lidocaine is 0.4. Caution should be exercised when LidoSite™ System is administered to a nursing woman. **Pediatric Use:** The safety and effectiveness of the LidoSite™ System have not been established in pediatric patients five years of age and older based on adequate and well-controlled studies (see **CLINICAL STUDIES**). The recommended dose for pediatric patients five years and older is the same as for adults. Safety and effectiveness in pediatric patients below the age of five years have not been established. **Geriatric Use:** In the

clinical studies, there were sixty patients over 65 years of age and thirty-one patients over 75 years of age. No overall differences in safety or efficacy were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between elderly and younger patients. However, greater sensitivity of individual patients greater than 65 years of age cannot be ruled out. In clinical studies of intravenously administered lidocaine, the elimination half-life of lidocaine was statistically significantly longer in elderly patients (2.5 hours) than in younger patients (1.5 hours) (See **CLINICAL PHARMACOLOGY**). **Labor and Delivery:** The effects of LidoSite™ System on the mother and fetus, on the duration of labor or delivery, and on neonatal outcome and maturation have not been studied. Should LidoSite™ System be used concomitantly with other products containing lidocaine and/or epinephrine, total doses contributed by all formulations must be considered (See **DOSAGE AND ADMINISTRATION**).

ADVERSE REACTIONS. Systemic (Dose Related) Reactions: Systemic adverse reactions following the iontophoresis of lidocaine and epinephrine using the LidoSite™ System according to the directions for use are unlikely due to the absorbed dose (See **PHARMACOKINETICS** section). Systemic adverse effects of lidocaine are similar in nature to those observed with other amide-type local anesthetics including either excitatory and/or depressant (lightheadedness, numbness, apprehension, euphoria, confusion, dizziness, drowsiness, lightheadedness, blurred or double vision, vomiting, sensations of heat, cold or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression and arrest) CNS manifestations. Excitatory CNS reactions may be brief or may not occur at all, in which case the first manifestation may be drowsiness leading to unconsciousness. Cardiovascular manifestations are usually depressant and are characterized by bradycardia, hypotension, conduction abnormalities, dysrhythmias and/or cardiovascular collapse which may lead to cardiac arrest. Systemic adverse effects of epinephrine may include palpitations, tachycardia, hypertension, sweating, nausea and vomiting, respiratory difficulty, pallor, dizziness, weakness, tremor, headache, apprehension, nervousness and anxiety. Cardiac arrhythmias may follow the administration of epinephrine. **Allergic:** Allergic reactions, including anaphylactoid and anaphylactic, may occur as a result of sensitivity either to the local anesthetic agents or to the preservatives such as sodium metabisulfite. They may be characterized by cutaneous lesions, urticaria, angioedema, bronchospasm, tachycardia, hypotension or shock. Allergic reactions as a result of sensitivity to lidocaine are extremely rare and, if they occur, should be managed by conventional means. The detection of sensitivity by skin testing is of doubtful value.

MOST COMMON ADVERSE EVENTS. In placebo-controlled studies with LidoSite™ System, 4.5% of patients on placebo (N=333) and 4.5% of patients on LidoSite™ System (N=330) reported an adverse event. Because the placebo groups were not "no treatment" groups, but instead generally utilized an unaltered LidoSite™ Patch or an epinephrine only-containing patch with application of current, comparing the incidence of adverse events between the placebo and LidoSite™ System groups may not fully elucidate the incidence of adverse events that are attributable to iontophoresis, epinephrine or local treatment from patch application. In these studies, adverse events that occurred at a higher incidence in LidoSite™ System treated subjects compared to placebo treated subjects included subcutaneous hematoma (0.3% vs. 0.3%) and vasoconstriction (0.5% vs. 0.3%). In one study, the incidence of application site pain was reported to be as high as 12% and in another study the incidence of burns was reported to be as high as 8%. There were no serious adverse events attributed to LidoSite™ System treatment. In the overall safety database (812 patients administered LidoSite™ System) 0.8% of patients discontinued due to an adverse event. The most common reasons for discontinuation were: application site pain, N=4 (0.5%), application site burning, N=3 (0.4%), and pruritus, N=1 (0.1%). The most frequently observed adverse events from all studies are presented below:

Summary of most frequently observed adverse events from all studies involving LidoSite™

Adverse Event	Placebo		
	LidoSite™ System (N= 827, N=925) n (%)	LidoSite™ System (N= 308, N=308) n (%)	LidoSite™ Patch without application of current (N=25, N=25) n (%)
Pain/burning sensation with iontophoresis	22 (2.4)	18 (5.8)	0
Rash (includes macular & papular)	45 (4.9)	0	0
Burns	13 (1.4)	1 (0.3)	0
Subcutaneous hematoma	3 (0.3)	1 (0.3)	0
Marked vasoconstriction	3 (0.3)	2 (0.6)	0
Erythema	1 (0.1)	0	0
Urticaria	1 (0.1)	0	0

*N₁=Number of Subjects, N₂=Number of Treatments; % computed based on the number of treatments (N₂). In three Pharmacokinetic studies each subject received three treatments during the study.

OVERDOSAGE: Acute emergencies from local anesthetics are generally related to high plasma levels encountered during therapeutic use (See **ADVERSE REACTIONS, WARNINGS** and **PRECAUTIONS**). High lidocaine plasma levels are unlikely to occur from administration of LidoSite™ System when used as directed. Repeated applications, multiple simultaneous applications, application in smaller patients, or in patients with impaired elimination may all contribute to increased blood concentrations of lidocaine. In addition, if other local anesthetics are administered at the same time, e.g. topically or by injection, the toxic effects are thought to be additive and could result in an overdose with systemic toxic reactions. There is generally an increase in severity of symptoms with increasing plasma concentrations of lidocaine. Systemic central nervous system (CNS) toxicity may occur over a range of plasma concentrations of local anesthetics. CNS toxicity may typically be found around 5000 ng/mL of lidocaine; however, a small number of patients reportedly may show signs of toxicity at approximately 1000 ng/mL. CNS symptoms usually precede cardiovascular manifestations. Plasma levels of lidocaine were below the minimum level of quantitation, 5 ng/mL, in healthy adult or pediatric subjects after three sequential LidoSite™ System applications on different sites over a 3.5-hour period. Toxic levels of lidocaine may cause seizures, decreases in cardiac output, total peripheral resistance and mean arterial pressure, as well as life-threatening dysrhythmias and cardiac arrest. The management of overdose includes close monitoring, supportive care, and symptomatic treatment. Dialysis is of negligible value in the treatment of acute overdose with lidocaine. In the absence of mass effect topical overdose or oral ingestion, evaluation should include assessment for other etiologies of these clinical effects and overdose from other sources of lidocaine (consult package insert for parenteral lidocaine for further information on the management of overdose). Epinephrine blood levels did not exceed the normal physiological range (<50 ng/mL), after a single LidoSite™ System application. Overdosage of epinephrine can cause hypertension, tachycardia, cardiac dysrhythmias, cerebral hemorrhage and pulmonary edema. It is unlikely that overdose would be caused by use of LidoSite™ System as labeled and patients with symptoms or signs of overdose should be evaluated for other etiologies of these clinical effects or overdose from other sources of epinephrine (consult package insert for epinephrine injection). **Local skin reactions:** Application of multiple patches to the same site or failure to promptly remove patches after iontophoretic treatment could result in increased risk of local skin reactions. **Over Current Condition:** If the controller detects a current in excess of the normal range of current, the current (and delivery) is stopped, the flashing YELLOW indicator is illuminated and the device beeps three times.

DOSAGE AND ADMINISTRATION: LidoSite™ Controllor can only be used with the LidoSite™ Patch as the complete LidoSite™ System, and LidoSite™ Patches should only be used with a LidoSite™ Controllor. LidoSite™ System should be applied only by a health care practitioner in a health care setting. **Patch Disposal:** LidoSite™ Patch should be disposed of as medical waste. **Storage Conditions:** Store LidoSite™ patches at controlled room temperature (20°C-25°C; 68°F-77°F). Warning: Do not subject the patches to freezing temperatures.

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The following suggestions for tablet splitting are based on an algorithm developed by the American Pharmacists Association Strategic Directions Committee (*J Am Pharm Assoc* 2004;44:324-325) and interviews with Daniel Hussar, PhD, Remington Professor of Pharmacy, Philadelphia College of Pharmacy, and David Parra, PharmD, Clinical Pharmacist, VA Medical Center, West Palm Beach, Fla.

The Prescription

Medications with narrow therapeutic indexes or unfavorable side-effect profiles are not suitable for tablet splitting. Capsules cannot be split, nor can tablets designed to have a sustained release or given enteric coatings to enable effective passage through the digestive system. Tablets should be able to withstand long-term exposure to air and moisture without degrading in texture or efficacy, especially if the pharmacist will split all tablets in advance.

The Patient

Physical limitations that may impede patients' ability to split tablets include lack of visual acuity or limited manual dexterity because of illnesses such as arthritis or parkinsonism and mental limitations such as Alzheimer's disease.

The Pharmacist

The pharmacist should take the following steps:

- Verify the relationship between the daily dosage prescribed and the dosage in the tablet as formulated;
- Ensure that both patient and prescription are suitable for a tablet-splitting program;
- Verify that the patient has a pill splitter and is educated on its use;
- Clarify with the patient what the prescriber has told him or her about the regimen and ensure that the patient receives a consistent message about how many doses to take each day; and
- Follow-up on delay in getting refills to promote patient adherence and to prevent the patient from mistakenly splitting pre-split tablets.

finds. But pharmacists in the nation's more prevalent types of healthcare facilities, such as community and county hospitals, have been slower to advance into ambulatory clinical positions.

Results from the 2004 American Society of Health-System Pharmacists (ASHP) Survey of Ambulatory Care Pharmacy Practice in Health Systems, show that 233 of responding organizations

Touro University—California in Vallejo, who led the ASHP research effort.

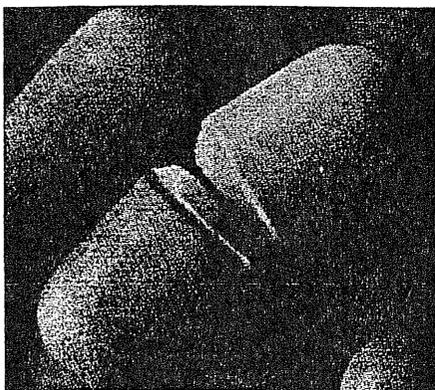
"If you're in a state or organization where your pharmacists are really stretched," said Dr. Knapp, "it's very difficult to take on new activities or expand into new areas when you're having trouble just keeping up with your traditional workload."

 **see Ambulatory Care, page 21**

Tablet Splitting: Half A Solution to Drug Costs

Saving millions, but at a cost to patient care?

NEW ORLEANS—Splitting simvastatin tablets saved \$1.26 million in 1999 at a Florida Department of Veterans Affairs (VA) network, with no loss in adherence or clinical outcomes, according to a retrospective analysis presented at the 2004 American Heart Association Scientific



Sessions. Full implementation of the simvastatin-splitting initiative across the VA system nationwide avoided costs of \$46.5 million in 2003, said lead researcher David Parra, PharmD, Clinical Pharmacist, VA Medical Center, West Palm Beach, Fla.

"[While] exploring ways to accommodate costs ... a number of VA hospitals had the same idea," said Dr. Parra. Simvastatin (Zocor, Merck) was chosen in part because prior research showed that statins could be administered in higher doses every second day and remain as effective as lower daily doses. "Simvastatin also has a very favorable dose-response profile and a good toxicity profile," he added. "If a patient splits a tablet 45/55 instead of 50/50, it won't matter."

 **see Tablet Splitting, page 16**

Tips for deciding when—and not—to split tablets

Technology

COMPOUNDING

USP Chapter 797: minimizing cleanroom costs

THE POCKET PHARMACIST

Nutrition-support PDA tool

Clinical

CNS

Drug creates brighter mood in mentally retarded

CARDIOVASCULAR

Nesiritide improves renal hemodynamics in patients with congestive heart failure

Educational Review

Effective Preventions For Stroke



Continuing Education

Anaphylactic and Anaphylactoid Reactions During Anesthesia: Detection and Diagnosis



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TECHNOLOGY UPDATE

section starts on page 16

Weight Uniformity of Split Tablets Required by a Veterans Affairs Policy

JAMES E. POLLI, PhD; SHARON KIM, BA; and BRIAN R. MARTIN, PharmD

ABSTRACT

OBJECTIVE: To split several tablet products relevant to the Veterans Affairs (VA) Maryland Healthcare System and assess whether the resulting half tablets provide equal doses.

METHODS: From a VA list of products that are required to be split, 7 products were evaluated, along with 5 other commonly split tablet products. A trained pharmacy student split tablets using a tablet splitter provided by the VA. Half tablets were assessed for weight uniformity.

RESULTS: Of the 12 products subjected to splitting, 8 products (atorvastatin, citalopram, furosemide, glipizide, metoprolol, paroxetine, sertraline, and warfarin) yielded half tablets that passed the weight-uniformity test. The 4 failing products were lisinopril, lovastatin, rofecoxib, and simvastatin. Unusual tablet shape and high tablet hardness predisposed products to failing the weight-uniformity test. The 4 failing products resulted in half tablets that were generally within 20% of their target weight range, suggesting that splitting these specific products would not result in adverse therapeutic effects due to dose variation created by tablet-splitting.

CONCLUSION: Split-tablet results were relatively favorable and generally support a VA practice to split specific tablets. Public quality standards for half tablets, including their content uniformity, are needed to better delineate the policies for acceptable tablet splitting.

KEYWORDS: Tablet splitting, Weight uniformity, Tablet-weight uniformity, Veterans Affairs

J Managed Care Pharm. 2003;9(5):401-07

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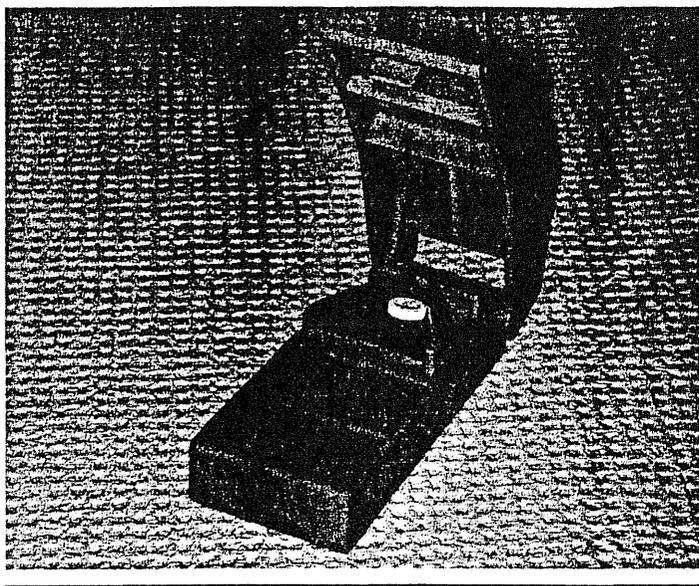
In recent years, the U.S. Department of Veterans Affairs (VA) has been faced with escalating pharmacy costs. These increased costs are the result of increased enrollment, an aging patient population that requires more prescription medicines, and increased acquisition costs of prescription medicines. The VA has turned to tablet-splitting programs as one approach to contain costs. Several pharmacoeconomic studies have indicated that splitting certain tablets can produce significant cost savings.¹⁻⁵

A tablet-splitting program was implemented 2 years ago at the VA Maryland Health Care System, which is part of the Veterans Integrated Service Network 5 (VISN 5) region. VISN 5 provides care for veterans in Maryland; Washington, D.C.; eastern West Virginia; Northern Virginia; and south central Pennsylvania.

Candidate drugs were considered for this tablet-splitting initiative if they had a relatively high cost, tablet splitting was not considered to be detrimental to drug release, and the tablets were easily split with a standard tablet-splitting device. VISN 5 now mandates tablet splitting of 8 tablet products for outpatients: atorvastatin, citalopram, lovastatin, paroxetine, rofecoxib, sertraline, sildenafil, and simvastatin. New prescriptions for these products are filled with a tablet that contains twice the prescribed dose, and patients are instructed to take 1 half tablet. A standard tablet-splitting device is also dispensed with the prescriptions. A patient may opt out of the tablet-splitting program if the splitting of tablets proves to be difficult. Also, several other tablets are frequently split, due to cost and therapeutic reasons. Between May 2001 and April 2002, the tablet-splitting initiative directly saved the VA Maryland Healthcare System about \$560,000; approximately 41,000 patients received pharmacy services from the health care system during this time.

Equal splitting is presumably necessary for weight uniformity from half tablet to half tablet. We previously found that several commonly split tablets, when split by a razor blade or by hand, usually did not produce evenly split tablet halves.⁶ We observed that no visible tablet features (e.g., tablet scoring) predisposed a product's half tablets from passing or failing the uniformity test. Rosenberg et al. found tablet splitting to yield half tablets that generally did not meet an expectation for dose uniformity.⁷ They determined the weights and weight uniformity of tablet halves dispensed by pharmacists. Rosenberg et al. found that only 7 of the 22 dispensed prescriptions met an expectation of accurate tablet halves (defined as less than 15% error) with acceptable weight uniformity (i.e., less than 6% relative standard deviation).

FIGURE 1 Photograph of Tablet Splitter



From these recent studies, we hypothesized that tablet splitting following practices of the VA Maryland Health Care System would result in half tablets that generally fail to provide acceptable dose uniformity. Specifically, the objective of our study was to split several tablet products relevant to the VA Maryland Healthcare System and assess whether the resulting half tablets provided equal weights. Seven of the 8 mandatory split products in the VISN 5 region (all but sildenafil) were evaluated, along with furosemide, glipizide, lisinopril, metoprolol, and warfarin, which are commonly split at the VA Maryland Healthcare System. Although not mandatory, splitting of these latter 5 products is permissible, at the discretion of the prescriber. Splitting tablets allows for more precise dosage adjustment and greater patient convenience, for example, by eliminating the need for 2 separate prescriptions to achieve a desired dose. For instance, a patient prescribed lisinopril 30 mg daily can take a 20 mg and a 10 mg tablet, which would require 2 copayments since a 30 mg tablet is not commercially available. Alternatively, the patient could be prescribed one and one-half 20 mg tablets daily, which requires only 1 prescription and only 1 copayment.

Methods

The following products were donated by either the VA Maryland Healthcare System or the University of Maryland School of Pharmacy: atorvastatin 40 mg (Lipitor, Pfizer, Lot #053XOV), citalopram 40 mg (Celexa, Forest, Lot #M0114M), furosemide 40 mg (Geneva, Lot #114028), glipizide 10 mg (Geneva, Lot #126255), lisinopril 40mg (Prinivil, Merck, Lot #L4686; generic lisinopril was not available at the time of this study but is now purchased by the VA), lovastatin 40 mg (Mevacor, Merck, Lot #L1143; generic lovastatin was not available at the time of this

study but is now purchased by the VA), metoprolol tartrate 50 mg (Caraco, Lot #1333A), paroxetine (Paxil, GlaxoSmithKline, Lot #400019B13), rofecoxib 25 mg (Vioxx, Merck, Lot #L3103), sertraline 100 mg (Zoloft, Pfizer, Lot #9JP018A), simvastatin 20 mg (Zocor, Merck, Lot #L1016), and warfarin 5 mg (Coumadin, DuPont Pharmaceuticals, Lot #SP094A).

The previously described tablet-splitting method and acceptance criteria were followed,⁶ with the exception that a tablet splitter (ACE-LIFE Pill Splitter model PS12E; Health Enterprises Inc., North Attleboro, MA) was used. This tablet splitter consists of upper and lower platforms, which are connected by a hinge. The lower platform provides for the placement of the tablet within a V-shaped region. A razor blade is centered on the upper platform. A tablet is split by pressing the upper platform onto the lower platform (Figure 1). This model of tablet splitter is distributed to VA patients who are instructed to split tablets. For this study, one trained, supervised pharmacy student (tester) performed all tablet splitting in a controlled laboratory environment. This study design did not employ patients; rather, it employed a trained tester to split tablets, since individual patients are known to vary in their ability to split tablets. In evaluating the hypothesis that tablet splitting would result in half tablets that generally fail to provide acceptable dose uniformity, our methodology represents a best-case approach.

Each tablet was carefully placed in the designed split area of the splitter; in all cases, the aim was to obtain evenly split tablet halves. The tester split Zestril 40 mg tablets to affirm the ability of the tester to obtain the favorable tablet-splitting results reported previously (i.e., weight uniformity that passes the acceptance criteria).⁶ If a tablet was scored, the tablet was situated in the splitter such that the blade would cut within the score groove. However, for warfarin and furosemide, splits were also performed when the tablet was randomly placed in the splitter (i.e., random orientation of the tablet score relative to the blade). Also, because of its trapezoid shape, lisinopril (Prinivil) could be placed into the splitter with 2 different orientations; both orientations were evaluated.

The previously applied criteria were followed in assessing whether the resulting half tablets split uniformly.⁶ The criteria were adapted from the U.S. Pharmacopeia's (USP) <905> "Uniformity of Dosage Units" test for whole tablets.⁸ Briefly, the test entailed subjecting 30 tablets of each product to the following:

- 30 tablets were weighed. The mean weight per tablet was calculated. The acceptable 85% to 115% range for a perfectly split tablet was determined from this mean weight. All weight measures employed a Mettler AE 100 analytical balance (Mettler Toledo, Inc., Columbus, OH).
- 10 of the 30 tablets were individually weighed. Each tablet was split, resulting in 20 half tablets. Each half tablet was weighed.
- From the 20 half tablets, the number of tablet halves outside the 85% to 115% range was counted. The number outside the 75% to 125% range was also counted. The relative standard

TABLE 1 Performance of Tablets That Split Successfully

Product	Percent Outliers Beyond 85%-115% (and Beyond 75%-125%)	Percent RSD	Percent Dose Loss (\leq Max)	Observations	Scored (Y/N)	Flat (Y/N)	Tablet Shape
Celexa 40 mg	0 (0)	6.1	0.2 (0.4)	Dramatic score; appears to facilitate accurate splitting	Yes	No	Oval
Coumadin 5 mg (orientation 1)	0 (0)	3.3	0.00 (0.18)	Tablet situated such that blade would split tablet along the score	Yes	No	Round
Coumadin 5 mg (orientation 2)	0 (0)	6.2	0.5 (1.4)	Tablet situated such that score was randomly oriented relative to blade	Yes	No	Round
Furosemide 40 mg (orientation 1)	0 (0)	3.9	0.8 (1.7)	Tablet situated such that blade would split tablet along the score	Yes	Yes	Round
Furosemide 40 mg (orientation 2)	0 (0)	7.8	1.3 (7.3)	Tablet situated such that score was randomly oriented relative to blade	Yes	Yes	Round
Glipizide 10 mg	0 (0)	6.1	0.08 (0.95)	Tablet situated such that blade would split tablet along the score	Yes	No	Round
Lipitor 40 mg	0 (0)	5.5	0.1 (0.4)	Tablet situated such that blade would split tablet where a score would be; difficult to position in the splitter	No	No	Oval
Metoprolol 50 mg	0 (0)	5.4	0.1 (0.4)	Tablet situated such that blade would split tablet along the score but the most difficult to position in the splitter since the tablet is oblong	Yes	No	Oblong
Paxil 40 mg	0 (0)	3.5	0.56 (1.00)	Tablet situated such that blade would split tablet where a score would be	No	No	Oval
Zolofit 100 mg	0 (0)	3.3	0.1 (0.3)	Tablet situated such that blade would split tablet along the score	Yes	No	Oblong

deviation (RSD) of the half-tablet weights was calculated. If, at most, 1 half tablet was outside the 85% to 115% range, but within the 75% to 125% range, and if the RSD was $\leq 10.0\%$, the half tablets passed this uniformity test.

- If 2 half tablets were outside the 85% to 115% range (but within 75% to 125% range) or if RSD $> 10.0\%$, the additional 20 tablets were split. To pass, none of the additional 40 half tablets could be outside the 85% to 115% range, and the RSD for all 60 half tablets needed to be $\leq 10.0\%$.
- If 3 or more of the 20 half tablets were outside the 85% to 15% range, the half tablets failed this uniform test. Also, if any half tablets were outside the 75% to 125% range, the half tablets failed this uniformity test.

Hence, like the USP "Uniformity of Dosage Units" test for whole tablets, half tablets could fail because of too many half tablets outside the 85% to 115% range, too many half tablets outside the 75% to 125% range, or too high an RSD. However, the criteria applied here are more liberal than the USP test for whole tablets, since the USP test allows an RSD of a maximum 6%. Also, half-tablet weight, rather than chemical assay of actual drug, was evaluated. These 2 aspects facilitate tablet halves to pass the uniformity test. The percent-dose loss due to the splitting process was also monitored. The percent-dose loss was the relative difference between the weight of the original tablet and the combined weight of its 2 half tablets.

Results

Of the 12 products subjected to splitting, 8 products (67%) yielded half tablets that passed the weight uniformity test. These results generally contrast with previous results where 8 of 11

razor-blade-split products provided half tablets that failed.⁶ Tables 1 and 2 list the products that passed and failed, respectively. Using a tablet splitter in this study, all 6 scored tablets passed, while most unscored tablets failed (4 of 6 failed). This tendency conflicts with a previous observation that no visible tablet features (e.g., tablet scoring, tablet shape) predisposed a product's half tablets from passing or failing the uniformity test.⁶ Among the 3 products included in both our previous and the present study, paroxetine and sertraline each passed in both studies, while atorvastatin failed previously but passed here.

Warfarin and furosemide passed, regardless of how the tablet score was oriented relative to the splitter's blade (Table 1). For each of these products, results from the random orientation were slightly less desirable than the results from the nonrandom orientation. Lisinopril failed, regardless of how the tablet score was oriented relative to the splitter's blade (Table 2).

Rofecoxib and simvastatin (Table 2) failed the uniformity test for every reason: too many half tablets outside the 85% to 115% range, too many half tablets outside the 75% to 125% range, and too high an RSD. Lovastatin and lisinopril in one orientation (i.e., the orientation that provided a more stable fit of the Prinivil tablet within the tablet splitter) failed for 2 of these 3 reasons. Lisinopril in the other orientation (i.e., the orientation that provided a poor fit of the tablet within the tablet splitter) failed for all 3 reasons.

Discussion

Favorable Tablet-Split Results

The objective of this report was to split several tablet products relevant to the VA Maryland Healthcare System and assess

Weight Uniformity of Split Tablets Required by a Veterans Affairs Policy

TABLE 2 Performance of Tablets That Did Not Split Successfully

Product	Percent Outliers Beyond 85%-115% (and Beyond 75%-125%)	Percent RSD	Percent Dose Loss (\leq Max)	Observations	Scored (Y/N)	Flat (Y/N)	Tablet Shape
Mevacor 40 mg	15 (0)	10.4	0.9 (3.2)	Failed by a small margin	No	Yes	Octagon; thick
Prinivil 40 mg (orientation 1)	20 (0)	13.4	1.5 (7.2)	This orientation provided a good fit of the tablet within the tablet splitter	No	Yes	Trapezoid (but not a square); top of the tablet was inserted toward the blade of the tablet splitter
Prinivil 40 mg (orientation 2)	40 (10)	15.8	0.6 (1.0)	This orientation provided a poor fit of the tablet within the tablet splitter	No	Yes	Trapezoid (but not a square); bottom corner of the tablet was inserted toward the blade of the tablet splitter
Vioxx 25 mg	50 (20)	21.1	1.9 (6.2)	Thick and hard tablet; most difficult to split since the blade is able to move tablet during splitting	No	No	Round; the tablet is almost spherical, due to its small tablet diameter, round shape, and convex (nonflat) surface
Zocor 20 mg	20 (10)	15.0	0.00 (1.30)	Difficult to position the tablet in the splitter	No	No	Shield-like; the tablet's sharpest point was inserted toward the blade of the tablet splitter

whether the resulting half tablets provided equal doses. Our findings here are surprisingly favorable. Using the same criteria applied here, our previous observations from razor-blade splitting showed that a majority of tablets did not split evenly and visible tablet features did not predict a product's half tablets from passing or failing the uniformity test.⁶ Using similar criteria, Rosenberg et al. also observed tablet splitting that resulted in half tablets that generally did not exhibit half-tablet uniformity.⁷

Hence, our expectations for this study were low. However, the results are relatively favorable and generally support the mandatory tablet-split policy of the VISN 5 region. Of the 12 products subjected to splitting, 8 products yielded half tablets that passed the weight-uniformity test. For these 8 products, including warfarin, it would appear that motivated and capable patients, under the direction of a pharmacist, would not experience any adverse therapeutic effects due to dose variation from tablet splitting. This conclusion is based on the half tablets of these 8 products exhibiting weight uniformity to whole tablets.

One possible explanation for the differences between this study, where a majority of tablets passed, and our previous results, where a majority of tablets failed, is that the use of a specific model of tablet splitter provided better tablet splitting. However, Sedrati et al. identified several tablet products that, when split using a tablet splitter, resulted in half tablets with doses outside a 85% to 115% range of the target half-tablet dose.⁹ Similarly, Horn et al. found several products used in pediatric patients to not split equally.¹⁰ Another possibility is that the VA was selective in identifying tablet products for splitting (i.e., preferentially selected tablets that split evenly). The VA has previously indicated that sertraline tablets split accurately.¹¹

Possible Role of Tablet Shape and Hardness in Less-Favorable Tablet-Split Results

The 4 products that failed the weight-uniformity standard were lovastatin, lisinopril, rofecoxib, and simvastatin. In contrast to our previous observations that scoring, or any other visible characteristic, could not predict uniformity test results,⁶ a tablet score here tended to explain whether a tablet passed or failed the uniformity test. However, we suspect that shape and tablet hardness, and not scoring, were perhaps the true determinants of acceptable uniformity. Relative to the products that split evenly (Table 1), 3 of the 4 failed products (Table 2) have unusual shapes. Lisinopril (Prinivil) is trapezoidal in shape, with no central axis that could provide an even split. Additionally, lisinopril, in either orientation, did not sit well within the tablet splitter; the tablet did not match the angle of the tablet splitter and rocked as the blade cut through the tablet, particularly for the second orientation (Table 2). Simvastatin's positioning within the splitter was unstable because of the tablet's shield shape. In contrast to the unusual shapes of lisinopril and simvastatin, the roundness of glipizide facilitated its favorable positioning within the tablet splitter.

The hardness and spherical shape of rofecoxib resulted in difficult, unreliable splitting. (Tablet hardness was assessed by the tester's perception of the force required to split the tablets; rofecoxib tablets were deemed the hardest tablets.) Rofecoxib's extreme hardness required that the tablet-splitter's blade be firmly pressed into the tablet. Subsequently, this great force caused the tablet to uncontrollably rock as the tablet was cut. Rofecoxib also lost the most tablet residue (i.e., "crumbs"), because of the need to press hard on the tablet splitter.

Lovastatin did not exhibit any apparent shape or hardness difficulties, but it marginally failed. Lovastatin is a relatively thick tablet for its small size.

Interestingly, all 4 products from Merck failed, and all non-Merck products passed. These Merck products—lisinopril, lovastatin, rofecoxib, and simvastatin—do not appear to share any one common physical characteristic, except that each has an unusual shape to some extent.

Lovastatin and Lisinopril: Clinical Considerations

For lovastatin, 15% of the half tablets exhibited weights greater than $\pm 15\%$ of target. For one orientation of lisinopril within the tablet splitter (i.e., orientation 1, where the top of this trapezoidal-shaped tablet was placed toward the splitter's blade), 20% of the half tablets exhibited weights greater than $\pm 15\%$ of target. The percent RSD for lovastatin and lisinopril half-tablet weights was just over 10%. A similar degree of failure was previously observed with several other products.⁶ Cohen has indicated that this degree in half-tablet weight variability is acceptable since therapeutic outcomes would likely be unchanged.⁵

Given the wide therapeutic index of lovastatin^{12,13} and lisinopril,¹⁴ it would appear that splitting these 2 products is acceptable. Gee et al. found that splitting HMG Co-A reductase inhibitors such as lovastatin had no negative effect on lipid panels or liver enzyme tests.¹⁵ Laboratory lipid and liver enzyme tests were conducted before and after 512 patients were enrolled in an HMG Co-A reductase inhibitor tablet-splitting program. Among the patients, 85% of the patients were treated with simvastatin, 15% were taking lovastatin, and 1 patient was administered atorvastatin. Patients were maintained on the same HMG Co-A reductase inhibitor and dose before and after implementation of the program. Laboratory results comparing whole- and half-tablet performance from all 512 patients indicated that there was no change in total cholesterol and triglycerides. Statistically, low-density lipoprotein (LDL) and high-density lipoprotein (HDL) changed favorably, and liver enzymes AST and ALT each increased, although these changes were apparently not clinically significant. These results suggest that a split-tablet program had no effect of HMG (e.g., lovastatin) clinical outcomes.

Rindone found that splitting lisinopril did not change control of stable hypertension.¹⁶ Rindone randomized 28 patients with hypertension, who were on stable doses of lisinopril, into a crossover clinical trial. Patient blood pressures were measured when they were taking whole tablets and split tablets. No statistically significant differences in systolic or diastolic blood pressures were observed between whole-tablet and split-tablet groups.

Simvastatin: Clinical Considerations

Relative to lovastatin and lisinopril, tablet-splitting results for simvastatin were less satisfactory (Table 2). Twenty percent of the half tablets fell outside the $\pm 15\%$ target weight range, with

half of those half tablets falling outside the $\pm 25\%$ target weight range. However, 3 studies have assessed the clinical performance of split simvastatin tablets and found favorable results. Using retrospective chart review, Duncan et al. evaluated the effect of splitting simvastatin on patient LDL cholesterol and total cholesterol.¹⁷ Patients were taking simvastatin whole tablets and obtained regular lipid management and cholesterol measurements. Patients were converted to split tablets and maintained the same milligram-per-day dose. There was no statistically significant increase in either LDL or total cholesterol after conversion to split tablets; in fact, each laboratory value decreased. Duncan et al. conclude that half-tablet dosing of simvastatin was as effective as whole-tablet dosing. They also found similar findings for atorvastatin.

In a similar study, Rindone and Arriola converted hyperlipidemic patients from fluvastatin to simvastatin, where patients were instructed to use a tablet splitter to split simvastatin tablets in half.¹⁸ In the 56 patients who completed the study, total cholesterol, triglycerides, and high-density lipoprotein were unchanged, with LDL statistically decreasing. Rindone and Arriola indicate that this substantial cost-savings approach, which, in part, relied on splitting simvastatin tablets, exhibited lipid control in the majority of patients. Most recently, Gee et al. measured laboratory lipids and liver enzyme levels in 512 patients who were enrolled in a HMG Co-A reductase inhibitor tablet-splitting program, where 85% of the patients were treated with simvastatin, as described above.¹⁵ These 3 studies, along with the present split-tablet results and wide therapeutic index of simvastatin,¹⁹ support the mandatory tablet-split policy for simvastatin.

Rofecoxib and Sildenafil: Clinical Considerations

Rofecoxib tablets provided the least desirable half tablets. Fifty percent of the half tablets fell outside the $\pm 15\%$ target weight range, 40% of those half tablets fell outside the $\pm 25\%$ target weight range. Since rofecoxib has a high therapeutic index,^{20,21} we anticipate that these rofecoxib dose variations will not result in adverse clinical outcomes. The effective daily dose of rofecoxib ranges from 12.5 mg to 50 mg, but the drug is not particularly sensitive to dose. Further, when healthy volunteers were administered up to 5 times the maximum recommended dose for a period of 14 days, no serious toxicities were observed²¹; hence, dose variations from rofecoxib half tablets do not present a toxicity problem.

While sildenafil tablets were not split here and are on the VISN 5 mandatory split list, a clinical study supporting VA policy by Orrico et al. found that the dose of sildenafil citrate could be titrated to the lowest effective dose while incorporating tablet splitting as a method to reduce drug cost.²² In 96 patients, 58% responded to 50 mg (half tablet) of the drug.

Further Managed Care Considerations

To date, the mandatory tablet-splitting program continues to

offer a substantial costs savings to the VA, both on a local and a national level. Results here support this program, as weight uniformity was generally acceptable for these products. Tablet-splitting initiatives offer the VA, and potentially other managed care organizations, an attractive cost benefit, while maintaining quality health care for health plan members.

As demonstrated here with the several nonmandatory split products tested, other prescription medications may be suitable for a tablet splitting program. For a product to be an appropriate candidate for splitting, several factors should be considered.¹ Sustained-release, enteric-coated, and other dosage forms where tablet splitting would compromise the product's intended release mechanism should not be considered. The product should be relatively flat-priced across dose or have an acquisition cost to the organization that would offer a savings by splitting the higher doses. To maximize savings, tablet splitting should be preferentially considered for more expensive medications. Using these criteria, VA and other health care organizations may prospectively identify prescription medications where mandated tablet splitting will reduce prescription costs while not compromising patient care.

It should be noted that the VA tablet-splitting program is cost-neutral to patients. The patient copayment is \$7 for a 30-day supply, although some patients are exempt from providing a copayment because of financial status or service-connected disabilities. Since copayments are based on days of therapy and not drug costs, VA patients do not have a financial motivation to split tablets. However, patients in other health care systems, particularly those patients who pay out-of-pocket for medications, would likely have a greater incentive to utilize tablet splitting. This motivation would be most pertinent to those products that are flat-priced, enabling patients to purchase twice the drug supply for a given cost.

Limitations

The results of this study generally support the mandatory tablet-splitting policy of the VISN 5 region but are subject to limitations. One limitation is that there are no publicly defined acceptance criteria for half-tablet weight uniformity. Hence, alternative criteria can be considered and applied to our results. In our consideration of the data, we applied criteria that we have used previously.⁶ These criteria are more liberal than the USP test for whole tablets, in part since the USP test allows only an initial RSD of no more than 6%, while the criteria that we applied allowed 10% RSD. If an initial 6% RSD limit were applied, several of the products in Table 1 that we found to pass would require further evaluation (i.e., "Stage 2" testing) and could possibly fail. Additionally, half tablets were assessed for dose uniformity immediately after being split; half tablets were not placed back into a prescription vial, where they may be subjected to attrition. At this time, we know of no specific evidence to favor any particular acceptance criteria for weight uni-

formity of half tablets. It has been suggested that patients, caregivers, and health systems would benefit from public quality standards for half tablets.^{6,7}

A second potential limitation of this study is the use of a trained pharmacy student to perform the tablet splitting. It is possible, and even likely, that different outcomes would result, depending on who performed the splitting. It would be perhaps desirable to evaluate the ability of various individuals and patients to split tablets and to elucidate the individual patient factors that contribute to successful tablet splitting. Given the positive results of our study, further research would be desirable to determine if VA patients can obtain similar favorable weight uniformity to better replicate the real-world environment. Other studies have assessed the ability of patients to split tablets. McDevitt et al. evaluated the ability of healthy volunteers to split hydrochlorothiazide tablets by hand.²³ Gender, age, education, or tablet-splitting experience were not found to be predictive of the ability of individuals to split tablets. Peek et al. evaluated the ability of patients to split simvastatin, metoprolol, warfarin, and lisinopril tablets.²⁴ Individual patients were assigned to one of 4 groups that differed in brand of tablet splitter and whether patients were instructed in the method of tablet splitting. Peek et al. found that both the brand of the tablet-splitting device and instruction improved tablet-splitting accuracy. Patient experience also resulted in more accurate splitting of warfarin tablets.

A third potential limitation was our use of a specific device to split tablets. Peek et al. found that one splitter performed better than another splitter.²⁴ The suggestion that different tablet-splitting devices can yield markedly different uniformity results reflects our previous anecdotal experience with a tablet-splitting device different from the device used in the present study. In our previous experience, the commercially available tablet splitter appeared to be of lower quality and poor design; a razor blade was simply glued onto a plastic housing at an angle not perpendicular with the plastic housing, resulting, commonly, in properly centered tablets splitting into approximately one third/two third "halves." The poor design and performance of this earlier device caused us to abandon the use of a tablet splitter and rely on splitting tablets with a simple razor blade, by hand.⁶ Hence, we suspect that the quality of the tablet splitter can directly affect half-tablet weight uniformity, and our results using the ACE-LIFE Pill Splitter model PS12E may not be applicable to all tablet-splitting devices.

We also did not measure patient outcomes. Tablet splitting could have an adverse effect on patient compliance. Several studies have examined the influence of patient tablet splitting on compliance and generally indicate that most patients accept tablet splitting. For example, Carr-Lopez et al. studied 233 patients, aged 35 to 87 years, who were prescribed 40 mg tablets of lovastatin and instructed to split them into two 20 mg doses.²⁵ Most patients reported that the tablet splitter was easy

use and did not affect their compliance. However, 6% reported that the tablet splitter was difficult to use, and they would not split tablets even to save money. Mendez et al. found similar results for patients taking half tablets of simvastatin, although 40% of patients believed that splitting would influence compliance.²⁶ Fawell et al. studied the relationship of tablet splitting and compliance, drug acquisition cost, and patient acceptance for fosinopril sodium.²⁷ Patients accepted tablet splitting, and the splitting of fosinopril sodium tablets reduced the drug acquisition costs in the health system without affecting patient compliance.

Another potential limitation is the unknown clinical significance of dose variability in half tablets. The focus of our work was on products relevant to the VISN 5 region. Other products of interest may include drugs with a narrower therapeutic index. Dose variability is expected to be of greater potential importance for drugs with a narrow therapeutic index. Warfarin was evaluated here and is considered a narrow therapeutic index drug. Given the small dose variations observed here for warfarin half tablets and the lack of evidence to suggest any adverse clinical effects of such small dose variations, we anticipate tablet splitting of warfarin to have no clinical consequence.

Conclusion

Previous observations from experience with razor blade tablet splitting showed that a majority of tablets did not split evenly and that visible tablet features did not predict success or failure of the half tablets to pass the weight-uniformity test. However, our results for weight uniformity in the current study were favorable and generally support the mandatory tablet-splitting policy of the VISN 5 region. We interpret our results to indicate that a tablet-splitting policy is a viable approach to provide patients with dosage forms with acceptable weight uniformity. There is, however, a need for quality standards for half tablets to permit health care providers to better delineate the acceptability of tablet-splitting policies.

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The Practice of Splitting Tablets

Cost and Therapeutic Aspects

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Abstract

Background: Tablet splitting is used in pharmacy practice to adjust the dose to be administered. It is also being advocated as a method of reducing prescription drug costs.

Methods: The potential for using this practice as a cost-saving method was examined. The top 200 prescription products in Canada were evaluated for their potential for tablet splitting to reduce costs.

The assessment was based on the dosage form (only tablets could be split), availability of dosages in multiples, whether the drug was used for long-term therapy, whether the product was packaged suitably (e.g. oral contraceptives in a therapeutic package), whether pricing structure would allow substantial saving, and the physical nature of the tablets (e.g. whether there were special dose-release characteristics). The products most commonly split in three Canadian pharmacies were compared with the products that had a substantial savings potential. Costs for splitting tablets in the pharmacy and costs of instructing patients to split tablets were calculated.

Results: Savings could be generated from tablet splitting for only 15 of the 200 products. There was little overlap between these 15 products and the products that were most frequently split in the three pharmacies. The costs associated with tablet splitting in the pharmacy were approximately 0.1 Canadian dollars (\$Can) per tablet. The cost of instructing a patient to split the tablets was approximately \$Can1.

Conclusions: Tablet splitting appears to have limited usefulness as a cost-reduction strategy. Only a small proportion of products are suitable for splitting and have the potential for savings. There are also costs arising from splitting tablets in the pharmacy, or instructing patients to do so, and from wastage of product. There are also issues such as patient compliance and the risk of an incorrect dose being taken that should be considered.

Tablet ('pill') splitting is an accepted practice in dispensing medication. It has been used when a dosage form of the required strength is not available commercially. This is a common clinical problem in prescribing low-dose therapy for elderly patients.^[1] More recently, the practice has been used in some countries as a method to control prescription expense. With the increasing cost

of medication this practice may become more common.

Splitting tablets for the purpose of providing a lower dose is done under various circumstances, including providing medication for a child or older person when the dosage form is not available in the prescribed strength, when tapering a dose, or when titrating the dose. Tablet splitting is one of many

techniques used by pharmacists and nurses to provide medication in the proper dosage.

A number of medications are used at doses much smaller than those traditionally used. For example, hydrochlorothiazide is commonly used at a dose of 12.5mg, but the lowest dose tablet currently available is 25mg. Thus, patients need to split tablets in order to receive the smaller dose. This approach contributes to a more cost-effective approach to treating hypertension.^[2]

Slow titration refers to starting a medication at a low dose and slowly increasing the dose to the target level. One example of the benefits of tablet splitting for slow titration is in patients post-myocardial infarction (MI). Often patients post-MI cannot tolerate full doses of β -blockers used in clinical trials and are often given a very small initial dose of a β -blocker, such as metoprolol 12.5mg, in order to see how they tolerate the drug. If the patient tolerates this dose, the dosage is gradually increased to reach the dosage used in comparative clinical trials. However, the smallest dose metoprolol tablet is 50mg, which requires that the tablet be split into quarters to provide the 12.5mg dose. The procedure of splitting tablets thereby allows for ease of dosage management by the patient, because only one tablet dosage is required. If several different dosages of tablet were used, this would have the potential of increasing the errors in taking medication, as well as increasing the cost of the medication to the patient.

Patients who are receiving anticoagulation therapy with warfarin may require frequent dosage changes to maintain an appropriate level of anticoagulation, especially when starting therapy. Patients are often prescribed warfarin 2mg tablets when therapy is initiated. This allows for modification of dosage by using one or more tablets, or breaking the tablets in half for smaller increments. Instead of purchasing numerous different dosage tablets, the patient would purchase one dosage of tablet, and then adjust the dosage as directed.

The accuracy that can be achieved in splitting tablets varies with the size of the tablet and its characteristics.^[3,4] For example, when halving small tablets there was a variation in weight of more than

20 for 44% of the tablet halves. This is outside the compendial limits of variation for tablets. It appears that for reasonable accuracy in dosage, tablet splitting should be restricted to large or scored tablets. This has been confirmed in an evaluation of a commercial product for splitting tablets. The Pill Splitter (LGS Health Products, Beachwood OH) was found to be effective in splitting all the tablets tested, with best results from large tablets (tablets approaching 0.5cm in size take longer to position for cutting) and those that were coated (film rather than sugar coated, for example).^[5]

In one small study comparing tablets that were split (40mg atorvastatin) with an equal dose of the formulated product (20mg), there were no differences in clinical outcomes, as measured by low-density lipoprotein cholesterol levels, in patients followed for 12 weeks.^[6] This study also demonstrated that there were no significant clinical implications relating to compliance/adherence with therapy when tablets are split.

The patient may be required to perform the tablet splitting and this would be indicated in the label directions, or verbally by the pharmacist. Alternatively, the tablets may be split by the pharmacy staff at the time of dispensing. There do not appear to be any problems of compliance or patient acceptance of therapy when split tablets are used.^[7]

Some countries have specifically set out instructions for splitting tablets; for example, Barbados, through the Barbados National Drug Formulary.^[8] Some health management organisations (HMOs) in the US also have guidelines for the splitting of tablets to effect savings. An instruction sheet from one HMO entitled 'Half-tablets: cost-effective and easy to do!' states that the purpose is to save money.^[9]

The cost savings achieved through tablet splitting may accrue either to the patient, where they must pay for their own medications out of pocket, or to a drug benefit programme. For many drugs, generic products are available at reduced cost. For newly marketed medications that do not yet have generic equivalents (e.g. an HMG-CoA reductase inhibitor, or 'statin'), the splitting of tablets may

provide substantial cost savings for the patient. They may be able to obtain a full prescribed dose of the medication at a fraction of the cost, by obtaining tablets containing twice the required dose and splitting them.

Tablet splitting has several drawbacks.

- *Unsuitability of some dosage forms:* Controlled release tablets have been designed to release the medication in a predictable manner over time. To do this a variety of methods have been used. Some methods, such as the use of coated granules, may be suitable for tablet splitting. Other dosage forms, however, would have their designed features impaired by splitting. The difficulty in assessing the suitability of each controlled dosage form and the probability of impairing their function makes it impractical to include these tablets for tablet splitting.
- *Wastage:* Because of poor technique or tablet characteristics, the tablets may crumble or shatter when splitting is attempted. This leads to wastage of the product, as the tablet fragments cannot be used because of dose inaccuracy. The loss from tablet wastage may significantly decrease the benefits of tablet splitting.
- *Incorrect dose:* For the reasons mentioned above, the patient may split tablets unevenly, resulting in an incorrect dose being administered. This would be a significant concern if it occurred with a drug with a narrow therapeutic index, such as digoxin. While 0.25mg tablets are available, it would be dangerous to have the patient split tablets to provide 0.125mg. It may also be difficult to split irregularly shaped tablets evenly.
- *Confusion/noncompliance:* Even patients who have excellent records of compliance may become confused about their regimen, especially if their medication dose is frequently adjusted or requires splitting tablets. In one reported case, a patient receiving two and a half 1mg warfarin tablets was prescribed 0.5mg warfarin tablets and continued to take two and a half tablets, not realising the difference in dose.^[10] A patient may not read the label accurately and

take a full tablet instead of splitting the tablet. If the pharmacy supplies the tablets already split, the patient may not realise that the tablets are already split and choose to split the half tablets again, thereby receiving only 50% of the prescribed dose. Patients who require a regimen including split tablets need to be counselled about how to administer and split the tablets. Compliance may be increased by having the pharmacy staff split the tablets and dispense them in an appropriate form of compliance packaging. This would increase the cost of providing the medication.

Older patients or patients with disabilities may have difficulty splitting tablets, either manually or with a tablet splitter.^[11,12] Those with vision or manual dexterity problems may find tablet splitting very difficult. In a study of acute geriatric patients, 94 (78.3%) were unable to open a container or break a scored tablet.^[11] Even using tablet-splitting devices may be challenging for these patients, because good eyesight and manual dexterity are essential to place the tablet in the cutting device, line it up appropriately, and ensure the tablet is evenly split before administering the product. Patients may also have difficulty splitting tablets if the tablets are not scored.

If they do not receive assistance, patients may become frustrated to the point that they become nonadherent to the prescribed regimen. They may try to adapt their regimen to their abilities, by taking a full tablet every other day. However, this type of alternate-day regimen can be dangerous. Patients must be continually encouraged, counselled and monitored if they are to succeed on a regimen that involves splitting tablets. This requirement for more professional time is a cost that will offset some of the economic gains from tablet splitting.

With the use of tablet splitting as a means of reducing prescription costs, there is a need to analyse the potential benefits and drawbacks to this practice. This paper sets out some of the potential savings available from the practice of tablet splitting, based on the top 200 products on the Cana-

dian market, and factors that constrain the possible savings.

Methods

Cost-Saving Potential

The top 200 prescription drugs in Canada, based on number of prescriptions, were selected to determine the potential for tablet splitting as a mechanism to reduce prescription price.^[13] The proportion of tablets suitable for splitting and the cost of the tablets for each dosage were determined for each drug.

The suitability for splitting was determined based on the dosage form (only tablets could be split), availability of dosages in multiples, whether the drug was used for long-term therapy, whether the product was packaged suitably (e.g. oral contraceptives in a therapeutic package), whether the pricing structure would allow substantial saving (more than \$Can0.10 per tablet – roughly the salary expense for a pharmacy staff member to split the tablets; 2000 values), whether they had special dose-release characteristics and the nature of the tablets (e.g. spherical or irregular tablets are difficult to split). The cost of a tablet-splitting device ranges from \$Can6 to \$Can10.

Comparison with Current Practice

Information was sought on the pharmaceutical products that are routinely split in practice. To identify these products, three Canadian (Edmonton) pharmacy managers specialising in geriatric services were asked to prepare a list of products they commonly split. These were then compared with the top 200 products list.

Time Required to Split Tablets in Pharmacy

The time required to split tablets in the pharmacy was determined by using a stopwatch. Two pharmacy students used a tablet splitter to split 20 tablets of four different products selected as a convenience sample. The average time was calculated

from these data and was used to calculate the cost to cover the added time cost in tablet splitting. This would be done in cases where the patient was unable to split the tablets accurately.

Time to Counsel Patients on Tablet Splitting

A pharmacy student counselled eight actual patients on tablet splitting. The procedure was timed by the pharmacy student using a stop watch.

Results

Cost-Saving Potential

The top 200 products had a variety of dosage forms, of which 148 were tablets. These tablets consisted of various tablet forms (sugar- or film-coated, sustained-release, sublingual). A number of products were found to be unsuitable for splitting because of their therapeutic characteristics or presentation. This reduced the potential number of products to 127. About 70 of the products were generic or low-cost products that would yield little saving from tablet splitting. For the remaining products, many had dosages that were not in multiples that could be used for tablet splitting, for example a 10mg and a 25mg tablet.

By narrowing the list to medications that are for long-term therapy, tablets that can be easily split and those for which there is a gain of at least 10 cents, the number of drugs was reduced to 15 [enalapril (Vasotec^{®1}), warfarin (Coumadin[®]), simvastatin (Zocor[®]), pravastatin (Pravachol[®]), atorvastatin (Lipitor[®]), lisinopril (Zestril[®]), fosinopril (Monopril[®]), lisinopril (Prinivil[®]), quinapril (Accupril[®]), risperidone (Risperdal[®]), sumatriptan (Imitrex[®]), alendronate (Fosamax[®]), nefazadone (Serzone[®]), cilazapril (Inhibace[®]) and lovastatin (Mevacor[®])]. They represent only 14 chemical entities and include four statins and five ACE inhibitors (table I).

The potential savings from tablet splitting for these products are substantial. Many of the products have similar prices for each of the dosages, so

1 Use of tradenames is for product identification only and does not imply endorsement.

Table I. Potential cost savings from tablet splitting of 15 products

Drug	Dose (mg)	Price per tablet (Canadian dollars; 2000 values)	Dose (mg)	Price per tablet	Saving (%)
Quinapril (Accupril®)	5	0.82	10	0.82	50
	20	0.82	40	0.82	50
Cilazapril (Inhibace®)	2.5	0.68	5	0.79	41
Fosinopril (Monopril®)	10	0.79	20	0.95	40
Enalapril (Vasotec®)	2.5	0.68	5	0.68	50
	5	0.68	10	0.96	29
	10	0.96	20	1.16	40
Lisinopril (Zestril®)	5	0.67	10	0.87	34
	10	0.87	20	1.05	40
K P Atorvastatin (Lipitor®)	10	1.16	20	2	38
	20	2	40	2.15	46
Lovastatin (Mevacor®)	20	1.73	40	3.19	8
Pravastatin (Pravachol®)	10	1.15	20	1.79	22
	20	1.79	40	2.15	40
K P Simvastatin (Zocor®)	5	0.9	10	1.78	1
	10	1.78	20	2.2	38
	20	2.2	40	2.2	50
	40	2.2	80	2.2	50
Y R Risperidone (Risperdal®)	0.25	0.42	0.5	0.7	17
	0.5	0.7	1	0.96	31
	1	0.96	2	1.92	0
	2	1.92	4	3.83	0
	K R Nefazadone (Serzone®)	50	0.73	100	0.8
	100	0.8	200	0.93	42
Alendronate (Fosamax®)	5	1.38	10	1.76	42
K P Sumatriptan (Imitrex®)	50	12.95	100	14.27	45
Warfarin (Coumadin®)	1	0.32	2	0.34	47
	2	0.34	4	0.42	38
	2.5	0.33	5	0.36	45
	5	0.36	10	0.57	19

savings of up to 50% are possible. Most savings are in the range of 30 to 50%. Maximum savings are obtained for quinapril, for which all dosages are priced the same.

Comparison with Current Practice

The list of tablets that were reported to be commonly split in three Edmonton pharmacies is as follows: amlodipine, atenolol, benzotropine, calcium (unspecified), carbamazepine, clonazepam, Dyazide®, hydrochlorothiazide, indapamide, loxapine, methylphenidate, metoprolol, oxybutynin, paroxetine, risperidone, sildenafil, sotalol, Stresstabs® (a high potency multivitamin product classified as a dietary supplement), warfarin and zopiclone (table II). The lists from each pharmacy

had little overlap. They represent routine medication for chronic disease.

For the listed products that were reported as being split in Edmonton, there is an overlap of only two products from the top 200 products: risperidone and warfarin. Savings were not substantial, with only 4 of 19 showing savings of more than \$Can10 for an average prescription representing a 1-month supply of medication. Six of the products did not have double-strength products that would generate savings by splitting.

Time Required to Split Tablets in Pharmacy

The results are presented in table III. The products used for timing were Desyrel® 50mg (trazodone), Norvasc® 10mg (amlodipine besylate),

Novo-cimetidine® 600mg (cimetidine) and Apo-Trimip® 25mg (trimipramine maleate).

The cost associated with tablet splitting was based on an hourly rate of \$Can60, which is representative of charges for pharmaceutical services in Canada.^[14] Based on an average time for tablet splitting of 5 seconds per tablet (table III), the service cost of splitting was \$0.0833 per tablet. This indicates that a cost of almost 10 cents per tablet would be incurred to cover the pharmacy cost of splitting tablets. The use of technicians or trained staff to split tablets may reduce the cost. If the patients split the tablets themselves, this pharmacy cost is avoided.

Other costs would be incurred in implementing a tablet-splitting procedure. The first of these is the product expense resulting from wastage when the tablets shatter or break unevenly. This cost is one that both pharmacy and patient might incur. Additional salary cost to cover the added calculation and record keeping is required.

Time to Counsel Patients on Tablet Splitting

Counselling time for eight patients on tablet splitting ranged from 37 to 80 seconds (table IV).

The patients ranged in age from 54 to 68 years. For the four patients who had split tablets previously, the average time was 57.5 seconds. The four patients who had not split tablets previously required an average of 64 seconds. Overall, the average time for counselling was 60.75 seconds. At an hourly cost of \$Can60, the counselling expense would be about \$Can1.00.

Discussion

From this limited sample it appears that in current practice, tablet splitting is more likely to be for clinical, than for economic, reasons. However, there appears to be some benefit in using tablet splitting as a means of reducing drug costs, and the procedure is used widely, both in Canada and elsewhere. The procedure can generate savings, not only for new, expensive products, but also for many products that have moderate costs. In Barbados, a small study of six drugs used in cardiovascular disease showed prescription savings from tablet splitting in the range of 15 to 35% (personal communication, Pamela Payne, 2001 Aug).

Similarly, HMOs in the US seek out savings and insist on tablet splitting for many products. The

Table II. Potential cost savings from tablet splitting in 3 pharmacies

Drug	Dose (mg)	Price per table (\$Can; 2000 values)	Dose (mg)	Price (\$Can; 2000 values)	Average no. of tablets/prescription	Saving (\$Can)
Amlodipine	5	1.23	10	1.82	44	14.08
Atenolol	100	0.11			51	
Benzotropine	2	0.02			35	
Carbamazepine controlled release	200	0.21	400	0.42	92	0
Clonazepam	0.05	0.12	1	0.19	49	1.23
Diazide ^a	0.05				40	
Hydrochlorothiazide	25	0.04	50	0.04	51	1.02
Indapamide	1.25	0.19	2.5	0.3	50	2
Loxapine	50				45	
Metoprolol	50	0.12	100	0.22	111	1.11
Oxybutynin	5				62	
Paroxetine	10	1.49	20	1.59	38	26.41
Risperidone	0.5	0.7	1	0.96	38	8.36
Sildenafil	50	10.8	100	10.8	6	32.4
Sotalol	80	0.59	160	0.65	78	20.67
Warfarin	2	0.34	4	0.42	62	8.06
Zopiclone	75	0.47			34	

a A combination product containing triamterene 50mg and hydrochlorothiazide 25mg; \$Can = Canadian dollars.

Table III. Average time (sec) to split four different products

Product	Student 1	Student 2
Trazodone (Desyre [®]) 50mg	4.05	4.35
Amlodipine (Norvasc [®]) 10mg	5.4	5.0
Cimetidine (Novo-cimetidine [®]) 600mg	5.5	6.0
Trimipramine (Apo-Trimip [®]) 25mg	4.1	4.4
Mean time (sec)	4.76	4.94

avoidance of expense by tablet splitting is recommended in the US by various nonprofit groups such as the Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure, as well as the publication Consumer Reports. An incentive for patients to economise is the requirement that they pay the full cost, or a substantial portion of the costs, of medication that is not covered by a drug benefit programme.

In countries where medication is dispensed in the original treatment pack (thus creating an obstacle to pharmacists splitting tablets for patients), it is possible for patients to realise savings as long as the pricing structure results in similar prices for varying doses. The disincentive for this to occur in many European countries is the extensive health insurance coverage for medication, which requires patients to pay only a portion of the cost. For this reason the use of tablet splitting as a method of generating health cost savings may be appropriate only for some countries.

The potential for using this method to reduce costs is severely restricted by the small number of products suitable for tablet splitting. The practice is largely dependent on the actions and policies of pharmaceutical manufacturers. Changes in pricing

policies could create a substantial reduction in possible savings. Pharmaceutical firms also have the capacity to encourage or hinder the practice of tablet splitting by the dosage forms they produce. The number of dosages available, the characteristics of the tablet, the use of controlled-release dosage forms and packaging all have an effect.

Errors involving split tablets are likely to result in double or half the dose being taken, which can be harmful to the patient. Widespread use of tablet splitting may increase the inappropriate use of medication, a problem that is now serious and in need of redress. To minimise problems, there is a need for effective instruction by pharmacy or other healthcare personnel, as well as some form of continual monitoring of drug use to detect inappropriate dosages being taken.

Patients have a major role in understanding the relationship of dosage to dosage forms, so that they are not confused by the splitting of tablets. They should be able to split the tablets easily, either by hand or with a tablet splitter. To achieve the therapeutic and economic benefits from tablet splitting, patients need to be educated on the rationale and procedures of tablet splitting. This process takes time and incurs a cost. For instruction on tablet splitting, counselling takes only about 1 minute. If more detailed counselling were required, based on dosage or disease factors, the time would be longer.

In cases where medication is prepared by the pharmacist, there is less problem with an inappropriate dose being used in an institutional setting, or if the medicine is dispensed in compliance pack-

Table IV. Time required to counsel patients on tablet splitting

Patient age (y)/gender	Drug	Repeat treatment?	Time (sec)
57 M	Hydrochlorothiazide 25mg	Yes	37
61 M	Hydrochlorothiazide 25mg	No	80
67 M	Atenolol 50mg	Yes	69
54 M	Atenolol 50mg	Yes	49
61 M	Atenolol 50mg	No	60
62 M	Paroxetine 20mg	Yes	75
68 F	Paroxetine 20mg	No	57
65 F	Metoprolol 50mg	No	59

F = female; M = male.

aging (weekly medication boxes or bubble packs) for ambulatory use. For ambulatory patients, medication provided without compliance packaging would require some patient instruction. There is, however, a cost generated by the preparation of the medication. At a cost of 10 Canadian cents per tablet for tablet splitting, a prescription of 100 tablets would cost an additional \$Can10.00. Compliance packaging would also incur additional costs.

Private or public drug benefit programmes have the greatest potential gain from a general trend towards tablet splitting to save on pharmaceutical expenditures. They can select products where savings will be realised and set out guidelines for the tablet-splitting procedure. There may be substantial cost savings for some expensive products. This is best realised for long-term therapies where the patients can consistently and accurately split the tablets. But it should be realised that major saving on a few products has little effect on the overall expenditure level.

A policy of attempting to implement tablet splitting on a widespread basis as a general approach to cost cutting, however, would be likely to create problems of inappropriate drug use, with resultant toxicity, decreased compliance with therapy and less attention to patient instruction and monitoring. In many cases, the costs incurred in following this approach for some products would be greater than the saving and make the healthcare system less efficient. The combination of administrative policy-making, product evaluation, implementation of procedures and monitoring could lead to substantial administrative overhead costs that would limit savings and increase programme complexity.

Limitations to the generalisability of this study result from local costs and practices that may not be comparable to those in other countries. Local conditions may be conducive to a widespread use of tablet splitting in one area and not in another.

Conclusion

Tablet splitting has a major role in dosage adjustment in a variety of therapeutic situations.

However, its potential for cost saving is limited and it is better suited to specific situations than as a method of general cost reduction in pharmaceutical programmes.

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The Potential of Pill Splitting to Achieve Cost Savings

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Objectives: To present a methodology for identifying specific medications for which pill splitting is clinically appropriate and cost saving, to present data from a commercial managed care population on current pill-splitting practices, and to estimate additional cost savings from extended use of this strategy.

Study Design: Retrospective pharmacy claims analysis.

Methods: Pharmacy claims data from a commercial managed care health plan covering 19,000 lives and national drug data were used to compile a list of frequently prescribed medications. Excluding medications in which packaging, formulation, and potential adverse pharmacologic outcomes prohibited splitting, we performed a cost analysis of medications amenable to splitting.

Results: Eleven medications amenable to pill splitting were identified based on potential cost savings and clinical appropriateness: clonazepam, doxazosin, atorvastatin, pravastatin, citalopram, sertraline, paroxetine, lisinopril, nefazadone, olanzapine, and sildenafil. For these medications, pill splitting is currently infrequent, accounting for annual savings of \$6200 (or \$0.03 per member per month), just 2% of the potential \$259,500 (or \$1.14 per member per month) that more comprehensive pill-splitting practices could save annually.

Conclusions: Pill splitting can be a cost-saving practice when implemented judiciously using drug- and patient-specific criteria aimed at clinical safety, although this strategy is used infrequently.

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In recent years, the cost of prescription drugs has accelerated drastically. Patients, insurers, and provider networks continue to bear the burden of prescription drug costs, which have increased nearly 60% since 1991 and tripled since 1980.¹

To alleviate rising prescription drug costs, physicians and providers have used various cost-saving strategies, including the use of generic medications, selection of more cost-effective medications, tiered systems of drug copayments, and formulary restrictions.

One cost-saving strategy that may not have yet reached its potential is pill splitting. Many prescription drugs are available at increased dosages for the same or similar costs as smaller dosages. By prescribing half as many higher strength pills and splitting them to achieve the desired dosage, patients and physician systems can save as much as 50% on the cost of selected medications. As a cost-saving approach, pill splitting has great potential. For example, a patient being treated with 10 mg lisinopril (Zestril; AstraZeneca Pharmaceuticals, Wilmington, DE) will have annual medication costs of \$340. By prescribing half the number of 20-mg tablets to be split, medication costs will drop to \$180 annually, savings of \$160 (47%).² Similarly, a recent study focusing on splitting psychotropic medications suggests the potential for annual national savings of \$1.4 billion.³

Pill splitting is a well-established medical practice,⁴ not uncommon in prescribing pediatric⁵ or geriatric dosages.⁶ However, fears of inaccurate dosing, noncompliance, and physical inability to split tablets have discouraged physicians and patients from adopting this practice. Opponents of pill splitting have cited unpredictable effects on the stability of the drug, loss of drug due to powdering, creation of uneven doses, lack of physical strength and dexterity, poor eyesight, reduced cognitive ability, and

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lack of instruction as arguments against pill splitting.⁴ However, prior studies suggest that most patients are able to accurately split pills with minimal loss of tablet content.^{4,7} With some notable exceptions, the chemical stability of most tablet formulations is not substantially altered by pill splitting.⁵ Concerns also have been expressed over patient adherence. There is a fear that prescribing higher dosages that require tablets to be halved will lower adherence: patients may not be willing to take the time to split a pill before taking it or may be unable to split a pill. Objectively, however, 1 study found that splitting tablets had no effect on adherence.⁸ It was further suggested that tablet splitting might increase adherence by reducing the cost barrier faced by some patients.⁸

Pill splitting is safer and easier when drug- and patient-specific criteria have been met. Medications should not be considered when packaging and pricing structure do not make splitting cost effective or even possible. Medications should not be split if splitting could result in adverse pharmacologic outcomes. Such medications include those with enteric coatings, extended-release formulations, a narrow therapeutic window, or a short half-life-to-dosing ratio. The use of pill-splitting devices can make splitting tablets easier for patients and often yields more accurate doses,⁹ and some physical properties of medications such as scoring, shape, and size affect the ease and accuracy of splitting.⁷

Patients should be instructed by pharmacists how to accurately split tablets manually or how to use a pill-splitting device. In most cases, patients should be comfortable with splitting their own medication, and they should be free from physical impairments, including poor eyesight, loss of a limb, tremors, debilitating arthritis, or any other condition that might hinder accurate pill splitting. Pill splitting by pharmacists may still be a viable option for impaired patients in selected states.⁴ Although consideration of these many factors suggests that pill splitting can be undertaken without compromising patient safety, explicit evaluation of this question has not been undertaken.

Pill splitting also has the advantages of making newer and expensive medications available to more people who might not otherwise be able to afford them, allowing physicians to individualize a patient's dosage when the medication is not available in the desired dosage, and offering cost savings without risking a withholding of needed services. Pill splitting for pediatric patients may have specific advantages regarding dosage, but may also require special caution.

Though a recent study suggests that pill splitting may be frequent in long-term care facilities,⁶ little is known about actual patterns of tablet splitting, particularly in ambulatory settings. This report describes a methodology for identifying medications amenable to pill splitting based on specific criteria, and uses pharmacy claims data to gauge current pill-splitting practices and the potential for additional cost savings.

METHODS

We investigated pill splitting within a commercial managed care population of 19,000 covered lives served by primary care physicians affiliated with the Massachusetts General Hospital (MGH). This population consisted of working-age beneficiaries receiving employer-based health insurance in the Boston metropolitan area.

We sought to identify specific medications for which pill splitting would be appropriate and cost saving in 2:1 splitting ratios; to determine current patterns of pill splitting among MGH physicians, to estimate the potential cost savings that would result from pill splitting; and to recommend guidelines for safe pill-splitting prescribing practices.

Pharmacy claims data from January 1, 2000, through August 30, 2000, were available for managed care members with MGH primary care providers. We compiled a list of the 265 most frequently prescribed proprietary and generic medications, both nationally² and within the MGH population. To determine medications amenable to splitting, we evaluated each medication using cost- and pharmacologic-specific criteria. Included were cost savings per dosage increase, based on the average wholesale price and actual costs to the health plan, pharmacokinetic interactions and therapeutic window, packaging, and formulation. Physical properties such as scoring and tablet size also were considered, although they were not necessarily determining factors for inclusion in this study.

Preliminary review of the 265 most frequently prescribed medications allowed us to eliminate 125 medications because pill splitting was not feasible. Among the most common reasons were that medications were available in only one dosage, that the medication was administered non-orally, that a capsule or other nonsplittable form was used, and that the tablets were prepackaged. Commonly prescribed medications available in a single dose

COST CONTROL

included fexofenadine (Allegra; Aventis Pharmaceuticals, Parsippany, NJ), oxaprozin (Daypro; G. D. Searle & Co., Chicago, IL), raloxifene (Evista; Eli Lilly and Company, Indianapolis, IN), and tramadol (Ultram; Ortho-McNeil Pharmaceutical, Raritan, NJ). Common nonoral medications included corticosteroid and β -agonist inhalers. Capsule formulations among frequently prescribed drugs include terazosin (Hytrin; Abbott Laboratories, Inc, North Chicago, IL), fluvastatin (Lescol; Novartis Pharmaceuticals Corporation, East Hanover, NJ), valsartan (Diovan; Novartis Pharmaceuticals Corporation, East Hanover, NJ), fluoxetine (Prozac; Eli Lilly and Company, Indianapolis, IN), and omeprazole (Prilosec; AstraZeneca Pharmaceuticals, Wilmington, DE). Oral contraceptives are the most common examples of prepackaged medications.

The remaining 140 medications were evaluated based on potential cost savings on a per-dosage basis. For continued consideration, a medication was required to have cost savings through splitting that exceeded 25% and/or \$0.40 per dosage (\$0.20 for generic medications) based on average wholesale price.² Of these 140 medications, 61 were eliminated because splitting offered no or minimal cost savings. Examples of commonly used medications that were eliminated because of the lack of per-dosage cost savings through pill splitting included buspirone (BuSpar; Bristol-Myers Squibb Company, Princeton, NJ), metformin (Glucophage; Bristol-Myers Squibb Company, Princeton, NJ), and famotidine (Pepcid; Johnson & Johnson/Merck, Fort Washington, PA).

Using the 1999 and 2001 *American Hospital Formulary Service Drug Information* indices,¹⁰ the 79 remaining medications were evaluated for potential adverse pharmacologic effects. Each medication was screened based on toxicity, rate of absorption, elimination half-life, and therapeutic window. Nine medications with a potential for adverse consequences from splitting were excluded based on manufacturer warning against pill breakage (eg, nitroglycerin [Nitrostat; Parke-Davis, Morris Plains, NJ]), nonproportional combination medications (amoxicillin-clavulanic acid [Augmentin; SmithKline Beecham, Philadelphia, PA]), narrow therapeutic window (eg, warfarin), or rapid half-life-to-dosing ratio (eg, tolterodine [Detrol; Pharmacia & Upjohn, Peapack, NJ]). The latter criteria refers to medications with elimination half-lives short enough relative to the dosing frequency to raise potential concerns about fluctuations in serum concentrations should splitting be inaccurate. Once-daily sertraline, with a half-life of 25 to 26 hours,¹⁰ is an

example of a medication with a substantial pharmacokinetic buffer against inaccurate pill splitting. Olanzapine was included because splitting is feasible as long as the split tablet is used within a week of splitting.

Twenty-two additional medications with extended-release formulations were excluded, as altering these medications' physical properties by splitting could negatively impact their pharmacokinetics. Examples of extended-release formulations included felodipine (Plendil; AstraZeneca Pharmaceuticals, Wilmington, DE), extended-release bupropion (Wellbutrin SR; Glaxo Wellcome, Inc, Research Triangle Park, NC), extended-release nifedipine (Procardia XL; Pfizer Inc, New York, NY; Adalat CC; Bayer Corporation, West Haven, CT), and isosorbide mononitrate (Imdur; Key Pharmaceuticals, Inc, Kenilworth, NJ).

A detailed cost analysis of the 48 remaining medications using data from the available pharmacy claims records allowed us to determine actual cost, current rates of pill splitting among MGH physicians, and potential savings from extended use of this strategy. Eliminating those medications with minimal usage in the MGH population, we identified 11 recommended medications for which pill splitting is clinically appropriate and cost saving. Enalapril (Vasotec; Merck & Co. West Point, PA), nefazadone (Serzone; Bristol-Myers Squibb Company, Princeton, NJ), mirtazapine (Remeron; Organon, Inc, West Orange, NJ), zafirlukast (Accolate; AstraZeneca Pharmaceuticals, Wilmington, DE), and clarithromycin (Biaxin; Merck & Co. West Point, PA) were examples of medications that could have been associated with cost savings if they were used more frequently in the MGH system.

To calculate current rates of pill splitting for these medications, we used the following methods: for each daily dose of each medication, we calculated the proportion of prescriptions for which 2-to-1 splitting was implied by the number of pills provided and the days of therapy supplied by the prescription. For example, for all patients prescribed lisinopril 10 mg per day, we compared the number achieving this dose via 10-mg tablets (30 tablets provided for 30 days) with the number achieving this dose via 20-mg tablets split 2-to-1 (15 tablets provided for 30 days). For each medication, we reported the aggregate rate of pill splitting across all possible 2-to-1 splitting possibilities. During our investigation, no organizational efforts were in place to promote pill splitting.

Pill Splitting in a Managed Care Plan

Our cost analysis was based on usage volume and the actual cost of select medications in a commercial HMO population. Our unit of analysis was the prescribed daily dose (mg/day) for each of the selected medications, whereas our outcome measures were the cost savings realized from halving higher-strength tablets to achieve the desired dosage. To estimate current costs and potential savings, we extracted the total number of days of therapy prescribed for each medication at each dosage for all

patients as well as the total number of days of therapy for each medication if higher-strength pills were split to achieve the desired dosage. We annualized our 8 months of data to represent expected utilization and costs for a full year. An annualized cost analysis indicated those medications for which sizable current or future cost savings could be expected from pill splitting.

Observed and potential cost savings were calculated using the following equations:

Table. Potential Cost Savings from Pill Splitting in a Commercial HMO Health Plan

Drug and Daily Dose (mg)	Cost in Health Plan Contract		Annual No. of Prescriptions	Observed Occurrences		Potential Annual Savings (\$)
	Per Pill (\$)	If Higher-Strength Pill Is Split (\$)		No. of Prescriptions From Splitting	Observed Annual Savings (\$)	
Clonazepam	0.5	0.40	380	-	0	1456
	1	0.47	79	-	0	510
Doxazosin (Cardura)	1	0.97	58	-	0	1207
	2	0.95	105	11	224	2320
	4	1.00	76	-	0	146
Citalopram (Celexa)	20	1.90	890	66	2409	25,758
Atorvastatin (Lipitor)	10	1.77	2184	3	120	44,746
	20	2.68	1121	-	0	62,465
Paroxetine (Paxil)	10	2.19	281	17	712	11,176
	20	2.19	468	-	0	15,202
Pravastatin (Pravachol)	10	2.03	88	-	0	4056
	20	2.17	481	-	0	11,209
Nefazodone (Serzone)	50	1.16	12	-	0	242
	100	1.19	33	-	0	565
Sildenafil (Viagra)	25	8.54	37	-	0	610
	50	8.52	513	-	0	8461
Lisinopril (Zestril)	2.5	0.55	85	20	123	415
	5	0.85	566	9	99	8265
	10	0.88	1214	-	0	23,754
	20	0.93	716	-	0	9708
Sertraline (Zoloft)	25	2.11	87	12	526	2656
	50	2.12	616	75	1669	20,535
Olanzapine (Zyprexa)	2.5	4.26	38	3	263	2302
	5	5.09	52	2	57	1752
Total cost savings					\$6202	\$259,516

Daily dosages reported here can be achieved as a whole tablet or from splitting a higher strength tablet in half. The highest reported daily dosage for each drug can be achieved from splitting a higher strength tablet not shown in the table.

Observed annual savings = (savings per day of therapy) × (# of observed annual days of therapy achieved from pill splitting)

Potential annual savings = (savings per day of therapy) × (total annual days of therapy)

RESULTS

Top Drugs for Splitting

We identified 11 medications for which pill splitting was clinically appropriate and could result in significant cost savings (Table). Of these medications, many are used for treatment of psychiatric disorders: clonazepam, citalopram (Celexa; Forest Pharmaceuticals, Inc, St. Louis, MO), paroxetine (Paxil; SmithKline Beecham, Philadelphia, PA), nefazadone, sertraline (Zoloft; Pfizer, Inc, New York, NY), and olanzapine (Zyprexa; Eli Lilly and Company, Indianapolis, IN). Also common were medications for lipid lowering: atorvastatin (Lipitor; Pfizer, Inc, New York, NY) and pravastatin (Pravachol; Bristol-Meyers Squibb Company, Princeton, NJ); and for hypertension: doxazosin (Cardura; Pfizer, Inc, New York, NY) and lisinopril. In addition, sildenafil (Viagra; Pfizer, Inc, New York, NY), a drug for erectile dysfunction, was included.

Of the 11 medications, 7 (70%) are scored: clonazepam, doxazosin, citalopram, paroxetine, nefazadone, lisinopril, and sertraline. The potential average cost savings from splitting was 36%. Cost savings ranged from 18% for lisinopril (2.5 mg dose) to 50% for doxazosin (1 mg), nefazadone (100 mg), and sildenafil (25 and 50 mg). Seventy-five percent (18 of 24) of the possible prescribed daily dosages for these medications could yield cost savings of at least 40% per pill.

Pill Splitting Is Currently Infrequent

Although pill splitting was used for a sizable number of HMO members, this practice was relatively infrequent. Splitting was most frequent for sertraline at a dose of 50 mg/day, for which 75 (12%) prescriptions were made from 100-mg tablets to be taken one half per day, compared with 616 (88%) receiving one 50-mg tablet once per day. Other medications for which splitting occurred were citalopram (8%), doxazosin (4%), and paroxetine (2%). Pill splitting was either negligible or not observed for the other selected medications.

Current and Potential Cost Savings

Among the selected 11 medications, we calculated that current pill-splitting practices saved \$6200

on an annualized basis, an equivalent of only \$0.03 per member per month. The largest contributor was citalopram (\$2400). Current cost savings, however, represent only 2.4% of the potential savings that could result from pill splitting among these 11 medications. Full use of tablet splitting for these drugs would generate \$259,500 in savings annually (or \$1.14 per member per month). The largest potential contributors to cost savings were atorvastatin (\$107,200), lisinopril (\$42,100), paroxetine (\$26,400), citalopram (\$25,700), sertraline (\$23,200), and pravastatin (\$15,300). Because not all patients should be considered for pill splitting, achievable savings would be less than these projections, although this report does offer a useful gauge of cost savings using this strategy.

DISCUSSION

Based on specific criteria focused on safety and frequency, we have identified 11 medications in which extended use of pill splitting could be cost saving for a commercial HMO plan. Of these medications, a preponderance were used to treat psychiatric disorders, hypertension, and hyperlipidemia. The selected medications shared relatively wide therapeutic windows, long half-life-to-dosing ratios, and substantial potential for cost savings. Pill splitting is currently infrequent among MGH physicians, accounting for only \$6200 in savings annually, just 2.4% of the potential \$259,500 that could be saved from extended use of this cost-reduction strategy for the selected medications. This represents overall savings of 36% off the costs of these selected medications.

A recent lawsuit alleging that a mandatory pill-splitting program adopted by one of the nation's largest health maintenance organizations jeopardized patient safety¹¹ highlights an important point about appropriate pill splitting: although the practice can save money, pill splitting should be considered only in the context of specific patient-physician assessment and discussion. Review of these legal issues suggests that physicians can reduce the liability risks associated with pill splitting by judiciously limiting pill splitting to those medications and patients for whom it is medically appropriate and by engaging in a candid discussion of the requirements, costs, and benefits of a pill-splitting regimen.

Pill splitting can be expected to be relatively safe when drug- and patient-specific criteria have been met. In addition to appropriate dialog between the

physician and the patient, the following medication characteristics should be considered in selecting medications for splitting:

- Wide therapeutic windows ensure a buffer against potential fluctuations in dosing that could occur because of inaccurate tablet splitting. This includes medications with a relatively large ratio of drug concentrations producing significant undesired effects to those producing desired effects.
- Fluctuations from misdosing also can be minimized by medications that have a long half-life relative to the frequency of dosing because steady-state drug levels are less sensitive to potential variation in individual doses.
- Drugs that have enteric coatings or that are formulated as extended release should not be split.
- Drugs that are prepackaged, such as oral contraceptives, should not be split.
- Medications that do not have a pricing structure that makes splitting cost effective should not be considered.
- Physical properties of medications affect the ease and accuracy of splitting. For example, tablets that are deeply scored or scored on both sides are easier to split than unscored tablets.⁷

Our list of medications incorporated these characteristics, as well as several others that were specific to our setting, including frequency of prescribing and pricing considerations. Whereas other systems may derive somewhat different lists of medications, the foundation for these decisions should always begin with drug characteristics.

Patient-specific characteristics are also vital to consider in tablet splitting. Patients should be willing and able to be instructed by pharmacists on how to accurately split tablets or in the use of a pill-splitting device and they should be comfortable with splitting their own medication. Additionally, patients should have no physical or cognitive impairments that could impede accurate pill splitting or reliable dosing once pills are split. While some states prohibit pharmacists from splitting tablets,⁴ pill splitting may still be a viable option for some impaired patients in selected states. For example, regulations controlling pharmacists do not include such a prohibition in Massachusetts, California, Oregon, and New York, among other states. Even where legal, however, lack of reimbursement to pharmacies for pill splitting may constrain the willingness of pharmacists to perform splitting.

The beneficiary of the cost savings generated by tablet splitting will vary depending on the system of

reimbursement. Self-pay patients or patients with capped pharmacy benefits will reduce their out-of-pocket expenses by splitting their pills. In other instances, physician systems or health insurance plans will realize the cost savings, as was the case with the population that we analyzed. For patients who would not otherwise benefit, it would be ideal if they could be offered an incentive to use split dosages (eg, a reduction in their copayment).

Out of convenience, we have used data from a commercial health plan, although data from other types of plans could augment our analysis. For example, information on a Medicare population would be appropriate given that elderly patients have greater medication use and experience greater out-of-pocket costs that could be diminished through pill splitting.

Limitations

Although we lack the information needed to estimate precisely the proportion of patients who are unwilling or unable to split pills, this proportion is likely to be smaller within an employed population compared with other populations. In our population, we estimated that approximately 10% to 30% of patients would be unable or unwilling to make use of prescriptions that require pill splitting. Our results, from a large academic medical center and its physicians, may not reflect current practices and potential cost savings in other practice settings. We focused only on medications that were preferred in the MGH managed care plan. This tactic excluded several drugs for which significant savings could be realized in other settings (ie, lisinopril as Prinivil was included, but not Zestril). We focused only on 2-to-1 splitting ratios, although savings may be significant with other dosing ratios (eg, prescribing 75 mg sertraline from splitting three 50-mg tablets over 2 days rather than three 25-mg tablets in one day).

We recognize that the potential cost savings as reported here might not be fully achievable, as pill splitting will not be appropriate for every patient. A number of factors may cause actual savings to fall below those potentially achievable, including a patient's unwillingness to accept split-dosing prescriptions, patient inability to split pills (either through self-splitting or through a pharmacist), and lack of familiarity by prescribers. Although we lack information needed to estimate the proportion of patients that fall into these categories, this proportion is likely smaller within a employed population compared with other populations.

Although many factors suggest that more widespread pill-splitting practices could be adopted without compromising patient safety, it was beyond the scope of this study to evaluate the safety of pill splitting in our population either currently or for our projections of increased splitting. A long-term consideration may be that consistent and widespread adoption of tablet splitting might result in pharmaceutical pricing strategies that eventually eliminate the advantages of splitting. More likely, however, is that some segments of the market for pharmaceuticals (eg, managed care or self-pay) may adopt pill splitting more than others.

Implications

Our analysis has indicated that significant cost savings are possible through tablet splitting for a set of medications selected using explicit criteria. We recommend that physicians talk with patients, review their medications, work with them to assess whether pill splitting is a viable option, and use this strategy when it can be carried out safely. The cost savings from this underused practice are significant and, if implemented judiciously, this strategy presents an opportunity to reduce healthcare costs without compromising quality.

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determining which pills are best suited to cutting.

Dr. Stafford considered a list of 256 medicines commonly prescribed nationally and particularly at a small health plan in Boston during nine months in the year 2000. He and his co-author, David Radley of the Institute for Health Policy at Massachusetts General Hospital in Boston, winnowed them down to a list of 48 medicines that could be split. But only 11 were prescribed often enough in the health plan to be found both clinically appropriate and cost-effective for the splitting strategy.

"It's important to note that it's a minority of medications that fall into this category," Dr. Stafford says. Yet he believes the potential for cost savings is substantial because drugs for high blood pressure and high cholesterol as well as antidepressants -- all widely used medications -- were on the final list.

Those on the list include the cholesterol reducer Lipitor and the impotency remedy Viagra, both marketed by **Pfizer** Inc.; the antidepressants Paxil from **GlaxoSmithKline** PLC and Celexa from **Forest Laboratories** Inc.; and the ACE inhibitor lisinopril, marketed as Prinivil by **Merck & Co.**, and as Zestril by **AstraZeneca** PLC. (Lisinopril just went off patent and thus wouldn't likely now be a cost-effective candidate for pill-splitting.)

The economic advantage results from the fact that many drug companies charge essentially the same price per tablet regardless of the dose. That's to ensure that doctors don't have to factor in price when prescribing a dose to their patients, says Marjorie Powell, assistant general counsel at Pharmaceutical Research and Manufacturers of America, the industry's Washington-based trade group.

In developing their list of medicines suitable for splitting, Dr. Randall and his colleague sought those with characteristics making them particularly easy to break in half, such as pills that are scored. They eliminated 125 drugs that either came only in one dose, were available only in a capsule, were prepackaged or weren't available in pills at all. These criteria-eliminated such drugs as the heartburn remedy Prilosec, the osteoporosis pill Evista and common asthma medications that are dispensed in inhalers.

An additional 61 pills were eliminated because the potential cost savings to be derived from splitting weren't worth the effort; 31 others were ruled out because they were time-release formulations or out of concern of adverse consequences if dosage varied to any significant extent.

"It's important for both consumers and managed-care organizations to note that pill-splitting is a strategy that needs to be used selectively," Dr. Randall says.

The drug-industry group challenges the strategy. Ms. Powell says she isn't convinced consumers are able to accurately split pills and that symptoms of heart disease and depression often require diligent efforts to get patients on the right dose of the right drug -- something splitting the medicines could undermine.

"It clearly isn't consistent with Food and Drug Administration labeling because you don't know exactly what dose the patient is getting," she says. If a doctor urged any of her family members to consider splitting their pills, she says, "I would make sure [they] changed doctors."

At Kaiser, Tony Barraeta, senior counsel, says officials remain confident in the clinical and economic wisdom of pill splitting despite the lawsuit. "You have to do it right," he says. "But it just makes a lot of sense."

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Evaluation of the Reproducibility of Tablet Splitting to Provide Accurate Doses for the Pediatric Population

Lori W. Horn, Robert J. Kuhn, Jamshed F. Kanga

Abstract

Portions of tablets are commonly administered to pediatric patients with virtually no data to demonstrate that the correct dose is consistently delivered to the patient. This study was conducted to assess the reproducibility of tablet splitting with two different commercially available tablet splitting devices. Twenty tablets were randomly selected and split into halves and, if clinically appropriate, into quarters. Each part was weighed and assessed for statistically significant differences. Tremendous variability was found to exist between doses. Some tablet parts could not be reproducibly cut into parts with either cutter. Therefore, it was concluded that solid dosage forms should not be cut, especially into quarters. Patients cannot be assured of receiving the prescribed dosage on a consistent basis.

Introduction

Children are especially exposed to the dangers of medication errors. The risk of drug administration errors is high in the pediatric population due to differing age, size, and development and function of organs, such as the liver and the kidney. Pediatric dosages must be calculated on a weight basis, such as milligram per kilogram, or by body surface area. Certain drugs may not be readily available in suitable formulations, strengths, and concentrations for pediatric patients. Consequently, the risk of medication errors in these patients is increased since often the alteration of available dosage forms is required.^{1,2}

The difficulty in assuring the delivery of an accurate dose of liquid medication has been appreciated.⁴ There are occasions when a fraction of a solid dosage form may be required. Issues related to tablet splitting include: homogenous distribution of active ingredient, the point at which an unscored tablet should be split, and the most appropriate device for splitting tablets. Although portions of tablets are commonly administered to pediatric patients, it is done with

virtually no data to support these actions.^{5,6}

Only two studies have attempted to address these questions. Stimpel, et al.⁵ evaluated fourteen brands of antihypertensive agents to determine how evenly the tablets would break along the scoring line. Most tablets broke easily, but deviations in half-tablet weights of up to 10% were frequent. Another study conducted by Sedrati, et al.⁶ examined the accuracy of a tablet splitting device with various shapes and sizes of tablets. They found the device was most accurate with larger tablets (> 600 mg), oblong tablets, and those that had flat edges.

We conducted a study with captopril, clonidine, amlodipine, atenolol, carbamazepine, and sertraline tablets to assess the reproducibility of tablet splitting using two different commercially available pill cutters. Tablet halves were evalu-

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Evaluation of the Reproducibility of Tablet Splitting to Provide Accurate Doses for the Pediatric Population

ated for all medications and quarters were evaluated with clonidine and captopril. The purpose of this study was to determine whether a statistically significant difference between tablet parts could be demonstrated.

Methods

Drugs to be evaluated were chosen by surveying physicians at our institution to determine what tablets they were commonly seeing split into parts. The chosen medications are listed in the Table. Three lots were obtained for each medication. Capoten® (captopril) and clonidine were provided by their pharmaceutical manufacturers. All other medications were obtained from the University of Kentucky outpatient pharmacy. After an initial practice session, two sets of twenty tablets were randomly selected from each lot, individually weighed on a Mettler AT201 analytical balance (sensitivity to 10 µg) (Mettler Instrument Corporation, Highstown, NJ), and split with two different commercially available pill cutters into halves and into quarters if appropriate based on usage. Each part was weighed on the analytical balance. For simplicity, these cutters will be referred to as the "beige" cutter (EZ Dose, Bumsville, MN) (Figure 1) and the "blue" cutter (Health Care Logistics, Inc., Circleville, OH) (Figure 2). A new pill cutter was used for every one-hundred cuts to minimize any variation due to dulling of the blade. If a tablet was

scored, an attempt was made to place the tablet in the cutter so that the blade would cut along the scoring line. If the tablet was not scored, the tablet was placed on the designated area in the cutter, and cut as close to the center as possible. Obvious physical and visual differences between tablet parts were noted by an independent observer. Homogenous distribution of the active ingredient throughout the entire tablet was assumed.

Descriptive statistics were used to assess the mean and the standard deviation of total tablet weight, the weight of the half, and the weight of the quarter. Normality of data distribution was assessed via observation of the similarity or closeness between standard deviations and was determined to be normally distributed. A two-tailed t-test, therefore, was used to test for differences between tablet halves. To test for differences between tablet quarters, a one-way ANOVA was used. A p value of < 0.05 was considered significant.

To address the uniformity of dosage units,⁷ the USP may consider an analytical assay of the active ingredient to be the most appropriate method to assess differences between tablet parts. A practical measure, however, examining weight variation between tablet parts was employed in this trial.⁷ If the variation in tablet weight is statistically significant, it could be deduced that the fraction of active ingredient delivered would be different for each part. Also, according to USP, to meet the uniformity of dosage unit requirements,

Figure 1. "Beige" cutter (EZ Dose, Bumsville, MN)

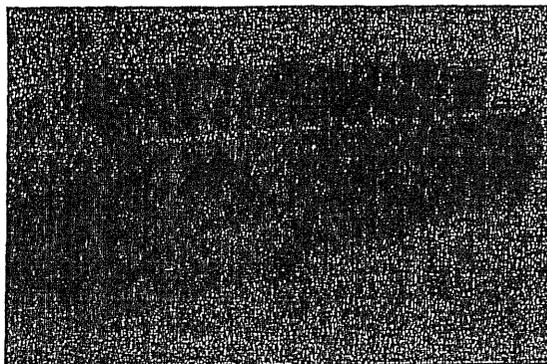


Figure 2. "blue" cutter (Health Care Logistics, Inc., Circleville, OH)

Drug	Lot	Blue Cutter				Biege Cutter			
		% halves weighing within $\pm 15\%$	p-value	% quarters weighing within $\pm 15\%$	p-value	% halves weighing within $\pm 15\%$	p-value	% quarters weighing within $\pm 15\%$	p-value
¹ Catapres 0.1mg ^s (136mg \pm 1.91)	63003B	81.3	< 0.001	47.5	< 0.001	90.0	0.725	68.8	0.628
	63002C	52.5	< 0.001	43.8	< 0.001	85.0	0.010	71.3	0.158
	064001B	100.0	< 0.001	60.0	< 0.001	90.0	0.001	57.5	0.076
² Clonidine 0.1mg ^s (70.06mg \pm 2.16)	2572-038	55.0	< 0.001	45.0	0.001	78.9	0.013	31.6	0.163
	058H32	47.5	< 0.001	41.2	< 0.001	62.5	0.159	48.8	0.341
	130C41	70.0	< 0.001	37.5	< 0.001	30	0.006	25.0	0.013
³ Capoten 12.5mg ^s (51.65mg \pm 0.55)	MAE015	67.5	< 0.001	37.5	< 0.001	95.0	0.053	28.8	0.084
	MCE026	58.3	< 0.001	48.6	< 0.001	100.0	0.027	36.1	0.005
	L3J26A	95.0	< 0.001	55.0	0.007	100.0	< 0.001	26.3	0.003
⁴ Amlodipine 5mg ^{NS} (199.5mg \pm 2.39)	D223D	85.0	0.002			90.5	0.417		
	H121A	85.7	0.120			76.9	0.009		
	A863H	77.5	0.040			77.5	0.070		
⁵ Tenormin 25mg ^{NS} (58.5mg \pm 1.00)	HA181	95.0	0.345			35.0	< 0.001		
	HA051	62.5	< 0.001			27.5	0.009		
	HA201	87.5	0.012			25.0	0.012		
⁶ Sertraline 50mg ^s (155.5mg \pm 2.5)	A593F	100.0	0.408			100.0	0.463		
	F533A	100.0	0.076			100.0	0.101		
	3JP050A	100.0	0.495			90.0	0.001		
⁷ Tegretol 100mg ^s (405.2mg \pm 4.66)	1T168197	92.5	0.1098			65.0	< 0.001		
	1T160545	92.5	0.006			80.0	< 0.001		
	1T165813	87.5	0.215			60.0	0.099		

S = Scored into halves; NS = Not scored

- Boehringer-Ingelheim Pharmaceuticals, Inc., Ridgefield, CT
- Rugby, Norcross, GA
- Bristol-Meyers Squibb Co, Princeton, NJ
- Pfizer Labs, New York, NY
- Zeneca Pharmaceuticals, Wilmington, DE
- Pfizer, Roerig Division, New York, NY
- Ciba Geneva, Summit, NJ

dosage units must contain within $\pm 15\%$ of their label claim and the relative standard deviation must be $< 6\%$.⁷ Therefore, a significant difference was also represented by tablet parts which fell outside the $\pm 15\%$ of the desired mean percentage of label claim.

Results

Statistically significant differences were demonstrated when cutting clonidine tablets into halves (p-values < 0.001). (Table) The brand name, Catapres®, reproducibly cut better than the generic clonidine. In fact, one lot of the brand name clonidine (Catapres®) demonstrated the ability to be reliably split into parts, as 100% of tablet parts fell within the desired specifications of $\pm 15\%$ of the desired weight. The range was 52.5% to 100%. In contrast, 78.9% of the generic clonidine tablet halves fell within the desired specifications at best case and only 30% at worst case. As a general rule, fewer than 50% of quarters were within USP accepted standards. Similar results were obtained with captopril tablets.

In general, the beige cutter appeared to be more accurate when cutting halves. However, neither cutter demonstrated satisfactory results when cutting quarters. Statistical analysis to determine the superiority of one tablet splitter over the other was not conducted, because neither splitter reproducibly cut tablets into the desired parts.

Because of the tremendous variability observed in phase one between tablet quarters, tablets in the second phase of this study were only split into halves. (Table) As in the first phase of this study, all of the drugs, except sertraline, could not be reproducibly cut into halves. In fact, only 25% to 35% of Tenormin® (atenolol) tablet halves weighed within $\pm 15\%$ of the desired mean percentage of the total tablet weight. Unlike the first phase, the beige cutter yielded less reproducible results than did the blue cutter. However, neither cutter yielded consistent results.

Obvious physical differences could be observed in greater than 50% of tablet halves. Some tablets, such as Tegretol® (carbamazepine) 100mg chewable tablets, even crumbled into mul-

tle pieces when split into parts. The pieces were weighed together as accurately as possible, unless the tablet was pulverized.

Discussion

Enormous variability exists between doses when tablets are halved or quartered. This data likely represents the best case scenario with respect to the accuracy of tablet splitting. In the real world, tablets are split by parents into parts with knives, razor blades, fingers, and other such devices. Occasionally, parents may have a tablet splitting device available to them. However, even with these devices, the inability for tablets to be reproducibly split into a desired part has been demonstrated. Moreover, if the assumption that the active ingredient is homogeneously distributed throughout a tablet is not valid, the potential for even larger variation in dosage exists. Although no pharmaceutical company will guarantee homogenous distribution of active ingredient, even for scored dosage forms, it is assumed daily by physicians and pharmacists. Analytical studies would be required to evaluate this further.

Pediatric practitioners and pharmacy administrators need to evaluate their policies and beliefs regarding the manner in which small dosages are delivered to pediatric patients. Alternative dosage forms should be investigated. Extemporaneous compounding of solutions, suspensions, suppositories, or powder papers may be required. For example, due to the significant variability demonstrated with captopril, these tablets are no longer cut into parts at our institution. In light of a recent study of captopril in solution,⁸ we are now dispensing only liquid dosages of captopril to our pediatric patients.

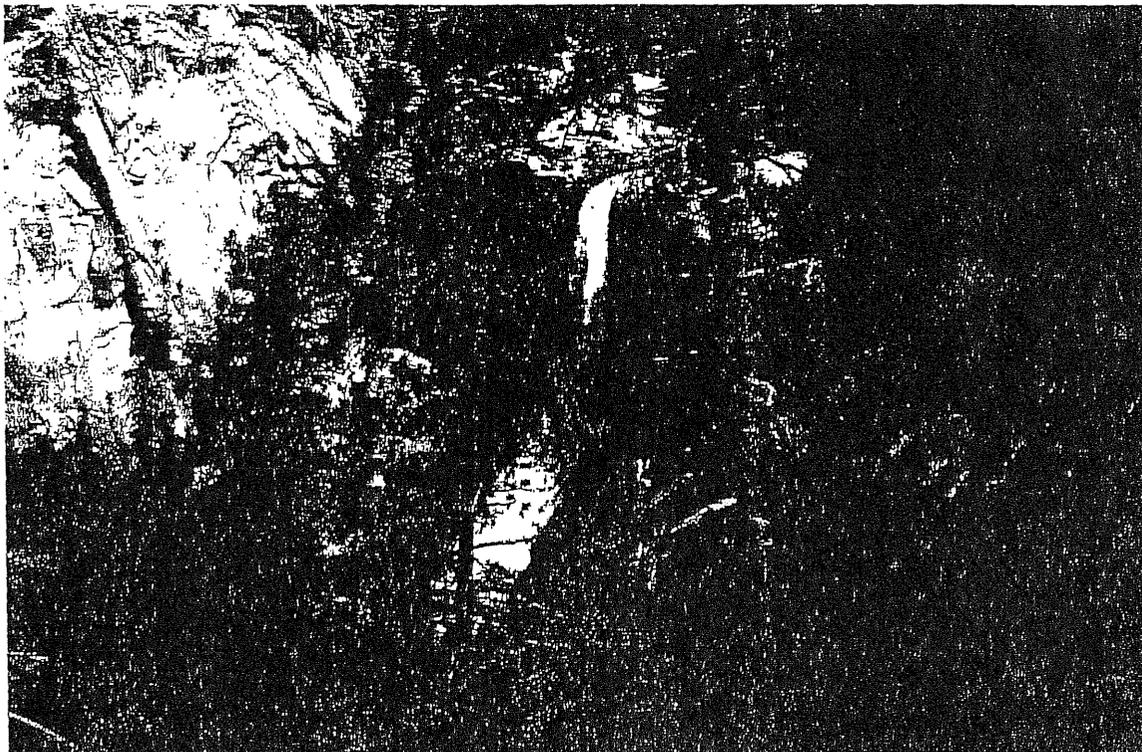
Clonidine was chosen in this study to examine the clinical dilemma of delivering small doses (e.g. 25 μ g by mouth) to our pediatric patients with attention deficit hyperactivity disorder. This therapy is being used more frequently for many pediatric patients.⁹ Dosing variability (e.g. differences in tablet weight) could affect the ability to assess successful drug therapy for this condition. Differences in tablet size and manufac-

turers for a given product may exacerbate these differences and complicate patient assessment. The approximate twofold greater initial tablet weight and size of Catapres® may explain the increased variability observed with generic clonidine.

A follow-up prospective evaluation of whether a correlation exists between variations in dose and clinical outcomes would be informative. This information would allow the full implication of the dosage variations to be appreciated. Until this information is known, however, tablets should not be split into parts for pediatric patients. Tablets should not be cut, especially into quarters. Patients cannot be assured of receiving the prescribed dosage on a consistent basis. The ultimate effect of this variation on patient outcome, however, remains to be determined. If tablets are split the health care team needs to carefully evaluate the patient and take into consideration this dosage variability in the desired outcome of their patient.

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Nevada Falls, Yosemite National Park, CA

Evaluation of the Reproducibility of Tablet Splitting to Provide Accurate Doses for the Pediatric Population

Attachment 5

New State Government Web Page Design



Office of the Governor

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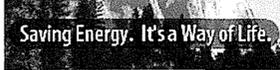
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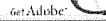
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Attachment 6

Public Outreach Activities



California State Board of Pharmacy

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

April 7, 2007

To: Board Members

Subject: Update on the Board's Public Outreach Activities

Public and licensee outreach activities performed since the January report to the board include:

- Executive Officer Herold provided information about the Board of Pharmacy as a speaker at the CPhA's House of Delegates during their annual meeting on February 15, 2007.
- The board staffed an information booth for two days at CPhA's annual meeting Outlook.
- Board Member Hiura provided information about pharmacy law to pharmacists at a Korean pharmacist association meeting.
- Supervising Inspector Nurse provided a PowerPoint presentation on California's Electronic Pedigree requirements to the Generic Pharmaceutical Manufacturers Association annual meeting in Phoenix on March 1.
- Supervising Inspector Ratcliff provided information about pharmacy law and the board to 80 UCSF students on March 6, 2007.
- Former Board Member John Jones provided a law update to Western University students on March 15.
- Analyst Karen Abbe and Inspector Wong will staff an information booth at the 2007 Consumer Protection Day forum in San Diego on March 24.
- Supervising Inspector Dennis Ming will provide an update on pharmacy law review to staff of Anaheim Memorial Hospital on April 6.

FUTURE:

- Board Member Goldenberg will provide information about pharmacy law to the Diablo Valley Pharmacists Association Meeting in April.
- Board Member Schell will present FAQs about licensing issues to the San Diego Pharmacists Association on April 26.
- The board will staff a public information booth at the City of Sacramento's Wellness Expo on April 26.
- Debbie Anderson will provide information about pharmacist licensure application and examination to Loma Linda graduating students on May 7.
- The board will staff a public information booth at the Family Safety and Health Expo at Safetyville, in Sacramento on May 12.
- Board Members Goldenberg and Conroy will provide information about pharmacy law to the UOP graduating class on May 17.

- Supervising Inspector Ratcliff will speak to Sutter Hospital pharmacists about pharmacy law on May 18.
- Supervising Inspector Nurse will provide information about California's electronic pedigree requirements for prescription medicine at the NABP Annual Meeting on May 19.