SOCIETY OF ACTUARIES Health Section

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Health Watch

Globalization of the Pharmaceutical Supply Chain: What are the Risks?

The FDA's Difficult Task

by Jill Van Den Bos

The Food and Drug Administration (FDA) is the gatekeeper of the U.S. pharmaceutical market. Its role in this capacity is to ensure the safety and efficacy of the drug supply. This role, however, is not an easy one. A few high-profile drug withdrawals over the years, including Thalidomide, Fen-Phen and Vioxx, and other post-marketing "black box" warnings, including widely prescribed antidepressants, have highlighted the difficulties of the FDA's function and caused the agency to become the subject of some fairly public criticism and congressional scrutiny. A 2007 article in *Fortune,* titled "FDA damned if it does, damned if it doesn't," illustrated the difficulties of being the FDA: criticized for being "too cozy with the industry" or for getting tough and thereby "standing in the way of new medicines."[i]

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Globalization: The New Thorny Issue

More recent developments surrounding the globalization of the pharmaceutical supply chain appear poised to provide the context for the next assault on the FDA's ability to protect the American public from unsafe or ineffective drugs. Previous post-marketing discoveries of safety issues may eventually pale in comparison to safety issues presented by globalization of pharmaceutical manufacturing.

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[i] Simons, John. FDA damned if it does, damned if it doesn't. Nov. 9, 2007. Accessed 01-07-2009. Available at: *http://money.cnn.com/2007/11/08/magazines/fortune/simons_fda.fortune/index.htm.*

Actuaries
Risk is Opportunity.®

Chairperson's Corner

by Jennifer Gillespie

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It feels like every day there is an announcement in the news about layoffs at yet another company. The pressure rises for everybody, including those who are currently employed, as we wonder what we can do to make ourselves either indispensable in our current job or perfect for a desired job. Consider what a list of career resolutions written by Amy Lindgren for the *St. Paul Pioneer Press* might mean for actuaries, as well as the many ways the Health Section and the SOA support us in these endeavors.

Resolution #1: "Find at least one club or professional association in my current or potential field and sign up for its newsletter so I can stay on top of current trends." Joining the SOA's Health Section is a great place to start! Other ideas include: joining a local actuarial club; joining other relevant sections of the SOA; and branching out to get involved with a related professional organization, such as the DMAA-The Care Continuum Alliance or the American Society of Health Economists, for instance. While working on "Untapped Opportunities for Actuaries in the Health Industry," the SOA has been reaching out to organizations such as these to strengthen the connection and demonstrate actuaries' relevance to them.

Resolution #2: "Attend at least one professional association meeting so I can connect with others." The Health Spring Meeting in Toronto in June will include many opportunities to network with other actuaries—receptions, lunches, breaks and even a baseball game! Closer to home, most of the local actuarial clubs host lunches, dinners, receptions and other meetings where you can get to know the other actuaries in your metro area or region.

Resolution #3: "Take one seminar, workshop or webinar in my field, or attend a conference." Many volunteers have been working hard to put together a great agenda of sessions for the Toronto meeting. The Health Section will also be holding another round of "boot camps"—intensive seminars providing in-depth knowledge of the key areas of health actuarial practice—this August in Seattle, Wash. Anticipated topics include: Medicare Pricing (Parts C & D), Disability and Long Term Care Pricing, Professionalism and Valuation. There are also a variety of webinars offered throughout the year by the Health Section, by the SOA and by the American Academy of Actuaries.

Resolution #4: "Read one book, magazine or online article about developments in my field." Keep reading this issue of *Health Watch*!

Resolution #5: "Identify someone in my department, company or field to contact for occasional advice." A great source for advice and inspiration is *imageoftheactuary.org,* the SOA's Web site devoted to promoting the "Actuaries Brand." The site includes stories of actuarial pioneers who have opened up new fields for actuaries to explore and to make our own special contributions, along with many other resources that will help you maximize your professional potential.

Resolution #6: "Review my work accomplishments to date and organize them in some way, perhaps in a portfolio of work samples or a list of projects." It's easy for actuaries to label ourselves simply by where we are in the exam process or by the department we work in. But our value to the company (and also to the market) is in the work that we do. What are some of the successful results you've achieved with the projects you've worked on or managed over the years? This is also an opportunity to position yourself to take part in endeavors that go beyond the day-to-day tasks that you've engaged in up to now. For example, with the recent call for essays on "Visions for the Future of the U.S. Health Care System," the SOA and the Health Section are seeking to promote the contributions that actuaries can make to the ongoing debate on health care reform.

Resolution #7: "Schedule at least two networking meetings with people outside my

field." What better place than the spring meeting to find non-actuaries with whom we have something in common! Many non-actuaries have been invited to speak on panels because their work and their perspectives are closely linked to what actuaries do, and they may be open to continuing the conversation.

Resolution #8: "Update my resume." Consider writing an article for Health Watch—and adding "author" to the list of your accomplishments! Other examples of volunteering for the SOA—an exam committee, council participation, speaking at a meeting—also look great on a resume.

Resolution #9: "Add one significant work experience to my life—a new project on the job, or a board membership at a local nonprofit, or a committee assignment at work." It's the time of year to consider running for the council of your favorite SOA section. This will increase your connection to other actuaries, advance your leadership skills and allow you to give back to the organization.

Resolution #10: "Finally explore my options and decide about finishing an old degree or training program, and get started or let it go for good." There are the obvious parallels here for those in the middle of actuarial exams. However, we can also work through the modules as continuing education to update and expand our knowledge of our current or desired field.

If you are inspired to get involved with the work of the Health Section (running for the Section Council, writing an article for *Health Watch,* presenting at a meeting, working on a task force, etc.) or you just want to learn more about these opportunities, please contact any member of the Health Section leadership listed on the masthead of this issue of *Health Watch*. We are always happy to have more people get involved. ■

Editorial Correction: In the January issue of *Health Watch*, Marianne Miller's contact information and author photo were missing from her article. We apologize for this oversight.

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Health **Watch**

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This publication is free to section members. Current-year issues are available from the Communications Department. Back issues of section publications have been placed in the SOA library and on the SOA Web site: (www.soa.org). Photocopies of back issues may be requested for a nominal fee.

LETTER FROM THE EDITOR

A Fond Farewell

by Gail Lawrence

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It has been my privilege to serve you and the Health Section Council as an editor of *Health Watch* since October 2004. When signing on, I had agreed to a three-year term, but extended my tour of duty for an extra year at the urging of Jim Toole.

In my role as editor, I have benefited from the support of many. I'd like to thank Jeff Miller for giving me this opportunity by nominating me to replace him as editor. *Health Watch* could not exist without the many volunteers who take time out of their busy schedules to contribute articles. As an active editor, I have appreciated the cooperation of authors as we have worked together to improve content. I'd especially like to recognize the following authors who have contributed more than one article during my tenure: Ian Duncan, Steve Siegel, Kara Clark, Karen Fitzner, Ross Winkelman, Peggy Herman, Dan Bailey, Steve Melek, Chris Stehno, John Cookson, Jim Toole and Bill Lane.

A loud shout-out also goes to Ross Winkelman, who volunteered over three years ago to be a co-editor for *Health Watch*. Thanks to his able assistance in writing and recruiting content, we were able to double the average size of the publication. His expertise was invaluable in peer reviewing articles and as a partner in making editorial decisions. Hopefully, between the two of us we got things right most of the time.

Besides our volunteer authors, I have depended on the Health Section Council to help recruit content. I would like to recognize the exceptional efforts of Karen Fitzner, Steve Siegel and Jim Toole for recruiting so many articles. By always keeping *Health Watch* in mind, we were able to leverage value from the many educational efforts taking place within the Health Section and the SOA.

I would also like to thank Donna Novak, who originated our regular feature, "Soundbites from the Academy," and Heather Jerbi, who has been a regular contributor. Kudos go to Jim Toole, who was instrumental in originating the "Navigating New Horizons" interview feature and to Peggy Herman, who authored several of the early interviews. The interview feature has continued with a professional writer thanks to the funding of the Health Section Council.

And finally, I would like to thank the SOA editors and production staff. The SOA created the new look for *Health Watch* that was introduced in the September 2008 issue. In addition, the increased support Ross and I have received from SOA staff editor, Kathryn Wiener, has lightened our load significantly and made it possible for us to continue as editors for an additional year. I'd also like to recognize Anne Guenther, who also helped with the editing and proofreading of many issues. We've worked with many graphic designers, including Joe Adduci and Julissa Sweeney, who have worked hard to maintain the professional look of *Health Watch*.

I am confident that our new editors, Grady Catterall and Mary van der Heijde, will make their own marks as they bring a fresh perspective and a new energy to *Health Watch*. I wish them well and I know they will remain true to the goal of continuous improvement in publication content.

It is an exciting time to be a health actuary as the stage is set for change. If anyone doubts the need for change, just consider how quickly you could lose your own health care benefits through uncontrollable life events. Then think again about the coverage you may or not be able to obtain in an individual market filled with declines, rate-ups and waivers. The health insurance industry is certainly unique where the best customers seem to enjoy the least value.

Implementing reforms will not be easy in a culture that is accustomed to accessible health care where wants tend to exceed needs and health care professionals are all to happy to provide care that is not always cost effective. As changes in health care financing continue to evolve, I am looking forward to reading about the actuarial spin in future editions of *Health Watch.* ■

LETTER FROM THE EDITOR

Passing the Torch

by Ross Winkelman

Well, I guess all good things must come to an end. I'll miss working on Health Watch, but am excited about taking on new challenges. I have appreciated the opportunity to assist with *Health Watch*, and work with some extraordinary actuaries and health care professionals. I want to thank the HealthWatch authors, the Society of Actuaries staff (both present and past) and our readers for making my work on *Health Watch* so much fun. I want to extend a special thanks to Gail Lawrence on behalf of the Health Section, since she is wrapping up almost five years as the Health Section newsletter editor. Her dedication has been impressive and inspiring. Between writing and "wrangling" articles, working with authors and the SOA staff and introducing innovative features such as "Navigating New Horizons," Gail has set a high standard for contributing to our profession. I'm looking forward to seeing where she focuses her substantial energy and talent next. ■

On behalf of the Health Section Council, I would like to add my sincere thanks to both Gail Lawrence and Ross Winkelman for their hard work and commitment to excellence in shepherding Health Watch. *Gail's substantial, long term contributions during a period with a lot of changes and challenges is especially appreciated. Congratulations for making access to this publication a true benefit to being a member of the Health Section!*
—Jennifer Gillespie

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Design and Pricing of Tiered Network Health Plans

by Peter Horman

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Pricing actuaries working at an HMO are often asked how to save money on a health plan without decreasing member benefits. Over the years, answers have included the introduction of HMOs themselves, mail order pharmacy and disease management. Another tool many HMOs and insurers have considered is the use of tiered network health plans (TNHPs). TNHPs subdivide network providers based on cost effectiveness and quality rankings to identify preferred providers, those who have lower cost without sacrificing quality. Members become consumers, choosing to either pay extra to receive care from non-preferred providers or shift to preferred providers.

TNHPs help keep the total cost down, and members are able to maintain existing benefit levels. As a result, policy makers are taking notice and implementing TNHP plans for both small group reform and state employee health plans. For example, the state of New Hampshire is requiring insurers in its small group market to offer a tiered hospital product called HealthFirst. New Hampshire's goal is to maintain the HealthFirst premiums at 10 percent of the state's median wage.

In order for an HMO to design a tiered plan that meets employers' or regulators' goals, they need a solid design, accurate pricing and must avoid potential pitfalls. This article will detail design, pricing and other key issues actuaries need to be aware of before implementing a TNHP.

Design and Tiering

In order to design a TNHP, insurers must first start with an existing plan; then select a provider category to tier; next tier providers in the chosen category on cost and quality measures; and finally add additional cost share to providers not meeting desired standards. The TNHP design possibilities are endless in that each HMO will set its own structure based on system capabilities, size and location of network, contracts, quality standards and marketing needs.

A provider category that would be a good candidate for a tiered structure must control a significant amount of claims volume in order to result in significant savings on a TNHP. Common provider types to tier include primary care physicians (PCPs), specialists and hospitals. Claims controlled by the provider include those they performed and those they may have triggered by their care decisions. For, instance a PCP indirectly has control over decisions made by a referred specialist, because that PCP has the ability to refer to a different specialist. As such, identifying the claims providers control is more challenging than simply identifying the services they perform, for instance:

- **PCPs:** Control all costs (because they prescribe, refer and admit);
- **Specialists:** Control all claims related to the given specialty;
- **Hospitals:** Control inpatient and outpatient facility charges.

However, with experience data and some clinical input it is possible to identify the claims any selected provider category controls.

Segmenting providers into tiers uses rankings developed from experts within the HMO including, but not limited to, actuarial, clinical and contracting staff. Rankings are based on the two important measures: cost effectiveness and quality. In this article, cost effectiveness refers to the balance of per unit cost and efficiency of care on all claims in control of the provider. For example, a reasonable cost effectiveness measure to tier groups of PCPs could be risk adjusted average per member per month claims of each group of PCPs patients. The clinical staff will decide on quality measures, and it may rely on a combination of internal and external rankings.

Once determined, the rankings are used to distinguish between providers in order to create a preferred tier and a non-preferred tier (providers subject to additional member cost sharing). One method of creating the tiers is to limit preferred providers to those meeting a quality standard. Next, for passing providers, draw a line at a low cost percentile, or choose the lowest cost provider in a designated region.

Regardless of the tiering strategy, two pricing variables are created from the process:

- **Claims under the control of non-preferred providers = N% =** the percent of total claims

controlled by providers segmented to the tier receiving additional cost share. Again, claims controlled by the providers include both those they performed and those that may have resulted from their care decisions.

- **Cost differential between tier providers = P% =** one minus ratio of average preferred cost per unit to average non-preferred cost per unit. A unit could be per member, per user or per admit, but the cost differential must cover all cost in control of the provider category.

These statistics are straightforward to develop because they are a direct result of the tiering process. Once the design process is complete, the plan pricing stage is next.

TNHP Pricing Formula

Although the TNHP savings formula is fairly simple, it requires a strong actuarial skill set to estimate the final two variables. The first variable is the impact of the additional member liability (copays, deductible, coinsurance, etc.) on non-preferred providers:

- **Member liability differential = M% =** change in actuarial value of benefits of non-preferred providers due to the additional member liability. This should be calculated as a percent of claims controlled.

As with any other benefit change, actuaries can use cost models, claims probability distributions, re-adjudication methods and claims experience to determine actuarial values related to the change in the member liability.

The shift assumption, or the percentage of non-preferred users moving to the preferred providers, is the most difficult variable to estimate:

- **Shift assumption = Shift =** the consumerism impact of a TNHP, which is the assumed percentage of non-preferred users reacting to increased member liability by switching to preferred providers.

In practice, when introducing TNHPs, an actuary will have very little information to develop a reasonable shift assumption. After introducing the TNHP savings formula, this article will present a method for estimating shift.

A reasonable estimate of TNHP plan savings can be calculated using the three variables previously developed and the shift assumptions (still unknown). The formula for the TNHP savings, as compared to a traditional plan, which is created by adding extra cost share to a non-preferred tier of providers, is:

- **TNHP savings formula = N % * [M % + Shift x (P % - M %)],**

which is the percent of total claims controlled by non-preferred providers (N%) multiplied by the additional member liability (M%) plus the shifted users (Shift) differential between tier cost savings (P%) and member liability. This is the algebraic equivalent of non-shifted claims times extra member liability savings plus shifted claims times provider savings.

A simple and intuitive result of this formula is that a TNHP's savings is somewhere between the impact of the extra member liability and the provider cost differential. In fact, the shift assumption determines where the true savings lies between extra member liability and provider cost savings. An important result of the formula is that when the level of additional cost sharing equals the provider differential (later referred to as equilibrium cost share level or just Equilibrium), the shift variable is no longer required to estimate TNHP savings. With this idea of an equilibrium cost share level, additional constraints and available data points can be used to estimate the shift assumption of the TNHP formula.

A simple and intuitive result of this formula is that a TNHP's savings is somewhere between the impact of the extra member liability and the provider cost differential.

Developing the TNHP Shift Assumption

Actuaries, as mathematicians, know to rely on the underlying constraints of a problem to develop a reasonable solution. In the absence of any other information on shift, it is helpful to consider three major constraints:

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1. Demand curve constraint: Shift will increase as the member liability differential increases;
2. Maximum shift constraint: At most, all non-preferred users can shift to preferred providers, which presents a limit to overall movement;
3. Limited network pricing constraint: Most TNHPs should never be priced at a level lower than that of a limited network plan composed of only the preferred provider tier (i.e., plan requiring members to access only preferred providers).

Before implementing a TNHP, it is key to understand how price varies by rating region, and any regulation impacting rate development.

The first constraint is from economic theory; the second is obvious; and the third is more of a general rule. The limited network pricing constraint holds for standard TNHPs, which are those that contain a low cost preferred provider tier, alongside a much higher cost non-preferred tier. In this case, a TNHP can be thought of as a limited network plan plus an option to use an extended network at a fee. As this option represents added value, a fair price on it should never be less then zero. A method to force the TNHP formula to meet this constraint is to assume 100 percent shift whenever member liability differential exceeds the provider cost differential between tiers. Thus the equilibrium member cost share level (Equilibrium), found where M% = P%, is a valuable point in a shift estimate. For exotic TNHPs, possibly ones designed strictly on quality rankings where the preferred tier could be more costly than the non-preferred tier, the third constraint may not be reasonable.

From the constraints, along with the initial condition (assuming no shift), one can limit the reasonable functions of the relationship between additional member liability and the propensity to shift. To build a reasonable function, first construct a line from two points. For example, two points subject to constraints are [No Liability Differential, 0% Shift] and [Equilibrium, 100% Shift]. The line follows:

- Shift Line: Y= m X + b = [100% / Equilibrium] x Member Liability Differential, where Shift is 100% for member liability greater then equilibrium.
- Y-intercept = b = 0%, i.e., no shift is expected without a cost share differential.
- Slope = m = 100% / Equilibrium, alternatively for a more aggressive shift increase the slope, that is, assume that 100% shift occurs at a member liability less then equilibrium.
- X variable = Member Liability Differential.

This shift line is a starting point that can be refined with available or observed data points. Prior to plan implementation, data points may be found from member surveys, geographical analysis or competitor pricing. After plan implementation, data points should be developed comparing pre- and post-implementation provider utilization. The graph below shows the initial shift line as well as a curve built around that line and data points. Although hypothetical, a similar graph could be used for hospital tiered products, where the member liability differential could represent added copay per hospital admit.

With a reasonable shift function specific to a given TNHP, an actuary can estimate shift for any additional cost share. This function along with the TNHP formula will allow for reasonably accurate, fair and consistent pricing. Once the pricing estimate is in place, the actuary should identify possible obstacles to success before implementation.

TNHP Pitfalls

As with any new plan, the HMO should consider the possible pitfalls of implementing a TNHP. Obstacles could arise from regulation, provider reaction, inability to maintain low cost providers or antiselection. Two major issues are pricing dependence on area and provider backlash.

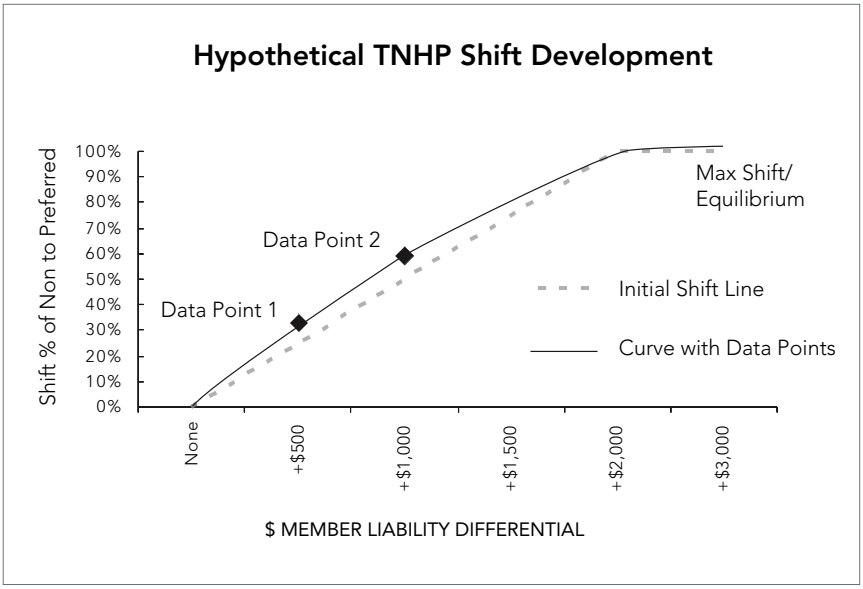
First, TNHPs are highly area specific. For instance, an HMO may have a metropolitan region and a rural region. The metropolitan area may have multiple hospitals and a natural ranking of providers. However, rural areas may have only one provider option, so tiering is impossible. Before implementing a TNHP, it is key to understand how price varies by rating region, and any regulation impacting rate development.

Another important pitfall is the provider backlash in response to being tiered. Providers may not appreciate quality rankings, especially so if

they are not placed in the preferred tier. For example, the Massachusetts Medical Society recently filed suit against the Massachusetts Group Insurance Commission (GIC) over rankings in their TNHP. Even as the suit is pending, the medical society is actively supporting physicians to appeal their tier designations. These reactions demonstrate how sensitive providers are to quality rankings. As a general rule, it is critical to ensure sound clinical evidence and methodology are used when making any statements about provider quality.

Closing Thoughts

Tiered network health plans are a valuable component of a health plan's product portfolio. Accurate pricing and design of these plans requires considerable knowledge of providers, medical quality and actuarial pricing. If pitfalls are avoided, the end result is a plan that lowers employers' costs and rewards members who choose low cost yet high quality providers. These savings are likely to encourage employers and policy makers to pressure HMOs to expand their tiered product offerings. Ultimately, TNHPs will have lasting success if they drive consumers to expect providers to lower cost and raise quality. ■



Taking Our Own Medicine Through Onsite Health

by Michael Clarke and Tom Sondergeld

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For years, Hewitt Associates and other leading health and welfare consulting/outsourcing organizations have led thousands of clients down the path of examining their health care program strategies, designs and funding approaches. We all know the end state need is to control the rising tide of health program costs—often the fastest inflating expense for employers—but to do so in a way that keeps the plan affordable and understandable for employees and their family members.

We also know that we have exhausted the trend reduction possibilities of flexible choice-making and wholesale purchasing through managed care that helped control employer costs through the 1990s and into the early 2000s. "Consumerism" has been the buzzword of late in the industry, and early on it took the form of encouraging more rational use of services through high deductibles and employee health accounts (HRAs and HSAs). The stark realization is that while employers still need to work closely with their administrator/insurer partners and consultants to hold the line on health care unit prices, the more powerful weapon in the "fight against trend" is partnering with plan participants to reduce the growing demand for services.

The Shoemaker's Children

For years, Hewitt has addressed its own health care program much the same way we have consulted with our clients—partner with great vendors to deliver deep discounts and robust service, and offer a range of designs that encourage associates to select "the right plan" for themselves. However, historically we hadn't stepped up our health promotion efforts in a robust, significant way. Sure, we offered Weight Watchers® programs, encouraged walking on our office pathways after lunch and provided a wealth of information on wellness (as well as offering blood pressure screenings and finger-stick cholesterol readings) during our benefits fairs—but most of our programmatic emphasis came back to the usual plan design and associate cost-sharing decisions.

In 2007, new leadership in Hewitt—led by our CEO and senior vice president of human resources (SVPHR), both new to our organization—asked a key question: What are we doing to make seeking health care easier for our associates, especially in our largest locations? Our Lincolnshire, Ill., headquarters became an immediate focus—with over 5,000 associates, we knew we were losing countless hours to people needing to leave during the day to address health issues (or not coming to work at all). We also wanted to do more to promote health as an organization knowing that—as is the case for our clients—many of our primary large claim diagnoses have roots in poor preventive care. Our consultants and delivery associates were doing a great job focusing on their clients, but were not doing as well focusing on their own health and wellness.

What is an Onsite Clinic?

Onsite clinics are small versions of a medical office that sit within or near an employer's physical space. They are able to offer a wide variety of services, based on the program design. Services can run from preventive care and wellness visits to full-fledged physician care (as we have in our Lincolnshire location). Onsite clinic staff can either be hired directly and managed by the employer or, as we recommend, outsourced to a third-party provider. The primary advantages with outsourcing are the greater confidentiality and privacy perception by the associates and the administrative expertise with operating a medical clinic that a vendor can provide. In an outsourced relationship, the employer pays the vendor all pass-through costs for staffing, supplies and equipment along with a negotiated management fee. One of the primary decisions in establishing an onsite clinic is whether to utilize nurse practitioners or physicians or both. This choice will rely on the types of services the clinic will provide and the budget for the project.

The Process of Implementing Onsite Health Care

Conceptually, onsite health care is a fantastic way to promote health messages and encourage frequent health checks. However, the hurdles to implementation are significant:

- The cost/benefit analysis: There is substantial upfront cost in opening an onsite health facility—how can that be funded with existing dollars in the health program, and how will it eventually "pay for itself"?

- Real estate: It's not as easy as deciding in what room in what building to install the facility—you will get to know your local zoning laws intimately!

- Time investment to select vendor partners: We decided to outsource the operation of our facility to an outside clinic management organization, which hires the medical director and health care delivery staff AND manages the electronic records and scheduling interface for our associates utilizing the facility.

  The use of electronic records is key for many reasons: privacy and confidentiality; elimination of paper storage requirements and processes; streamlining data entry and the patient visit; record retention and redundancy; and ease of obtaining and sharing information with other providers and service vendors (such as primary care providers, labs and X-ray facilities).

- Legal considerations: An onsite health facility is an ERISA plan, and as such we needed to comply with certain provisions such as making COBRA available for former associates using the facility—and we had the added wrinkle of determining prevailing costs for services to facilitate compliance for associates enrolled in our High Deductible Health Plan with an HSA.[1]

- Security considerations: As a corporation with security guidelines, the facility needed to comply within the broad framework of our security requirements. (As a result, at present only associates have access to the facility, while family members do not.)

Ultimately the cost/benefit analysis supported moving ahead with the center implementation—with the added feature of an onsite pharmacy managed by our prescription benefit manager. We had dollars available in our benefit program to apply towards the cost of implementation, shifting $300 in annual wellness credits (based on associate pledges to refrain from tobacco use, use seat belts/safety devices and exercise regularly) into the new program by:

- establishing a $150 incentive for employees to take action by completing an online Health Risk Questionnaire (over 90 percent of our associates completed it!); and

- using the remaining dollars to fund onsite center start-up costs and vendor management fees.

Cost/Benefit Considerations

Like any other cost-saving endeavor, aside from it just being the right thing to do, establishing an onsite clinic in a workplace does require a rigorous cost/benefit analysis. Considerations for the capital costs, operating costs, management fees and the like need to be measured against the anticipated return on the investment (ROI). The ROI should include both cost avoidance and productivity savings. The cost avoidance calculation includes both the costs that were directly avoided (by not being paid to an external provider) as well as potential future costs avoided

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Hewitt's onsite pharmacy in their Lincolnshire, Ill. center is filling about 225 prescriptions per week.

The Wellness Center clinic, adjacent to the pharmacy, averages 60 associate visits per week.

by eliminating health risks and/or minimizing costs for associates with chronic disease. While evaluating potential productivity gains can be tricky, we know intuitively that staying at the worksite for care results in much less work time missed during the day than seeking care elsewhere. Take the example of a biweekly allergy shot: an associate in this situation is required to take time off from work an average of four hours every other week. By moving these allergy shots to an onsite clinic, the associate can return to work within 30 minutes of the appointment. That's a 3.5 hour ROI! At an hourly rate of $20, that is a savings to the company of $70 in productivity alone.

The Results So Far

Our Lincolnshire onsite health facility and pharmacy opened just before the holidays in December 2008, and through just five weeks our activity was tremendous:

- To build visibility, we partnered with our clinic and pharmacy managers to raffle prizes during our grand opening week in January—and over 1,000 associates (or about 20 percent of our Lincolnshire workforce) visited the center as a result.
- In the first five weeks of operation, the medical center has seen over 200 patients, for over 300 visits in total.
- At the time of this writing, barely a month after the opening of the clinic, there have been over 700 "charges" generated for services, totaling about $65,000—this is pure cost avoidance from external care expenses.

  It is interesting to note that this $65,000 represents the cost of the care based on the clinic's established fee schedule. This fee schedule was developed to be competitive with other physician services in the community. It therefore is representative of the gross cost that was prevented from hitting the benefit budget.

  The 700 charges that have been processed comprise a wide variety of services, including but not limited to: laboratory blood draws, physician/nurse practitioner office visits, wellness visits, emergency services, immunizations, vaccinations and allergy shots.
- The pharmacy is filling about 225 prescriptions a week since its January 2009 opening, with 20 percent of those filled coming as transfers from other pharmacies.
- Already, 20 associates who previously did not have a prior relationship with a primary care physician have now established one with our center's physician.
- Four emergency cases have already been triaged at the facility, allowing care to start before an ambulance arrived.

We have had overwhelming positive feedback from our associates—including those who say, "Wow, I now see that my employer DOES care about my health!"

Most importantly, the clinic has helped individuals identify existing or potential adverse health conditions and start on the pathway of addressing these conditions. Three new cases of diabetes have been identified as a result of visits to the center, and nearly 70 percent of the patients that have been seen to date have elevated cholesterol levels—for which we have been able to intervene at an early stage. We have had overwhelming positive feedback from our associates—including those who say, "Wow, I now see that my employer DOES care about my health!"

We will continue to monitor activity and measure the financial return from implementation of our

center and pharmacy. But we will also measure the impact on each individual that visits our center and benefits from our coaching resources and frequent biometric assessments, and ultimately improves his or her health because of the interaction with our clinic and pharmacy staff. Metrics will include: improvement of body mass index and blood pressure (for those working on this at the clinic); cost per visit; prescription compliance; and productivity improvement compared to those not having care in the clinic. Other measures are also under consideration.

We are also moving ahead with plans to implement similar facilities in other major Hewitt locations, targeting those with 1,000 associates or more. Why 1,000? Because our calculations show that it's quite challenging to secure a return on the total implementation cost with less than this number. In order to serve locations that have fewer than 1,000 associates, we will be looking for discount relationships with neighborhood pharmacies and stand-alone clinics, both to control costs and to provide better access for these associates.

There are reasons beyond the financial benefits of improved purchasing techniques for employers with large populations concentrated in one site to consider onsite health services. Productivity improves when employees lose less work time seeking health services, and early identification and protocol adherence will lead to better health outcomes—and reduced demand for services—in the future. ■

[1] In order to allow those in the HDHP with an HSA access to care in the clinic, a fee schedule and process for collecting payment up to the deductible had to be established. In order to make the clinic pricing attractive to associates in this plan, the fee schedule was competitively priced using area comparison data as well as pricing averages from our health care provider. Rules and regulations dictate that fees charged cannot differ from those that would otherwise be charged to any other provider or payor.

Navigating New Horizons...

Dawn E. Helwig, FSA, MAAA

by Mary van der Heijde

Long-term care (LTC) insurance was a relatively new and little understood subset of the health care market when Dawn Helwig first began working on it in 1986. Since then she has been involved in virtually every aspect of LTC product development and analysis, a witness to the segment's growth and an active participant in its development.

Dawn Helwig, FSA, MAAA, is a principal and consulting actuary for Milliman in Chicago, Ill. She can be reached at dawn.helwig@milliman.com.

"Everything about LTC has changed in the past 23 years," she says. "From the benefits structure to the underlying pricing assumptions to the underwriting and claims methods." Just about every corner of the business has incorporated major innovations and made substantial changes to stay relevant in the face of new data, advances in health care and changing demographics.

And Helwig has changed too, becoming, in her own words, "a huge proponent of LTC." The experience and knowledge she has gained over the years have instilled in her a strong belief that both individuals and governments need to anticipate and fund adequately their LTC needs.

Early Choices

Helwig's path to LTC actuarial work was relatively straightforward, if not exactly planned. She admits she was "one of those people who didn't know what an actuary was," when she was about to graduate from college with a double major in English and math.

"I had no real plan about what to do," she says. "Initially I thought I might go on to get a master's in English and teach." An employment ad in her college newspaper changed everything. Combined Insurance was looking for math students to work part-time in their actuarial department. The company hired Helwig, then offered her a full-time position doing health product pricing and analysis upon graduation. Still unsure of her future, she took the job as a temporary measure and found, to her own surprise, that she enjoyed the work.

"At first I thought I'd work at Combined a few years and then go back to get that English master's," she says. "But somehow—nearly 33 years later—here I am, now at Milliman, but still doing this work and still excited about it."

She may not have become a teacher, but Helwig says she particularly enjoys the educational aspect of her job.

"LTC has been a new product line for many of the companies I've worked with. Just teaching them about the industry and its products—how it's changed over the years, helping them prepare for where it maybe be going in the future based on current trends—all of that has been very satisfying to me."

Changes Over the Years

LTC was just beginning to take off as a product line when Helwig left Combined and arrived at Milliman, Inc., in 1986. Demographic trends were projecting an aging of the population over time, suggesting a potential growth market for LTC.

"There were a few companies that had been selling LTC insurance," she says, "but a lot more that were just jumping into it."

Pricing was aggressive, as new entrants competed with both each other and the more established companies for market share. But even companies that had been in the business for a few years had few claimants yet and little idea what the LTC claims experience might be like in the future. The historical data necessary to establish appropriate pricing or adequate reserves was scarce to nonexistent, and mistakes were made.

Time and experience have eased some of those initial problems, Helwig points out, and the environment for LTC has changed dramatically for the better during the current decade.

"We've started to get a good number of incurred claims over the past 10 years and built up a lot more experience on the product. We have a much better feel now for what the slope of the claim cost should look like."

One example of an early misstep involved the original lapse rate assumptions for LTC, which turned out to be much too high. Voluntary lapse rates, in particular, were set far higher in the ’80s—around seven or eight percent—than subsequent experience indicated they should be. Today, based on historical data accrued so far, they hover at between one and two percent, and could go even lower.

Two other areas that have changed radically since the ’80s involve how products are structured and benefits paid out.

“When I started working on LTC, most of the products were nursing-home-only, with perhaps a few stand-alone home health care products available.” Today, she notes, almost all LTC sales involve “comprehensive products”—policies that combine nursing home benefits with home health care, assisted living and other benefits.

A dramatic change that occurred early on involved the level and cause of disability triggering a payout. Originally, benefits were paid only when an insured required LTC in response to a debilitating accident, or to a medical emergency such as a stroke, and the care was deemed “medically necessary.” But new requirements for payment were established mandating payment for any cognitive impairment or for any condition that limited an insured’s ability to perform the activities of daily living.

At about the same time, it became apparent that the industry had some underwriting problems that had to be addressed. “Many of the policies issued back in the ’80s and ’90s were fairly loosely underwritten,” Helwig remembers. “There were no cognitive tests generally available, or none that the industry as a whole could agree upon. Yet many of the early claims on the policies of that time were increasingly cognitive in nature.” This developed into a major issue and had a substantial impact on how LTC companies performed underwriting.

Some of those changes were the result of work done by Helwig herself on one of her very first assignments for Milliman. She was asked to take a close look at those companies that had always insisted upon good, tight LTC underwriting standards, track their results against companies that had a reputation for loose underwriting, then report on any experiential differences.

“The difference in loss ratios for the two groups was huge,” she says. “So we really started getting the message out that the underwriting for these LTC policies was extremely important and needed to be tightened up significantly.”

LTC Challenges Today

Many of the LTC challenges of today are still a result of early missteps. Blocks of LTC business still in effect at some companies were originally priced back in the ’70s, ’80s and even the ’90s. Some of those books are in trouble today due to the poor underwriting and overly optimistic lapse assumptions of an earlier time. Others have been revamped and brought back to health. Helwig has spent much of her time at Milliman helping companies recover from earlier mistakes.

“Working with those companies to make sure they have taken the right rate increases and are using the right lapse assumptions going forward has been a major challenge during this decade,” Helwig says. “But it’s been an interesting one to address, and very satisfying when the final result is a good one.”

Another major LTC issue still being worked out today—similar to the underwriting issue of the past—has to do with claims management. According to Helwig, companies today are beginning to understand how important it is to strengthen their claims management procedures. They are no longer agreeing automatically with a claim simply because a doctor recommends LTC. They are, instead, examining those claims more closely on their own to ensure they are in agreement with the diagnosis and the plan of care.

But many of the ongoing issues are still based on insufficient data due to LTC’s relative youth in relation to the product’s long tail.

“We still don’t know everything there is to know about what the tail of the LTC morbidity curve is going to look like,” Helwig says. “When we look

Many of the LTC challenges of today are still a result of early missteps.

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at the companies that were in this business early, in the 1970s and 1980s, we see that most of their claimants are now in their 80s. We're still waiting to see what things will look like when there are a substantial number of claimants or policyholders in their late 90s. That's a real concern."

Another concern is the voluntary lapse rate, which continues to drop. "How far can it fall?" Helwig asks. "There are companies today with a projected lapse rate under one percent. How close will they get to 0 before it stops falling?"

Mortality, too, is an important rate about which little is known or documented. It is a given that mortality rates will be higher for claimants because, as a population, they are elderly and/or impaired. But no one has done a mortality table for either active or impaired LTC policyholders—certainly not one that is generally accepted by the LTC industry.

"We also don't know," Helwig says, "what new cures, drugs or other advances in health care would do to LTC costs—driving them either up or down."

A new drug arresting or even reversing the effects of Alzheimer's—one of the most significant causes of claims—could cut up to 20 percent out of the cost of LTC across the board, she says. On the other hand, obesity and related morbidity trends could cause LTC claims to increase in both number and cost. "What will happen if we have a group of aging, obese policyholders with diabetes and everything that comes with that?"

A more immediate and pressing concern for Helwig is political in nature: With all of the recent emphasis on providing health benefits for children or for adults who have lost jobs or otherwise cannot afford coverage, LTC is likely to take a back seat when it comes to government funding.

With all of the recent emphasis on providing health benefits for children or for adults who have lost jobs or otherwise cannot afford coverage, LTC is likely to take a back seat when it comes to government funding.

"LTC is already grossly underfunded in the United States," she says. "We are not putting aside the kind of dollars that we will need to fund the future LTC needs of the country."

"State Medicaid programs have been going bankrupt, or states have been having trouble funding them. Ultimately, the dollars just aren't going to be there through Medicaid, which is on a pay-as-you-go basis. As a result, the quality of care provided through Medicaid is generally inferior to what a person can get with private pay. I've seen the projections of what tax rates would have to increase to in order to fund Medicaid LTC 20 years down the road, assuming we're still on a pay-as-you-go basis. And those rates are just astronomical. They are not the kinds of tax increases people will be willing to pay."

It all comes back, Helwig says, to personal responsibility.

"If consumers want to ensure they will have good choices and good dollars for funding their future LTC expenses, they are probably going to have to take care of that for themselves."

The biggest challenge of all may be raising that awareness of the need for more LTC coverage among the public, convincing people of the wisdom of purchasing a policy years before they will need the benefits. "LTC is in the place life insurance was in 100 years ago," Helwig says, "when people were reluctant to buy a policy because they didn't want to think about dying."

No one wants to think about the time when they may not be able to take care of themselves or have to go into a nursing home. "But the product has changed so much over the past few decades," she says. "It pays now for care in the home, which is where most people want to be, and for assisted living facilities, which are generally far better than most nursing homes. There are simply much more comprehensive policies available, designed to meet the full LTC needs a person might have. We need to get that message out."

Gratifying Work

Despite all of the challenges and pressing issues facing LTC, Helwig says she finds the work even more exciting and enjoyable today than she did when she first started.

"Those of us who specialize in this kind of insurance call ourselves 'LTC Geeks,'" she says, laughing.

"We're a small, tightly knit group of professionals, and when we get together at conferences and meetings you see the same people time and again for years. The people who get involved with this sector tend to stay with it, because we believe in it, and feel as though we're making a difference in people's lives.

"It's gratifying when you hear all of the testimonials from people who have been recipients of LTC benefits. Even though they don't touch on me personally, I find them personally satisfying because I feel like I've played a part in making that happen." ■

New SOA Research Study Evaluates Cost Impact of Drug Therapy for Crohn's Disease

by Steven C. Siegel

Steven Siegel, FSA, MAAA, is a research actuary with Society of Actuaries in Schaumburg, Ill. He can be reached at *ssiegel@soa.org*.

Several years ago, the Health Section issued a request for research proposals (RFP) to study the effect of a specific prescription drug on the overall medical costs and utilization for a population of patients who shared a similar medical condition. The group that developed the RFP was not as interested in the choice of the actual drug and condition to be evaluated as much as the process and methodology for undertaking such an analysis. As a result, both the specific drug and condition to be studied were deliberately left open in the RFP.

The Health Section was motivated to issue the RFP through a recommendation from an earlier effort that identified analysis of prescription drug expenses as an area where actuaries could play an important role in the national health care debate. Given the rapid increase in the cost of prescription drugs over the past decade, I imagine there are not many actuaries out there who would challenge this recommendation.

Overall, the results indicated that infliximab therapy is not associated with an overall reduction in direct health care utilization and expenditures when used in actual practice by privately insured individuals with Crohn's.

One of the proposals received in response to the RFP was from a team of researchers at the University of Wisconsin. The team included Patrick Meek, the lead researcher who later transferred to the Albany College of Pharmacy, as well as Marjorie Rosenberg and Nilay Shah. The research team proposed to compare health care utilization and expenditures between individuals with Crohn's disease who had used a prescription drug called infliximab and those who had not. The study was to be based on observational data collected during the initial years of availability of the drug. After a thorough review by a project oversight group that was recruited to evaluate the proposal, funding for the effort was enthusiastically approved.

For those unfamiliar with the condition, Crohn's is a chronic inflammatory disease of the intestines that is named after the physician who first described it in 1932. Common symptoms of Crohn's disease include abdominal pain, diarrhea and weight loss. This is the result of the disease causing ulcerations in the lining of the small and large intestines. As well, it can adversely impact just about any region of the digestive system starting all the way up to the mouth. Listening to the firsthand experience of several friends with the condition, I can say, without hesitation, that living with it is no Sunday stroll in the park (or any other day of the week, for that matter).

Infliximab, introduced in 1998, is a biologic drug that blocks the effects of a substance involved in the inflammation seen in Crohn's disease and other autoimmune diseases. When taken by patients with Crohn's, infliximab use was related to substantial improvements in their health status, need for intensive medical management and overall quality of life. Infliximab is a central part of the treatment management of approximately 50 percent of the 650,000 people in the United States diagnosed with Crohn's who are most affected by the disease.

Using claims data from the 1999–2003 Thomson Reuters MarketScan commercial claims and encounters databases, the research team analyzed inpatient, outpatient and prescription drug claims data for individuals older than 18 years of age with a diagnosis of Crohn's. The team compared results using two primary approaches: a retrospective cohort analysis and a 12-month pre-post (before and after infliximab) analysis. To help reduce some of the data issues that are inherent in these types of analysis, the team also applied a combination of risk adjustment and propensity score methods.

Overall, the results indicated that infliximab therapy is not associated with an overall reduction in direct health care utilization and expenditures when used in actual practice by privately insured individuals with Crohn's. The study also points out some of the limitations in trying to generalize the results to other settings. But, most importantly, it helps to further the discussion about the ultimate trade-offs between the cost versus the benefit of such thera-

pies. And, as a further benefit, the methodology laid out in the study can be used as a foundation for future research in this area.

I highly encourage you to review the study and draw your own conclusions. The study can be found on the Society of Actuaries' Web site at: *http://www.soa.org/research/health/research-infliximab-therapy.aspx.*

As of this writing, the study has been submitted to a prestigious, peer-reviewed journal for publication consideration. The study may also ultimately serve as inspiration for the SOA to become involved in efforts related to exploring Comparative Effectiveness, which is a feature of the Obama administration's recent stimulus package.

I'd like to express my appreciation to the following individuals who helped to originally launch the study with their careful review of the proposal and initial recommendations: Margaret Wear, John Bertko, Kevin Dolsky, Gregory Durant, John Governale, Toby Hall and Thomas Tomczyk.

As always, I'd welcome any feedback you have on the report and thoughts for similar future studies. ■

Soundbites

from the American Academy of Actuaries' Health Practice Council

by Heather Jerbi and Melissa Lawler

Editor's note: *If it looks like the list of activities under "What's New" is longer—and goes back further—than it normally does, that's because we inadvertently omitted this feature from our January issue. Our apologies to the Academy and to our readers for this oversight!*

What's New

The American Academy of Actuaries' Health Practice Council hosted a free webcast on Friday, Jan. 23, 2009. The webcast, cosponsored by the Society of Actuaries and the Conference of Consulting Actuaries, provided health actuaries with an understanding of a new microsimulation model created by the RAND Corporation. The Comprehensive Assessment of Reform Efforts (COMPARE) model examines the intended and unintended effects of different health care reform proposals. The model's Web interface allows users to compare policy options under different scenarios and assumptions.

In December, the Academy's Medicare Steering Committee and Health Care Quality Work Group submitted comments to Senators Baucus and Grassley regarding draft legislation, Medicare Hospital Quality Improvement Act of 2008, which would link Medicare hospital payments to performance on certain quality measures. The letter encouraged policymakers to act quickly to restore Medicare's financial soundness and noted that moving to a value-based purchasing program would be a step toward better alignment of reimbursement with improved health outcomes. The letter can be found online at: *http://www.actuary.org/pdf/health/hospitalquality08.pdf.*

In October, the Academy's Health Practice Financial Reporting Council (HPFRC) sent a letter to the American Institute of Certified Public Accountants commenting on a draft Technical Practice Aid (TPA) regarding prospective unlocking for long-duration insurance contracts that allow for premium increases. In the letter, HPFRC said that the draft TPA is an appropriate guideline, but suggested that it be expanded to include a discussion of implementation considerations. The letter listed specific implementation questions that should be answered as part of the draft TPA, and suggested that absent those answers there will be significant variations in practice among companies. The letter can be found online at: *http://www.actuary.org/pdf/health/aicpa_nov08.pdf.*

Also in October, the Academy's Individual Medical Insurance Market Task Force released a new issue brief, The Individual Medical Insurance Market: A Guide for Policymakers. The brief is intended to provide policymakers with an understanding of how the current individual market works, the relative ease or difficulty a person may have acquiring coverage in this market and the cost implications once the individual is covered. This brief was also submitted as a statement by the Academy for the written record of a House Ways and Means Subcommittee on Health hearing on the health of the private insurance market. The brief can be found online at: *http://www.actuary.org/pdf/health/med_market_1008.pdf.*

In September, the Academy's Health Care Quality Work Group released a new issue brief, Health Insurance Coverage and Reimbursement Decisions: Implications for Increased Comparative Effectiveness Research, which provides a current assessment of health care quality, outlines the process for incorporating new treatment protocols and technologies into health insurance coverage and discusses the policy implications of comparative effectiveness research. The issue brief can be found at: *http://www.actuary.org/pdf/health/comparative.pdf.*

The Academy's Uninsured Work Group also released two issue briefs. The first one, Fundamentals of Insurance: Implications for Health Coverage, was released in August. In the context of recent health reform proposals that aim to increase coverage for the uninsured, the brief discusses the fundamental principles of insurance, whether and how they apply to health coverage plans, and the implications of deviating from those principles. The issue brief

can be found at: *http://www.actuary.org/pdf/health/coverage_ib_08.pdf.*

The second brief, Taking Control: An Actuarial Perspective on Health Spending Growth, was released in September. The brief discusses a number of the major causes of health spending growth—drivers that increase health care service prices and drivers that increase utilization—and also examines various options that have been proposed to address these drivers. This issue brief was released in conjunction with a Capitol Hill briefing on Sept. 22. Cathy Murphy-Barron, chairperson of the Uninsured Work Group, and Stacey Lampkin, vice-chairperson of the Uninsured Work Group, presented at the briefing. The issue brief can be found at: *http://www.actuary.org/pdf/health/spending_ib_08.pdf.*

In August, the Academy's Health RBC Trend Test Work Group submitted a report on a health RBC trend test to the NAIC's Health RBC (E) Working Group. The NAIC group asked the Academy to determine whether or not a leading indicator based on annual financial statement information could be developed to identify those companies with reported HRBC ratios above 200 percent that face a significant risk of subsequently falling below 200 percent in the following year. Based in part on the Academy work group's report, the NAIC working group voted on November 12 to adopt a trend test identifying companies with an RBC ratio between 200 percent and 300 percent, and a combined ratio greater than 150 percent.

Ongoing Activities

The Academy's Health Practice Council has many ongoing activities. Below is a snapshot of some current projects.

- **Consumer Driven Health Plans Emerging Data Subgroup** (David Tuomala, Chairperson)—This work group is developing a paper analyzing emerging CDHP data, which is expected to be available in 2009.
- **Health Practice Financial Reporting Committee** (Darrell Knapp, Chairperson)—The committee continues to work on updating several practice notes (Small Group Certification, Large Group Medical and General Considerations).
- **Long-Term Care Principles-Based Work Group** (Bob Yee, Chairperson)—This work group is in the modeling phase of its work and will be providing quarterly updates to the NAIC Accident and Health Work Group in 2009.
- **Uninsured Work Group** (Cathy Murphy-Barron, Chairperson)—The work group is currently working on a project that discusses approaches to expand health insurance coverage among high-risk individuals.
- **Health Care Quality Work Group** (Michael Thompson, Chairperson)—This work group is developing an issue brief that examines value-based insurance design (VBID), including the issues that are considered by insurers and employers when developing plan designs.
- **State Mandated Coverage Task Force** (Kevin Borchert, Chairperson)—This task force is developing an issue brief that will discuss the mandated purchase of health insurance coverage. The brief will address the goals of such programs, funding considerations for implementing mandated coverage legislation, benefit design considerations and modeling issues (including data availability).

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- **Stop-Loss Work Group** (Shaun Peterson, Chairperson)—This work group is continuing to update a 1994 report to the NAIC on stop-loss factors, and is currently checking data calculations prior to re-starting the modeling phase of their work.
- **Medicare Part D Risk-Based Capital Subgroup** (Jim Braue, Chairperson)—The subgroup has submitted to the NAIC Health RBC Working Group a report updating the Part D RBC risk factors.
- **Disease Management Work Group** (Ian Duncan, Chairperson) —This work group has begun development of a public statement on evaluating wellness programs.
- **Small Group Market Task Force** (Karen Bender, Chairperson)—This work group has begun work on an issue brief that looks at transition issues when considering health care reform proposals—specifically those related to rating reform, underwriting/issue reform and changing the definition of small group. In addition, a subgroup of the Small Group Market Task Force and the **Individual Market Task Force** (Mike Abroe, Chairperson) is considering a brief that would examine the implications of reform proposals that would merge the two markets.
- **Medicare Supplement Work Group** (Michael Carstens, Chairperson)—This work group submitted recommendations for changing the Medicare Supplement Refund Formula to the NAIC's Medicare Supplement Refund Formula Subgroup (of the Accident and Health Working Group), per the request of the subgroup.

Other NAIC Projects

The Committee on State Health Issues and the Health Practice Financial Reporting Committee continue to monitor NAIC-related issues, including LTC, Medicare Part D, principle-based methodologies, Medigap modernization and general health insurance issues.

If you want to participate in any of these activities or want more information about the work of the Academy's Health Practice Council, contact Heather Jerbi at *Jerbi@actuary.org* or Melissa Lawler at *Lawler@actuary.org.* ■

Whereas most ingredients used to be manufactured in the United States, 80 percent of active ingredients are now manufactured in China and India.

Whereas most ingredients used to be manufactured in the United States, 80 percent of active ingredients are now manufactured in China and India. Regulation of these manufacturers is limited and variable.[ii]

For example, Chinese pharmaceutical companies that produce active pharmaceutical ingredients (APIs) are regulated by the State Food and Drug Administration. However, companies that are officially part of another industry, such as chemical companies, also manufacture APIs and are not regulated in the same manner. Of the 80,000 or so chemical companies in China, the number that manufacture APIs is unknown. Furthermore, the State Food and Drug Administration in China does not monitor the manufacturers of intermediate compounds, the building blocks for APIs.[iii]

Although many globally produced APIs wind up on the U.S. pharmaceutical market, the FDA lacks the overseas capacity to inspect foreign manufacturers. Indeed, the FDA may not have accurate information on foreign manufacturers that are subject to investigation. As such, fewer than two percent of these facilities are examined by the FDA.[iv] In fact, investigators from the House Energy and Commerce Committee recently accompanied FDA officials on inspections of drug plants in China and India. They concluded that the FDA was unable to provide basic information such as the number of firms exporting to the United States, and overseas FDA inspectors lacked necessary logistical support. Since the FDA only conducts about 20 inspections per year, it would take the FDA 13 years to inspect all of the manufacturers of bulk ingredients with its current staff.[v]

As a result of the globalization of the supply chain, there are greater opportunities for the production and dissemination of unsafe drugs in the United States.[vi]

Counterfeit Products

Counterfeit drugs are substandard medicines whose composition and ingredients do not meet the correct scientific specifications and are fraudulently mislabeled with respect to a product's identity or source. This can come about in several ways:

- ingredients are mislabeled as API when they are impure or inactive,
- the correct API is replaced with an incorrect potency/dosage,
- the correct API is replaced with a cheaper version, or
- an expired API is labeled with a new and false expiration date.[vii]

The FDA estimates that 10 percent of medicines on the global market are counterfeit. This value has been closer to one percent in markets such as the United States and Canada, and much higher in developing markets. In 2005, there were 100 reported incidents of counterfeiting in the United States and 42 seizures. The production of counterfeit drugs does not occur in large infrastructure or facilities, but is carried out in ordinary households, small cottage industries or in backyards. Counterfeiting is highly lucrative because of high demand and low production costs. There is no deterring legislation in most countries because there is no fear of being apprehended and prosecuted. The willingness of patients to buy medicines through the Internet has

[ii] Bogdanich, Walt. F.D.A is Unable to Ensure Drugs are Safe, Panel is Told. Nov. 2, 2007. Accessed 01-07-2009. Available at: *http://www.nytimes.com/2007/11/02/washington/02FDA.html*.

[iii] Bogdanich, Walt. Chinese Chemicals Flow Unchecked Onto World Drug Market. Oct. 31, 2007. Accessed 01-07-2009. Available at: *http://www.nytimes.com/2007/10/31/world/asia/31chemical.html*.

[iv] Barnes, Kirsty. F.D.A. Failure on Foreign Inspections Frightening. Nov. 5, 2007. Accessed 01-07-2009. Available at: *http://www.outsourcing-pharma.com/Contract-Manufacturing/FDA-failure-on-foreign-inspections-frightening*.

[v] Bogdanich, Walt. F.D.A is Unable to Ensure Drugs are Safe, Panel is Told. Nov. 2007. Accessed 01-07-2009. Available at: *http://www.nytimes.com/2007/11/02/washington/02FDA.html*.

[vi] World Health Organization. Substandard and Counterfeit Medicines Fact Sheet No. 275. Nov. 2003. Accessed 01-07-2009. Available at: *http://www.who.int/mediacentre/factsheets/fs275/en/*.

[vii] World Health Organization. Substandard and Counterfeit Medicines Fact Sheet No. 275. Nov. 2003. Accessed 01-07-2009. Available at: *http://www.who.int/mediacentre/factsheets/fs275/en/*.

been quickly recognized by criminals as a profitable way to supply counterfeit medicines to unsuspecting customers.[viii] Counterfeiters have targeted a wide range of modern drugs in the areas of cancer, erectile dysfunction, cardiology, hormones, steroids and antihistamines.[ix]

Pharmaceutical counterfeiting has been described as the perfect crime: if the patient's condition improves, there is no investigation. If the patient's condition deteriorates, it will be attributed to the medical condition or disease.[x]

What is the Risk?

Counterfeit drugs can have two basic impacts on patients: the active ingredient is less than the stated dose, or missing altogether; or the drug is downright harmful in that it contains what amounts to poison. Both of these situations occur with alarming frequency.

In the first case, patients will be taking drugs that do not have the expected therapeutic effect, leading to ineffective treatment and therapeutic failure, which can be disastrous depending on the condition being treated. To make matters worse, this happens while spending money that is expected to lead to therapeutic benefit—the patient and the health plan are paying for this ineffective treatment. As an example, a recent study by the World Health Organization (WHO) found that 38 percent of antimalarial drugs in pharmacies in Southeast Asia contained no active ingredient.[xi]

In the second case, patients will be taking drugs that may have the expected therapeutic effect, but also have an additional deleterious effect. Again, the impact can be disastrous, as illustrated by a 2008 case of tainted heparin in the United States. In this case, up to 50 percent of the active ingredient was replaced with oversulfated chondroitin sulfate, a cheaper ingredient that has similar properties to that of heparin.[xii] At least 95 Americans died and hundreds had severe allergic reactions after taking this counterfeit drug.[xiii]

What is the possible cost to a health plan if a commonly prescribed drug, such as a statin, were replaced with a counterfeit drug? Statins (HMG-CoA reductase inhibitors) are a class of drugs prescribed to reduce hyperlipidemia, which is high levels of fatty molecules (cholesterol and triglycerides) in the blood. Hyperlipidemia is, in turn, associated with increased speed of hardening of the arteries, leading to increased risk for heart disease, stroke and other vascular diseases. Statins are generally effective, if potentially costly, at reducing the morbid outcomes of hyperlipidemia.[xiv]

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Statins are taken by many people. Statins, as a class, have the second highest per member per month claim cost (PMPM) among all drug classes for the commercially insured at $6.47, and the highest PMPM for the Medicare eligible population at $37.81. If a commonly prescribed statin were replaced with a counterfeit version having no active ingredient, the resulting cost to a health plan would include the price paid for the counterfeit drugs themselves plus the cost of nontreatment for the populating taking this statin. If instead this target statin were replaced with a counterfeit version having no active ingredient and also containing a chemical that caused a severe allergic reaction requiring long hospitalizations for even a small portion of affected patients, the cost to a health plan could be substantial. Add to this the more important costs in terms of health to the patients themselves.

The FDA estimates that 10 percent of medicines on the global market are counterfeit.

There are many relevant variables that would come into play, naturally, including time until the "bad" drugs were discovered, the size of the population impacted, type of drug and what condition it treated. However, this "what if" exercise suggests that the costs in terms of health, quality of life and dollars could be substantial if a relatively big "slip" occurred.

The Future

In recent years the FDA has responded to the threat of counterfeit pharmaceuticals by stepping up efforts to improve the safety of the nation's drug supply. One method has been to encourage the use of technologically advanced tags that electronically label drug packages. Radiofrequency identification (RFID) enables manufacturers and others in the drug supply chain to track drug products, making inserting counterfeit products into the supply chain more difficult.[xv]

In November 2008, the FDA opened an office in Beijing, China. The FDA plans to open more offices in China as well as in other international locations.[xvi] Congress has also taken an interest in the safety of the drug supply chain, with possible legislative action that may include tracking requirements.[xvii]

Another FDA initiative, announced Jan. 14, 2009, is a voluntary program called the Secure Supply Chain pilot program to promote and improve the safety of drugs and APIs manufactured outside the United States. To do this, the FDA will select 100 applicant companies that meet certain criteria to participate.[xviii] "The program creates incentives for drug manufacturers to develop and maintain secure supply chains," according to Deborah Autor, director of the office of compliance in the FDA's Center for Drug Evaluation and Research.[xix]

Although the U.S. pharmaceutical market is still one of the safest in the world, the impact of the globalization of pharmaceutical manufacturing has brought with it a well-deserved element of fear that is galvanizing the FDA and others into action.

"Best safety lies in fear."

—*Hamlet*, William Shakespeare. ■

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