

# PUTTING THE PATIENT FIRST: Making Compliance a Priority

**Although patient noncompliance has been an industry focus for more than 30 years,** PHARMACEUTICAL COMPANIES CONTINUE TO SEARCH **for solutions to keep patients compliant and persistent.**

**A**n estimated 70% of all medical prescriptions go unconsumed, leading to \$77 billion in excess healthcare costs each year, according to Cutting Edge Information. The main cause for noncompliance is a breakdown in communications. Often,

## The Cost of Noncompliance

### How Big is the Noncompliance Problem?

**70%** of all medical prescriptions go unconsumed, leading to \$77 billion in excess healthcare costs each year.

**30% to 85%** of patients may disregard refills, depending on the disease and treatment regimen.

Up to **85%** of patients do not refill prescriptions and complete their treatment regimens.

**10% to 20%** of initial prescriptions go unfilled.

Up to **20%** of all hospital and nursing home admissions and 125,000 deaths annually are attributed to noncompliance.

Source: Cutting Edge Information, Pharmaceutical Patient Compliance and Disease Management, Durham, N.C. For more information, visit [cuttingedgeinfo.com](http://cuttingedgeinfo.com).

patients may not understand, and doctors or pharmacists may fail to explain, treatment regimens, product efficacy, or drug side effects. It is estimated that 40% of patients who receive outpatient drug therapy will experience a treatment failure or a new medical problem as a result of improper use. Noncompliance has been attributed to 125,000 deaths and up to 20% of all hospital and nursing home admissions a year.

Solutions to improving compliance take the form of patient education, reminders, and ongoing monitoring, including call centers, e-mail reminder programs, computer programs, high-tech packaging, and other tools to remind patients of dosages and refills.

As the industry moves from its traditional product-focused mindset to one that is more customer focused, pharmaceutical companies are realigning efforts on tackling patient compliance. This strategy is being

aided by continued technological advancements that are enabling personalized communications with patients, smart packaging, and patient-focused compliance aids.

**ADRIA NULLMEIER** PediaMed - The Pediatrics Company

GETTING TEENAGE PATIENTS TO USE ANY ACNE PRODUCT AS PRESCRIBED IS A CHALLENGE. Our compliance program reminds them on a regular basis — in a format they are comfortable with — how to use the medicine correctly.

**THE LONG ROAD TO COMPLIANCE CHANGE**

*Compliance and persistency issues have been on the industry's radar for at least 30 years. The complexity of patient behavior is partially the reason why it has been difficult to make an impact in this area, but a more customer-focused industry coupled with new technologies present hope that companies can enhance patient compliance.*

**LEBMEIER.** Noncompliance is an issue as old

as medicine; but solutions can be found by researching the mechanics of compliance to better understand it and find ways to improve it. History has proven that when patients are in an environment where they believe someone is looking after them, their outcomes are better. This has been demonstrated in studies concerning the organization and applies to patient compliance.

**SMITH.** What has been wrong with patient compliance since the 1960s is that the majority of the patient programs are not effective.

The marketing arms of the companies are not developing materials that meet the needs of patients and caregivers. Companies publish millions of copies of pamphlets that don't work. Although they are pretty, the reason they don't work is because they were developed like an ad, and patients won't use those types of materials. Patients really need information to help them understand if the drug will help them, how to take the drug correct-

**THOUGHT LEADERS**

**WM. RAY BULLMAN.** Executive VP, National Council on Patient Information and Education, Bethesda, Md.; NCPIE is a leading authority for informing the general public and healthcare professionals on safe medicine use through better communication. For more information, visit [talkaboutrx.org](http://talkaboutrx.org).

**TED DACKO.** President and CEO, HealthMedia, Ann Arbor, Mich.; HealthMedia is a technology and health-management company that builds and delivers individualized, one-to-one solutions for the pharmaceutical and medical-device markets, the healthcare market, and organizations focused on disease management. For more information, visit [healthmedia.com](http://healthmedia.com).

**SCOTT GREISLER.** Senior VP, Dorland Global Health Communications, Philadelphia; Dorland is an independent advertising and PR agency specializing in healthcare/pharma, biotech, and medical devices. For more information, visit [dorland.com](http://dorland.com).

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and robust clinical development solutions to biopharmaceutical companies. For more information, visit [kendle.com](http://kendle.com).

**MAXIMILIAN LEBMEIER.** Project Manager, Global Health Economics and Outcomes Research, Abbott GmbH and Co. KG, Ludwigshafen, Germany; Abbott is a global, diversified healthcare company devoted to the discovery, development, manufacture, and marketing of pharmaceutical, diagnostic, nutritional, and hospital products. For more information, visit [abbott.com](http://abbott.com).

**PETER NALEN.** President and CEO, Compass Healthcare Communications, Princeton, N.J.; Compass Healthcare Communications is a full-service, online marketing agency. For more information, visit [compasshc.com](http://compasshc.com).

**ADRIA NULLMEIER.** Tazorac Brand Manager, PediaMed - The Pediatrics Company, Florence, Ky.; PediaMed is devoted to identifying, developing, and marketing branded pharmaceutical products within the pediatric market. For more information, visit [pediamedpharma.com](http://pediamedpharma.com).

**TARA OLSON.** Owner, AllPoints Research Inc., Winston-Salem, N.C.; AllPoints Research is a

full-service marketing research firm that employs state-of-the-art quantitative and qualitative techniques to deliver accurate, prompt, and insightful results. For more information, visit [allpoints.biz](http://allpoints.biz).

**ROBERT PAULSON.** Director of National Accounts, Marketing Technology Solutions Inc., Edison, N.J.; MTS is a health-focused information company that provides quality consumer engagement and data insights to drive business results. For more information, visit [mateso.com](http://mateso.com).

**FRED PETHER.** CEO, PharmaDesign Inc., Warren, N.J.; PharmaDesign designs and manufactures compliance aids and compliance packaging for the pharmaceutical industry. For more information, visit [pharmadesign.com](http://pharmadesign.com).

**DOROTHY SMITH.** President and CEO, Consumer Health Information Corp.; Consumer Health Information is an industry leader in patient education with cutting-edge expertise in clinical practice, consumer behavior, and direct-to-consumer communications. For more information, visit [consumer-health.com](http://consumer-health.com).

**PETER NALEN**

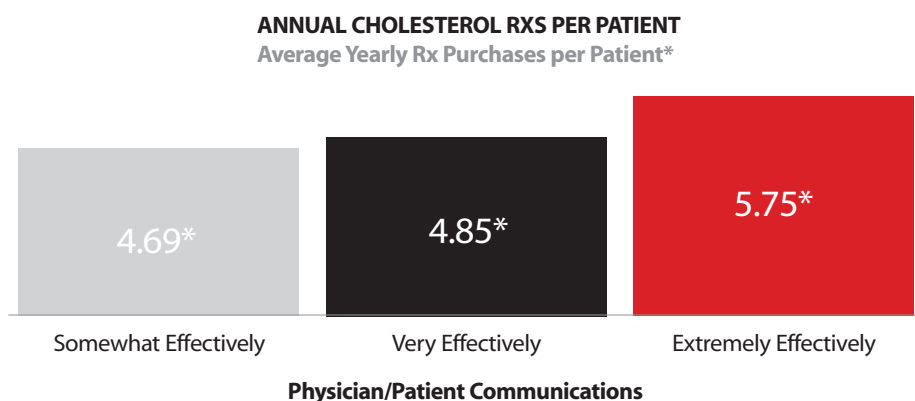
**Compass Healthcare Communications**

THE BEST WAY FOR THE INDUSTRY TO REDUCE PATIENT ANXIETY ABOUT MEDICATIONS is by ensuring that patients' information and educational needs are met in a format that is most accessible to them. We need to understand each patient's preferred method for gathering information, whether on the phone, online, or on TV.

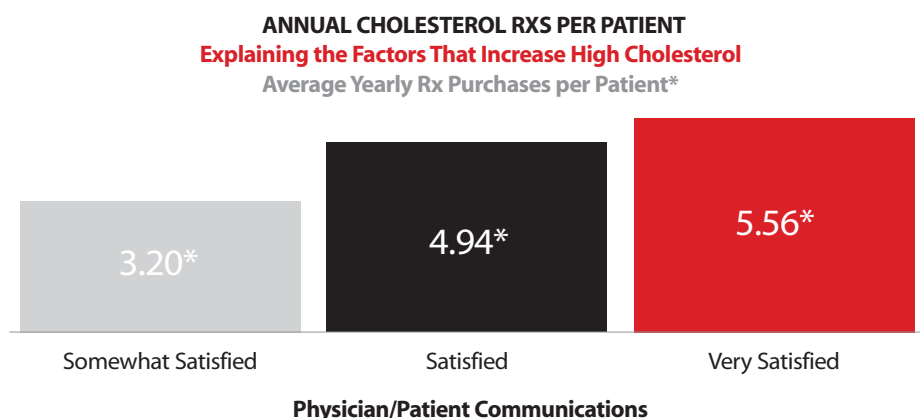


### The Compliance Difference

#### A Look at High Cholesterol



**Conclusion:** Patients who view their communications with their physician as extremely effective had 23% more prescriptions in a year for the cholesterol medication studied than those patients who viewed the communication as somewhat effective.



**Conclusion:** Patients that were very satisfied with the explanation of the factors that increase their cholesterol filled 74% more prescriptions in a year than patients who were somewhat satisfied.

Note: Marketing Technology Solutions ran two surveys with 340 and 341 patients respectively and matched the surveys to actual pharmacy claims data on a one-to-one basis.  
Source: Marketing Technology Solutions Inc., Edison, N.J. For more information, visit mateso.com.

ly, and what to do if they think they are having a side effect. Once they start taking a drug, patients need to know how to determine if the drug is helping them get better. Patients will not drop out of treatment if they can see personal progress. To develop patient-education materials that work requires translation of the clinical information, which then must be integrated with behavior modification techniques that will target the potential patient compliance problems that can be expected to occur with the specific medication, disease, and patient population. The content and design go hand in hand; they must meet patient-education requirements and must help promote empathy and trust.

**PAULSON.** Despite the industry's well-conceived and executed post-prescription compliance programs, overall adherence rates have remained unchanged at about 50% for many years. Noncompliance continues to plague the industry because it is tangled in a multitude of psychosocial factors. More than half of all patients forget verbal information communicated by their physicians, and 60% forget what they are advised to do within one hour of leaving the office. Worse yet, only 35% of patients receive instructions on how to take their medications to begin with. It is crucial for a pharmaceutical company or brand team to get patients information and educate them before they meet with their physicians.

**NALEN.** The major reason compliance has been a difficult nut to crack is because the industry is requiring significant behavior change and adoption by consumers. People are

more compliant with vitamins than prescription medications. Why? Because we took vitamins as kids, not Flintstones chewable Lipitor. Starting in childhood people develop habits, such as taking a vitamin or brushing their teeth. It is not a natural behavior for people to take a prescription medication because we never adopted it in our development years. We need to address compliance from a behavior perspective rather than from an advertising and communications perspective. There are many tools now available to do this, so hopefully compliance will only get better.

**BULLMAN.** We subscribe to the belief that a better informed patient is better equipped to use his or her medicine safely and appropriately, which can lead to better adherence and health outcomes. When developing educational messages and materials, not just for the public but for health professionals and the pharma industry, there is the need to meet in the mid-

## 5 Pieces of Essential Information for Good Patient Compliance

Based on hundreds of physician/patient interactions, PharmaDesign researchers conclude that patients who are aware of the following information tend to be twice as compliant, in terms of medicine taken correctly, as patients who don't know this information:

- 1 What the drug is and how it works in terms that are easily understandable.
- 2 How and when to take the drug.
- 3 How long the medicine will have to be taken.
- 4 What side effects can be expected.
- 5 The consequences of stopping the medication.

Source: Fred Pether, CEO, PharmaDesign Inc., Warren, N.J. For more information, visit [pharmadesign.com](http://pharmadesign.com).

## TARA OLSON AllPoints Research

Consumers are schooled on what to ask before they start to take a medication, but they are not schooled on how long to stay on the prescription. **THEY NEED TO UNDERSTAND WHAT THE CONSEQUENCES ARE IF THEY STOP TAKING THEIR MEDICATION.**

dle to close what has been referred to as a Grand Canyon-sized communications gap.

**OLSON.** Humans are fickle, and doctors can't control what goes on in a patient's household. Often patients are not forthcoming with information; they do not call their doctor to say they have stopped taking their medicine. Or a patient may only see a doctor once a year, so the physician may not find out a medication wasn't working or that the patient stopped taking the prescription until he or she comes back for the annual visit.

**DACKO.** Compliance progress should change for the better. With the advancements in technology and the Internet, companies can create a one-on-one experience with each individual user. Initially, pharmaceutical firms simply tried to repurpose their pamphlets for use on the Internet, but they are now starting to take advantage of the medium. There are Websites where people can build their own cars and see what they will look like; this type of personalization should be used for patient compliance.

## MEDICINES IN THE NEWS

*Negative news about pharmaceutical companies and their products is having a deleterious impact on an already poor compliance picture in the United States. Experts interviewed for this Forum say the industry needs to alleviate patient fears and keep noncompliance from rising.*

**BULLMAN.** We are already starting to witness some implications of "medicine in the news." It is certainly likely that across the board consumers may stop, or have already stopped, taking necessary medicines or have not filled their prescriptions. It is as likely that prescribers are



not writing prescriptions as frequently for some medicines as well. A study was just released revealing that there has been a 20% drop in prescriptions written for pediatric antidepressants, which follows negative press in that area last year. Uncertainty or confusion about medicines in the news certainly has an impact on consumers' decisions to take medicines or to administer medicines to their children. This is a clear call for the need for a very frank and personalized discussion about medication risks, benefits, and safety. Consumers should be informed continuously that all medicines have risks. That discussion should begin when the medicine is prescribed or recommended. Consumers also need to recognize the value of medicines — properly used — and that everyone has some personal responsibility to know about their medicines. This means, for example, speaking up and asking questions when a medicine is being considered as part of treatment. It also means keeping a current list of medicines and making sure healthcare providers review that list before any new medicines are prescribed or recommended. And it means knowing about possible side effects and what to do if they occur, for example.

**OLSON.** Recent product recalls are expected to have an impact on patient compliance. Many times when consumers hear things on the news they react without considering the consequences. In the case of Vioxx, people are

## Patient Compliance at Work

A few of the executives interviewed for this Forum provided examples of successful patient-compliance initiatives.

### Eli Lilly & Co./PharmaDesign The Forteo Bone Model



**PharmaDesign** produced the Forteo Model for Lilly to help show patients the fragile condition of their bones and the significant improvement in bone

strength and density that could result from treatment. Lilly's Forteo is approved for use in both men and postmenopausal women with osteoporosis who are at high risk for having fractures. The portable teaching aid is a 3-D model that precisely replicates before-and-after treatment bone biopsies from the hip of a Forteo clinical-trial patient.

"Forteo had severe compliance problems because it is not easy to take; patients have to inject themselves every day for up to two years for what is basically an asymptomatic condition," says Fred Pether, CEO of PharmaDesign. "It is very difficult to explain to patients about their condition when they can't see it. They don't feel osteoporotic and don't understand why they should go through the hassle of injecting themselves. Additionally, the treatment can be expensive, depending on insurance coverage."

To help deal with this compliance issue, PharmaDesign produced a model based on bone biopsies that Lilly took from a patient with a severe case of osteoporosis before treatment and then another biopsy from the same patient after 21 months of daily injections with Forteo.

"Doctors and patients can instantly see how fragile the before biopsy model is and the incredible difference in bone regrowth in the after model," Mr. Pether says. "The model enabled Lilly to convince doctors and then, more importantly, it allowed doctors to convince patients they were doing something worthwhile."

The introduction of this model coincided with a significant increase in the sales of Forteo, and the team was awarded Lilly's President's Award, the

company's highest recognition for work done by Lilly and the first time that the President's Award was given for a sales aid. More than 40,000 models have been provided to physicians in the United States, and another 20,000 to physicians in various other countries.

### GlaxoSmithKline/HealthMedia Committed Quitters for NiQuitin CQ



**HealthMedia** created a program to support GlaxoSmithKline's NiQuitin CQ, a stop smoking aid

available in the United Kingdom, Germany, and the Republic of Ireland. The product is designed to help alleviate a smoker's physical dependence on smoking. GSK has a similar program for its U.S. products: NicoDerm CQ, Nicorette, and Commit.

HealthMedia designed the European program, click2quit.com, to help smokers break their associated psychological dependence and improve their compliance with the treatment. The agency recently conducted a study to assess the results from the program. The results represent the first time that an online smoking-cessation support program has been clinically proven to increase quit rates — in this case, by 28%.

In the randomized controlled study, 3,971 smokers used the NiQuitin CQ 21mg patch and received either HealthMedia's tailored Committed Quitters Stop Smoking Plan (CQ Plan) or untailored support. The participants who were directed to the tailored Website completed an in-depth questionnaire that was developed by HealthMedia's team of healthcare professionals, including health educators, psychologists, and physicians. The

other participants were directed to a nontailored Website where they received generic information on how to quit.

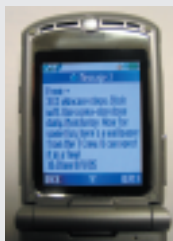
Participants who received the questionnaire answered 60 questions designed to understand their smoking history and habits, motivations for quitting, and perceived obstacles. Questions covered everything from internal barriers — such as readiness to quit, level of social support, and confidence — to condition-specific concerns, including years of smoking and addiction level. Once the questionnaire was completed, users received a tailored support program within 24 hours. Each smoker's plan remained available on the Website for 15 weeks. All participants were asked to complete 6- and 12-week follow-up surveys. Of those who used the product and received HealthMedia's tailored CQ Plan, more than half (55%) were able to sustain 10 weeks of continuous abstinence from smoking. This is a 28% increase in effectiveness over those using the product and the untailored support materials (43%). The trial also demonstrated that the CQ Plan helped smokers get closer to the recommended treatment goal of 10 boxes of medication over a 10-week period. The average number of boxes of medication purchased in the study was 9.16 for people in the tailored CQ Plan, versus 8.49 for people receiving the untailored materials.

"The CQ Plan combines the best of more traditional approaches to smoking cessation to deliver an effective yet affordable tailored health program," says Tom M. Dacko, president and CEO of HealthMedia.

The programs are deeply tailored, compared with one-size-fits-all brochures and are as effective and private as expensive one-on-one counseling and stop-smoking groups.

The program was conducted entirely online. All participants enrolled through the CQ product Website, which was advertised in the patient leaflet in the NiQuitin CQ range of nicotine therapies (patches, gum, and lozenges).

### PediaMed/Dudnyk Healthcare Group Tazorac Mobile Compliance Program



**Dudnyk Healthcare Group** created a program for Tazorac that was designed to encourage teens to regularly apply the acne medicine.

Messages are delivered through text messages received on teens' cell phones from a mobile "buddy" they selected. The program offers patients a series of incentives and rewards, such as wallpapers and ring tones throughout the treatment period.

"We had heard from our customers, the pediatricians, that one of the hardest things about treating acne is getting teenagers to stay compliant and use the medication properly and consistently," says Adria Nullmeier, Tazorac brand manager at PediaMed - The Pediatrics Company. Working with its ad agency, Dudnyk Healthcare, and Virtu Mobile, PediaMed looked into the mobile marketing programs that Virtu Mobile used in consumer fields.

"We thought this was a great option to communicate with this audience; statistics show that 16 million people between the ages of 10 and 18 use mobile phones," Ms. Nullmeier says. "We believed teens would be receptive to getting messages through this medium."

Messages, such as "remember to use a moisturizer" and "use a pea-sized dose," were sent to teens to remind them to use the medicine properly. By signing up on the Website, 8TDAZE.com, teens can opt in to the program. The Website, which launched in late July, has had more than 1,000 hits to date. The program is still in a pilot phase, and the company is evaluating preliminary results.

judging the severity of their pain and deciding they can just do without their medicine. In the case of the hormone therapy news, women rethought their treatment and many decided that menopause is a natural part of life and just stopped their hormone therapy, and then experienced severe symptoms. News does have a big impact on compliance. The best thing pharmaceutical companies can do is to provide doctors with information that they can give to their patients about the downside of discontinuing medication and the adverse reactions they can expect if they suddenly discontinue the medication.

**SMITH.** The No. 1 concern that consumers have about taking prescription drugs is the risk of side effects. If patients think they are developing a side effect or read in the newspaper that they might develop a severe adverse effect, that is one of the major reasons that people stop treatment.

**PAULSON.** The recall of products not only has a profound impact on the product and the manufacturer, but also on all stakeholders in the industry. These events call into question the actions and judgments of everyone in the drug-development process, from regulators to prescribers. It can actually erode confidence in pharmaceutical research and development, clinical trials, and the innovation process, and it can raise questions about how companies market products to physicians and consumers, as well as how products are priced. The industry has long attached the higher prices of medicines to increased spending on research to develop a drug. When something is wrong with a product, the industry is saying the research wasn't really qualified.

**GREISLER.** There is a definite subsection of the patient community that is always skeptical and would not take the medication anyway. Then there is the group who is always willing to try what it needs to and goes back to the doctor to ask if they are taking the right medication properly. Bad news will have a short-term impact on overall compliance, but over the long term it won't have a major influence.

**PETHER.** Bad publicity about a drug withdrawal or lawsuits against pharmaceutical companies just serves to undermine people's general attitudes about pharmaceuticals, which already aren't particularly good. So the Vioxx recall is one of those things that will just make a bad situation worse. The industry would benefit if companies came together and created a public campaign about compliance. *Pharmacy Times* estimates that up to 340 peo-



### SCOTT GREISLER Dorland Global Health Communications

PHARMA COMPANIES NEED TO LISTEN TO THEIR PATIENTS, IDENTIFY THE MAIN REASONS WHY PEOPLE ARE NOT COMPLIANT, and then address each of those barriers with easy-to-use tools.

ple die every day as a result of noncompliance. This is shocking; it is the same as a jumbo jet crashing every day. But this doesn't get public attention. It may help if patients saw public-service announcements on the importance of taking medication and what can happen when they stop.

**NALEN.** There will definitely be a scare factor for certain segments of the population following a product recall. We have found the best way to reduce patient anxiety is through information and education. Pharmaceutical companies need to be sure they are the ones meeting patients' information and education needs at this critical time and in the most desirable format — a toll-free number, Internet, direct mail, and so on. If they don't, someone else will.

## Compliance Toolbox

Many options exist for pharmaceutical companies to make medication compliance easier and to connect with patients.

These recently launched products represent a selection of new tools that can help patients achieve better outcomes through compliance.

### CEREPAK



**DARYL MADEIRA** is Manager of Compliance Packaging at MeadWestvaco Healthcare Packaging, Stamford, Conn., a division of MeadWestvaco, a

global packaging company that delivers solutions and products to the world's most recognized companies in the food and beverage, media and entertainment, personal care, cosmetic, and healthcare industries. For more information, visit [meadwestvaco.com](http://meadwestvaco.com).

Cerepak is a standard blister pack with an electronic module or computer chip sealed within the package, designed to enhance physician and patient interaction, brand loyalty, product differentiation, and persistence.

Using radio frequency, the data upload to a PC database (or directly to Internet-based software) via a mouse pad-like "reader." Cerepak records the time and date of the removal of medication from the package, as well as the specific pill location on the package. The ability to track the removal of a specific tablet is a critical capability for titration, dosing studies, and placebo periods.

Cerepak also integrates a patient questionnaire into the package with reusable buttons on the package. The questionnaire logs patient side effects, such as pain, insomnia, thirst, and time to onset, as well as time-stamps for these responses.

"Cerepak's value lies within the data," says Daryl Madeira, manager of compliance packaging at MeadWestvaco Healthcare Packaging. "We also have software that can extract those data in their raw form to be displayed to the patient, the doctor, or whoever is analyzing the treatment."

Electronic compliance data can then be used for submission or as an intervention to improve compliance, by empowering patients

to change their behavior based on actual compliance data. Cerepak improves the speed, cost, and accuracy of packaging and patient diary reconciliation in clinical trials and further enables electronic clinical-trial efficiency and data flow.

Cerepak was launched this summer and is being initially targeted to the clinical market space, with plans for introduction to the commercial space in early 2006.

"We recognized the need to capture and get better data for trials in the clinical space, which is where the demand initiated," Mr. Madeira says. "We are in the process of expanding into the larger segment of smart packaging. The commercial space has a different set of needs, so we are adapting Cerepak's use based on what we have learned from this package."

### ORBIT CUFF



**CHRISTINE WINTERS** is Product Manager, Cuffs, at SunTech Medical Inc., Research Triangle Park, N.C., a producer of motion-tolerant,

noninvasive blood pressure monitoring products and technology. For more information, visit [suntechmed.com](http://suntechmed.com).

SunTech Medical Inc.'s knowledge of the ambulatory blood pressure market enabled the company to develop a way to overcome the limitations and obstacles to obtaining a successful series of blood-pressure readings during the data-collection period of a clinical trial. The two key points that the company addressed with the development of its Orbit cuff line were patient compliance and eliminating the issue of the cuff sliding

down the patient's arm throughout the study.

"In designing the integral sleeve with a lycra material, we were able to comfortably hold the cuff on the patient's arm without affecting the measurements," says Christine Winters, product manager, Cuffs, at SunTech Medical. "Not only does this keep the patient from getting aggravated, but it also ensures consistent measurements throughout the study because the cuff remains in place for each reading."

Doctors have commented on how much more compliant their patients are throughout the ambulatory blood-pressure test period.

"By using this tool, doctors and patients are happier," Ms. Winters says. "And the rich amount of data collected means that the doctors have a more complete picture of their patients' blood pressure trends over that test period."

The Orbit cuff line was launched in September and is part of the Oscar 2 product line, SunTech Medical's ambulatory blood pressure monitor. The Oscar 2 is used to monitor patients over a 24-hour period while they go about their daily activities.

"These monitors, while ideal for clinical trials, are not limited to clinical-trial use," Ms. Winters says. "The Orbit cuff and Oscar 2 monitor are also used for aiding in the diagnosis of hypertension, as well as monitoring responses to hypertensive drug treatments."

### SIMpill



**DAVE ROSA** is President and Chief Advisor of Clinical Technology Advisors Inc., Acton, Mass., a bridge between technology companies and

those in the clinical-trial industry who are considering the implementation of

technology solutions to expedite the clinical-trials process. Clinical Technology Advisors is the primary distributor of SIMpill in North America and Europe. For more information, visit [clintechadvisors.com](http://clintechadvisors.com).

SIMpill, a product developer based in South Africa, is addressing the problem of medication compliance through the SIMpill medication bottle. This is a standard medication bottle with the components of a quadband cell phone attached to it. When a patient opens the bottle, the phone delivers a message to a central server documenting the "medication event." The message also contains a unique pill bottle ID number, a date/time stamp, and the battery level. The central server knows the patient's drug regimen and whether the incoming message is received within the set time limit. If a message is not received within the allotted time, a chain of events takes place.

"If a patient is supposed to take a pill at 8 a.m. and 8 p.m., we program that regimen into the server; if by 8:30 a.m. the server hasn't received a notice that the patient's bottle has been opened, a text message will be sent to the patient's cell phone with a reminder to take the medication," says Dave Rosa, president and chief advisor of Clinical Technology Advisors Inc., the product's U.S. distributor. "If within 15 minutes of that patient reminder the server hasn't gotten a signal that the pill bottle has been opened then a second message is sent to a designated caregiver."

Data on compliance levels, as measured by the device, are stored for future analysis.

"One of the things that distinguishes this tool from other solutions is that there is the possibility of a real-time intervention into a subject's life," Mr. Rosa says.

The product has more than 6,000 users in South Africa and Europe. SIMpill was launched in the United States in September and is being used in the clinical-trial space.

**DACKO.** There are two primary barriers to compliance that we run into with just about every medication: concern over side effects and the perceived benefits of the drug. If people are feeling good, they often stop taking their medication. Or, if people with asymptomatic conditions don't notice any benefits, they may also stop taking their medication. Couple these barriers with recent media coverage regarding problems with certain drugs, and the result is increased noncompliance.

**JONES.** The impact of negative product news on compliance isn't as great in the clinical-trial setting as it would be in the general population because of the patients' close relationship with their doctors.

## COMMUNICATION BREAKDOWN

*The main cause for noncompliance has been identified as a breakdown in communication at many levels: between pharmaceutical companies and physicians; between physicians and patients; and between pharmaceutical companies and patients. Experts interviewed for this Forum believe better communication is a first step to improving the noncompliance and persistency problem.*

**SMITH.** The first step is ensuring that all the materials are written so patients understand them and are motivated to follow the instructions. The second step, where many pharmaceutical companies are falling short, is keeping physicians and pharmacists informed as to the various types of programs being developed for consumers and patients and providing health professionals with a quick background on how these patient materials can be used effectively in their day-to-day practices. Pharmaceutical companies have to do more than provide these healthcare professionals with a pad of tear sheets to give to a patient.



**WM. RAY BULLMAN**  
National Council on Patient  
Information and Education

All of the stakeholder groups — pharma companies, prescribers, pharmacists — have a role to play when there is confusion or uncertainty in the marketplace about a medication and **THAT MEANS ONGOING AND CONSISTENT COMMUNICATIONS, AS WELL AS CONSISTENT FULL DISCLOSURE FROM PHARMA COMPANIES.**

To make the system work, patients need high-quality information that motivates them to take the medication, and health professionals need assurance that the patient information is accurate and will reduce patient counseling time in their busy practices. The best programs will encourage consumers to contact their physicians so that the





**FRED PETHER**  
PharmaDesign

Noncompliance is more often than not a communications problem, and it has become more acute over the last decade.

UNFORTUNATELY, THE DAYS OF BEING ABLE TO SIT DOWN WITH THE DOCTOR AND TALK ABOUT THINGS, INCLUDING PROPER MEDICATION USE, ARE LONG GONE.

physician does not feel isolated. Many DTC programs have run into problems because they did not gain physician cooperation. There has to be teamwork and good communications between the pharmaceutical industry, health professionals, and any educational programs developed for patients and consumers if the patient compliance cycle is ever going to improve.

**NULLMEIER.** Lack of communication is one of the aspects of noncompliance, and pharmaceutical companies can help by providing the tools to physicians to help with interaction with the patient. By providing the right tools, companies can make it easier for physicians to instruct patients on how to use the product properly, things to look for when using the product, and so on.

**JONES.** The biggest breakdown in compli-



**TED DACKO**  
HealthMedia

THERE IS TREMENDOUS VARIABILITY IN INDIVIDUALS AND THEIR BARRIERS TO TAKING THEIR MEDICATIONS. It is absolutely imperative that we understand the impact that variations within populations have in regard to compliance issues; there is no one simple answer to noncompliance.

ance is communication failure. This is one of the key areas where companies can help by giving physicians the messages and materials to talk to their patients in a friendly and informative way. Providing materials for communication is important, and supporting that communication is essential.

**GREISLER.** Since there is a breakdown in communication, pharma companies have to assume the responsibility to provide additional data, whether it is Internet information, print materials for distribution in the physician office, or information given out with the medication at the pharmacy. The more pharmaceutical companies do to increase patient compliance, the more everyone benefits, not only from a financial standpoint, but from a healthy outcomes standpoint.

**BULLMAN.** I am not sure the compliance problem is completely solvable. The problem is so multidimensional and so behaviorally laden. That being said, however, better communication is really central to compliance improvement. NCPIE worked very closely with the American Medical Association to develop guidelines for physicians for counseling patients about prescription medicines in the ambulatory setting; these guidelines provide an efficient framework for communicating with every patient, particularly when a new prescription is written. The provider is encouraged to touch on the overall treatment plan; the name of the medicine; what it is supposed to do; how and when to take it and for how long; the appropriate foods, drinks, and activities to avoid while taking the medicines; side-effect recognition and management; information on refills; and the availability and importance of written information. If that dialogue could occur with the 3.2 billion outpatient prescriptions, there is a clear likelihood that safer, more appropriate medicine use would occur.

**DACKO.** It is very important for pharmaceuti-

cal companies not to position their programs solely as medication compliance programs. Their efforts should be positioned as a patient-education program with a focus on medication compliance. The industry will turn consumers off if it takes a hard-sell approach. But if a pharmaceutical company's programs teach

## Recommendations to Improve Compliance for Pharmaceutical Manufacturers

- Individually and as an industry, support **DEVELOPMENT OF A NATIONAL PUBLIC-AWARENESS CAMPAIGN** promoting patient medication compliance with therapy.
- Support health professionals' **EDUCATION TO DEVELOP EFFECTIVE COMMUNICATORS** in a patient-centered healthcare system.
- Recognize and promote **ROLE MODELS** who can demonstrate improved compliance from a patient-centered approach.
- **PROVIDE NCPIE'S** "Get the Answers" questions with all responses to consumer information requests or toll-free program responses.
- Support **INTERDISCIPLINARY TEAMS** that provide patient education and programs for compliance and health promotion.

Source: National Council on Patient Information and Education, Bethesda, Md.  
For more information, visit [talkaboutrx.org](http://talkaboutrx.org).

## DR. JANET JONES Kendle

For any patient-related communications, **THE MOST EFFECTIVE MEDIUM OF DISSEMINATING MESSAGES IS THROUGH THE SUPPORT OF DOCTORS** who spend a significant amount of time with patients in clinical trials.



people how to, for example, better manage their diabetes and impart the importance of taking the medication as part of that effort, then a company will develop a better relationship with the patient.

**NALEN.** We conducted an online study, including about 80 prescription drug brands, to gauge what people are looking for when they go online. We found that 20% of people who type a brand name into a search engine have an unfilled prescription in their hand. These are people who needed more information from their doctor to feel comfortable enough to fill that prescription. The doctor writing a prescription is a starting point for a pharmaceutical company to answer the patient's questions. Patients and sponsor companies are going to experience better outcomes if they have a better start. As online marketers, we believe a Website address should be on every sample bottle and every piece of patient-support material. It should be a sort of "prescription for information" provided with the drug prescription.

**PETHER.** Compliance is primarily about the communication between the physician and the patient. Tools, such as anatomical models, by themselves are not going to do anything to make the patient more compliant. But an anatomical model can precipitate a conversation between a physician and patient about a condition, which can have a direct effect on compliance.

## TAKING IT TO THE PATIENT

*In 2004, the FDA issued a guidance on patient package inserts, encouraging pharmaceutical manufacturers to provide information with their products in patient-friendly language. This is just one example of how the industry is increasingly interacting with the patient with product information and messages of compliance.*

**NULLMEIER.** Through our mobile compliance program for Tazorac, we interact directly with the patient throughout the treatment period to remind them how to properly use their medication for the best results and to avoid tolerability issues. Patient starter kits are another way we communicate with patients to improve compliance. These kits contain a brochure that describes in layman's terms or teen terms information about using the product.

**LEBMEIER.** There are many different ways to make compliance easier for patients. One way is through packaging; offering blisters packs with information printed on them is one example. Companies can support patients through reminder devices or offer them some feedback tools via the Internet, mobile phones, or call centers. Whatever method is used, it is important for patients to receive information about a drug's effects, the impact the drug might have on their illness, and the importance of taking the medicine.

**SMITH.** Patients need a consistent message. A big problem today is that patients are receiving different information from the pharmaceutical industry (through the product Websites, FDA-approved patient package inserts, DTC collateral materials, etc.) and health professionals. The Consumer Medication Instruction sheets distributed by pharmacies are developed by a variety of different vendors and vary significantly. Some are good, and some are poor. There is a very high probability that the FDA-approved patient package inserts that a company has developed will not be given to the patient at the pharmacy; and instead the patient will receive medication instructions that may be confusing and not contain risk management information that the pharmaceutical company wants patients to receive. The



## ROBERT PAULSON Marketing Technology Solutions

**PHARMACEUTICAL COMPANIES NEED TO STEP UP TO THE PLATE AND EDUCATE PATIENTS THROUGH THE WHOLE PROCESS**, not just after they get the prescription, but before they go to the doctor by teaching them about the disease and symptoms, how to take the medication, and how to deal with any side effects.

other major problem with both the pharmaceutical company and the pharmacy medication instruction sheets is that the same sheets are handed out at pharmacies every time the patient receives a refill. Patients throw out the instruction sheets after the first few refills, which also helps explain why patient retention for chronic disease medications is such a major problem for the pharmaceutical industry. Patients need different information on the first prescription than they do for subsequent ones. When people first start taking a medicine they need to know how to take it correctly. But once the person begins using the medication regularly, then side effects could occur. So at a refill, it would be beneficial to provide the patient

with information on how to recognize the early warning signs of commonly expected side effects and the appropriate steps to take. Patients need to know if they can self-treat minor annoying side effects, such as a dry mouth, or whether they need to contact their doctor. It would help patients greatly if the information with the next prescription explained that not only is dry mouth a side effect, but it can be effectively managed by sucking an ice chip or hard sour candy, and reminded patients to brush their gums to avoid periodontal disease associated with dry mouth. This enables patients to manage the side effects. Currently most information given to patients just tells them that they might get dry mouth and leaves it at that.

**OLSON.** There needs to be more work done on making the patient package inserts user friendly. For example, companies need to consider whether the type size is large enough for older patients to see. Also, the information has to be presented in such a way that consumers know they are receiving something different as opposed to the scientific jargon they usually receive.

**PETHER.** We see quite a lot of companies providing patient prescribing information, but we see very little in terms of patient uptake of that. Part of the reason is that about 30% of the population is functionally illiterate, and many people don't speak or read English as their first language. Patient prescribing info is a nice concept, but in practice it has its drawbacks.

**PAULSON.** For way too long the industry created an air of mystery around the labeling, with terminology that was intimidating and not understandable to the average patient. Basic education that follows the patient throughout the entire care continuum is probably the best way to help compliance and persistency. And the place to start is with the written material that accompanies the product.

**DACKO.** Some companies will send a sheet of paper home with patients that is provided by the pharmacist, and others will capture the names and addresses of the people who purchase the drug and then send them information afterward. But since most drugs picked up at a pharmacy don't come with packaging, there's limited opportunity to include collateral in the box.

**NALEN.** Patients sometimes respond better when they really understand why they should take a medicine. Patient-centric tools are great for this type of education. Some of our clients have had success with interactive e-learning modules that ask the visitor questions, show

how the drug works, demonstrate what the drug is supposed to do, and explain what the implications are when the medication is taken and when it's not.

**BULLMAN.** Written drug information can be critically important to patients understanding the instructions for use, the precautions, the side effects, warnings, and other risk-related information. But the written information should not be just a static communication vehicle, a piece of paper stapled to the bag, as it were. Value needs to be placed on the information. And that information is much more likely to be valued and referred to if key points are reviewed and reinforced by the healthcare professional. This is a great opportunity to encourage the consumer to read and heed the written information that comes with the medicine.

**GREISLER.** The best thing a pharmaceutical company can do is put together really good CRM programs and target them so patients understand both the psychology and social reasons behind noncompliance. If companies provide the right tools to target the specific reasons for noncompliance, they will be able to help patients.

## THE COST OF NONCOMPLIANCE

*For patients, the costs of noncompliance are significant, whether realized through exacerbated health problems and more medications, hospital stays, expensive treatments, or death. This message is not often communicated to the patient. While experts interviewed for this Forum agree that as a stand-alone message, cost might not be the most powerful driver for compliance, it certainly should be included in the messaging mix to give the patient the complete picture.*

**OLSON.** The cost aspect of noncompliance is certainly one of the messages that the industry needs to get out there because patients don't make that link. Patients don't have a clear understanding of the importance of taking medications so as to not develop more serious, and expensive, conditions.

**LEBMEIER.** It is better to start with messages about patients' well being, including the complete definition of health as defined by the World Health Organization, which is not only the absence of sickness but the quality of life and the social and psychological well-being of the patient. This message should be combined with an explanation of the financial benefits of optimized patient compliance. If a patient is sick, this will not only have an impact on his or



**DR. DOROTHY SMITH**  
Consumer Health Information

**BETWEEN 10% TO 20% OF PATIENTS DO NOT GET THE INITIAL PRESCRIPTION FILLED BECAUSE THE PHYSICIAN HAS NOT CONVINCED THEM WHY THEY NEED TO TAKE IT.** It is very important for the industry to provide physicians with practical and time-saving counseling tools so that they can be more effective explaining the reason the prescribed medication can help the patient.

her health, but the patient will lose income from work missed and will have to pay extra expenses for recovering. Avoiding the complications of noncompliance means avoiding expenses for the patient, as well as for the payers.

**PAULSON.** It is important to motivate patients to improve their quality of life; and if they are compliant, they will actually have financial savings. But many patients don't even understand the key attributes regarding their specific medications, the impact on their health status, and the importance of a drug's use in relation to their health outcomes. With some segments of the patient population, finances can undermine the ability to access appropriate medication, but I don't believe a message about the financial stake will drive compliance among the majority of patients.

**NALEN.** Because the challenge to compliance is primarily about changing behavior, the financial message alone probably won't resonate. Adding the financial message in the context of other reasons for taking the

medicine could be effective. Some compliance issues may just be because a patient can't afford to take his or her drug every day. Explaining that they could avoid a costly hospital stay down the road by taking their

meds today might be an important message to include.

**DACKO.** Communicating a financial value message to the patient certainly would

## Sound Bites from the Field

### PHARMAVOICE ASKED EXPERTS TO DISCUSS WHETHER MEDICARE PART D PROGRAMS OFFER AN OPPORTUNITY TO IMPACT PATIENT COMPLIANCE. ADDITIONALLY, EXPERTS WERE ASKED HOW DISEASE-MANAGEMENT PROGRAMS CAN BE MOST EFFECTIVE IN TERMS OF IMPROVING COMPLIANCE AND PERSISTENCY.

#### MEDICARE PART D



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technologies and customer relationship management applications for chain pharmacies, hospitals, and pharmaceutical marketers. For more information, visit [ateb.com](http://ateb.com).

“The vision of CMS is primarily for medication therapy management services (MTM) to become the cornerstone of the Medicare Prescription Drug Benefit programs. Medicare Part D programs offer an unprecedented opportunity to impact patient compliance. This is due partly to the increased eligibility of patients for affordable prescription medication assistance. MTM's mission to improve patient education allows the industry to proactively increase focus on patient adherence. MTM's strategy to identify high-risk patients and implement intervention plans, in concert with other sponsored complementary education programs, will improve compliance. Because of this endorsement and the impact on drug affordability, the industry trend for compliance and preventive wellness will increase.”



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“The implementation of the prescription

drug benefit will undoubtedly serve as a catalyst to drive significant changes in the way medical care and products are provided and reimbursed for seniors in the United States. The implementation of Medicare Part D and the enhanced prescription drug coverage will ultimately have positive implications on patient compliance, adherence, and drug use because financing for prescription drugs will be minimized as a barrier to patient's prescription needs.

Additionally, the MMA mandates the implementation of MTM services or programs that optimize therapeutic outcomes for high-risk Medicare beneficiaries who receive medication for chronic diseases. Specifically, the legislation requires that all prescription drug plan sponsors and Medicare Advantage plans offer a MTM program to help ensure drugs are used to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events, including adverse drug reactions, in certain high-risk patients.

In essence, MTMs are designed to increase adherence and decrease adverse drug events among the Medicare population by calling for medication treatment plans, regular drug reviews, therapy response monitoring, verbal education and training, and support services for patients. Ultimately, the Medicare Part D change, coupled with enhanced technologies within the pharmacy and physician office, will serve as catalysts to drive patient compliance.”

#### DISEASE-MANAGEMENT PROGRAMS



**HELEN APPELBAUM** is Partner and Chief Operating Officer, of Flashpoint Medica, New York, an agency whose goal is to identify new opportunities in pharmaceutical marketing and a member of the Omnicom Group of healthcare

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“While diet plans and exercise regimens are an essential part of a healthy lifestyle, disease-management programs generally center around chronic diseases such as diabetes, heart failure, and asthma, which are conditions that have high comorbidities. While brochures and reading materials are important, the most effective programs are interactive, allowing patients to be involved in — and have some control over — their own care and well-being. Examples might include nurse interventions, including phone calls and/or visits to patients, and e-mails to and from patients, who can provide updates on their care and ask questions they may have about their treatment. As we become increasingly more sophisticated in the use of electronic and digital technologies, patients have more, easier, and faster ways to monitor heart beat, blood pressure, blood sugar levels, lung functions, and weight. On the simplest level, patients with heart failure can weigh themselves at home and phone in their reading to nurses, who can then follow their progress regularly. On the other hand, newly developed pacemakers allow heart patients to phone into a center, which can measure their heart rates and then transmit the results via electronic communications to their doctor or center of care.”



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“Well-conceived patient relationship-oriented programs can improve compliance and generate ROI, especially for expensive biologics where adherence is vital for successful outcomes. While

help with compliance. By doing so, a company would be more likely to get a health-care plan to endorse its compliance program and encourage participants to use a medicine.

**PETHER.** The drug companies are not taking advantage of the opportunity to make people aware of the fact that not taking their medicines can have very severe consequences for their health, their finances, their health

insurance, and the economy as a whole. ♦

PharmaVOICE welcomes comments about this article. E-mail us at [feedback@pharmavoice.com](mailto:feedback@pharmavoice.com).

marketers have traditionally used brochures and other reading material to keep patients involved, many are now moving to more patient-driven programs that meet the needs of individual patients. With wide differences in geographic, psychographic, demographic, and socioeconomic orientation, a one-size-fits-all approach simply does not work in today's busy and heterogeneous world.

For a disease-management program to be successful, we need to solicit input and feedback from patients, then develop customized programs based on the data. It's all about identifying and meeting patients' needs with specific information that fulfills their specific needs. This helps build relationships and strengthens compliance. Technology and other communications platforms allow us to reach, collect, and distribute treatment information more effectively, thereby enhancing compliance. Throughout this process, patients come to rely on the source that provides the information they seek and directly fulfills their needs. Even with the increasing sophistication of technology, it is vital to continue to develop effective, successful patient-education programs that keep patients informed — and even engaged — to assure ongoing compliance and persistency. "



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"Disease management is such a big topic, and compliance programs are a smaller segment in this area. What we know is 'good content' is relevant to the patient and is critical in either an adherence or disease-management program. In addition, understanding a patient's belief system about his or her medication has a tremendous influence on the patient's ability to comply with the medication regimen. Designing programs that

assess patients' behavioral beliefs and deliver content to help patients overcome these viewpoints is more effective than having programs without these processes. To date, companies have seen that these programs produce significantly better results in patient adherence and are now measuring the health outcome value of improved adherence.

Consider the cholesterol/lipid category of devices and medication. Using Liposcience's diagnostic test in conjunction with lipid-lowering therapy can give patients and their physicians a more accurate reflection of the benefits medication adherence is having on the patient over time. This diagnostic is much more than a simple blood test that just measures LDL and HDL levels. This test can not only assess cholesterol levels, but the cholesterol particle size, which many now view as an early precursor to coronary heart disease. The two pieces together can help manage patients at greater risk in the future. Over time, physicians may be able to tailor effective drug regimens for patients to obtain an improved outcome with medication therapy. Without this combined approach, physicians may not detect the condition early enough and end up treating the patient differently. "



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"History has shown that disease-management programs rarely work if patients are not personally motivated to change their behaviors. Hence, programs for asymptomatic diseases are typically less successful than ones for symptomatic conditions, which impact the patient's day-to-day life. We are an 'out of site/out of mind' culture, motivated by immediate rewards. That said, it would be logical to expect that the most effective disease-management programs are those that focus on the right patient (those already self-

motivated to improve) and deliver ongoing reinforcement of a type designed to resonate specifically with that individual.

Disease-management tools should be uncomplicated to use and easy to understand. Blood glucose monitors, as an example, are easy for patients to use and are very effective tools in assisting motivated patients (those who understand consequences of noncompliance) to better manage their condition.

As long as the tools are not too sophisticated, complex, or cumbersome for the patient to use, they can undoubtedly serve a role in fostering patient compliance. Simple tools serve as a reminder, encourage patient ownership in managing their conditions, and foster communications between the patients and their healthcare providers. "



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"It has become imperative to design targeted programs that can reach and influence particular life stage groups within a single disease state. Employers are very aware that employees who would benefit from any disease-management program are not just seniors, but rather span several generations and life stages and therefore require different communication strategies and delivery channels to influence their minds, emotions, and ultimately their behaviors.

Program delivery has to fit in with the intended patient's modus operandi, and not the other way around. "