

“Leading Through Challenges”

Keynote Speech

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Thank you, Bert, for that kind introduction. I am delighted to be here this afternoon for this important conference.

Before I focus in detail on the role of ethics and compliance at Purdue Pharma, I would like to start by talking a little about our company’s history, since we have had a unique set of challenges to address.

Although Purdue’s roots go back to 1892, the company’s current incarnation began in 1952 when two brothers, both physicians, bought The Purdue Frederick Company. Its motto – “Dedicated to Physician and Patient” – resonated with these new owners and they kept it.

Purdue’s national reputation got its first big boost from the historic Apollo 11 mission in 1969. Searching for a broad-spectrum microbicide to kill potential “moon germs” that the astronauts might bring back to Earth, NASA scientists tested all the major products on the U.S. market. They selected Purdue’s Betadine[®]. After the astronauts returned to Earth, NASA frogmen used Betadine to wash down the space capsule. As might be expected, sales of Betadine rose rapidly.

In 1984, Purdue introduced MS Contin[®], the world’s first long-acting, controlled-release morphine tablet. The prolonged dosing intervals provided by a controlled-release product such as MS Contin are generally more convenient for patients, many of whom may benefit by not having to take their medication during the night. This marked our significant entry into pain management, which was to become Purdue’s defining niche in the pharmaceutical industry. Back in 1984, there simply wasn’t general awareness of the magnitude of the problem of pain and its cost to society. People were being hospitalized who, if properly treated, could have been walking around and leading productive lives. Many were not being treated at all. Although pain is the most common reason people see a doctor, medical schools spent little time teaching doctors how to assess and treat pain.

But not all patients respond to opioids in the same way, and doctors need choices. In late 1995, Purdue launched OxyContin[®] – a controlled-release oxycodone tablet. Next year we plan to launch Palladone[™], a once-a-day, extended-release formulation of hydromorphone. And we have several more analgesics in our pipeline. Our top research priority is the development of abuse-resistant analgesics – medicines that provide pain relief to patients but are unattractive to abusers. We have already invested more than \$200 million in this research.

Undertreated pain is an epidemic in this country. According to the American Pain Society, an estimated 50 million Americans are partially or totally disabled by pain, with a cost approximating \$100 billion a year. However, prescription drug abuse is also a serious public

health problem. As OxyContin swiftly became a valuable weapon for doctors treating pain patients, it was also becoming a target for abuse.

In 2000, five years after we introduced OxyContin, we first recognized that disturbingly high levels of abuse and diversion were being reported for the product in certain parts of the country. This caught all of us by surprise. In 17 years of marketing MS Contin, a C-II controlled medication with the same abuse potential as OxyContin, we had never experienced any unusual abuse and diversion. But OxyContin abuse was spreading rapidly, and by 2001 the product had become synonymous with prescription drug abuse – even though government statistics confirm that it has never been the nation’s most abused opioid medication.

I cannot emphasize enough how devastating this was for our company, which had dedicated itself to meeting the needs of patients and physicians. My colleagues and I have always felt proud that we work for a company that makes products to alleviate human suffering. The knowledge that our medicine was being misused and causing harm to abusers, their families, and their communities came as a terrible blow.

Furthermore, that abuse was jeopardizing the progress the healthcare community had made toward the appropriate treatment of pain. After decades in which pain was largely ignored, in 1998 the Federation of State Medical Boards had issued Model Guidelines for the Use of Controlled Substances for the Treatment of Pain. The Veterans Administration Hospital System has recognized pain as the “Fifth Vital Sign,” which meant that it had to be charted along with patients’ temperature, pulse, respiration rate, and blood pressure. And JCAHO, the Joint Commission on Accreditation of Healthcare Organizations, had implemented new standards making pain management a required part of all treatment plans at accredited facilities.

We struggled to come up with a way to help fight prescription drug abuse without hurting the patients who need these medicines. You won’t read about these initiatives in an OIG Compliance Guidance, or in the Federal Sentencing Guidelines – but preventing abuse of our products has become a critical part of Purdue’s compliance program. I’d like to highlight what we are doing in this area, not only because we are proud of our efforts, but also to illustrate their multi-dimensional and evolving nature.

First we set out to learn how best to do our part. This is, after all, a problem that law enforcement, schools, parents, religious organizations, healthcare professionals, social service agencies, regulatory bodies, and the pharmaceutical industry must join together to address.

We formed a response team of senior executives and physicians, and began meeting with U.S. Attorneys, state Attorneys General, state legislators, regulators, law enforcement officials, and community leaders in more than 12 states where abuse was being reported, in an effort to come up with practical solutions. We developed and distributed brochures that informed pharmacists and physicians of the various actions they could take to prevent diversion and abuse. Then we learned from some doctors that they wanted to use urine testing to screen for illicit substances, but not all of them knew how. So we made a grant to the California Academy of Family Practitioners, whose experts created a monograph called “Urine Testing in Primary Care.” We have now distributed more than 77,000 copies of this publication in response to requests from

physicians, and it is also available for downloading from the California Academy's website. It is our most requested educational piece.

We also created slide kits aimed at teaching doctors how to lawfully prescribe opioids to patients who need them and how to keep these medicines away from abusers. When doctors told us they didn't know what track marks and skin-popping scars look like, we revised the kits and added pictures.

We learned that many in the law enforcement community needed help recognizing which pills were being abused. Police officers told us that if they came across a stash of pills in a car, they couldn't tell whether they were blood pressure medicine, asthma pills, or controlled substances. So we helped the National Association of Drug Diversion Investigators print photo ID cards with pictures of the most abused prescription drugs. More than 100,000 of these cards have been distributed to law enforcement officials.

To help reduce fraudulent prescriptions, a common way criminals divert drugs, we started distributing tamper- and copy-resistant prescription pads. We have provided nearly 250,000 of these pads, at no charge and containing no product advertising, to almost 16,000 doctors in 34 states and the District of Columbia. The pads utilize a number of security features. If you try to photocopy a prescription, the word VOID appears. There's also a watermark and a security pattern like you see on checks, so attempts to alter a prescription become very obvious. A special heat-sensitive Rx symbol on the back disappears when rubbed, further verifying the prescription's authenticity.

To combat "doctor shopping" – the practice of misleading physicians in order to obtain multiple prescriptions – we have supported legislation to implement appropriately designed state prescription monitoring programs and are supporting federal legislation to mandate and fund these programs in all states.

Pharmacy robberies are another way criminals acquire drugs. As I stand here in Washington, I am within a half-hour's drive of two states and at least five counties – but law enforcement officers in different jurisdictions didn't have an easy way to share information about pharmacy robberies. So we created RxPATROL[®], a national information clearinghouse that analyzes theft information for trends and patterns and disseminates pertinent leads to the law enforcement community. It was launched in June 2003 by a partnership that includes the National Community Pharmacists Association, National Association of Drug Diversion Investigators, Pharmaceutical Security Institute, and the FBI's Law Enforcement Executive Development Association. More than 530 reported incidents of pharmacy theft have already been recorded in the RxPATROL system, resulting in numerous arrests.

Public officials are very enthusiastic about this database, which is now searchable by state law enforcement. Ohio Attorney General Jim Petro recently said: "With RxPATROL, Ohio law enforcement officials now have instant access to a great deal of information about pharmaceutical crimes. RxPATROL will be an important tool for solving and preventing prescription drug thefts."

To further help law enforcement, Purdue hired two former DEA special agents, two former state police diversion investigators, a former medical board investigator, and other experts to provide free educational sessions on methods of combating prescription drug crime. Last month, for example, law enforcement officers from all across North Carolina gathered to hear three Purdue colleagues provide eight hours of instruction about signs of abuse, how to identify altered prescriptions, doctor shopping, and, as the local newspaper put it, “simply how to identify which prescription drugs are which.” This year alone, we have educated more than 4,500 law enforcement officers.

Purdue also helps to fund tip hotlines. One of these is DAMMADD, which stands for Dads and Mad Moms Against Drug Dealers. More than 1,600 tips have already come in to this web-based tip hotline, resulting in 58 arrests and 31 convictions. Recently, an anonymous tip received through DAMMADD led to the arrest of a South Carolina couple running a methamphetamine lab in the home they shared with their young daughter. We have supported similar programs in Massachusetts and Pennsylvania.

We also realized that doctors, pharmacists, and law enforcement officers weren’t the only people who needed education on prescription drug abuse. Young middle-school kids – not even in their teens – were experimenting with prescription drugs, and there was no literature directed to this generation. So we developed public service ads warning parents that kids don’t only find drugs on the street – they may be taking them out of the medicine cabinets in their own homes. The television version of the ad shown here [refer to slide] was honored with the 2004 Clarion Award for public service advertising from the Association of Women in Communications.

We proceeded to develop an education and awareness program called Painfully Obvious[®] to help young people understand the dangers of prescription drug abuse in terms that they can relate to. The program uses “gross-out humor” to show how drug abuse can destroy your social life and make you “uncool” – through side-effects like explosive diarrhea or projectile vomiting. Videotapes of a teen focus group examining the Painfully Obvious materials show that the kids get it – and that the fear of social humiliation can be more persuasive than the fear of actually dying. In fact, one young man couldn’t stop talking about how humiliated he would be if he experienced such disgusting consequences. The Painfully Obvious website has had more than 200,000 visits, and its brochures have been distributed by Safeway, Value Drug, McKesson, and Spartan Stores. In Boston, Mayor Thomas M. Menino introduced Painfully Obvious as a new initiative that – and I quote – “will help to bring more awareness to this serious public health issue and to prevent the abuse of prescription drugs amongst our teens.”

Recently, Lifetime Learning Systems, the publisher of *Weekly Reader*, distributed drug abuse awareness booklets based on Painfully Obvious to more than 40,000 middle school classrooms in 18 states. Through this effort, important information about the dangers of prescription drug abuse will reach up to 5 million young people in the 5th through 8th grades.

I’d like to also mention a wonderful program called Communities That Care[®]. We learned that this science-based program has developed ways to diagnose communities where young people are at risk of dropping out, violence, teen pregnancy, prescription drug abuse, and other problem behaviors. Using more than 20 years of NIH-funded science, Communities That Care has

developed strategies to help communities make themselves into better places for young people to live. Communities That Care has a great track record of improving kids' lives, and we are proud to be partnering with 21 communities around the country to implement this program. This is what Steve Pasierb, President and CEO of the Partnership for a Drug Free America, recently said of our initiatives: "Corporate support like Purdue Pharma's of community organizations is exactly the kind of corporate leadership we need as we work to fight prescription drug abuse."

One of the problems we've encountered in fighting prescription drug abuse is that federal databases tell you which drugs were abused in the past but don't spot trends in a timely way. To address this, we created the RADARS[®] System. RADARS is an early warning system to track abuse, addiction, and diversion of the seven major controlled opioid medications. It is designed to spot increased abuse of an opioid in a specific locality or region.

We believe the RADARS System is the most advanced method of accumulating abuse and diversion data ever developed by a pharmaceutical company. Quarterly meetings of its External Advisory Board are held right here in Washington to make it easy for representatives of various federal agencies to attend. Observers from the FDA, DEA, SAMHSA, and NIDA have come to a number of these meetings.

We are very aware that we have a responsibility to maintain the tightest possible security of our controlled prescription medicines – from the moment they leave our manufacturing facilities until they are safely delivered to our customers. Our comprehensive approach to transportation security involves the use of armored vehicles, counter-surveillance, and GPS tracking systems. Just this month, Purdue is launching the industry's first integrated, anti-counterfeiting, track-and-trace packaging for a scheduled pharmaceutical product. The label of each 100-tablet bottle of OxyContin will include an RFID tag that can be scanned by special sensors. This will make it possible for our products to be tracked and validated along every step of the supply chain. We are also adding a special variable-effect, color-shifting ink – similar to that on the new \$20 bills – to our labels to thwart would-be counterfeiters.

Referring to Purdue's overall support of the law enforcement community, John Burke, Vice President of the National Association of Drug Diversion Investigators, wrote in *NADDI Rx News* last month: "Purdue Pharma has done more in a few short years to assist law enforcement and regulatory agencies in fighting drug diversion than any entity I know." But while we're pleased at such a visible endorsement of our efforts, we realize all too well how much more there is to be done in this critical area.

That's why Purdue helped form the Rx Action Alliance, chaired by Former Mayor Rudolph Giuliani. This consortium of stakeholders from the public, corporate, and nonprofit sectors has joined together to advocate for a dialogue and sound policies directed toward improving patient access to medicines and combating prescription drug abuse. The Alliance includes among its 20 members such diverse organizations as the National Association of Drug Diversion Investigators, Center for Practical Bioethics, National Community Pharmacists Association, American Society of Pain Management Nurses, and Novartis. I would strongly encourage others to join the coalition to address this important challenge.

As both a cancer survivor and a former U.S. Attorney, Rudy Giuliani is keenly aware of the need to ensure that prescription drugs remain available for patients but not for abusers. He said: “The promise and potential of modern medicines will be among the great legacies of our time. Unfortunately, the abuse and diversion of these medications has created a significant public health problem. We must strive to achieve a balance between addressing abuse and diversion, and maintaining access for patients.”

It is tragic when a patient who is being appropriately treated by a properly practicing doctor has to worry about losing access to effective pain medication. And it is tragic when abusers destroy their own lives and their families. Balancing these two objectives – preventing abuse while protecting proper patient access – is not an easy task. We have tried to strike the proper balance, and I wish I could tell you that our efforts haven’t been criticized – from both sides. I *can* tell you we’ve tried to learn from our mistakes.

We sympathize with both the patients in pain who have been caught in the crossfire resulting from prescription drug abuse and the abusers who need treatment and help. We reserve our enmity for the drug dealers and diverters who make money on the misfortunes of others – endangering patients in pain and stigmatizing an important medication.

Patients have also suffered from the barrage of media coverage and litigation that have sprung up around prescription drug abuse. The media has been quick to report on all aspects of what is, after all, a serious public health problem. Many reporters have sought to bring understanding and balance to this complex issue, while others have sought to sensationalize it. Tom Shales, the television critic for *The Washington Post*, wrote an article in *Electronic Media* describing network coverage of OxyContin abuse as an “epidemic” of “bad journalism” with “stories filled with hype and half-truths.” Many stories completely ignored patients who used OxyContin appropriately. In mid-2001, one publication ran an 8,000-word cover story called “The OxyContin Underground” in which not a single patient was interviewed.

Negative, inaccurate reporting has hurt our company, but more importantly, it has discouraged prescribing and use of OxyContin in cases where the medication has been needed. This editorial in the Lexington *Herald-Leader* articulates the danger particularly well.

One of the clearest examples was the impact on patients and their doctors from a Florida newspaper’s five-day, front-page series claiming that OxyContin had caused hundreds of overdose deaths, many of them patients in pain for whom it was appropriately prescribed. Nine months later the newspaper ran a front-page correction, explaining that it had grossly overstated the number of deaths and falsely portrayed a substance abuser who had been convicted on drug trafficking conspiracy charges as a – quote – “accidental addict” whose “idyllic” life had been destroyed after he was prescribed OxyContin for back pain. During the nine months it took the newspaper to correct its blatantly false report, the governor, a congressional committee, and a state panel considered taking action based on the series’ bogus findings. The newspaper’s false death data were even referenced in a GAO report. Patients in pain and pain physicians who lived in the area were frightened and stigmatized.

Further compounding the problem, high-profile media coverage often leads to unwarranted litigation, and that has certainly been our experience. We are saddened by the personal tragedies underlying many of these lawsuits. However, their fundamental premise – that OxyContin is a dangerous product that we have marketed improperly – is simply wrong. Again, patients have been caught in the crossfire.

A survey recently released by the U.S. Chamber of Commerce demonstrated that lawsuits about prescription medications cause some patients to stop taking the medications prescribed for them by their healthcare professionals. Lisa A. Rickard, President of the U.S. Chamber Institute for Legal Reform, which sponsored the survey, said: “Plaintiff lawyers’ addiction to lawsuits has changed the way doctors prescribe, pharmacists dispense and patients use medicine. A troublesome pattern is emerging – with even the fear of litigation interfering with the way health care professionals practice medicine.”

As you can see, a lot of the initiatives that we have taken to combat abuse and diversion really boil down to compliance – not just doing what’s required, but taking the extra step to try to fix the problem. Like all of you, Purdue has grappled with a number of compliance-related issues over the years – and we’ve learned from the experience.

We have responded to compliance challenges by working collaboratively with our regulators, finding the best advisors and experts to work with us, and taking an approach to problem-solving that is both practical and creative. When change is needed, we believe it is important to bring in the right people and the right technology to institutionalize those changes.

Furthermore, I am convinced that good compliance – doing the right thing – is, quite simply, good business. People may think that compliance costs a company money and reduces profits. However, an effective compliance program actually saves money by helping companies avoid costly mistakes. Employees take great pride in being part of a company that is highly ethical and compliant, and seeks to become part of the solution. They are happier when they can go home at night thinking about the help they’ve provided to law enforcement, doctors, pharmacists, young people, and communities.

I’m certainly not alone in this view. In fact, in the past five years or so, the entire pharmaceutical industry has begun to move its commitment to compliance up another notch. That’s why forums such as this conference have become so important – and why they attract the high-level attendance that we see here today.

For a long time, Purdue handled issues relating to compliance in a decentralized way – through various functional areas including Law, HR, Manufacturing, Finance, R&D, Sales, and Regulatory Affairs. Now, however, because of our rapid growth, the increased scrutiny to which we have been subjected, and our growing recognition of how critical compliance is to our company and our industry, we have built a centralized Corporate Compliance department – headed up by Bert Weinstein and reporting directly to me – to focus and formalize processes and procedures throughout our organization.

Bert and his team are moving compliance organization, program reviews, education and training, auditing, and monitoring to the next level. In addition, we take pride in the stringent compliance standards we impose on manufacturing, sales, marketing, research, and clinical studies. And since a commitment to doing the right thing has always been so deeply ingrained in Purdue's corporate culture, our employees have been quick to embrace these initiatives.

Like many of you, Purdue has done a lot of one-on-one and classroom training on compliance issues. This year we added a web-based component to our education efforts with the launch of an Online Workplace Learning program, fondly known as OWL. Our employees have been very enthusiastic in their response to this new tool. The first module – focusing on ethical awareness and decision-making, and requiring each employee to complete a quiz with a 100% passing grade – was completed by our entire workforce in just three weeks. We had similar success with our second module, which addresses healthcare law compliance policies, including fraud and abuse, the False Claims Act, and other important healthcare regulations. I personally take pride in having been among the first to complete both these courses, and I support them strongly. Purdue's workforce maintains an extremely high level of support for compliance and awareness of our compliance policies.

To sum up, there is a strong commitment to ethics and compliance throughout Purdue – led by senior management and shared by employees at all levels. I think the fact that Bert reports directly to me and serves as a member of our company's Executive Committee illustrates the importance we place on the compliance function.

I know from conversations with my peers on the Board of PhRMA that this is a highly valued function throughout the pharmaceutical industry. I encourage the compliance professionals here today to use this meeting – and your involvement on the Pharmaceutical Compliance Forum – to share best practices among you. It will be good for your companies and will contribute to the greater good of our industry.

Thank you.