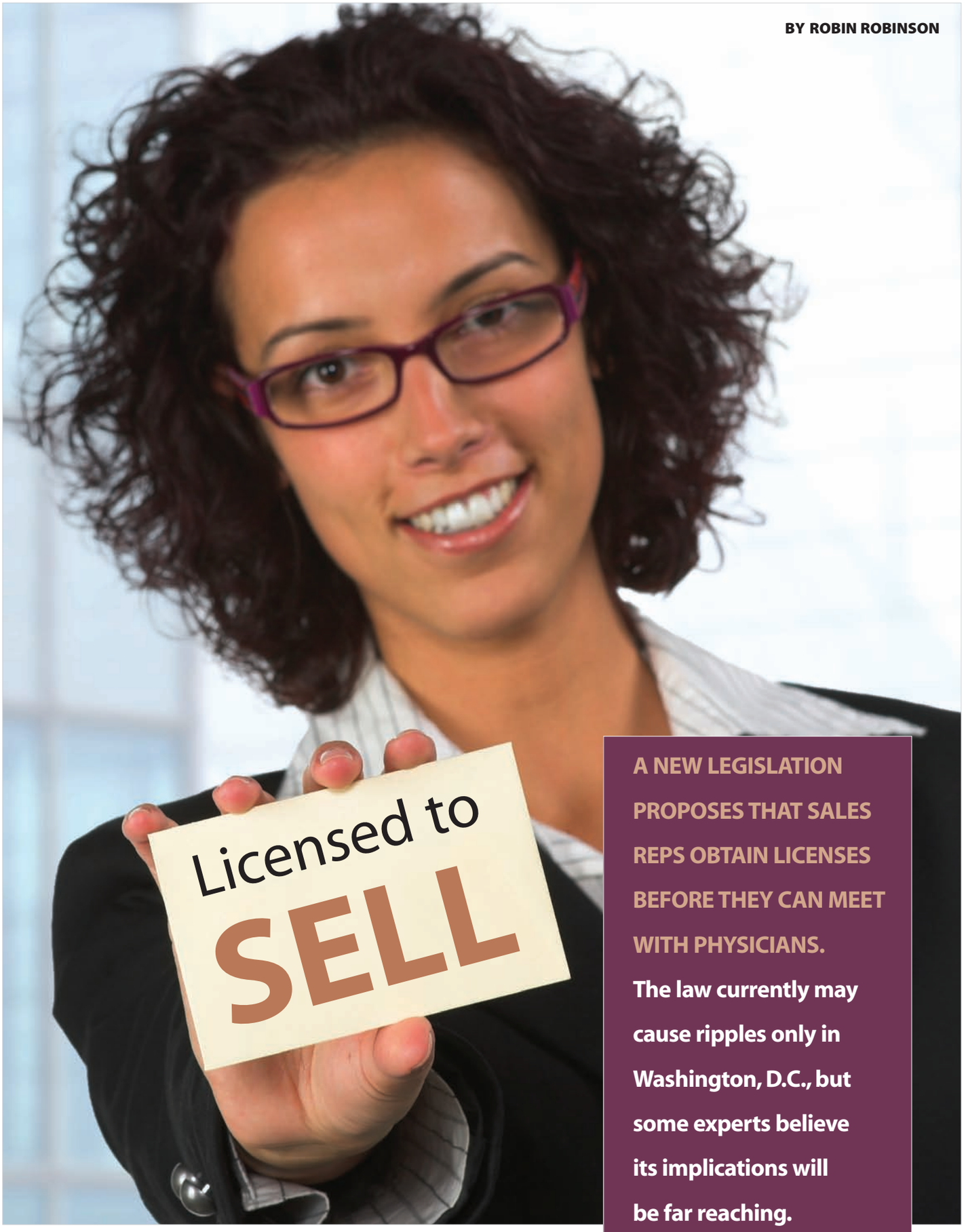
BY ROBIN ROBINSON



A NEW LEGISLATION PROPOSES THAT SALES REPS OBTAIN LICENSES BEFORE THEY CAN MEET WITH PHYSICIANS.

The law currently may cause ripples only in Washington, D.C., but some experts believe its implications will be far reaching.

The job of a sales rep working in the District of Columbia just got a little more difficult and a bit more confusing, thanks to The SafeRx Act, a bill passed by the District of Columbia Council in January and scheduled to become law in April. Starting this year, a sales rep working in the District will not be allowed to detail physicians unless he or she has a license from the D.C. Board of Pharmacy.

To meet the requirements, a newly hired rep must hold at least a bachelor's degree and then apply for a D.C. Board of Pharmacy license by paying a $250 fee and submitting a notarized acceptance of an industry code of ethics, which includes criteria such as participating in continuing education and not knowingly providing false information to physicians. Sales reps must renew their licenses regularly and continue to pursue further medical education. There is a grandfather clause for salespeople who already have at least one year on the job.

I am concerned about the competitiveness of the American pharma industry within the rapidly increasing regulatory environment.

MARK DUVAL, DuVal Associates

While states may show interest in what other jurisdictions are doing, state legislators are amazingly independent minded.

RICHARD CAUCHI, National Conference of State Legislatures

In addition to regulating sales reps, the bill creates a program to educate physicians on the latest developments in pharmaceutical research and prohibits members of the District's Medical Advisory Committees from receiving gifts from pharmaceutical companies.

The D.C. Health Department will evaluate the effectiveness of the new law by recording the fines collected and tracking the number of licensed salespeople after the end of 2010.

INDUSTRY REACTION

Marjorie Powell, senior assistant general counsel for the Pharmaceutical Research and Manufacturers of America (PhRMA), says the new law is redundant and convoluted. For example, down the road if Maryland and Virginia decide to require licenses for reps, and all the systems are different, a rep may need to meet three different requirements to work in a very small geographic area.

"The law makes no sense from either the physician's perspective or the pharmaceutical company's perspective," she says.

Another glitch arises when D.C. physicians have multiple offices and practice in nearby Maryland or Virginia. A rep without a D.C. license could visit a D.C. physician at one of the offices in one of the unregulated areas.

"This law just makes assigning salesforces more complicated," Ms. Powell says. "We think the whole legislation is unnecessary. The provision that deals with the licensing of a sales rep is particularly unfortunate and given the number of problems with healthcare in the District of Columbia, the District could better spend its resources. This regulation actually costs the city money."

Attorney Mark DuVal, president of DuVal & Associates, is equally frustrated with the legislation, as it makes it more difficult for the companies he services to comply with both state and federal laws, and it increases the cost of compliance for his clients.

"Regulations like this are not helpful; the industry has to deal with a patchwork quilt of legislation coming out of 50 state governments, in addition to the federal government," he says. "It is getting nearly impossible for companies to keep up with and comply with all of them. FDA attorneys can't provide advice on just a federal level anymore. We have to consider 50 fairly active legislatures and try to keep up to date month by month or week by week and it is getting ridiculous."

Washington, D.C., Councilmember David Catania brought the bill to life in September 2007. By the time the legislation passed Jan. 8, 2008, with a 7-6 vote, it had lost some of its punch. It no longer contained requirements for salespeople to hold specific science-related bachelor's degrees, or for physicians to receive patients' written consent before prescribing medicines off-label, or for a state-level registry of every ongoing clinical trial. (For more information, turn to page 63.)

Some in the industry were a bit surprised that the bill got passed at all, but the fact that Councilmember Catania was the sponsor didn't seem to surprise anybody. The Chairman of the Committee on Health is no newcomer to anti-industry legislation. A member of the National Legislative Association on Prescription Drug Prices, Councilmember Catania has sponsored several bills that proposed to further regulate or control the industry. In 2005, his law regulating prescription drug costs by making "excessive" prices illegal was declared unconstitutional and overturned by the U.S. District Court.

"David Catania has been talking about this legislation for a couple of years, and he has been targeting the industry for the last several years; this is a pet project of his," says Jeff Trewhitt, senior director for communications and public affairs at PhRMA.

"The motivation behind this type of legislation is pure and simple — it's politics," Mr. DuVal says. "The common wisdom was that this bill wasn't going to pass. And low and behold it has. It just shows the extent of the anger, frustration, and disdain the government holds for the pharma industry. When will it end, when we destroy the U.S. pharma industry?"

When asked if Ms. Powell perceived Councilmember Catania's legislative efforts as political maneuvering, she replied: "Well, it's difficult for me to view it as a public health move."

INDUSTRY IMPLICATIONS

Because of the small area of the District and the number of sales reps affected, the law may cause only ripples in the industry today, but some experts believe the implications of this legislation could be far reaching.

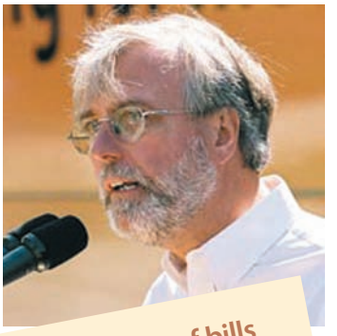
"We are going to be living with this one," says Susan Dorfman, VP of global marketing at Skila. "Not only are we going to have to live

with the law, but I suspect that this legislation is going to stick."

Ms. Dorfman predicts that the different legislations pending in so many states can only lead to more action.

"Success breeds success, and success also breeds expansion," she says. "It will be interesting to see if more states will start to jump on the bandwagon."

If other states do join the District in requiring sales reps to be licensed, it will create a confusing mix of state laws that are totally unnecessary in light of the national uniformity provided by the Food, Drug and Cosmetic Act, Mr. Trewhitt says.



There are a number of bills that we don't like, and we don't always challenge them.

JEFF TREWHITT, PhRMA

Ms. Powell, Ms. Dorfman, and Mr. DuVal all have concerns regarding how this type of legislation could affect the smaller pharma and biotech companies.

"The potential of a dozen licensing systems in a dozen different states could create real difficulties, particularly for small biotech companies with small salesforces," Ms. Powell says. "Biotech companies will at some point have to make a decision whether it is more feasible to market their own products or enter into a joint venture with a bigger company. It is clearly easier for a big company to deal with multiple state licensing systems than a small one."

Ms. Dorfman also raises the concern that medical science liaisons (MSLs) might some day be required to comply with the new law.

"I wonder what will happen to medical liaisons under this law as they are allowed to respond to an off-label request from a physician or thought leader," she says. "The official legislation doesn't label the professional as a pharma sales rep, but rather as a detailer. Could that imply that a detail is a scientific dialogue between an MSL and a thought leader or a physician?"

The law could also have implications for other industries as well, Ms. Dorfman says.

"Certainly sales people in pharma can't be required to become certified and not require others industries to do the same."

Mr. DuVal agrees, adding, "This type of legislation is more than a pharma issue. There should be a huge public outcry around this law because it regulates hiring qualifications and will preclude the hiring of qualified people who don't meet the statutory criteria. This is a sad state of affairs and is unprecedented in other industries."

THE STATE LEGISLATIVE TREND

According to Richard Cauchi, health program director of the National Conference of State Legislatures (NCSL), a recent report by

HIGHLIGHTS OF THE SAFERX ACT

- An individual shall be licensed by the Board of Pharmacy before engaging in the practice of pharmaceutical detailing in the District of Columbia.
- A pharmaceutical detailer shall not:
  - Engage in any deceptive or misleading marketing of a pharmaceutical product, including the knowing concealment, suppression, omission, misleading representation, or misstatement of any material fact
  - Use a title or designation that might lead a physician to believe that the pharmaceutical detailer is licensed to practice medicine, unless the detailer currently holds such a license
  - Attend patient examinations without the consent of the patient.
- An individual shall establish, to the satisfaction of the Board of Pharmacy, that he or she is a graduate of a recognized institution of higher education.
- Pay the required licensure fee.
- Submit to the Board of Pharmacy a notarized statement that he or she understands and agrees to abide by the requirements for the practice of pharmaceutical detailing, including the code of ethics, as established by the Board pursuant to section 208.
- The Mayor shall establish by rule continuing education requirements as a condition for renewal of the license to practice pharmaceutical detailing.
- In addition to the penalties set forth in this act, a person who practices pharmaceutical detailing without a license shall be subject to a fine of up to $10,000.

Source: Council of District Columbia SafeRx Act document.

CMR STUDY SHOWS SALES REP EDUCATION IS KEY TO COMMUNICATING WITH PHYSICIANS

ACCORDING TO A STUDY CONDUCTED BY THE CMR INSTITUTE, A NONPROFIT ORGANIZATION THAT PROVIDES ADVANCED EDUCATION AND CERTIFICATION FOR MEDICAL SALES REPRESENTATIVES, PHYSICIANS WHO PARTICIPATED IN A RECENT RESEARCH STUDY PLACED A HIGH VALUE ON THE EDUCATION AND KNOWLEDGE LEVEL OF SALES REPRESENTATIVES.

Information and skills that sales representatives should be well-versed in and listed as very important by the majority of physicians included:

- Basic principles of drug actions and interactions, including pharmacokinetics, factors that modify the drug response, and adverse reactions related to the representative's product(s)
- Therapeutic classes of drugs and indications for each
- Drug resistance trends
- How the representative's product compares with other products in the same therapeutic class
- Presenting and explaining evidence-based clinical studies
- Outcome measurements and quality-of-life issues
- Cost benefits of pharmaceuticals
- Adherence to ethical business practices
- Knowledge of physician's specialty and training
- Effective communications skills
- Interpersonal skills
- The role of disease management and clinical practice guidelines in treating patients
- Disease profiles, related complications, diagnostic procedures, and treatment methods
- Third party payers (insurance companies, Medicare, Medicaid), Medicare Part D

Source: CMR Institute, Roanoke, Va. For more information, visit cmrinstitute.org.

HealthEd is proud to announce the launch of its newly formed sister agency, HealthEd Encore. HealthEd Encore supports the individual needs of patients, their families, and the treatment teams who care for them. And both companies share a passion for changing how patients think and act in ways that benefit your brand.

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the organization shows that while many states may consider implementing such bills, whether they end up passing them into law is another story. The NCSL reports that in 2007, 109 pharma-related bills were passed among more than 500 that were pending.

The SafeRx Act is the first law relating to pharmaceuticals to be passed in 2008, and there are 540 more up for consideration, according to the NCSL's 2008 report. More than 100 of those have been filed for 2008 legislative sessions, while the rest are carried over from last year. The proposals cover a wide range of state-sponsored approaches, from the creation of subsidies or discount programs, to promoting safer pharmaceuticals, to regulating the management, marketing, and distribution of prescription products.

Although many in the industry may fear this law could represent the beginning of more to come, a state-by-state uptake of an idea does not necessarily identify a national trend, Mr. Cauchi says.

"While states may show interest in what other jurisdictions are doing, state legislators are amazingly independent minded," he says. "An idea from one state may look like a new trend because many other states start to consider similar measures, but 18 months later, there may be only two or three states that pass the legislation."

New regulations will require companies to know their physicians much better than they currently do.

SUSAN DORFMAN, Skila

Similar efforts in New Hampshire, Maine, and Vermont are already taking place. The New Hampshire Health Committee chaired by National Legislative Association on Prescription Drug Prices (NLARx) member Rep. (D) Cindy Rosenwald held hearings on an academic detailing bill in February. The House Commerce Committee held hearings on a bill sponsored by New Hampshire Rep. (D&R) Thomas Donovan regarding banning gifts to health practitioners and requiring disclosure of payments and spending on advertising and marketing. The disclosure bill is based on the model bill developed by NLARx and The Prescription Project. (See the NLARx Website nlarx.com for more information on state actions.)

Mr. Cauchi says the height of legislative activity over the past 10 years began in 2000 and peaked in 2005/2006, when laws surrounding prescription access, Medicare, and pricing were implemented. If there is a trend today the push is a comprehensive health reform as just one component of that bigger picture.

"I think companies need to recognize there is going to be continuing pressure in some states to license pharma reps, although we are hopeful that more rational heads will prevail," Ms. Powell says. "A patchwork licensing system won't benefit anybody, and it will make the process more complicated, but I think the reality is we are going to be fighting these types of bills in the future."

If this law does encourage other states to adopt similar legislation, PhRMA will appear before the state boards, as the organization did during hearings for the SafeRx Act, and suggest that this type of legislation may be a poor use of

Sound Bites From The Field

PHARMAVOICE ASKED INDUSTRY EXPERTS WHAT THEY EXPECTED THE LONG-TERM RAMIFICATIONS OF THE SAFERX ACT LAW MIGHT BE.

PETER LURIE, M.D., MPH, is the Deputy Director of the Health Research Group at Public Citizen, Washington, D.C., a national, nonprofit consumer advocacy organization representing consumer interests in Congress, the executive branch, and the courts. For more information, visit citizen.org.

"Our perspective is that detailers have gotten way out of hand and driven people to use medications that are variously too expensive, too dangerous, or no more effective than their competitors. It is about time people started paying attention to this problem and if the act shines a light on the practices of these detailers, I think it will be a great benefit. The law is exciting in that it addresses a wide variety of problems in prescription drug marketing and creates ideas on how to address those problems. Many states will look at the law and perhaps consider passing something similar to it. The states keep track of one another and get ideas from one another. I would assume that legislators in a number of states will be giving serious consideration to such a law. Whether they will introduce it or will pass it I can't say."

ED SILVERMAN is the editor of an industry blog called Pharmalot. For more information, visit pharmalot.com.

"The reaction to the bill was moderate in terms of the number of comments, although those who did comment were about evenly split between support and opposition. The supporters were thrilled that such a move was being taken, while the opposition thought it was a foolish waste of time that would accomplish little. None of the reactions surprised me.

Some of industry people were loath to identify themselves, but one person commented that the law was "nothing but a shake down for money under the guise of protecting public health."

Other comments posted on the blog included: "It's about time additional steps were taken to control promotional waste and abuses of pharma industry. Hopefully this is the first step. Companies are selling medicines, not cars." "This must be a stopgap measure to replace reduced parking fines for D.C.; it's about time D.C. got its fair share of the big pharma money. Who's next into the lunch box?" "I would guess the number of reps in pharma without a college degree is nearly zero at this point in time." "I hope that Mr. Catania and the D.C. Council start a trend that will clean up a dirty industry, one that ends up killing and maiming for profit. States should step forward with this and other measures, as the federal agency that is to protect our public health, has been bought by the industry."

As near as I can tell, this particular law was different, being the first to require sales reps to be licensed, and because passage took place in Washington, D.C., as opposed to, say, Nowheresville, USA, it generated a great deal of attention. D.C. is small but it is the Capital's front and back yard. This same law could have occurred halfway across the country and not gotten as much attention."

ONE ON ONE WITH WASHINGTON, D.C. COUNCILMEMBER DAVID CATANIA

IN AN EXCLUSIVE INTERVIEW WITH PHARMAVOICE, MR. CATANIA SPEAKS CANDIDLY ABOUT HIS SUPPORT BEHIND THE SAFERX ACT.

PV: WHY WAS SAFERX AN IMPORTANT PIECE OF LEGISLATION FOR THE DISTRICT OF COLUMBIA?

CATANIA: As the title suggests, the reason behind the legislation is to provide a safer environment in which drugs are prescribed in the District of Columbia. There were several aspects to the bill: one part required the licensure of sales reps, one part mandated informed consent for off-label prescribing, and another portion banned gifts to Pharmacy and Therapeutic (P&T) committees. When all of these aspects are combined, they work to provide a safer environment for consumers to access drugs.

Councilmember David Catania

PV: HOW DOES LAW BILL AFFECT P&T COMMITTEES?

CATANIA: Physicians who serve on District supported P&T committees should not receive remunerations from pharmaceutical companies because it creates a conflict of interest for someone in the position to recommend one particular drug over another. That is why SafeRx prohibits compensation and gifts from pharmaceutical companies to members of government P&T committees.

PV: THE ORIGINAL BILL WOULD HAVE REQUIRED A PATIENT'S CONSENT TO RECEIVE AN OFF-LABEL PRESCRIPTION. WHY WAS THIS IMPORTANT?

CATANIA: SafeRx would have required physicians to make their best effort to inform a patient when they are prescribing them a drug for a purpose other than its FDA approved use. Consumers — that is, patients — have been entirely too trusting of the pharmaceutical industry, generally, and their physician's knowledge of pharmacology, specifically.

It is important to note, however, that the law does not ban doctors from writing off-label prescriptions. I certainly recognize, and people who are experts on the subject recognize, that there are legitimate reasons to prescribe a drug that is off-label. There are drugs that, for whatever reason, have not gone through Phase III trials for a particular purpose but that are recognized as safe and effective for that purpose by the medical profession. With that said, there is a growing body of evidence suggesting that an increasing proportion of products are being prescribed off-label with little to no evidence supporting their efficacy for the intended use. In fact, in many cases there is evidence to suggest the contrary. This provision represented an effort to require physicians to be more informed about exactly what they are prescribing in an off-label capacity. We plan to work with physicians and help them fulfill this requirement.

PV: WHAT ELSE DOES THE LEGISLATION COVER?

CATANIA: Another part of the legislation requires a component of physicians' continuing medical education to cover evidence-based, academic detailing. It also creates an academic detailing program in the District, which will be modeled on the one in Pennsylvania. Doctors are busy individuals in busy practices and we want to assist them in determining which drugs are most the efficacious and most the affordable within a particular therapeutic class. This is not simply a way to pile on new regulations and requirements. Rather it is an attempt to adjust to the current reality where pharmaceutical companies dominate the arena of doctor education about prescription drugs. If we are successful, District physicians will find this information helpful and will welcome it.

For a long time the pharmaceutical industry has tried to have it both ways. It has tried to make pharmaceutical detailers appear more professional or to cultivate the notion of professionalism. But they have consistently rejected the proposals to actually establish professional requirements and standards for the practice of detailing.

The companies understand that physicians will not accept information from someone they view as simply a sales person, but that they will accept information from someone who they believe to be an industry professional. In short, they have done their best to establish an aura of professionalism from voluntary standards and codes of conduct and so on — but it's a mirage. In reality, we don't know what the training protocols are or how the individual companies regulate their sales reps. We do know that the companies' financial interest is to have individuals who are successful in selling their products. And while there is nothing wrong with that — indeed, it is part of doing business — there has been no one protecting the consumer.

As we moved forward on the notion of regulating detailers, a good deal of the information we received from the pharmaceutical industry was an absolute lie. The industry claimed that the FDA regulates detailers, which we learned not to be true. The Division of Drug Marketing, Advertising, and Communications (DDMAC) within the FDA has 30 people who focus on the entire sector of drug marketing. For a industry that spends more than $20 billion in advertising alone, the FDA has 20 people that focus on advertising to professionals and 10 that focus on direct-to-consumer marketing. It's not surprising then, that DDMAC has been entirely toothless. In fact, it was only last year that the law was amended permitting DDMAC to fine pharmaceutical companies for false and misleading advertising. How do you regulate an industry when there are no penalties for bad behavior? It was a joke.

PV: WHAT WOULD YOU LIKE OUR READERS TO KNOW ABOUT THE LAW?

CATANIA: I would suggest they start playing it straight with public officials and not to simply use their resources to confuse and obscure the facts. We could have had a better process had the industry engaged in a constructive manner as opposed to the way it went about trying to defeat the legislation here in the District. I believe reasonable people can sit down and hear both sides and come up with a solution.

This is not going to be a perfect system but it's better than what we have now. Generally speaking, detailers in the District, knowing they could lose their license and their livelihood when they violate the law, will be more careful in how they engage physicians.

resources. Ms. Powell also recommends that senior sales staff be aware of the mindset of some legislators and make efforts to educate them on industry sales and training practices.

"Senior sales managers need to understand that there are some legislators who truly believe a pharma rep has the power to override a physician's professional training and convince a doctor to prescribe a medicine that is not appropriate for a patient, and those legislators will continue to try to find ways to make it more and more difficult for doctors to have any interaction with pharma reps," she says.

At press time, PhRMA was still deciding how to react to the SafeRx Act. Councilmember Catania wrote in a prepared statement that he expects that the industry organization will fight the law. PhRMA is weighing its options.

"We have a fairly complicated process," Mr. Trewhitt says. "In the Council debate, Mr. Catania made the assumption we would challenge the bill. But there are a number of bills that we don't like and we don't always challenge them."

Peter Pitts, president of the Center for Medicine in the Public Interest and senior VP for health affairs at Manning, Selvage & Lee, says he doesn't expect the law to last "15 seconds in front of a judge."

"This legislation has no redeeming value and is completely an antipatient law," says Mr. Pitts, who was also a former FDA Associate Commissioner. "As soon as it reaches a judge it will be overturned."

It is a grandstanding piece of legislation, and it will be overturned in the courts in 15 seconds.

PETER PITTS, Center for Medicine in the Public Interest

With the onslaught of more legislation, there are lots of implications and a larger burden on what a company is going to have to know about its customers.

"New regulations will require companies to know their physicians much better than they do now," Ms. Dorfman says. "They will need more than just address and phone number, and it's not just the sales rep who will need the data; information will need to be shared across the organization. For example, with any legislation that bans any type of gift or remuneration to physicians, the company will need to know what committees and boards physicians are serving on. Companies need to develop physician profiles and identify who engages with physicians across the entire organization. This type of record keeping is costly and complicated, and it is difficult to keep the information updated.

"I am concerned about the competitiveness of the American pharma industry within the rapidly increasing regulatory environment," Mr. DuVal says. "I don't know how the industry can continue to compete on a global level. Much of the business already is going to India or Asia and that trend will continue. I am anxious about where the shift of power will go in the next decade in terms of which pharma companies will become the dominant global players. The industry is being crippled and if the government and legislators keep hammering at it, it is going to take its toll." ✦

It's pretty hard for me to view the legislation as a public health move.

MARJORIE POWELL, PhRMA

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

Experts on this topic

DAVID CATANIA. Councilmember, Council of the District of Columbia, Washington, D.C.; Mr. Catania chairs the Committee on Health and serves on the Committees on Finance and Revenue and Parks, Recreation, and Libraries. For more information, visit davidcatania.com.

RICHARD CAUCHI. Health Program Director, National Conference of State Legislatures, Denver; NCSL is the bipartisan organization that serves the legislators and staff of the states, commonwealths, and territories. For more information, visit ncsl.org.

SUSAN DORFMAN. VP of Global Marketing, Skila, Morris Plains, N.J.; Skila develops knowledge-driven effectiveness solutions for the pharmaceutical industry, including key opinion leader management. For more information, visit skila.com.

MARK DUVAL. President, DuVal & Associates, Minneapolis; DuVal & Associates is a law firm focused on pharmaceutical, biotech, medical-device, and nutritional supplement companies. For more information, visit duvalfdalaw.com.

PETER PITTS. President, Center for Medicine in the Public Interest, former FDA Associate Commissioner, and Senior VP, Health Affairs, Manning, Selvage & Lee, New York; Center for Medicine in the Public Interest is a nonprofit, nonpartisan research and educational organization that seeks to foster debate and discussion on health issues by demonstrating how technological progress coupled with smart public policy will enhance and advance 21st-century health care. For more information, visit cmpi.org.

MARJORIE POWELL. Senior Assistant General Counsel, Pharmaceutical Research and Manufacturers of America (PhRMA), Washington, D.C.; PhRMA represents the country's leading pharmaceutical research and biotechnology companies. For more information, visit phrma.org.

JEFF TREWHITT. Senior Director for Communications and Public Affairs, Pharmaceutical Research and Manufacturers of America (PhRMA), Washington, D.C.; PhRMA represents the country's leading pharmaceutical research and biotechnology companies. For more information, visit phrma.org.