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Pharmaceutical Law & Industry Report®

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Legal/Regulatory Outlook

Biosimilars Policy, Accelerating Medical Breakthroughs Among Year's Key Topics

In 2015, the key concerns for drug and biotech companies will include how the government implements a new pathway for approving biosimilar drugs, the ''21st Century Cures'' legislation intended to accelerate medical breakthroughs, structuring settlements in pharmaceutical patent litigation, and using inter partes review proceedings at the Patent and Trademark Office (PTO) as an alternative to traditional Hatch-Waxman Act litigation in the federal district courts.

Bloomberg BNA contacted stakeholders and interviewed members of the advisory board for the *Pharmaceutical Law & Industry Report* to identify the important 2015 issues for drug and biotech companies in the courts, Congress and regulatory agencies.

Other key issues to watch will be what happens with the Food and Drug Administration's final generic drug labeling rule, possible corporate tax reforms that could reduce or eliminate the deductibility of marketing costs and the continued trend of mergers and acquisitions in the pharmaceutical field, creating hybrid brand-generic drug companies.

New Ways to Challenge Patents. In the pharmaceutical patent world, advisory board members told Bloomberg BNA that 2015 will continue to see the increasing use of inter partes review (IPR) proceedings at the PTO as an alternative to more costly district court patent litigation.

''In 2015, we expect to see more bio/pharma cases filed under the America Invents Act's IPR procedures,'' Terry G. Mahn, of Fish & Richardson's Washington office, said. ''As compared to Hatch-Waxman litigation, IPR would be a much a cheaper way to invalidate an Orange Book patent and may also lead to a quicker resolution. IPR could be a vehicle for non first-to-file generics to trigger 180 day-exclusivity or a forfeiture of exclusivity,'' he said.

Steven H. Sklar, of Leydig, Voit & Mayer Ltd., in Chicago, agreed, noting that a ''trend seems to be developing that where multiple generic manufacturers have been sued, then a non-first filer will likely submit an IPR on one or more of the Orange Book patents. This seems to be a way for the later-filer to meaningfully participate in the proceedings at a reduced cost.''

''Importantly,'' he said, ''the IPR process seems to be another bite at attempting to invalidate one or more patents concurrently with the ongoing Paragraph IV litigation.''

And Gaby L. Longsworth, with Sterne Kessler Goldstein Fox in Washington, predicted that IPRs may also be used in the biosimilar arena. ''So far most IPRs in the pharma space have been filed on small molecules as an alternative or in conjunction with Hatch-Waxman litigation,'' she said. ''As more aBLAs [abbreviated biologics license applications] are being filed, we can expect to see IPRs for biologics/biosimilars and biotech patents in a BLA [biologics license applications] context.''

Longsworth also predicted that 2015 would bring an uptick in the filing of post grant reviews in the biotech and pharma sectors ''as more and more patents issue post March 16, 2013.''

Sklar said a case that should be watched is the U.S. Supreme Court's handling of Teva's appeal over Copaxone. The case involves whether a district court's ruling on claim construction involves factual findings that are subject to deferential review on appeal or, alternatively, are properly reviewed de novo.

Sklar said, ''From a substantive patent law standpoint, a decision favorable to Teva may likely mean that more district court decisions involving claim construction will be affirmed as the standard of review on appeal will be heightened. From a business standpoint, Teva is certainly looking for a successful resolution of its litigation to maintain exclusivity over its blockbuster drug product.''

Settlements, Antitrust Concerns. Advisory board members also said the issue of how to structure settlements of pharmaceutical patent litigation without triggering antitrust liability will continue to be an issue in 2015, following the U.S. Supreme Court's ruling in the 2013 *Actavis* case and the recent ruling from a Boston federal district court in *In re Nexium (Esomeprazole) Antitrust Litigation*.

''In the *Nexium* case, a jury found that AstraZeneca had not violated the antitrust laws when reaching a patent litigation settlement with Ranbaxy pursuant to which Ranbaxy agreed to delay entry of its generic drug that would compete with Nexium,'' board member James M. Burns, of Dickinson Wright PLLC's Washington office, said.

And, he said, it was noteworthy that the jury in the *Nexium* case rejected the plaintiffs' claims, despite finding that the plaintiffs (including wholesalers and consumers) had shown that AstraZeneca had market power, that the settlement payment was ''large and unjustified'' and that the anticompetitive harm caused by the settlement outweighed any potential procompetitive benefits. Nonetheless, Burns said, the jury found that the plaintiffs hadn't proven that Ranbaxy would have been able to enter the market any earlier absent the

agreement, and, thus, the plaintiffs hadn't proven the necessary element of causation.

''As the first case litigated to trial after the Supreme Court's decision in *Actavis*, the case demonstrates, quite clearly, that the law continues to be unsettled with respect to the lawfulness of 'reverse payments' in pharmaceutical patent litigation settlements,'' Burns said.

Wells Wilkinson, project director of the Prescription Access Litigation at Boston-based Community Catalyst, said industry watchers will be looking to see whether the verdict in the recent *Nexium* litigation will have an impact on other so-called pay-for-delay cases or whether the facts in that case will limit the verdict's impact to that case alone.

Regardless of the reach of the Nexium verdict, Burns predicted that 2015 would be a year in which these types of cases will continue to make news because ''the risks on both sides of such litigation are so significant.''

''With an inability to predict the likelihood of success or failure in such cases, 'reverse payment' litigation will continue to be the most significant antitrust issue facing the pharmaceutical industry in 2015,'' he said.

On the antitrust front generally, board members said they expected to see more merger and acquisition activity in the pharma space in the coming year. Sterne Kessler's Longsworth said 2015 would likely bring more mergers and acquisitions of innovator companies by traditional generics. ''Hybrid companies are the wave of the future,'' she said, noting that Actavis Inc. recently acquired or is in the process of acquiring Warner Chilcott, Forest Laboratories, and Allergan Inc.

Burns said big pharma may get even bigger in 2015. ''Over the last several years, there have been a number of mergers among pharmaceutical companies that have changed the pharmaceutical industry. Most significantly, the number of manufacturers has been reduced, creating even more significant competitors, and in some circumstances, the differences between branded and generic manufacturers has blurred with combinations between the two.''

''In a continuation of this trend, the recent announcement of a merger between Actavis and Allergan (which would create a top 10 worldwide pharma company), Sun Pharma and Ranbaxy (which will create the 5th largest generic manufacturer), and Merck's announced acquisition of Cubist presented significant antitrust merger issues for the pharmaceutical industry,'' he said.

FDA Priorities, Workload. Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research (CDER), said at a Dec. 10 conference that CDER's priorities for 2015 include issuing final guidance on abuse-deterrent opioids, responding to the Ebola outbreak and implementing the biosimilars program.

Regarding abuse-deterrent opioids, board member James N. Czaban, of Wiley Rein LLP's Washington office, told Bloomberg BNA that these issues will remain controversial, and predicted that ''pressure will continue to mount on the FDA to make meaningful progress on several issues, including the scientific and regulatory criteria for approval of abuse-deterrent claims, whether non-abuse-deterrent products may remain on the market after abuse-deterrent versions are approved, and criteria for approval of generic or competing versions of abuse-deterrent products'' under abbreviated new drug applications (ANDAs) and 505(b)(2) new drug applications.

Woodcock, who spoke at the FDA/CMS Summit for Biopharma Executives, said the agency is ''aggressively implementing biosimilars'' and that is a ''very high priority.'' The 2010 health reform law, through its Biologics Price Competition and Innovation Act (BPCIA), created a pathway for the FDA to approve follow-on biologic drugs, or biosimilars, but the agency still is working on implementation.

CDER's priorities also include meeting the Generic Drug User Fee Amendments (GDUFA) goals for newly filed ANDAs that went into effect on Oct. 1, 2014, and continuing to reduce pending ANDAs, Woodcock said. Currently there are about 3,000 pending ANDAs, she said.

Woodcock said CDER also is working on an initiative to improve drug labels because many labels are out of date. Also, she said 700 generic drugs no longer have a reference listed drug so the burden to keep the labels of these drugs up to date is on CDER.

Also, CDER will be evaluating the impact of the breakthrough therapy designation, Woodcock said. The breakthrough designation, enacted as part of the FDA Safety and Innovation Act (FDASIA) in 2012, is intended to expedite the development and review of a potential new medicine if it is intended to treat a serious or life-threatening disease or condition.

Woodcock said CDER is developing an implementation plan and training for the new drug labeling rule on pregnancy and breastfeeding. On Dec. 4, the FDA published a final rule and a draft guidance that set standards for how information about using medicines during pregnancy and breastfeeding is presented in the labeling of prescription drugs and biological products (79 Fed. Reg. 72,063; 72,104).

CDER also is working on the new Office of Pharmaceutical Quality (OPQ), Woodcock said. The OPQ officially opened on Jan. 12, according to an agency announcement.

The new OPQ ''centralizes quality review for new drug and generic drugs,'' she said previously.

Cathy L. Burgess, of Alston & Bird LLP's Washington office, said drug quality concerns have prompted the FDA to develop new strategies for oversight and monitoring of drug product quality. The efforts include the formation of OPQ and a new program that seeks to develop manufacturing quality metrics. She said that, ''In 2015, as industry and FDA continue their efforts to select and define a standard set of metrics that can apply across industry to different types of product and manufacturers, industry hopes to gain greater clarity on certain unanswered questions such as what those metrics will be; how they will be used with respect to establishment inspections; how to interpret FDA's comments regarding quality metrics 'scores'; and whether establishment metrics will be available to third parties.''

Woodcock said CDER's other priorities, besides filling over 600 staff vacancies, include:

- implementing statutory provisions related to the drug supply train and the tracking and tracing system;
- developing a strategic plan for managing drug imports;
- continuing to refine policies around personalized medicine;

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■ continuing to develop a policy approach on the development of antimicrobials;

■ implementing the new statutory provisions on drug compounding;

■ implementing new data and document management IT systems;

■ re-evaluating drug advertising and promotion in light of current jurisprudence around the First Amendment;

■ continuing to develop the Sentinel Network;

■ continuing to refine the drug safety program;

■ continuing to work on streamlining clinical trials; and

■ continuing to conduct and assess the impact of patient-focused drug development meetings.

Compounding, Data Integrity. Regarding pharmacy compounding, Burgess said, based on recent agency warning letters, ''it appears that the line between a drug manufacturer and outsourcing facility is all but indistinguishable in terms of'' current good manufacturing practice obligations.

In 2015, she said, ''it is likely that FDA will continue to conduct rigorous inspections of outsourcing facilities,'' and that there will be more warning letters due to the inability of outsourcing facilities to meet manufacturing practice requirements in a July 2014 guidance for outsourcing facilities.

Burgess also highlighted another area involving FDA warning letters—concerns about data integrity. She said the agency's warning letters ''show an unfavorable new trend of data integrity issues related to drug product manufacturing, and increasing number of these letters 'highly recommend' the retention of a data integrity expert, and provide suggestions for the data integrity expert's evaluation.''

In 2015, industry should expect a heightened focus on data integrity issues and the role of the data integrity expert, Burgess said. She added it's likely the FDA ''will strengthen the language in Warning Letters related to data integrity, and will go beyond 'recommendations' in order to gain a better understanding of the conduct that led to data integrity problems and management's commitment to address those problems.''

21st Century Cures Legislation. The FDA's Woodcock also said CDER ''will respond as needed and participate as requested in the 21st Century Cures initiative.''

The 21st Century Cures initiative was launched by the House Energy and Commerce Committee in May 2014 to discuss opportunities to accelerate the discovery, development and delivery of new drugs and devices.

The committee plans to release a discussion draft in early January of legislation intended to accelerate medical breakthroughs as part of the initiative, with the intention of passing the bill by mid-2015, Health Subcommittee Chairman Joe Pitts (R-Pa.) said Oct. 14, 2014, at a conference.

One piece of legislation that might be included in the larger 21st Century Cures bill would reform the FDA's expanded access program to ensure seriously ill patients know the compassionate use policies of pharmaceutical companies. The FDA permits patients, on a case-by-case basis, to access treatments still in the development process and outside of the clinical trial setting when certain criteria are met.

In December, Rep. Michael McCaul (R-Texas) introduced (H.R. 5805), the Andrea Sloan Compassionate Use Reform and Enhancement (CURE) Act. McCaul said in a press release that the Andrea Sloan CURE Act will be introduced again in 2015, when he hopes to advance the legislation through the 21st Century Cures Initiative. The bill would:

■ ensure that drug companies have publicly accessible compassionate use policies for drugs treating serious or life-threatening conditions;

■ require companies to give patients an explanation if their request for compassionate use is denied;

■ require the Government Accountability Office to conduct a thorough analysis of the current compassionate use program, including the number of patient denials and reasons why companies reject requests;

■ establish a compassionate use task force to provide recommendations to further improve the compassionate use program; and

■ require the FDA to issue a final version of its May 2013 draft compassionate use guidance for industry, and clarify how the agency interprets and uses adverse drug event data in compassionate use cases.

Generic Drug Labeling. Ralph G. Neas, president and chief executive officer of the Generic Pharmaceutical Association (GPhA) told Bloomberg BNA that generic drug labeling will be a big issue in 2015 because of the FDA's proposed rule from the fall of 2013 (RIN 0910-AG94) that would allow generic drug manufacturers to use the same process as brand drug manufacturers to update safety information in product labeling.

Neas said the proposed rule would create safety issues ''in terms of the massive confusion that would ensue if there were multiple labels'' for the same drug.

In November 2014, the FDA delayed publication of the final rule until Sept. 30, 2015. The agency previously planned to publish the final rule in December 2014. The proposed rule would allow generic drug manufacturers to independently update and distribute updated safety information by submitting a ''changes being effected'' (CBE) supplement to the FDA, which is the current process used by branded drug manufacturers.

A notice announcing the proposed rule was published in the Nov. 13, 2013, Federal Register (78 Fed. Reg. 67,985).

Neas said the FDA delayed publishing the final rule because ''there has been such a large and diverse set of opponents that have expressed their views.'' Neas also said bipartisan members of the House and Senate have expressed concerns with the proposed rule.

''There's been lots of momentum, increasingly so, since 2013 and we're pleased obviously with all of this support,'' Neas said. ''We're pleased that the FDA wants to continue to talk'' about the proposed rule.

Neas said GPhA will continue to talk to FDA officials on every level about the proposed rule.

''We are very pleased that there's this deliberative process in place right now and it looks like all voices are going to be heard,'' Neas said. ''We hope in the end

there will be a rule that's greatly improved from the November 2013 proposed rule.''

Mahn said the generic drug labeling rule is ''long overdue'' but added that 2015 may ''be the year that something finally happens with new FDA rules that will put generics at the same risk as pioneers under state failure to warn laws.''

Expedited Labeling Review. Neas said the GPhA has submitted a proposal to the FDA that would expedite the review of labeling changes. The proposal would address the FDA's concerns without incurring ''all of the downsides of the current proposed labeling rule,'' he said.

Under the proposal, when the agency gets adverse event information about a particular drug, it would be given a certain amount of time to review the new label that contains the adverse event information, Neas said.

''Right now a new label can take an average of nine months to be approved,'' Neas said. ''Of course, everyone wants to get that safety information out there. We're under a legal obligation to provide any new safety problems, any adverse events, within two weeks.''

Neas said GPhA is ''trying to get something in place where the FDA has to act in a certain amount of time.''

GPhA also ''strongly'' recommends electronic labeling, ''because part of the problem is that they're using paper,'' Neas said. If e-labeling is implemented, label changes could be made right away, he said.

In December 2014, the FDA issued a proposed rule (RIN 0910-AG18) on drug labeling to require electronic distribution of the prescribing information intended for health-care professionals.

Biosimilars. Neas said biosimilars also will be a big issue in 2015 because the FDA may approve a biosimilar product.

''In other parts of the world, they're been using biosimilars since 2005. There seems to be more and more momentum,'' Neas said. ''I do think we're getting closer and closer to biosimilars being approved.''

On Dec. 17, Apotex Inc. announced that the FDA had accepted for filing its application for pegfilgrastim, a biosimilar version of Amgen's chemotherapy drug Neulasta. The potential biosimilar of Neulasta joins already accepted applications by Novartis AG's Sandoz unit, which wants to sell a version of Amgen Inc.'s biologic cancer drug Neupogen, and Celltrion for a biosimilar of Johnson & Johnson's arthritis drug Remicade.

Michael Reilly, executive director of the Alliance for Safe Biologic Medicines (ASBM) told Bloomberg BNA that he expects the FDA to approve the first biosimilar by the spring of 2015. ''In fact there may be multiple approvals by then,'' Reilly said.

''They're going to have to issue guidance on naming, basically in the form of approving a product,'' Reilly said. ''They'll let us know by then'' how products should be named.

Reilly said ''it's really hard to say'' how the FDA will go on biosimilar names. He said he has heard that the agency is leaning toward distinguishable names but that's only speculation until they say something.

Reilly also said the FDA hasn't yet addressed interchangeability for biosimilars so if the FDA approves a product, it won't be interchangeable.

Neas of GPhA also told Bloomberg BNA that the naming issue is about whether or not the brand and the biosimilars are going to have the same international nonproprietary name (INN). ''There's lots of activity on this,'' Neas said. ''There are a number of proposals.''

GPhA also is fighting international efforts by the pharmaceutical and biotechnology industries to get the 12 years of exclusivity for brand biologics to apply outside the U.S., Neas said. The Affordable Care Act of 2010 gave brand biologic companies 12 years of exclusivity in the U.S. before a biosimilar version can be approved. ''That's still a live issue,'' Neas said.

These international efforts by the pharmaceutical and biotechnology industries involved the Trans-Pacific Partnership (TPP) treaty. The U.S. position in the latest leaked draft of the Trans-Pacific Partnership (TPP) intellectual property chapter, which is dated May 16, 2014, is that biologic manufacturers should have 12 years of exclusivity. ''We're trying to make sure that the PhRMA and BIO proposals that go into the draft don't get into the final,'' Neas said. ''I'm hopeful we can have a significant impact on what they're doing.''

Neas also said he thinks FDA will issue more guidance on biosimilars ''in the near future.''

State Biosimilar Laws. Neas said state biosimilar implementation laws are moving forward and several states will be looking at biosimilar implementation legislation in 2015. The substitution of a biosimilar product for the innovator or brand-name biologic product can't be done without a state law in place to authorize the substitution.

On Dec. 9, GPhA said it has agreed to support compromise automatic substitution language for state laws that would clarify how physicians and patients should be made aware of pharmacies' substitution of interchangeable biologics for brand name biologics. The compromise language, developed in collaboration with the Biotechnology Industry Organization, replaces the concept of physician ''notification'' about the substitution with that of ''communication'' with the physician about the substitution, an issue on which innovator and biosimilar companies had disagreed.

Carol Kelly, senior vice president of government affairs and public policy for the National Association of Chain Drug Stores (NACDS), told Bloomberg BNA that NACDS has ''been actively working at the state level to ensure that there are no barriers to the substitution of biosimilars.''

''We think that as long as the FDA says it is okay to substitute, then we should be able to do so for the patients, to save them money and provide them with the best quality of care,'' Kelly said. ''So, we'll be working at the state level to continue that position throughout the year ahead.''

Meanwhile, advisory board members told Bloomberg BNA that industry watchers should keep their eyes on the patent aspects of biosimilar applications.

''Biosimilar applications are beginning to take off, with a third application recently having been filed,'' Czaban, of Wiley Rein, said. ''The 'patent dance' prelitigation procedures will be one of the more complex and interesting aspects to watch, especially if Sandoz prevails in its dispute with Amgen over the applicability of certain elements of the BPCIA procedures for its recently filed application.''

Mahn, of Fish & Richardson, said that in 2015, biosimilar applicants will likely continue their efforts to keep their BLA and manufacturing data out of the

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hands of the pioneers, ''mainly because they view the BPCIA confidentiality provisions to be inadequate as compared to a court protective order.''

Under the BPCIA, if confidential access is refused, Mahn said, the pioneer can bring a declaratory judgment action for infringement of any composition or method patent (but not for process patents) pursuant to 35 USC 271(e)(2)(C)(ii). And, he said, the FDA would still be required to process the BLA, regardless of whether the patent exchange process is ever initiated.

''We expect this to be the next battleground between pioneers and biosimilar applicants,'' he said.

GDUFA. GPhA's Neas also said the generic drug industry will be looking at the generic drug user fee program to make sure it's working.

GPhA wants the FDA to improve the approval rate of ANDAs, Neas said. ''Unfortunately, the ANDAs pending now at the FDA are well over 3,000,'' he said. ''The average time right now is 36 months for a generic drug approval. The FDA, by the end of year five [of GDUFA], is supposed to get 90 percent of generic drug applications down to 10 months. Thirty-six months is a long way from 10 months.''

''We want to work very closely with the FDA to close that gap as soon as possible,'' Neas said. ''But it's very important because the GDUFA II negotiations probably will start sometime next year and of course, you want those to be fruitful and successful and you want people to agree, but if GDUFA I is not working, that's going to be a real challenge.'' The first generic drug industry user fee law was passed in 2012.

Czaban predicted that, in 2015, the FDA will continue to struggle with implementing GDUFA and in meeting its performance goals. ''The recent restructuring of the Office of Generic Drugs may help, but there are still categories of ANDAs that risk falling between the cracks in the FDA's review process,'' he said.

User Fee Scrutiny. John Manthei, with Latham & Watkins LLP in Washington, said in a Nov. 5 briefing after the election that the next Congress will want to make sure the FDA is using its industry-paid user fees effectively, and lawmakers will ramp up scrutiny of the agency.

Manthei said the FDA ''should fully expect to be in the crosshairs of the Hill,'' based on the Nov. 4 election results. Republicans took control of both the Senate and House in 2015 for the first time since 2007.

According to Manthei, the agency has been receiving more funding from user fees, which are paid by the drug and device industries, and lawmakers want to make sure those resources are being used efficiently.

Since the FDA and industry renegotiated the user fee agreements for drugs and devices in 2012, the agency has received more money in exchange for meeting certain performance goals. According to Manthei, lawmakers will focus specifically on the agency's hiring practices, and whether enough staff is being hired fast enough to keep up with the user fee goals. That increased oversight is expected to lay the groundwork for the next round of user fee negotiations in 2016 for reauthorization in 2017.

REMS Bill. Neas said GPhA ''strongly'' supports a bill introduced in 2014 seeking to help generic companies obtain samples of drugs subject to risk evaluation and mitigation strategies (REMS).

Generic drug manufacturers have faced increasing difficulty obtaining samples of a branded drug manufacturer's product for the bioequivalence testing necessary to obtain generic approval for their drug from the FDA. On occasion, the branded manufacturer has maintained that restrictions on access set forth in REMS, required by the FDA for certain drugs due to safety concerns, precluded them from providing samples to the generic manufacturer.

Recognizing that any delay in providing samples to the generic could also lead to a delay in market entry of lower-priced generic alternatives, in December 2014, the FDA issued draft guidance designed to assist generics in obtaining samples of reference listed drugs. Comments on the draft guidance are due Feb. 3.

Burns, of Dickinson Wright, said the FDA draft guidance is designed to assist generics in obtaining samples by clarifying that the provision of a sample to a generic drug company wouldn't constitute a violation of the branded manufacturer's safety requirements.

In issuing the guidance, the FDA signalled a hope that the branded manufacturer now would more willingly provide a sample to the generic manufacturer. While the FDA guidance, if finalized, will eliminate a potential cause for branded manufacturer unwillingness to provide generic companies with samples, it won't likely lead to an end to the issue, Burns said.

''The guidance wouldn't require a branded manufacturer to provide a sample to a generic, and thus, given the competitive implications associated with the introduction of a generic drug in the market, branded manufacturers will continue to have an incentive to try to delay such entry,'' he said. ''The guidance does, however, potentially eliminate a clear, non-anticompetitive justification for such refusal. Accordingly, if the guidance is finalized, 2015 may become a year in which antitrust actions involving a claim that a branded manufacturer's refusal to provide samples constitutes an antitrust violation may blossom.''

A legislative solution also is on the table. During the previous Congress, in September 2014, Reps. Steve Stivers (R-Ohio) and Peter Welch (D-Vt.) introduced a bill (H.R. 5657) that would prevent branded drug manufacturers from using REMS to delay generic drug launches.

Neas said the FDA's draft guidance ''is good, but we still strongly support the legislation'' because ''it's stronger'' than the draft guidance.

Corporate Tax Reform. John Kamp, executive director of the Coalition for Healthcare Communication and a consulting counsel to Wiley Rein LLP in Washington, told Bloomberg BNA that corporate tax reform will be a big issue on the Hill in 2015.

''Tax reform could go a lot of different ways but the fact that both the White House and the Congress now believe that tax reform is a good idea, especially corporate tax reform, we could see some things that could be helpful to some in pharma and not helpful to others in pharma,'' Kamp said. ''Specifically, the one that I'm concerned about is the reduction or elimination of the tax deductibility of marketing costs.''

Kamp said there were corporate tax reform proposals in the last Congress, that would have immediately reduced the tax deductibility of marketing costs to 50 percent and then reduce the rest of the 50 percent over five to 10 years.

Off-Label Promotion Guidance. Kamp also said the FDA has promised to give some guidance on issues related to off-label drug promotion. That guidance was supposed to be out by the end of 2014 or in early 2015, he said.

The off-label guidance ''will be interesting and important,'' Kamp said. ''We could see some changes in the advice on scientific exchange [of information] and maybe even in the social media context of responses to unsolicited questions. We could see some movement on that.''

Kamp also said he hopes in 2015 to see Congress pass legislation on reprints and textbooks under the Physician Payments Sunshine Act, which would essentially clarify the intent of Congress on whether they are exempt from the Sunshine Act. Under the sunshine law, which is part of the Affordable Care Act, the Centers for Medicare & Medicaid Services established a database in 2014, known as Open Payments, which provides details about financial relationships between doctors and manufacturers.

''I'm hoping, too, that the HHS and CMS will get their act together on the Sunshine reporting,'' Kamp said. ''So far, the database has not been all that consumer or doctor friendly and they've got a long way to go to get that done. I'm hoping that they're essentially going to . . . move forward and make the data easier to use from the industry standpoint and consumers.''

Drug Quality and Security Act. Carol Kelly, with NACDS, told Bloomberg BNA that NACDS has been working with its members and the Pharmaceutical Distribution Security Alliance (PDSA) to keep Capitol Hill informed about concerns with the implementation of the Drug Quality and Security Act (Pub. L. No. 113-54).

''To date, our work with FDA has gone relatively smoothly,'' Kelly said.

The Drug Quality and Security Act requires drug trading partners such as manufacturers, wholesale distributors, dispensers and repackagers to capture, maintain and provide the subsequent purchaser with transaction information for certain prescription drugs. Manufacturers, wholesale distributors and repackagers must meet these requirements by Jan. 1, 2015, and dispensers must meet them by July 1, 2015. However, on Dec. 24, 2014, the FDA posted a compliance policy guidance to inform industry that it doesn't intend to take action against manufacturers, wholesale distributors or repackagers who don't, prior to May 1, 2015, provide or capture prescription drug tracking information (13 PLIR 11, 1/2/15).

''There is also a July 1 deadline for additional responsibilities that pharmacies need to engage in and we'll continue to work with FDA and the PDSA coalition, and to keep the Hill informed,'' Kelly said. ''So far I think that implementation is moving along well.''

Medicare, Medicaid Programs. ''For the year ahead, both at the federal and state levels, you'll really see us focus in on pharmacy care and the ability to help patients through the pharmacy,'' Kelly said. ''Whether it's in the Medicare program or the Medicaid program, we want to ensure that pharmacists have the ability to use their education and training to help with the care of patients. And working with those two entitlement programs will be key to making that happen.''

Kelly said NACDS will continue to work on provider status under the Medicare program.

In March 2014, Rep. Brett Guthrie (R-Ky.) introduced H.R. 4190, which would amend title XVIII of the Social Security Act to provide coverage of pharmacist services under the Medicare program.

NACDS expects H.R. 4190 to be reintroduced in the House in 2015 and the group will ''continue to look for opportunities to move that legislation through the process so that pharmacists, consistent with their education and training, can help Medicare beneficiaries in medically underserved areas,'' Kelly said. ''We are also hopeful the legislation will be introduced early on in the Senate. A bipartisan group of senators are definitely working towards that.''

Another priority ''will be the medication therapy management legislation,'' Kelly said. In March 2013, Rep. Cathy McMorris Rodgers (R-Wash.) introduced H.R. 1024, the Medication Therapy Management Empowerment Act of 2013 . The legislation would allow seniors participating in Medicare Part D with any one chronic disease to thoroughly review all of their medications with a pharmacist or other health-care provider in a one-on-one session.

''We'll continue to pursue this [legislation] both working with Congressman McMorris Rodgers and a working group that was created by the House Energy and Commerce Committee, directly with the Senate Finance Committee, and also with the administration to make sure we're able, to the extent possible, to help patients with their medication, to make sure they get them and take them appropriately and have good high quality outcomes as a result of doing so,'' Kelly said.

Kelly also said NACDS hopes the CMS will release the final prescription drug coverage outpatient rule for Medicaid in 2015. ''Right now they're saying sometime in the Spring,'' she said.

The proposed Medicaid pricing rule for outpatient drugs (CMS-2345-P) was published Feb. 2, 2012 (77 Fed. Reg. 5,318). The rule would use the average manufacturer price (AMP) model to determine Medicaid reimbursements for prescription drugs.

The rule ''is very important to us,'' Kelly said. ''It's important that it be done properly and consistently. It's also important that the release of the information provide sufficient guidance for states to do what they need to do to implement the new federal upper limits consistent with the statute and then, we have an opportunity to comment on all of this and work with the states.''

Wilkinson said, ''These high-cost drugs are wreaking havoc on public programs like Medicaid, and could become the impetus for policy reforms around pricing or coverage.''

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