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## PRODUCT LIABILITY/JURISDICTION

## As Plavix due process case proceeds, high court is urged to take similar Paxil suit

By Michael Scott Leonard

California's courts have filed U.S. Supreme Court papers defending their jurisdictional approach to personal injury litigation over the Bristol-Myers Squibb Co. blood thinner Plavix, while GlaxoSmithKline LLC has asked the high court to broaden its inquiry by taking a companion case involving the antidepressant Paxil.

***Bristol-Myers Squibb Co. v. Superior Court of California et al., No. 16-466, respondents' brief filed (U.S. Mar. 31, 2017).***

***GlaxoSmithKline LLC v. M.M. ex rel. Meyers et al., No. 16-1171, petition for cert. filed (U.S. Mar. 23, 2017).***

In a March 31 respondents' brief, the San Francisco Superior Court, joined by 575 non-California resident plaintiffs in the Plavix

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U.S. Supreme Court building

REUTERS/Joshua Roberts

## EXPERT ANALYSIS

## Reviewing changes made by the 21st Century Cures Act to drug and device development

Lowenstein Sandler LLP attorneys Jim Shehan, Tara D'Orsi and Donna Hanrahan answer questions about how the 21st Century Cures Act, which President Barack Obama signed into law in December, will affect the life sciences industry.

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## EXPERT ANALYSIS

## Obamacare's 'risk corridor' program: Litigation status and prospects

Health law attorneys Deborah Dorman-Rodriguez and David M. Kaufman analyze the controversy surrounding Obamacare's "risk corridor" program — which was designed to reduce risks for insurers entering new marketplaces — and the resulting litigation.

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## Westlaw Journal Pharmaceutical

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## Reviewing changes made by the 21st Century Cures Act to drug and device development

By James C. Shehan, Esq., Tara D’Orsi, Esq., and Donna Hanrahan, Esq.  
Lowenstein Sandler LLP

### *How will the act affect the approval process for drugs and biologics?*

The Cures Act, Pub. L. 114-255, amended multiple provisions of the Public Health Service Act and the Food, Drug and Cosmetic Act. The law includes several provisions that loosen restrictions or add flexibility to the approval process for drugs and biologics.

One section, for instance, directs the Food and Drug Administration to better incorporate the use of patient experience data in approvals. Another requires the agency to hold a public meeting and issue guidance about the use of adaptive and other novel clinical trial designs during the regulatory review process.

An “adaptive design” drug trial is one that re-evaluates the study’s underlying mechanics on an ongoing basis, based on the data as it comes in. Researchers using adaptive designs often update or revise their methods after analyzing early results.

The concept, which is already being used to develop some products, may make studies more efficient, more likely to demonstrate an effect if one exists, or more informative.

The forthcoming FDA guidance will address the types of quantitative and qualitative information that should be submitted following an adaptive-design trial and how such trials may show “substantial evidence” of safety and effectiveness.

Several different sections of the Cures Act also tell the FDA to make it easier for drug companies to win approval for new uses of previously approved drugs.

One provision allows applicants to use “real-world evidence” when seeking approval for new indications. Another allows the FDA to rely on “qualified data summaries” — clinical data that demonstrates a drug’s safety and effectiveness for one specific purpose — when approving supplemental applications.

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Several different sections of the Cures Act tell the FDA to make it easier for drug companies to win approval for new uses of previously approved drugs.

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The act also clarifies the agency’s authority over genetically targeted drugs by allowing companies to reuse data from their own previously approved applications.

### *How will the act affect the approval process for medical devices?*

The Cures Act makes several substantial changes to device regulation, the most significant of which is the establishment of a new “breakthrough device” pathway.

Breakthrough devices are those that offer significant advantages over existing alternatives, including the potential to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate

patient autonomy, or establish long-term clinical efficiencies.

The FDA is expected to build on the existing “priority review device” pathway covered in a guidance the agency issued April 13, 2015.

Other significant changes to device regulation include permitting centralized institutional review boards, or IRBs, for clinical trials of device prospects; requiring the FDA to consider the least burdensome means of demonstrating safety and effectiveness at

the pre-market approval stage; five new categories of medical software that will not count as medical devices; and raising the cap for “humanitarian device” eligibility from 4,000 to 8,000 affected patients.

Moreover, the Cures Act also aims to speed the approval of drug-device combination products by clarifying how the FDA should determine a product’s “primary mode of action” by requiring the agency to coordinate with the maker of combination product about how best to classify it.

The law also establishes procedures for resolving disagreements that arise as part of that process.

### *How does the act affect the ability of drug and device makers to use economic data?*

The Cures Act authorizes the dissemination of health care economic information, or HCEI, to the insurance company or government officials responsible for drug coverage and reimbursement decisions.

The law broadens the definition of HCEI to include any analysis that identifies, measures or describes a drug’s economic consequences. Such analyses may include comparisons to a different drug, to another



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type of health care intervention, or to no intervention at all.

The act allows drug companies to provide HCEI to “a payer, formulary committee or other similar entity” responsible for “the selection of drugs for coverage or reimbursement.” By liberalizing the definition of HCEI, the law overturns the FDA’s prior efforts to restrict HCEI to evidence derived from double-blind clinical trials.

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## The law clarifies the agency’s authority over genetically targeted drugs by allowing companies to reuse data from their own previously approved applications.

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Within five weeks of the Cures Act’s passage, the FDA released a new draft HCEI guidance that establishes two key principles: HCEI must “relate to an approved indication,” and HCEI must be based on “competent and reliable scientific evidence.”

The draft guidance explicitly states that under certain circumstances, companies may give payers information about unapproved products without violating FDA regulations that ban the promotion of investigational drugs and devices.

### ***How does the act affect false claims?***

The Cures Act allows the U.S. Health and Human Services Department to impose new civil monetary penalties for false or fraudulent claims. If HHS determines a party has filed a false or fraudulent reimbursement claim with the agency, it can impose penalties of up to

\$50,000 per transgression, as well as triple liability for the claim itself.

HHS may also exclude the false claimant from future participation in state and federal health care programs. These new penalties under the Cures Act apply separately and on top of liability under the False Claims Act.

### ***When will Cures Act take effect?***

The short answer is: It depends.

Some provisions, such as those relating to “qualified data summaries” as part of supplemental applications for new drug uses, took effect immediately.

Another provision that requires drug companies developing drugs for “serious diseases” to post their expanded access policies online became effective 60 days after enactment.

But many of the most important provisions require the FDA to take additional actions before they are fully effective.

For example, the law requires the FDA to hold a public meeting within 18 months on adaptive clinical trial designs, then gives the agency 18 months after that to issue its draft guidance and an additional year to finalize the policy after the comment period closes.

The act gives the FDA five years to implement a patient-focused drug development guidance and 6 1/2 years to issue a final guidance or a “revised draft guidance” governing the use of real-world evidence.

Implementation of these guidelines will take time, and the FDA has a long tradition of missing congressionally imposed deadlines.

But drug and device makers should not rule out trying to take advantage of some of these programs before the guidelines are final.

The FDA has for several years allowed applicants to use adaptive clinical designs even though it is only now developing formal guidelines covering them. It is certainly possible the agency will take a similar approach to parts of the Cures Act.

### ***What kind of funding does the act provide?***

The law authorizes approximately \$6.8 billion in spending for major initiatives.

Of that, \$500 million will go to the FDA for regulatory modernization and personnel recruitment and retention.

About \$4.8 billion is allocated to the National Institutes of Health for research on personalized medicine, Alzheimer’s disease, adult stem cells, and the “Cancer Moonshot” program.

Finally, \$1 billion will be available to the states to fight opioid abuse.

All of these expenditures depend upon specific congressional appropriations. [WJ](#)

## 3rd Circuit resurrects Fosamax injury MDL

By Michael Scott Leonard

A federal appeals court has revived multidistrict litigation accusing Merck & Co. of failing to warn Fosamax users that the osteoporosis drug can cause thigh bone fractures, saying the drugmaker did not show the Food and Drug Administration would reject the label proposed by the plaintiffs.

***In re Fosamax (alendronate sodium) Products Liability Litigation, No. 14-1900, 2017 WL 1075047 (3d Cir. Mar. 22, 2017).***

In a March 22 ruling of first impression, the 3rd U.S. Circuit Court of Appeals said Merck cannot invoke a defense of “impossibility preemption” unless the company proves to a jury by “clear and convincing evidence” that the FDA would have refused a stronger warning about the risk of “atypical femoral fractures.”

A state law cause of action is invalid under the doctrine of “impossibility preemption” when a company or defendant can only avoid liability by violating federal law.

A New Jersey federal judge tossed the suit on preemption grounds in 2014 without letting it go to a jury, citing communications between



REUTERS/Mike Blake

Fuentes wrote for the panel. “That is enough for plaintiffs to defeat summary judgment and proceed to trial.”

U.S. Circuit Judges Michael A. Chagares and Luis F. Restrepo joined the opinion.

The 3rd Circuit decision overturns a ruling by U.S. District Judge Joel A. Pisano of the District of New Jersey, who agreed with

manufacturer posits a theoretical association between drug use and an adverse event.”

The agency also has a mandate to consider the way drug labels can discourage proper use by exaggerating minor or speculative risks, the panel noted.

As part of that balancing act, the FDA in April 2009 allowed Merck to add a femoral fracture warning to the Fosamax label’s “adverse reactions” section.

But the agency rejected a more prominent notice, in the label’s “warnings and precautions” section, about potential femoral “stress fractures,” saying that term inaccurately described the sorts of atypical fractures users reported suffering.

After additional data came in over the next year and a half, the FDA changed course in October 2010, requiring the more prominent notice — in the warnings and precautions section of the Fosamax label — that it had previously rejected.

The agency again refused to let Merck refer to the femoral fractures as “stress fractures,” but it otherwise accepted the proposed April 2009 warning nearly verbatim, according to the 3rd Circuit opinion.

### MULTIDISTRICT LITIGATION

After the label change, more than 1,000 Fosamax users around the country sued Merck, saying the company should have found a way to include the final version of the femoral fracture warning years before it did.

The Judicial Panel on Multidistrict Litigation eventually consolidated the claims in Judge Pisano’s Newark courtroom.

Following a bellwether trial in one of the individual suits, the judge granted summary judgment for the drug company, tossing the entire multidistrict case.

Judge Pisano said it would be impossible for the drugmaker to update the Fosamax

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“Plaintiffs have produced sufficient evidence for a reasonable jury to conclude that the FDA would have approved a properly worded warning about the risk of thigh fractures,”  
the 3rd Circuit said.

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the FDA and Merck showing that the agency repeatedly rejected the drugmaker’s attempt to strengthen its femoral fracture warning. *In re Fosamax Prods. Liab. Litig.*, MDL No. 2243, 2014 WL 1266994 (D.N.J. Mar. 26, 2014).

Reversing, the 3rd Circuit panel said the plaintiffs offered enough evidence to go before a jury with their argument that the FDA would have accepted a more carefully drafted label than Merck submitted.

“Plaintiffs have produced sufficient evidence for a reasonable jury to conclude that the FDA would have approved a properly worded warning about the risk of thigh fractures — or at the very least, to conclude that the odds of FDA rejection were less than highly probable,” U.S. Circuit Judge Julio M.

Merck that preemption is always a question of law for a court, not a question of fact for a jury.

### FEMORAL FRACTURES

The case stems from label changes Merck proposed, and the FDA rejected, after an apparent association emerged in 2008 between Fosamax — already approved and on the market — and atypical femoral fractures.

In light of the new data, Merck negotiated with the agency throughout 2008 and 2009 about how best to warn doctors and Fosamax users without overstating the risks.

According to the appellate opinion, the FDA “does not simply approve warnings out of an abundance of caution whenever the

label without flouting the FDA, which had expressly rejected stronger warning language on several occasions.

The judge cited the U.S. Supreme Court's landmark ruling in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), which said drugmakers can assert impossibility preemption in failure-to-warn cases only if they show by "clear and convincing evidence" that the FDA would have refused to adopt the plaintiffs' proposed warning.

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"It is true that most preemption cases present purely legal questions," the 3rd Circuit said. "But it is equally clear that preemption can be, and sometimes must be, a fact question for the jury."

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Merck's evidence showing that the agency repeatedly rejected the company's warning proposals is enough to establish preemption under *Wyeth* as a matter of law, Judge Pisano found.

The plaintiffs appealed.

## CLEAR AND CONVINCING EVIDENCE

The 3rd Circuit reversed.

Confronting a question of first impression within the circuit, the panel found that the *Wyeth* decision had announced not just a substantive rule of law but a standard of proof as well.

When the *Wyeth* court said drug companies must establish impossibility preemption by "clear and convincing evidence," the justices

were using a well-known legal standard covering questions of fact for a jury, not questions of law for a court, the appeals court said.

According to the panel opinion, the plaintiffs presented evidence from which a jury could

reasonably conclude that the FDA rejected Merck's original proposed warnings and precautions label only because the drug company had misused the phrase "stress fracture."

If a jury made that finding, Merck likely could not meet the heavy burden of showing by clear and convincing evidence that the FDA would have rejected a properly written warning, the appeals court concluded, reversing the summary judgment grant.

The panel also rejected Merck's argument that preemption questions are always legal, not factual, in nature.

"The 'rule' Merck cites ... is one of thumb rather than law," Judge Fuentes wrote. "It is true that most preemption cases present purely legal questions. ... But it is equally clear that preemption can be, and sometimes must be, a fact question for the jury." **WJ**

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Opinion: 2017 WL 1075047

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# Sandoz says Amgen's Supreme Court arguments in Neupogen case ignore key issues

By Michael Scott Leonard

Drugmaker Sandoz Inc., locked in a patent dispute with rival Amgen Inc. over generic versions of Amgen's immune-system booster Neupogen, says in a U.S. Supreme Court brief that the other company's most recent court filing failed even to address Sandoz's main argument.

## ***Sandoz Inc. v. Amgen Inc. et al., Nos. 15-1039 and 15-1195, response and reply brief filed (U.S. Mar. 31, 2017).***

In a March 31 response and reply brief, Sandoz portrays Amgen's earlier-filed court papers as not responsive to the central claim of Sandoz's petition: that the early dispute resolution provisions of the Biologics Price Competition and Innovation Act, 42 U.S.C.A. § 262, specify only optional procedural mechanisms, not enforceable standalone rights.

In bypassing the discovery-style disclosures that trigger those mechanisms, Sandoz says it was simply choosing to forgo the dispute resolution process altogether, not violating a mandatory rule for rolling out its generic version of Neupogen (filgrastim), which works by stimulating bone marrow activity.

Amgen's contention to the contrary would require the high court to interpret statutory language "rip[ped] from context and read[] in isolation," Sandoz argues.

"Amgen emphasizes the statute's mandatory language but fails to recognize the contingent nature of its commands: Parties *must* take certain steps to start or continue the process, but if they do not, the statute explicitly sets out what happens as a consequence," Sandoz says in its brief.

"In place of those consequences, Amgen asks the court to invent new ones — causes of action for injunctions mandating procedural compliance," the brief adds. "The statute as written precludes this approach."

## **BIOSIMILARS ACT**

Enacted as part of the Affordable Care Act, the Biologics Price Competition and Innovation Act was supposed to encourage the development of generic versions of biologic drugs like Neupogen and to streamline the lawsuits they inevitably bring,

as the Hatch-Waxman Act had done for conventional generics.

Biologics, or biopharmaceuticals, are medicines derived from living organisms rather than synthetic chemicals. The category includes traditional therapies such as vaccines and donor blood, but modern biologics typically involve advanced genetic engineering, often aimed at boosting the immune system.

The mechanisms established by the BPCIA, also called the Biosimilars Act, include a quasi-discovery process triggered when the manufacturer of a generic, or "biosimilar," turns over to the brand-name drugmaker research showing its version is eligible for streamlined regulatory approval because it will work the same way.

Sandoz, seeking to market a biosimilar filgrastim product called Zarxio, refused to make those disclosures, and Amgen sued, claiming they were mandatory under statutory language saying applicants "shall" open up their research.

## **2 RULINGS, 2 APPEALS, 1 CASE**

The U.S. Court of Appeals for the Federal Circuit, the country's top patent court, confronting an issue of first impression, rejected Amgen's argument in a three-judge 2015 ruling that yielded three separate opinions. *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347 (Fed. Cir. 2015).

A biosimilar applicant is not violating the BPCIA if it opts to forgo the dispute resolution procedures, since the law expressly establishes a different litigation-initiating process for brand-name biologics makers that do not receive that information, the appeals court said.

Amgen appealed that part of the ruling to the Supreme Court.

But the Federal Circuit panel found that Sandoz could not enter the filgrastim market until 180 days after the U.S. Food and Drug Administration approved Zarxio in March 2015, rather than 180 days after Sandoz notified Amgen in July 2014 of its intention to roll out a filgrastim competitor.

The panel cited a BPCIA section requiring the biosimilar applicant to notify the brand-name drugmaker 180 days before marketing its "licensed" biologic.

Under that provision, an applicant cannot give effective notice until the FDA has already approved and licensed its product, meaning the six-month countdown cannot start until then, the appeals court said.

Sandoz appealed that part of the decision.

The Supreme Court accepted both cross-petitions in January.

## **MANDATORY OR CONDITIONAL?**

In its March 31 brief, Sandoz says Amgen has failed so far to rebut the Federal Circuit's ruling on the question of whether the BPCIA's use of "shall" is enough to make its dispute resolution process mandatory.

Instead of responding to the court's reasoning, Amgen is just repeating arguments that have already failed, trying to sell the justices on its out-of-context interpretation, Sandoz says.

The BPCIA "specifies an action that an applicant *must* take to proceed with the process: *If* an applicant wishes to engage in the information exchange, it 'shall' timely provide its application," Sandoz says in its brief. "When that condition is unsatisfied, the parties shift to a different patent resolution track."

The provision is "analogous [to] statutes and rules mandating that a party act by a deadline — or else suffer consequences," the brief adds.

Sandoz also assails the Federal Circuit's interpretation of the law's 180-day waiting period and Amgen's defense of that ruling, saying the court simply "invented" the requirement that a biosimilar must receive FDA approval before the clock can start to run.

"The notice of commercial marketing provision includes only one timing element: Notice comes '180 days before the date of the first commercial marketing' of the biosimilar," the reply brief says. "The provision includes no 'after' requirement." **WJ**

#### Attorney

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Brief: 2017 WL 1244348



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## DRUG DEVELOPMENT

### The cost of cancer: new drugs show success at a steep price

(Reuters) – Newer cancer drugs that enlist the body's immune system are improving the odds of survival, but competition between them is not reining in prices that can now top \$250,000 a year.

The drugs' success for patients is the result of big bets in cancer therapy made by Bristol-Myers Squibb Co., Merck & Co. and Roche Holding AG, among others in big pharma. The industry's pipeline of cancer drugs expanded by 63 percent between 2005 and 2015, according to the QuintilesIMS Institute, and a good number are reaching the market.

The global market for cancer immunotherapies alone is expected to grow more than fourfold globally to \$75.8 billion by 2022 from \$16.9 billion in 2015, according to research firm GlobalData.

"For cancer drugs in general ... it is hard for us to drive down cost," said Steve Miller, chief medical officer at Express Scripts Holding Co., the nation's largest manager of drug benefit plans for employers and insurers. "You don't want to be in the position of being told to use the second-best cancer drug for your child."

Lawmakers on both sides of the aisle, as well as President Donald Trump, have been grappling with how to restrain rising prescription drug costs. They have talked about solutions ranging from more price negotiation to faster approval of new drugs, often invoking increased competition between drugmakers.

"Competition is key to lowering drug prices," Trump told pharmaceutical executives at an Oval Office meeting in January.

But that is not happening with new drugs called checkpoint inhibitors that work by releasing a molecular brake, allowing the immune system to recognize and attack cancer cells the same way it fights infections caused by bacteria or viruses.

For cancers like melanoma, the treatments can mean long-term survival for around 20 percent of patients.

Bristol's Yervoy, first approved in 2011, targets a protein known as CTLA-4. Other immunotherapies, including Bristol's Opdivo,

Keytruda from Merck, Roche's Tecentriq, and Pfizer Inc.'s Bavencio, involve a different protein called PD-1.

Current checkpoint inhibitors each have a list price near \$150,000 a year. A combination of Yervoy and Opdivo, approved by the Food and Drug Administration for advanced or inoperable melanoma, has a cost of \$256,000 a year for patients who respond to the treatment.

Similar immunotherapies are in development at companies like AstraZeneca PLC. Merck, which declined to comment on pricing plans, expects an FDA decision by May 10 on its combination of Keytruda and chemotherapy as an initial treatment for the most common form of lung cancer — by far the biggest market for cancer drugs.

Pfizer said Bavencio, cleared by the FDA in early April to treat Merkel cell carcinoma, a rare type of skin cancer, has a price "comparable to other checkpoint inhibitors approved for different indications."

The pharmaceutical industry holds that discussion of prescription drug prices has to take into account the major investment required for innovation and discovery of new lifesaving drugs.

#### 'UNRESTRAINED PRICING POWER'

Scientific progress, and pricing power, are driving pharmaceutical companies to emphasize oncology research.

"Most of the strategy on the part of pharmaceutical companies assumes unrestrained pricing power," said Dr. Peter Bach, director of Memorial Sloan Kettering's Center for Health Policy Outcomes in New York. "We don't see evidence that companies are pursuing cost-effective strategies."

Health insurers have had success in demanding price concessions in some drug categories — like diabetes, where several companies sell similar products and insurers

are able to negotiate price discounts or rebates in exchange for coverage.

According to IMS, that tactic capped the overall rise in spending on diabetes medicines at 8 percent in 2015, compared with an increase of 30 percent in billed invoices. All of the invoice price growth for insulin was offset by price cuts, the institute said.

But discounting is much less common for newer, innovative cancer drugs, mostly given by injection and approved for defined patient populations.

Net price growth for branded oncology drugs averaged 4.8 percent in 2015, versus 6.4 percent for invoices, according to IMS.

Express Scripts' Miller and others said makers of new cancer medications enjoy pricing power due to coverage requirements, insurance plan structure and a lack of head-to-head comparison studies.

"Cancer drugs don't compete on price," said Dr. Aaron Kesselheim, a researcher at Harvard Medical School and author of several studies of drug pricing. "Drug companies have market exclusivity and we require payers to cover cancer drugs — Medicare has six protected classes, including cancer."

Medicare, the federal government's health care plan for seniors and the disabled, covers most prescription drugs under its "Part D" pharmacy benefits. The plans are required to cover all drugs in six classes: cancer, HIV, antidepressants, antipsychotics, seizure disorders like epilepsy, and immune system suppressants for people undergoing organ transplantation.

Trump met recently with Reps. Elijah Cummings and Peter Welch, both Democrats, to discuss draft legislation allowing the government to negotiate

Medicare drug prices — but the bill preserves the six protected classes.

In addition, drugs given by injection, including many cancer therapies, are covered under Medicare's main medical benefit.

Bristol disappointed investors when it did not pursue accelerated FDA review of the Opdivo/Yervoy combination for newly diagnosed lung cancer — putting Merck ahead in the lucrative lung cancer market.

"All of the immunotherapies have similar price points," said Miller at Express Scripts. "When you stack therapies, it means more expense for patients and (health) plan sponsors." **WJ**

*(Reporting by Deena Beasley; editing by Edward Tobin)*

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## FOOD AND DRUG ADMINISTRATION

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# Trump nominee to lead FDA probed on ties to pharmacy industry

(Reuters) — President Donald Trump's nominee to lead the U.S. Food and Drug Administration, Dr. Scott Gottlieb, was questioned about his ties to the pharmaceutical industry by Democrats on a key Senate committee April 5 ahead of a vote on whether to advance his nomination for a vote by the full Senate.

Gottlieb, 44, is a former FDA deputy commissioner who has advocated a loosening of requirements needed for approval of new medical products. He is also a resident fellow at the conservative American Enterprise Institute think tank, a partner at a large venture capital fund and sits on the boards of multiple health care companies.

Democrats on the Senate Committee on Health, Education, Labor and Pensions questioned whether Gottlieb's ties to the pharmaceutical industry would compromise his ability to act impartially.

Sen. Chris Murphy of Connecticut said Democrats had "a level of discomfort" with Gottlieb's nomination, not just due to his private industry background but because of his prior activity as a political adviser to

Republican presidential candidates and opposition to the Affordable Care Act.

"The worry about impartiality is certainly connected to the private sector experience but it's also to your very deep political involvement as well," Murphy said.

Gottlieb acknowledged the concern but said he would "work hard to make sure I preserve my impartiality" and that he wanted to "earn and keep the public trust."

In an ethics disclosure form filed in March, Gottlieb said he would resign from multiple corporate boards, divest his health care company holdings and resign from the company boards he sits on.

Overall, the hearing went smoothly for Gottlieb and covered his views on clinical trials, e-cigarettes, the opioid epidemic and vaccines.



REUTERS/Aaron P. Bernstein

**Senate Democrats question the impartiality of Dr. Scott Gottlieb, shown here, President Donald Trump's nominee to lead the FDA, because of his ties to the pharmaceutical industry.**

If approved by the committee, Gottlieb's nomination will go to the Senate floor for a full vote. He is generally expected to be approved. **WJ**

*(Reporting by Toni Clarke; editing by Alistair Bell)*

# Biopharmaceutical IPOs start April strong

By Cory Hester

Four biopharmaceutical companies, three of them foreign issuers, launched initial public offerings in the first week of April worth a combined \$311 million.

New Haven, Connecticut-based Biohaven Pharmaceutical Holding Co. initiated an IPO with a placeholder value of \$100 million, according to a registration statement filed April 7 with the U.S. Securities and Exchange Commission.

Biohaven is a clinical-stage biopharmaceutical company with a portfolio of product candidates targeting neurological diseases, the filing said. The company has yet to determine the number of shares for sale in the IPO.

On the same day, UroGen Pharma Ltd. also filed a registration statement to commence an IPO valued at \$50 million. The company has not set pricing terms in the offering.

Israel-based UroGen said it is at the clinical stage of developing novel therapies aimed at changing the standard of care for urological pathologies.

Canadian biopharmaceutical company Zymeworks Inc. on April 3 launched an IPO valued at \$75 million. The company develops

multifunctional biotherapeutics focused on cancer treatment, the filing said.

Zymeworks also has not determined the number of shares it will sell or set a price.

U.K.-based Verona Pharma PLC launched plans to go public April 3, filing a registration statement in connection with a nearly \$86.3 million offering.

Verona, which has not set pricing terms for the IPO, develops treatments for respiratory diseases, according to the filing.

In January market analysts projected a boost in biotechnology IPOs this year, specifically in the clinical-stage biopharmaceutical sector.

**WJ**

### Related Filings:

Form S-1 (Biohaven): 2017 WL 01288779

Form F-1 (UroGen): 2017 WL 01287598

Form F-1 (Zymeworks): 2017 WL 01197449

Form F-1 (Verona): 2017 WL 01205659

## MERGERS

# Cigna-Anthem merger should stay blocked, government says

By Conor O'Brien

Saying the embattled merger between insurance giants Cigna Corp. and Anthem Inc. would reduce competition, federal and state officials have asked a federal appeals court to uphold a trial judge's order halting the \$54 billion deal.

***United States et al. v. Anthem Inc. et al., Nos. 17-5024 and 17-5028, appellees' brief filed (D.C. Cir. Mar. 13, 2017).***

In a brief filed March 13 in the District of Columbia U.S. Circuit Court of Appeals, the U.S. attorney general's office, the Justice Department, 11 states and the District of Columbia say the anti-competitive effects of the proposed merger would greatly outweigh any resulting cost savings for customers.

The trial judge's Feb. 8 injunction blocking the transaction "reflects an application of modern antitrust principles and rests on a firm evidentiary foundation," the brief says.

Anthem and Cigna are the country's second- and third-largest health insurers, respectively. If they were allowed to combine, only three national carriers would be left standing, the government brief argues.

"The merger of two firms with combined market shares of 64-78 percent would

greatly increase concentration in an already concentrated market and eliminate substantial head-to-head competition that would not be replaced by the expansion or entry of other firms," it says.

### GOVERNMENT, CIGNA SEEKING TO END MERGER

Anthem and Cigna agreed in July 2015 to merge. After a yearlong investigation, federal and state regulators filed suit last July to block the merger, claiming it violated Section 7 of the Clayton Act, 15 U.S.C.A. § 18.

U.S. District Judge Amy Berman Jackson of the District of Columbia agreed in February. *U.S. v. Anthem Inc.*, No. 16-cv-1493, 2017 WL 527923 (D.D.C. Feb. 8, 2017).

She concluded the combination was likely to reduce health insurance competition for large employers in Richmond, Virginia, and 14 states where Anthem operates.

But relations between the insurers began to sour even before the government concluded its investigation, with each accusing the other of frustrating post-merger integration planning, according to the government's brief.

On the heels of Judge Jackson's ruling, Cigna filed suit in the Delaware Chancery Court to terminate the deal, seeking a \$1.85 billion breakup fee from Anthem plus \$13 billion in damages. *Cigna Corp. v. Anthem Inc.*, No. 2017-0109, *complaint released publicly*, 2017 WL 714284 (Del. Ch. Feb. 17, 2017).

Anthem responded with its own lawsuit and on Feb. 15 won a temporary restraining order preventing Cigna from backing out. *Anthem Inc. v. Cigna Corp.*, No. 2017-0114, 2017 WL 667174 (Del. Ch. Feb. 15, 2017).

### GOVERNMENT OPPOSES APPEAL

Both insurers nonetheless filed briefs with the District of Columbia Circuit seeking to

overturn Judge Jackson's decision, with Cigna largely deferring to Anthem in its terse, 600-word court filing.

Anthem has argued the judge wrongly rejected its claim that the merger would result in "cognizable efficiencies," in the form of \$2.4 billion in customer savings, that make up for any of the deal's anti-competitive effects.

But Anthem could not show that the savings were likely to occur or that they depended on the merger, the government says in its reply brief.

"Anthem had no real plan to achieve these savings, and every proffered strategy either foundered in the face of business realities or was disconnected from the merger itself (or both)," the brief says.

Moreover, "ample evidence" supports Judge Jackson's finding that the merger is likely

to lessen competition in Richmond, the government argues.

Should the appeals court find for the insurers, the government has asked it to remand the case to the District Court for further findings, including whether the merger would lessen health insurance competition for large employers outside of Richmond. [WJ](#)

**Related Filing:**  
Cigna's brief: 2017 WL 975382

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## AFFORDABLE CARE ACT

# Amid Obamacare repeal battle, Trump team defended law before Supreme Court

By Michael Scott Leonard

Two weeks before the collapse of President Donald Trump's plan to "repeal and replace" the Affordable Care Act, his administration was already defending parts of the law against a U.S. Supreme Court challenge by the state of West Virginia.

***West Virginia v. Department of Health and Human Services, No. 16-721, opposition brief filed (U.S. Mar. 10, 2017).***

Facing dozens of defections by House Republicans and unified opposition from Democrats, Trump and House Speaker Paul Ryan on March 24 yanked their Obamacare replacement bill, called the American Health Care Act, without letting the full House of Representatives vote on it.

Ryan, speaking to reporters after the move, acknowledged that GOP leaders were effectively backing away from their longtime pledge to repeal President Barack Obama's signature domestic achievement, which has been a lightning rod for political controversy and high-stakes litigation since becoming law in 2010.

"We're going to be living with Obamacare for the foreseeable future," Ryan said March 24.

The GOP plan would have resulted in 24 million fewer insured Americans by 2026, according a March 13 analysis by the nonpartisan Congressional Budget Office.

### TRANSITIONAL POLICY

But March 10 — at the height of Trump's campaign-style push promoting the AHCA — the new administration filed a brief urging the Supreme Court not to review the legality



REUTERS/Kevin Lamarque

***President Donald Trump and House Speaker Paul Ryan on March 24 yanked their Obamacare replacement bill without letting the full House of Representatives vote on it. Here, protesters demonstrate a day earlier against Trump's plans to repeal the health care law.***

of an Obama administration "transitional" policy that is essential to the ACA's political solvency.

The transitional rules vastly expanded Obamacare's grandfather clause for noncompliant health plans by indefinitely postponing some of the law's minimum coverage requirements for insurers.

The policy let millions of Americans keep low-cost, low-benefits health plans, helping Obama honor a campaign promise that no one would lose their existing insurance under the ACA.

It has since been renewed multiple times, including by the Trump administration in February.

Citing an agency policy of not commenting on pending litigation, a U.S. Health and Human Services Department spokesman declined to say whether the government's litigation stance — defending part of the Affordable Care Act against West Virginia, a state that went strongly for Trump — is consistent with the president's public position.

But Trump himself, taking to Twitter the day after the AHCA failed, predicted March 25 that "ObamaCare will explode," a claim that would seem to conflict with his administration's defense of a key ACA component.

West Virginia Solicitor General Elbert Lin had not replied as of press time to a request for comment.

## A CAMPAIGN PROMISE

The transitional rules at the heart of the Supreme Court case trace to late 2013, just before the ACA's "individual mandate," requiring most people to buy insurance or pay a tax penalty, was set to take effect at the beginning of 2014.

The policy delayed federal implementation of minimum health coverage requirements following widespread plan cancellations in advance of the deadline.

Each state remained free to enforce or not enforce the coverage minimums.

Obama had said while promoting the law that "if you like your insurance you can keep it," and millions of Americans cried foul at the loss of low-cost health plans that offered fewer benefits than the minimum allowed under Obamacare.

The transitional policy helped the Obama administration stop that public outcry from blooming into a full-blown political crisis.

But West Virginia says HHS overstepped its constitutional authority, effectively rewriting the health care law to keep Obama's campaign promise.

## POLITICAL ACCOUNTABILITY

In its lawsuit, West Virginia claims the transitional policy passed the buck from HHS to the states, making them choose between angering Affordable Care Act supporters on the one hand and, on the other, taking the blame for any plan cancellations resulting from the coverage minimums.

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President Trump took to Twitter the day after the Republican health care bill failed, predicting that "ObamaCare will explode."

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According to the suit, the law as written gave the states a way to benefit from some Obamacare provisions while still blaming any unpopular consequences, such as the loss of low-cost, low-coverage plans, on the Obama administration.

But the transitional policy harmed the states by forcing them to bear "political accountability" for enforcing the health care law or declining to do so, West Virginia has argued.

West Virginia chose not to enforce the coverage requirements.

A federal judge in Washington, D.C., and the District of Columbia U.S. Circuit Court of Appeals sided with the Obama administration on standing grounds, saying West Virginia had failed to allege a legally cognizable injury. *W. Va. v. U.S. Dep't of Health & Human Servs.*, 145 F. Supp. 3d 94 (D.D.C. 2015), *aff'd*, 827 F.3d 81 (D.C. Cir. 2016).

Increased political accountability "is the kind of inherently immeasurable harm that our standing doctrines have been designed to screen out," the appellate panel said in July 2016.

West Virginia filed its Supreme Court petition Nov. 28, almost three weeks after Trump won the presidential election.

## TRUMP'S HHS DEFENDS OBAMACARE

Instead of dropping the government's defense of the law, HHS urged the high court to leave the lower court rulings intact.

"The prospect of ... political blame does not qualify as a concrete injury sufficient to confer Article III standing," HHS wrote in its opposition brief, citing the District of Columbia Circuit's opinion. "Increased political accountability is abstract and 'inherently immeasurable.'"

"Virtually any decision by the federal government to regulate (or refrain from regulating) in a particular area, or to spend (or refrain from spending) on a particular domestic program could also be cast as altering the 'political terrain' facing states," the brief added. "Unlike traditional Article III injuries, such political harms are not readily subject to judicial assessment." [WJ](#)

### Attorneys:

*Respondent:* acting Solicitor General Noel J. Francisco, acting Assistant Attorney General Chad A. Readler, Mark B. Stern, Alisa B. Klein and Jennifer L. Utrecht, Justice Department, Washington, DC

### Related Filings:

Opposition brief: 2017 WL 957234  
Petition: 2016 WL 7011431

# Anti-abortion pregnancy centers take California disclosure rules to high court

By Michael Scott Leonard

Three “crisis pregnancy centers,” counseling facilities that try to steer women away from abortion, have filed U.S. Supreme Court petitions challenging a California law requiring them to post information about low-cost health care, including abortion, that is available at state-subsidized clinics.

**National Institute of Family and Life Advocates et al. v. Becerra, No. 16-1140, petition for cert. filed (U.S. Mar. 20, 2017).**

**A Woman’s Friend Pregnancy Resource Clinic and Alternative Women’s Center v. Harris, No. 16-1146, petition for cert. filed (U.S. Mar. 20, 2017).**

**Livingwell Medical Clinic Inc. et al. v. Becerra, No. 16-1153, petition for cert. filed (U.S. Mar. 20, 2017).**

In separate March 20 petitions, the crisis pregnancy centers, or CPCs, say the federal appellate rulings against them last year diverged from other high-level decisions about the proper approach to abortion-related speech and the constitutionality of mandatory disclosure requirements like California’s.

The three petitioners are the Livingwell Medical Clinic, A Woman’s Friend Pregnancy Resource Clinic and Alternative Women’s Center, and the National Institute of Family and Life Advocates, or NIFLA, a nonprofit that runs several CPCs and advocates against abortion.

They filed separate First Amendment suits over the mandatory notification requirements of the California Reproductive Freedom, Accountability, Comprehensive Care and Transparency Act, Cal. Health & Safety Code § 123471, commonly called the FACT Act.

A 9th U.S. Circuit Court of Appeals panel rejected all three suits together last October, saying the law’s goals were important enough, and its methods reasonable enough, to overcome the intermediate judicial scrutiny that applies to restrictions on professional speech.

The CPCs are now challenging both the panel’s analytic framework and its conclusions, saying the case implicates divisions among the federal appeals courts over significant unresolved issues.

“Despite decades of case law establishing the principle that one cannot be conscripted into acting as a ventriloquist’s dummy for a governmental message ... the 9th Circuit has upheld such a speech regulation here,” the Livingwell clinic wrote.

“By giving California the green light to coerce charities to utter a message that undermines a significant reason for their very existence, the 9th Circuit has vitiated a bedrock protection afforded by the First Amendment: the autonomy to choose the content of one’s own speech,” the petition added.

## FACT ACT

The cases concern two sections of the FACT Act, which applies to California’s 200-plus crisis pregnancy centers.

First, the suits challenged a provision requiring CPCs that are not licensed medical facilities to disclose that information. Unlicensed CPCs generally provide testing, counseling about alternatives to abortion, some prenatal care and referrals for nonabortion medical services.

The suits also took aim at a second provision requiring state-licensed CPCs, which provide some reproductive health services not involving abortion or contraception, to post signs notifying women that California subsidizes “free or low-cost access to ... contraception, prenatal care and abortion for eligible women.”

They sought injunctions, claiming the state was violating the First Amendment’s ban on compelled speech, which exists alongside its ban on censorship, by forcing them to post legal notices that conflict with their anti-abortion viewpoint.

Three federal judges declined to block the requirement, and the CPCs appealed.

## INTERMEDIATE SCRUTINY

After consolidating the suits for oral argument, the 9th Circuit affirmed in October, issuing a published opinion only in the NIFLA case. *Nat’l Inst. of Family & Life Advocates v. Harris*, 839 F.3d 823 (9th Cir. 2016).

The unanimous panel applied the 9th Circuit’s ruling in *Pickup v. Brown*, 740 F.3d 1208 (9th Cir. 2013), which articulated a test for determining the appropriate standard of review in speech cases.

Under *Pickup*, the panel said, the intensity of judicial scrutiny depends on where the regulated speech falls along a continuum stretching from viewpoint-based political or religious speech, which receives the most First Amendment protection, to “conduct” that happens to take the form of speech, such as psychotherapy, which gets little to none.

Since laws regulating professional or commercial speech fall in the middle of that spectrum, they must overcome intermediate scrutiny, the panel said, meaning they must directly and narrowly advance a substantial government interest, even if they do not represent the least restrictive way of doing so.

That is a test the law passes, the panel concluded.

The CPCs sought Supreme Court review.

## EARLIER RULINGS

According to their Supreme Court petitions, the 9th Circuit departed from the approach previously taken by the 2nd and 4th circuits in cases involving disclosure requirements for CPCs.

The 4th Circuit in 2013 partially rejected a similar law in Maryland, saying the state could make CPCs disclose the lack of a staff doctor but could not force them to tell women

about health services available elsewhere. *Centro Tepeyac v. Montgomery Cty.*, 722 F.3d 184 (4th Cir. 2013).

The ruling did not explicitly spell out the appropriate standard of judicial review for abortion-related disclosures.

The 2nd Circuit, meanwhile, reached the same conclusion in *Evergreen Association v. City of New York*, 740 F.3d 233 (2d Cir. 2014), finding that because the mandatory disclosures concerned a matter of political significance — abortion — they should have to overcome strict judicial scrutiny.

The Supreme Court declined to review the ruling. *Evergreen Ass'n v. City of New York*, 135 S. Ct. 435 (2014).

But now that there is a serious split among the federal appeals courts, the justices should step in, the CPCs say.

“The circuits are divided on abortion-related speech and disclosure cases, and this court should resolve that division,” A Woman’s Friend wrote in its petition. “Regardless of whether the 9th Circuit stands with one other circuit or has become an isolated island on this question, abortion-related speech is not,

and should not become, an exception to the free speech clause.”

### ANOTHER CIRCUIT SPLIT

Moreover, the CPCs say, the 9th Circuit’s ruling also widened a different split about the proper rubric for evaluating restrictions on professional or commercial speech after the Supreme Court’s potentially sweeping decision *Reed v. Town of Gilbert*, 135 S. Ct. 2218 (2015).

In *Reed* a six-justice majority led by Justice Clarence Thomas seemed to redefine the First Amendment rule permitting “content neutral” speech restrictions aimed at a goal other than suppressing speech.

Before *Reed*, it was well settled that “content” meant “viewpoint” or “ideological message.” The decades-old rule against content-based speech restrictions prohibited statutes or ordinances that regulated some speech but not others, depending on the speaker’s point of view.

Under that approach, courts have traditionally subjected regulations of professional communications and speech in public places to intermediate scrutiny.

But Justice Thomas, writing in *Reed*, used the word “content” very differently, to mean not “viewpoint” but something more like “topic” or “subject.”

The CPCs argue in their petitions that after *Reed*, the doctrine of intermediate scrutiny is virtually dead, at least with respect to professional speech. Five circuits have reached that conclusion, they say, with only the 9th and 11th circuits coming out the other way.

“The reason why the 9th Circuit stated that it did not apply strict scrutiny under *Reed* is that it found [the FACT Act] to be viewpoint-neutral, even though it is content-based,” NIFLA wrote in its petition. “But that makes no difference, according to *Reed*.”

“The 9th Circuit erred by not applying strict scrutiny,” the petition added. **WI**

#### Related Filings:

NIFLA petition: 2017 WL 1076379

A Woman’s Friend petition: 2017 WL 1090548

Livingwell petition: 2017 WL 1101567



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# Obamacare’s ‘risk corridor’ program: Litigation status and prospects

By **Deborah Dorman-Rodriguez, Esq.**, and **David M. Kaufman, Esq.**  
*Health Care Service Corp.*

Currently there is much attention and focus on how the Trump administration will administer the Affordable Care Act,<sup>1</sup> following the failure to pass the proposed American Health Care Act.<sup>2</sup>

Complex issues involving the ACA remain, including those present in existing litigation over an obscure but financially significant ACA program. Those issues are now percolating through the federal courts.

The so-called risk corridor program has been the subject of intense controversy and litigation. In fact, it is the subject of some 19 lawsuits filed by the issuers of the qualified health plans, or QHPs, selling individual coverage on the health insurance exchanges.

The amounts at issue are remarkably significant. In fact, the federal government may owe more than \$8 billion to QHP issuers under the program when the litigation reaches its conclusion.

## PROGRAM BACKGROUND

To encourage insurer participation in the new health insurance exchanges, Congress included three market stabilization programs in the ACA: risk corridors, reinsurance and risk adjustment, referred to collectively as

the 3Rs.<sup>3</sup> The programs were designed to partially mitigate the risks to insurers considering entry into the new and uncertain ACA marketplaces.

Under the risk corridor program, insurers with losses exceeding certain financial limits would receive funds through the program while those that earned profits above upper boundaries would pay into it. These “corridors” were established for the first three operational years of the ACA marketplaces: 2014, 2015 and 2016.

The target amount is set by HHS and includes premiums received by the plan less allowable administrative (nonclaim) costs. The ratio of the allowable cost and the target amount is then calculated. If the allowable costs are more than 103 and not more than 108 percent of the target amount, the QHP issuer is to be paid 50 percent of those costs over 103 percent of the target amount.

If the QHP’s costs for operating the plan exceed 108 percent of the target amount, the QHP issuer can then receive 2.5 percent

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QHP losses were larger than amounts paid into the program by profitable QHPs, and Congress did not appropriate additional funds to cover the losses.

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The Health and Human Services Department adopted regulations to implement the program, including a formula for calculating whether carriers would pay into or receive funds from the program.<sup>4</sup>

The risk corridor formula is complex, comparing “allowable cost” to a “target amount.”<sup>5</sup> Allowable costs are defined as those expenses (excluding administrative costs) incurred by the plan in providing covered benefits to enrollees for a year.

of the target amount plus 80 percent of its allowable costs that exceed 108 percent of the target amount in risk corridor payments.

If a QHP’s allowable costs for a benefit year are lower than anticipated, beyond the boundaries of the “corridor,” the QHP must pay into the program.

If the allowable costs are less than 97 percent (but not less than 92 percent) of the target amount, the plan is required pay HHS 50 percent of the difference between 97 percent of the target amount and the allowable costs.

If a plan’s allowable costs are less than 92 percent of the target amount, the plan must pay 2.5 percent of the target amount plus 80 percent of the difference between 92 percent of the target amount and the allowable costs.

The federal agencies responsible for ACA implementation did not anticipate what actually occurred: QHP losses were larger than amounts paid into the program by profitable QHPs.

In addition, Congress did not appropriate additional ACA funds to cover the QHPs’ losses — leaving open the question of



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whether the federal agency responsible for administering the 3R programs, the Centers for Medicare and Medicaid Services, (a sub-agency of HHS) is authorized to make full risk corridor payments given that profitable QHP issuers paid in less to the program than non-profitable QHPs were owed.

As a result, CMS paid only 12.6 percent of the \$2.87 billion owed QHPs for 2014. The agency said it would make up the shortfall in future years as funds become available. Additional amounts collected for 2015 went to make up the shortfall for 2014.

Given the extent of the financial losses experienced by QHP issuers to date, it is unlikely that without another source of funding full payment will be made for 2014 — or that any payments will be made for 2015 and 2016.

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## As of March, at least 19 QHP issuers have filed lawsuits against the federal government seeking risk corridor payments.

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Some newer, less well-financed QHPs based the success of their business models on receiving millions of dollars more from the 3Rs than were actually paid. Those companies needed 3R funds for continued viability.

Some more established, better-financed companies have simply written off the amounts due under the program, increasing their overall recorded losses from the ACA marketplaces. To compensate for the loss in revenues, some QHP issuers have increased rates or withdrawn from certain markets.

As of March, at least 19 QHP issuers have filed lawsuits against the federal government seeking risk corridor payments. Plaintiffs include QHP issuers from across the country, including, for example, Highmark, which is a Blue Cross Blue Shield plan operating in Pennsylvania; CoOpportunity Health, a Consumer Operated and Oriented Plan, or CO-OP, doing business Iowa and Nebraska; and Moda Health Plan, a plan operating in the Pacific Northwest; and most recently by Blue Cross and Blue Shield plans from Alabama and Tennessee.

To date, federal Court of Federal Claims judges have issued three decisions in these cases. Those rulings reflect the judges' different views regarding the obligations of the federal government under the risk

corridor program. They also demonstrate the complexity of the issues and indicate that they will not be resolved any time soon.

### **LAND OF LINCOLN MUTUAL HEALTH INSURANCE CO. V. UNITED STATES**

The first decision in the risk corridor cases was issued by Judge Charles F. Lettow on Nov. 10 in a suit filed by Land of Lincoln Mutual Health Insurance Co., one of the ACA CO-OPs.<sup>6</sup>

Land of Lincoln, declared insolvent and currently in liquidation, operated in Illinois and provided coverage to about 49,000 enrollees.

The company claimed in its lawsuit that the failure to pay it \$72 million in risk corridor payments breached an express or implied-in-fact contract, the covenant of good faith

and fair dealing, and the Takings Clause of the Fifth Amendment.

HHS moved to dismiss the case under Federal Rule of Civil Procedure Rule 12(b)(6) for failure to state a claim on which relief could be granted.

Judge Lettow determined that the Court of Claims had jurisdiction over Land of Lincoln's claims but ruled in favor of HHS on each of them.

The judge found that the ACA does not clearly entitle health plans to risk corridor payments, that HHS reasonably interpreted the statute to not require full risk corridor payments on an annual basis, and that neither Land of Lincoln's QHP contract with HHS nor any implied contract required full annual risk corridor payments.

The court also rejected Land of Lincoln's claim based on its reliance on the government's promises as well as its claim that the failure to fully pay risk corridor payments is a taking of property in violation of the Constitution.

Land of Lincoln has appealed the decision to the U.S. Court of Appeals for the Federal Circuit, where it is currently pending.

### **HEALTH REPUBLIC INSURANCE CO. V. UNITED STATES**

In a second decision, issued Jan. 10 in a case filed by Health Republic Insurance Co.,

a CO-OP that operated in Oregon, Judge Margaret M. Sweeney reached a different conclusion.

Health Republic filed its case as a putative class action on behalf of all QHP issuers, seeking the \$7 million it claims the company is owed as well as the \$5 billion the government allegedly owes to QHP issuers collectively.<sup>7</sup>

First, Judge Sweeney certified the class, meaning that a decision in the case could apply to other QHP issuers. On the merits, the judge rejected the government's motion to dismiss and concluded that under the ACA, Congress intended for HHS to make risk corridor payments to eligible insurers on an annual basis regardless of specific appropriations.

She pointed out that if the ACA risk stabilization programs fail to provide for prompt compensation to insurers after HHS has calculated the amounts due, insurers might not participate in the exchanges, thus defeating the ACA's goal of creating competitive health insurance markets.

The judge ordered the government to file its answer to Health Republic's complaint, and the government has since filed a motion for summary judgment.

### **MODA HEALTH PLAN INC. V. UNITED STATES**

The third decision was issued Feb. 9 in a suit filed by Moda Health Plan Inc., an insurer providing coverage in Alaska, Oregon and Washington.<sup>8</sup>

In that case, Judge Thomas C. Wheeler granted Moda's motion for summary judgment, ruling that the government must pay Moda the full amount it is owed for annual risk corridor payments for 2014 and 2015.

Moda is seeking risk corridors payments of \$89 million for its 2014 QHPs and \$101 million for its 2015 QHPs.

Judge Wheeler rejected the government's arguments and determined that the government has withheld risk corridor payments from Moda unlawfully, concluding that the ACA requires that the payments be made to insurers on an annual basis.

Looking at the statute and how it was initially interpreted by the federal agencies, he determined that Congress did not design

the risk corridor program to be budget neutral, meaning that even if the risk corridor amounts paid into CMS by QHPs are less than what QHP issuers are owed under the program, QHPs are still entitled to full annual payment — regardless of congressional appropriation.

In addition, the judge determined that even if the program were designed to be budget neutral, the ACA QHP contracts drafted by HHS constituted an offer for a unilateral contract, which Moda accepted by agreeing to participate on the exchanges.

The court concluded that the government made a promise in the risk corridor program that it must keep. In a memorable phrase, the judge stated that to say, “‘The joke is on you. You should not have trusted us,’ is hardly worthy of our great government.”

## POSSIBLE OUTCOMES

Without appropriations to cover risk corridor payments, it is unlikely that the disputes regarding the program will be resolved any time soon.

Considering the complexity of the issues, the significant amounts at stake and the highly political nature of issues involving the ACA, there is a wide range of possible outcomes from the current litigation and related QHP disputes.

HHS issued a bulletin Sept. 9, 2016, stating that it was open to settlement discussions to resolve risk corridor claims. At the same time, the Justice Department filed briefs seeking dismissal of the QHP issuers’ claims.

Absent a congressional appropriation to resolve the cases, payment of any settlement would likely be made from the federal government’s judgment fund. The fund has been used to pay court judgments

and compromise settlements of actual or imminent lawsuits against the government. However, use of the fund to resolve the risk corridor cases is controversial.

The House of Representatives filed an amicus brief in the *Health Republic* case stating its objections to use of the judgment fund to pay risk corridor claims. The House argues that the fund can only be used in cases where payment is “not otherwise provided for” by Congress.

Regarding risk corridors, the House asserts that payments from insurers into the program provided for payment even if the amount was not sufficient to cover the claims. Thus, the House argues, the fund may not be available to pay risk corridors claims.

Legislation has been introduced in both the House and the Senate to prevent such a resolution.<sup>9</sup>

With 19 cases possibly being decided by independent judges who are not required to follow the decisions of their judicial colleagues (and due to a lack of binding precedent), a variety of rulings in the remaining risk corridor cases can be anticipated.

In the meantime, now that there have been two decisions favorable to QHPs, more cases may be filed by other issuers in the Court of Federal Claims or in the federal district courts, such as the case filed by the Iowa CO-OP, CoOpportunity Health.<sup>10</sup>

The Federal Circuit has jurisdiction over appeals from the Court of Federal Claims; appeals resulting from cases filed in federal district courts will be heard by federal circuit courts.

Given the likelihood of different case outcomes, the significant amounts at stake and the novel legal issues involved, the parties are almost certain to seek U.S.

Supreme Court review of any lower court decisions.

Outside of the courts, it remains to be seen whether the new administration may seek to resolve issues surrounding the risk corridor program via some type of administrative settlement through HHS, or with Congress through legislation. **WJ**

## NOTES

<sup>1</sup> Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (Mar. 23, 2010).

<sup>2</sup> Subtitle \_\_: Budget Reconciliation Legislative Recommendations Relating to Repeal and Replace of Health-Related Tax Policy, <http://bit.ly/2lQ1LyL>.

<sup>3</sup> The risk corridor program is established in Section 1341 of the ACA.

<sup>4</sup> 45 C.F.R. Part 153.

<sup>5</sup> For a detailed discussion of the risk corridor program formula and examples of how the formula operates in different scenarios, see Doug Norris, Mary van der Heijde and Hans Leida, *Risk Corridors Under the Affordable Care Act — A Bridge over Troubled Waters, but the Devil’s in the Details*, HEALTH WATCH (October 2013), <http://bit.ly/2n7jZxU>.

<sup>6</sup> *Land of Lincoln Mut. Health Ins. Co. v. United States*, 129 Fed. Cl. 81 (2016), appeal docketed, No. 17-1224 (Fed. Cir. Nov. 16, 2016).

<sup>7</sup> *Health Republic Ins. Co. v. United States*, 129 Fed. Cl. 757 (Fed. Cl. 2017).

<sup>8</sup> *Moda Health Plan Inc. v. United States*, No. 16-649, 2017 WL 527588 (Fed. Cl. Feb. 9, 2017).

<sup>9</sup> See HHS Slush Fund Elimination Act (S. 3481); To limit the use of the judgment fund to settle any lawsuit arising under Section 1342 of the Patient Protection and Affordable Care Act, and for other purposes (H.R. 6339).

<sup>10</sup> *Gerhart v. United States*, No. 16-cv-151, complaint filed (S.D. Iowa June 10, 2016).

## MYLAN SAYS EPIPEN MANUFACTURING PARTNER TO EXPAND DEVICE RECALL

(Reuters) – Generic drugmaker Mylan NV said March 31 that its manufacturing partner for EpiPen devices had expanded a recall of the life-saving allergy shot in the United States and other markets. The announcement comes a week after Mylan said it had recalled about 81,000 EpiPen devices in countries outside the United States following two reports of the company's allergy treatment failing to work in emergencies. The recall is being initiated in the United States and will extend to Europe, Asia, and North and South America, Mylan said. The recalled product was manufactured by Meridian Medical Technologies, a Pfizer Inc. company, and distributed by Mylan between December 2015 and July 2016. Mylan, which is the focus of multiple federal investigations, has come under fire for staggering price increases on the emergency shot in the United States. Mylan has also been heavily criticized for classifying EpiPen as a generic rather than a branded product, which led to much smaller rebates from the company to state Medicaid programs. *(Reporting by Akankshita Mukhopadhyay)*

## SUIT OVER MEDICAID COMPUTER ERROR ISN'T MOOT, 6TH CIRCUIT SAYS

A federal appeals court has revived a proposed class action accusing Michigan of violating the due process rights of thousands of noncitizen residents by significantly reducing their Medicaid benefits because of a computer error. In a March 31 ruling, a unanimous 6th U.S. Circuit Court of Appeals panel partly overturned a summary judgment decision in the state's favor by U.S. District Judge Marianne O. Battani of the Eastern District of Michigan, who found the case moot in January 2016. Reversing Judge Battani, the 6th Circuit panel found that even though Michigan retroactively awarded lead plaintiffs Aelen Unan and Patricia Quintino full Medicaid benefits two days after they filed suit, the case falls under a mootness exception barring defendants from "picking off" class-action plaintiffs by undermining their individual standing. The suit by Unan and Quintino challenges their designation as "emergency services only" beneficiaries rather than full participants in Medicaid, the joint state-federal government health insurance program for the poor and disabled. If addressing the lead plaintiffs' individual claims rendered the entire class action moot, Michigan could indefinitely evade judicial accountability by immediately reclassifying any Medicaid beneficiary who challenges their eligibility status, the panel said.

***Unan et al. v. Lyon, No. 16-1185, 2017 WL 1192906 (6th Cir. Mar. 31, 2017).***

### Related Filing:

Opinion: 2017 WL 1192906

## NEEDLE-PHOBIC RITE AID PHARMACIST CAN'T CHALLENGE FIRING FOR REFUSAL TO VACCINATE

A longtime Rite Aid retail pharmacist who suffers from "trypanophobia," the pathological fear of needles, cannot challenge his firing for failing to comply with a relatively new company policy requiring pharmacists to administer flu vaccines, a federal appeals court has decided. In a March 21 ruling, a 2nd U.S. Circuit Court of Appeals panel rejected the Americans with Disabilities Act suit by Christopher Stevens, who lost his job of 34 years in August 2011 because he could not handle vaccination duties the company imposed on its pharmacists the previous April. Stevens was fired after a Rite Aid human resources manager concluded his needle-related panic attacks, and even fainting spells, would prevent him from doing his job effectively. He sued the company under the ADA, winning a jury verdict of more than \$1.7 million, which a federal judge in upstate New York upheld. Rite Aid appealed. Reversing the trial judge, the 2nd Circuit said performing immunizations was an essential part of a Rite Aid pharmacist's job for which no reasonable accommodation could prepare Stevens. No matter how sympathetic Stevens' long tenure at the company and "unusual phobia" make him, the ADA does not require businesses to retain workers who cannot perform their core duties, the panel said.

***Stevens v. Rite Aid Corp., Nos. 15-277, 15-279 and 15-3491, 2017 WL 1055566 (2d Cir. Mar. 21, 2017).***

### Related Filing:

Opinion: 2017 WL 1055566

## PHARMACY BENEFIT MANAGERS ARE CUTTING OUT INDEPENDENT PHARMACIES, SUIT SAYS

Pharmacy benefits giants Express Scripts and CVS have conspired with other pharmacy benefit managers to eliminate independent pharmacies from the market for mail-order drug services, an independent pharmacy claims in St. Louis federal court. In a March 20 complaint, New York-based Park Irmat Drug Corp. accuses Express Scripts of striking horizontal agreements with CVS and other pharmacy benefit managers, or PBMs, that function as a boycott of independent mail-order pharmacies. PBMs are middleman companies that run drug-benefit networks for health insurers. According to the complaint, PBMs manage 95 percent of all the drugs prescribed and covered by health insurance in the United States. St. Louis-based Express Scripts and CVS, based in Woonsocket, Rhode Island, together control 65 percent of the PBM market, and two other large PBMs control 15 percent, the suit says. The complaint alleges multiple violations of the Sherman Act, as well as state law claims for breach of contract, equitable estoppel and violations of "any willing provider" laws.

***Park Irmat Drug Corp. v. Express Scripts Holding Co., No. 17-cv-979, complaint filed (E.D. Mo. Mar. 20, 2017).***

### Related Filing:

Complaint: 2017 WL 1054871

## HIGH COURT REJECTS REVIEW OF FALSE-ADVERTISING ANTITRUST CASE

The U.S. Supreme Court will not review a federal appellate decision refusing to impose antitrust liability on a medical device manufacturer for false advertisements disparaging a competitor. The high court rejected without comment a request by syringe manufacturer Retractable Technologies Inc. and inventor Thomas Shaw to reconcile what they portrayed as a split among the federal appeals courts regarding antitrust claims based on false advertising. The courts are divided over whether false commercial speech can constitute actionable anti-competitive behavior under the Sherman Act, the petitioners claimed. According to their petition, the 3rd, 8th and District of Columbia circuits all use a traditional case-by-case analysis to decide whether false commercial speech can form the basis of a Sherman Act monopolization claim. The 2nd, 6th, 9th, 10th and 11th circuits, on the other hand, presume that false speech has a minimal effect on competition, and they use multifactor tests to determine whether the false advertising at issue rises to the level of being anti-competitive, RTI said. In reversing the jury's verdict, the 5th Circuit joined the 7th Circuit in erecting a "near-impenetrable barrier" to claims based on false commercial speech, by characterizing false speech as competition on the merits, the petition argued. The defendant, Becton, Dickinson & Co., opposed certiorari, saying the case was "an exceptionally poor vehicle" for Supreme Court review.

***Retractable Technologies Inc. et al. v. Becton, Dickinson & Co., No. 16-953, cert. denied (U.S. Mar. 20, 2017).***

## PRE-ELIGIBILITY DEBT SHOULD COUNT FOR MEDICAID NURSING BENEFITS, PETITION SAYS

A Medicaid beneficiary living in a nursing home has filed U.S. Supreme Court papers challenging Florida's decision to exclude her pre-eligibility medical debt when calculating her "cost sharing" obligations under the joint state-federal insurance program for the poor and disabled. In a March 7 certiorari petition, nursing home patient Gabrielle Goodwin says the state Department of Children and Families violated federal law by counting a \$70,000 debt to the nursing home as part of her official income when determining what portion of her care Medicaid would cover. Goodwin allegedly incurred the debt before she became Medicaid-eligible. A state appellate court upheld the calculations, deferring to the agency's conclusion that a law requiring Medicaid to deduct uncovered medical expenses from a beneficiary's income applies only post-eligibility. The Florida Supreme Court refused to take up the case, and Goodwin filed her U.S. Supreme Court appeal. In her petition, Goodwin says the agency's interpretation of the Medicaid provision in question was plainly wrong since Congress enacted it specifically "to overturn a [previous] rule that would have given states the discretion to do precisely what Florida did."

***Goodwin v. Florida Department of Children and Families, No. 16-1083, petition for cert. filed (U.S. Mar. 7, 2017).***

**Related Filing:**  
Petition: 2017 WL 943912

## MEDICARE AGENCY USED REASONABLE CRITERIA TO SET RURAL HOSPITAL REIMBURSEMENT RULE

The agency that administers Medicare acted legally when it based its definition of "critical access hospitals," facilities that get the highest reimbursement rates among rural hospitals, partly on whether state or federal highways lead to them, a federal appeals court has decided. In a unanimous March 7 ruling, a 5th U.S. Circuit Court of Appeals panel rejected a challenge to the government's methodology by Seymour Hospital, a rural facility in northern Texas. The hospital claimed the Centers for Medicare and Medicaid Services, or CMS, adopted unreasonable standards for determining whether the roads connecting one rural hospital to others in the area are "primary" or "secondary" under the Rural Hospital Flexibility Program. That provision authorizes higher reimbursement rates for any critical access hospital, meaning any facility more than 35 miles from the next one — unless only "secondary roads" connect the two hospitals, in which case the required distance is just 15 miles. In implementing the program, CMS has defined secondary roads as all roadways except the three types of "primary roads": numbered federal highways, divided state highways with at least four lanes and roads marked on official U.S. Geological Survey maps as divided "primary highways." Seymour Hospital challenged the agency's criteria as arbitrary, saying some secondary roads are busier and faster than some primary roads. But the 5th Circuit panel rejected the hospital's argument, calling it "a fact-specific quarrel with a general rule."

***Baylor County Hospital District v. Price, No. 16-10310, 2017 WL 908222 (5th Cir. Mar. 7, 2017).***

**Related Filing:**  
Opinion: 2017 WL 908222

## CANNABIS COMPANIES WARN TRUMP POLICY COULD BURN BUSINESS

A growing number of companies in the cannabis industry are warning that the Trump administration's unknown stance on federal drug enforcement could blunt their profits. GrowLife Inc. recently said in a March 31 filing with the U.S. Securities and Exchange Commission that stricter enforcement of federal drug laws, which still ban marijuana, could cause significant financial damage to the company and its shareholders. The Washington-based company services indoor cultivation facilities and sells hydroponics equipment, organic plant nutrients and other products. The cannabis industry has made legalization strides in 28 states and the District of Columbia. Similarly, General Cannabis Corp. said in a March 31 annual report that enforcement of federal drug laws in states that have legalized some form of marijuana could also harm its business and expose it to criminal liability. The Denver-based company offers security, cash transportation, finance, real estate, marketing and consulting services to cannabis-related businesses. Mentor Capital Inc., which invests in cannabis-related businesses, also warned March 28 that the Trump administration could take a hardline stance against medical and recreational marijuana use. President Barack Obama's administration had directed federal law enforcement agencies to refrain from prosecuting people abiding by state laws, according to Mentor's filing.

**Related Filings:**  
Form 10-K (GrowLife): 2017 WL 01180296  
Form 10-K (General Cannabis): 2017 WL 01178478  
Form 10-K (Mentor Capital): 2017 WL 01138596

## Supreme Court

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case, urged the justices to affirm a California Supreme Court decision asserting specific personal jurisdiction over the out-of-state plaintiffs' claims.

The Plavix litigation, which is not a class action but a set of coordinated individual suits, also involves 86 California plaintiffs.

"These kinds of complex, multi-party cases have been common in state courts for decades, have been validated in on-point precedents of this court, and rest on doctrines essential to making complex civil litigation possible and efficient," the respondents' brief says. "It is hard to even estimate how much damage [Bristol-Myers' argument against jurisdiction] would cause."

The suits accuse the Plavix maker of failing to warn users about the anti-platelet drug's unacceptable risk of causing some of the serious conditions it is supposed to prevent, including heart attacks, strokes, internal bleeding and potentially fatal blood disorders.

In their decision last year allowing the case to go forward, California's justices found that the state's courts had specific personal jurisdiction over the drugmaker based on its "single, coordinated, nationwide" scheme to market and distribute Plavix. *Bristol-Myers Squibb Co. v. Super. Ct.*, 377 P.3d 874 (Cal. 2016).

### A HYBRID TEST?

Normally, a state's courts have general jurisdiction over any defendant with such "continuous and systematic" business connections there that it is fair to say the company is "at home."

Specific jurisdiction, on the other hand, applies when a corporate defendant's in-state contacts relate directly to the plaintiff's claims.

But Bristol-Myers has argued that California's high court improperly blurred the line between specific and general jurisdiction through a "sliding scale" test, a hybrid standard requiring a less direct link between the plaintiff's claims and the defendant's contacts when the defendant has a greater overall presence in the state.

The company, which says it is not subject to general jurisdiction because it has no major operations in California, has insisted throughout the case that it did not develop,

manufacture or prepare marketing materials for Plavix in the state.

Bristol-Myers is a Delaware corporation headquartered in New York.

### DEFENDING LONGTIME PRACTICES

According to Bristol-Myers' Supreme Court filings, the California courts violated the due process clause of the 14th Amendment by letting the out-of-state Plavix plaintiffs proceed without showing a causal link between the company's contacts with the state and their alleged injuries.

Companies have the right to avoid going to court in jurisdictions where they did not knowingly expose themselves to litigation, either through their specific conduct or their general presence, Bristol-Myers says.

The justices took the case in January. *Bristol-Myers Squibb Co. v. Super. Ct.*, 137 S. Ct. 827 (2017).

In its merits brief urging the Supreme Court to affirm, the Superior Court says Bristol-Myers has conjured a challenge out of thin air to the routine practice of joining claims that allege the same injuries caused by the same product, even if not all the plaintiffs are from the forum state.

"According to [the company], no out-of-state plaintiff can join a California case properly brought against it by California plaintiffs — no matter how related their claims may be — unless [the company's] contacts with California themselves caused that particular plaintiff's injury," the brief says.

"The state courts have long adjudicated such claims without controversy," the brief adds, ridiculing Bristol-Myers as arguing "that this practice has actually always been unconstitutional, although no one ever realized it."

### PAXIL ALLEGATIONS

Meanwhile, in a March 23 petition, GlaxoSmithKline urged the justices to accept the Paxil case and hold it pending the outcome in the Plavix case.

The Paxil suit, filed by eight mothers, claims the antidepressant caused birth defects in their children, named as co-plaintiffs. It accuses the company of ignoring that risk from the outset by excluding pregnant women from all its drug trials.

Glaxo's certiorari petition challenges an appellate decision letting out-of-state plaintiffs proceed against the company in

state court in Illinois — where only four of the 16 plaintiffs live and the company is not headquartered — based on a "handful" of Paxil clinical trials conducted in the state. *M.M. ex rel. Meyers v. GlaxoSmithKline*, 61 N.E.3d 1026 (Ill. App. Ct., 1st Dist. 2016).

The state Supreme Court refused to hear the case in November. *M.M. ex rel. Meyers v. GlaxoSmithKline*, 65 N.E.3d 842 (Ill. 2016).

### DIRECT VS. PROXIMATE CAUSE

According to Glaxo's petition, the Plavix case presents only one side of a three-way split among various federal appeals circuits and state high courts over the proper standard for specific personal jurisdiction over out-of-state plaintiffs in mass product liability suits.

Some high-level courts have held that specific personal jurisdiction is proper if a company's actions in the forum state were a direct cause, or "but-for cause," of the plaintiffs' injuries, the drugmaker notes.

Others focus instead on proximate cause, asking whether a company's having to defend itself in a given state would have been a reasonably foreseeable consequence of the defendant's lawsuit-related business contacts, the petition says.

If the justices in the Plavix case end up requiring a causal link between a defendant's in-state business activities and the plaintiff's injuries, they should then review the Paxil suit to decide whether the causal link must be direct or proximate, Glaxo argues.

"This case is an excellent vehicle to decide the but-for versus proximate cause side of the [court] split, and that aspect of the split is just as cert-worthy as the no-causation versus causation side," the petition says. "At a minimum, the court should hold this petition pending its decision in [the Plavix case]." **WJ**

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#### Related Filings:

Respondents' brief (California Superior Court): 2017 WL 1207530  
Petition (Glaxo): 2017 WL 1162412

**See Document Section A (P. 23) for the respondents' brief.**

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