Opioid Drug crisis: Measure to Control

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The Scope of Tribal Immunity With Respect to the U.S. Patent Laws

Recent Supreme Court Tribal Immunity Cases

- In *Kiowa Tribe of Okla. V. Mfg. Techs., Inc.*, 523 U.S. 751 (1998) and *Michigan v. Bay Mills Indian Cmty.*, 134 S. Ct. 2024 (2014), the Supreme Court held that Indian tribes retain their sovereign immunity from suits under state law unless there is a Congressional provision otherwise. *Kiowa* walked through the early development of the doctrine, started with *Turner v. United States*, 28 U.S. 354 (1919), congressional statute required for suit against dissolved tribe for damages to fence, "the obstacle to recovery is not the immunity of a sovereign to suit." *Kiowa* extends sovereign immunity to off-reservation commercial activity and *Bay Mills* reaffirms that.
- Most recent: *Lewis v. Clarke*, 137 S. Ct. 1285 (2017) – tribal immunity only extends to real party in interest. Tribal employee not immune from auto accident suit under state law, tribe is not the real party in interest.

Supreme Court Cases Limiting Sovereign Immunity

- *United States v. Wheeler*, 435 U.S. 313, 323 (1978), the Court said that "Indian tribes still possess those aspects of sovereignty not withdrawn by treaty or statute, or by implication as a necessary result of their dependent status."
- *Duro v. Reina*, 495 U.S. 676, 685–86 (1990) said that "the retained sovereignty of the tribes is that needed to control their own internal relations, and preserve their own customs and social order." *Duro* declines to extend tribal criminal jurisdiction to non-Indians.

Immunity from Suit Under Federal Statutes of General Applicability

- Fed. Power Comm'n v. Tuscarora Indian Nation, 362 U.S. 99, 120 (1940), the Supreme Court said that "general Acts of Congress apply to Indians as well as all others in the absence of a clear expression to the contrary."
- Circuit Split: the 2d, 6th, 9th, and 11th circuits have adopted the *Tuscarora* view and found tribes amenable to suits relating to the OSHA and NLRB (*see, e.g.*, *Donovan v. Couer d'Alene Tribal Farm*, 751 F.2d 1113 (9th Cir. 1985); *Nat'l Labor Relations Bd. v. Little River Band of Ottawa Indians Tribal Gov't*, 788 F.3d 537 (6th Cir. 2015) (adopting *Donovan*); *Fla. Paraplegic Ass'n v. Miccosukee Tribe of Indians of Fla.*, 166 F.3d 1126, 1129–30 (11th Cir. 1999) (same); *Reich v. Mashantucket Sand & Gravel*, 95 F.3d 174 (2d Cir. 1996) (same)), the 8th and 10th require a clear congressional waiver statement (*see, e.g.*, *N. States Power Co. v. Prairie Island Mdewakanton Sioux Indian Cmty.*, 991 F.2d 458 (8th Cir. 1993); *Nat'l Labor Relations Bd. v. Pueblo of San Juan*, 276 F.3d 1186 (10th Cir. 2002)), and the D.C. circuit created a test that looked at the tribes "traditional customs and practices" to determine that NLRB suits could be brought against a tribe. *San Manuel Indian Bingo & Casino v. Nat'l Labor Relations Bd.*, 475 F.3d 1306 (D.C. Cir. 2007).
- The 2d and 11th circuits have taken the position that even if a federal statute applies, there is still immunity from a private suit to enforce it. *See Bassett v. Mashantucket Pequot Tribe*, 204 F.3d 343 (2d Cir. 2000); *Fla. Paraplegic Ass'n v. Miccosukee Tribe of Indians of Fla.*, 166 F.3d 1126, 1134 (11th Cir. 1999).

Immunity to Suit for Patent Infringement

- *Home Bingo Network v. Multimedia Games, Inc.*, No. 1:05-CV-0608, 2005 WL 2098056 (N.D.N.Y. 2005), and *Specialty House of Creation, Inc. v. Quapaw Tribe*, No. 10-CV-371-GKF-TLW, 2011 WL 308903 (N.D. Okla. 2011) say that Indian tribes retain their sovereign immunity from suit, which includes immunity from patent infringement suits.

Waiver of Immunity to IPR

- *Ericsson v. Univ. of Minnesota*, IPR2017-01186 (Dec. 19, 2017): PTAB had previously held that Eleventh Amendment immunity could be applied in IPR because it was sufficiently similar to civil litigation. However, in this case, it ruled that when a state entity patent owner files an infringement suit in district court, it also waives its immunity in IPR because otherwise it would be unfair, because the defendant could not use the same forum to challenge the patent in the manner it could in IPR. By not allowing waiver, it would block the forum entirely in these situations. Concurring opinion proposes that IPRs are essentially *in rem* proceedings and sovereign immunity doesn't apply.

To: All Attorneys General, Chief Deputies, and Executive Assistants
From: Attorney General Pam Bondi, Florida
Attorney General Joseph Foster, New Hampshire
Re: Letter to the CDC in Support of Draft Guidelines for Prescribing Opiates
Date: January 11, 2016

Dear Colleagues:

Please join us in voicing support for the recently issued draft Guidelines for Prescribing Opiates for Chronic Pain. The deadline for comments is **12:00 pm ET Wednesday, January 13, 2016.**

Opiate abuse is a significant public health and public safety concern throughout this nation. While some states have been successful in curbing the number of opiate overdose deaths, the overall number of such deaths and emergency room visit related to opioid abuse continues to rise nationwide. In order to reduce these deaths and injuries, we must provide clear guidance for prescribers to assess the appropriate balance between the potential harms and benefits of opioid use.

The CDC's proposed guidelines, http://www.regulations.gov/#!documentDetail;D=CDC-2015-0112-0001, provide a foundation for prescribers, which can be adapted to meet the individual needs of patients. They provide guidance on when to prescribe opiates, and how to safely manage patients on opiates. They also recognize the importance of opiates as a tool for responding to intractable pain.

By better informing and guiding prescribers, these Guidelines will not only provide a strong framework for providers, but they will also improve the access to opioids for patients for whom they are the best choice. For these reasons, we ask you to join us in expressing to the CDC our support for the draft Guidelines by signing on the attached letter. If you have any questions, please feel free to contact Ann Rice of the New Hampshire Attorney General's Office at 603-271-4900 or ann.rice@doj.nh.gov, or Tyler Cathey of the Florida Attorney General's Office at (850) 245-0140 or tyler.cathey@myfloridalegal.com.

The deadline to sign on to this letter is 12:00 pm ET, on Wednesday, January 13, 2016. Please send your fax or email completed response to Katie Coyne at NAAG either via facsimile to (202) 521-4052 or kcoyne@naag.org. Thank you for your consideration

Respectfully,

Pam Bondi
Florida Attorney General

Joseph A. Foster
New Hampshire Attorney General

January 8, 2016

Via Electronic Submission

Dockets Management
Centers for Disease Control and Prevention
United States Department of Health & Human Services
1600 Clifton Road
Atlanta, GA 30329

Re: *Docket No. CDC-2015-0112*
Proposed 2016 Guideline for Prescribing Opioids for Chronic Pain

Dear Dr. Frieden:

As attorneys general whose states and residents have been affected by the epidemic of opioid abuse, addiction, diversion, overdose, and death, we write to urge the speedy adoption of the CDC's Proposed 2016 Guideline for Prescribing Opioids for Chronic Pain (the "Guidelines").

As statewide public officials who work collaboratively with law enforcement, we are regularly confronted with the problems caused by opioid abuse. While some states have reduced the number of deaths due to opioid drug overdose, overall deaths from overdoses continue to rise in our nation. Unfortunately, the opioid overdose deaths and emergency room visits continue to increase in proportion to the increase in prescribed opioids.[1] In order to reduce these deaths and injuries, we must provide clear guidance for prescribers to assess the appropriate balance between the potential harms and benefits of opioid use.

[1] *See* Vital Signs: Overdoses of Prescription Opioid Pain Relievers --- United States, 1999—2008; Morbidity and Mortality Weekly Report, Nov. 4, 2011.

The increase in overdose deaths has made the efforts to improve informed prescribing both a law enforcement and public safety issue. Unfortunately, many prescribers, particularly primary care and family physicians, note they can lack clear and practical guidance in deciding when and how to prescribe opioids. Some are afraid to prescribe opioids at all, for fear that they will jeopardize their patients – or even their licenses. Others provide their patients with opioids when alternative treatments may serve as a more effective long term method of care.

We recognize that the Guidelines are just that. The Guidelines provide a foundation for practice, recognizing that doctors will need to adapt them to meet the individual needs of their patients. But the core message — that many patients can be treated with lower doses or alternative treatment methods, provides much-needed direction to doctors. It gives doctors the knowledge and confidence to prescribe opioids when appropriate, and to more safely manage patients on opioids. The Guidelines also recognize that opioids remain an important tool for responding to extreme or intractable pain.

By better informing and guiding prescribers, these Guidelines will not only provide a strong framework for providers, but they will also improve the access to opioids for patients for whom they are the best choice. For these reasons, we urge the CDC to promptly adopt these Guidelines.

Respectfully submitted,

Pam Bondi
Florida Attorney General

Joseph A. Foster
New Hampshire Attorney General

RESPONSE FORM FOR SIGN-ON LETTER TO THE CENTER FOR DISEASE CONTROL REGARDING PRESCRIBING OPIOIDS:

DEADLINE FOR RESPONSE: 12:00 PM ET, WEDNESDAY, JANUARY 13, 2016

PLEASE RETURN FORM TO:
Katie Coyne
National Association of Attorneys General
kcoyne@naag.org
or
(202) 521-4052 (fax)

○ **YES, I authorize NAAG to affix my signature** to the letter to the Center for Disease Control regarding Prescribing Opioids.

○ **NO, I do not authorize NAAG to affix my signature** to the letter.

PLEASE PRINT OR TYPE LEGIBLY

_____ (name)

Attorney General of _____ (state name)

Contact Name, Phone Number, Email and Fax Number

_____

_____

_____

If you have any questions, please feel free to contact Ann Rice of the New Hampshire Attorney General's Office at 603-271-4900 or ann.rice@doj.nh.gov, or Tyler Cathey of the Florida Attorney General's Office at (850) 245-0140 or tyler.cathey@myfloridalegal.com.

If you have any questions about your state's response, please contact Katie Coyne at (202) 326-6262 or kcoyne@naag.org.

Remarks by Dr. Gottlieb at the FTC

Speech by Scott Gottlieb, M.D.
Commissioner of Food and Drugs
Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics
Federal Trade Commission, Washington, DC
November 8, 2017

(Remarks as prepared for delivery)

Thank you for inviting me to join you today for this important workshop. Although the FDA and the FTC have very different responsibilities relating to healthcare, among our shared goals is the critical one of ensuring that all Americans are able to benefit from competition when it comes to medical products.

This is especially true when it comes to drugs, and the availability of safe and effective generic medicines. Generic drugs provide a vital benefit to the public. They can cost a fraction of the price of the brand-name version of the same medication. It should come as no surprise that nine out of ten prescriptions today are filled using generic drugs.

Yet even as generic medicines comprise a growing share of the overall drugs that people use, many patients still find themselves priced out of getting the medicines they need. That reflects a number of trends.

Many of today's medicines are transformative drugs that are highly effective -- where patients quite literally can't live without one of these new medicines. This includes many new and innovative treatments for serious and sometimes fatal diseases, such as cancer or rare diseases.

The good news is many critical medical problems can now be addressed through safe and effective medicines. But a patient can't benefit from a medicine if they can't afford to pay for it.

The costs are high for many of these drugs because they face little or no competition when they're first launched. That's precisely because they're so novel, and the investment in developing these innovative treatments and cures is so high. On average, the price to develop a single novel drug can top $2 billion once all the costs are added up. Even the direct costs can be $1 billion. Those costs factor into the price.

Moreover, these medicines often treat increasingly targeted, and thus small, populations of patients. To make the economic model work in cases where the high costs of drug development are being applied to drugs that are increasingly specialized and spread over a small number of patients, the result is that the drugs are often very expensive.

And then there's also an issue with the inefficiency of the pharmaceutical supply chain. Discounts and rebates may be provided, but these typically don't flow directly to the consumers who use those drugs. The system as it exists today does not incentivize savings for consumers who are paying the high costs for a medicine they need.

The question is what can be done about this. While some elements of this issue are not in FDA's purview, I think there's a lot we can do at the agency, and even more by working together with our partners at FTC and elsewhere, to address some of these challenges and help address the needs of patients. I want to talk about some of the places where I think there could be common ground between the FDA and FTC to address these issues, and where I hope to steer our collaboration.

A lot of this boils down to the steps we can take to address a root cause of high drug prices – and that's often a lack of competition.

Sometimes competition is lacking because a pioneering drug has a monopoly on some highly novel and highly effective new technology.

In these cases, we want the market to be efficient and to reward the innovation. If a biotech company discovers a novel cure for a rare cancer; that's precisely the kind of innovation we want to encourage because patients deserve to have such treatments.

But we still want to see competition enter all categories, and especially these transformative categories as quickly as possible.

Patients benefit when they have more than one choice of a drug – both clinically and economically. There are often small differences between even similar medicines that can have important clinical implications.

But just as important, we've seen when a second drug enters a new drug category, it creates competition that can lower prices and improve access, even in rare diseases. That's an important public health goal.

FDA is taking steps to make the drug development process more efficient; so competition can enter novel drug categories more quickly. We'll have much more to say on this effort in the coming weeks.

But I'm also committed to making sure that we allow for brisk competition when the exclusivity periods have lapsed on these branded drugs, and they're eligible to be subject to generic competition.

Chairman Ohlhausen has outlined some of the history and critical responsibilities of the FTC within the regulatory and judicial framework surrounding generic drugs and her agency's key role in helping to address some of the challenges that impact the cost of generic drugs.

I'd like to spend a few minutes filling you in on the details of FDA's role in the development and approval of generic drugs, and how we're helping to strengthen competition to benefit the American consumer.

First, we've taken a number of actions that will help encourage the development of generic versions of drugs that lack competition so that safe, effective generics can come to market as quickly as possible.

For instance, we've expanded our prioritization policy to expedite the review of the first three generic drug applications where competition is limited. New generic entry predicts lower generic prices. Earlier work suggests that there are large price declines with competition among as few as three generic products. Soon we'll be updating this analysis.

In addition, earlier this year, we posted a list of off-patent, off-exclusivity products with no approved generic to proactively signal which products are available for immediate generic competition.

We also held a public meeting to discuss additional ways we can work to more address unfair practices that can forestall generic entry.

At that meeting, Markus Meier from FTC's Bureau of Competition joined us in a similar way that FDA colleagues are here today. I'll pause to note that our docket related to that meeting remains open a little while longer and we'd welcome your comments there as well.

One of the practices that concerns me the most is when branded firms "game" the system: taking advantage of certain rules, or exploiting loopholes in our system, to delay generic approval – and thereby extend a drug's monopoly beyond what Congress intended.

I see this clearly, for example, in steps branded companies sometimes take to make it hard, or altogether impossible, for generic firms to get access to the doses of the branded drug needed in order to complete bioequivalence studies that FDA requires for a generic approval.

Consider this: FDA requires generic firms to complete certain bioequivalence and bioavailability studies as a condition of the approval of a generic drug. To do these studies, they need to purchase doses of the branded drug that they seek to copy, to prove that the generic copy performs the same way original medicine.

The generic companies are willing to go into the market and buy these branded doses at full market price. They're not asking for a discount.

They're just asking for the right to be able to buy the drug at its retail price, just like a pharmacy or a hospital can make these legal purchases.

But we know that branded companies sometimes adopt tactics to make it nearly impossible for the generic firms to accumulate the doses they need to run their studies. That's a real concern of mine.

We have a system that relies on, and requires, the ability of generic firms to conduct certain studies for approval.

When drug manufacturers game the system in ways such as this, they upend the generic drug framework created by Hatch Waxman.

The effects of this gaming do not end within FDA or drug manufacturers. Medicare relies on this process working to help make sure its beneficiaries can get access to the benefits of low cost generics.

Patients depend on this system. So does innovation. I'll say this plainly:

Our economic model, which rewards highly innovative drugs with the opportunity to hold monopolies for a limited period of time through patents and exclusivities, and to freely price their products to a measure of the value that a transformative drug offers, also depends on the generic approval process working as intended.

It depends on the ability to have vigorous competition once those patents and exclusivities have lapsed.

Our system would not have functioned so well for so long without this carefully crafted balance between access and innovation.

If innovators want the current structure to continue to work, but they actively prevent certain parts of the system from functioning as Congress intended, then at some point, they'll find more advocacy for moving away from this incentive based model.

I don't want to see that day come. Because I'm convinced that this model -- one that was the result of careful compromise -- properly balances rewards for innovation with eventual competition and increased access. It's worked for decades and, as a result, America has the most productive and innovative life science sectors in the world.

But it has to continue to work.

That means that it must work at both ends of the marketplace: the end where the highly innovative drugs are developed and rewarded, and also at the other end, where those medicines face brisk competition once their patents and exclusivities have lapsed.

So my message is this: end the shenanigans.

Branded companies' use of REMS – which FDA adopts as a way to ensure the safe use of certain drugs – is also sometimes being used as a way to frustrate the ability of generic firms to purchase the doses of a branded drug that they need to run their studies. This needs to stop.

I believe drug makers also sometimes use restrictive agreements with pharmaceutical supply chain intermediaries – like specialty pharmacies – to frustrate or block the sale of a branded drug to a generic firm.

I consider these tactics unfair and exploitative practices, and they're in direct conflict with our broader public health goals.

These practices frustrate the generic drug regulatory system that Congress created, and that Americans depend on FDA to execute.

So in coming weeks I plan to take other steps to address this anti-competitive behavior. Among other things, I'm going to contact pharmaceutical supply chain intermediaries to inform them of the FDA's interest in making sure that generic firms can gain access to the doses they need to run bioequivalence studies.

When intermediaries sign on to these restrictive games, I want them to know that they're challenging a broader public health goal.

I'm also going to make sure that our own regulatory processes are harder to abuse in ways that can disadvantage consumers. That means changing how we implement our REMS programs.

For example, we're announcing today steps we're taking to make it easier for branded companies and generic entrants to develop one common master file for the implemntation of a REMS.

I view this as a first step toward also making it easier to implement a single shared REMS. Our goal is to see sponsors share REMS systems to reduce burdens on providers. But when branded drug makers drag out these negotiations – sometimes as a way to forestall generic entry – we're going to be in a stronger position now to say enough is enough.

Now that we've taken steps to make it easier to share a REMS as part of one program, when drug makers wont share their systems, we'll have a stronger basis to issue a waiver that will allow the generic drug makers to go their own way if they have to, and develop their own REMS.

These aren't the only things we're doing to help increase generic competition. We've also announced several new polices concerning complex generics -- a category of medicines that represent some very expensive and widely used drugs for which there is not robust generic competition. We believe that our new policies will make it more feasible to expand generic competition for these complex drugs.

We're also streamlining our process for reviewing generic drug files, to reduce review times. We're especially focused on continuing to reduce the number of review cycles an application undergoes.

We promised to reduce review times to just eight months for priority drugs, down from a previous average of as much as 42 months.

Efficiencies in the drug development and approval processes, along with regulatory certainty, help to drive down costs of drug development and create incentives for new market entrants.

We know there's no easy or single solution to the challenges posed by high drug development costs, and the high prices that result from these and other factors. But we also know that by strengthening and effectively applying our policies and regulations and our scientific and clinical standards to this problem, we can make significant headway.

I look forward to forward to building on and enhancing our partnership with FTC in order to achieve our shared goal of increasing competition, expanding access to quality generic drugs, and protecting consumers.

Thank you.

More in Speeches by FDA Officials (/NewsEvents/Speeches/default.htm)

STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

ERIC T. SCHNEIDERMAN
ATTORNEY GENERAL

DIVISION OF SOCIAL JUSTICE
HEALTH CARE BUREAU

January 13, 2016

Dr. Debra Houry, M.D., M.P.H.
Director, National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
4770 Buford Highway NE., Mailstop F–63
Atlanta, Georgia 30341

RE: Docket CDC–2015–0112,
Proposed 2016 Guideline for Prescribing Opioids for Chronic Pain

Dear Dr. Houry:

Thank you for your agency's efforts in developing the draft Guideline for Prescribing Opioids for Chronic Pain (the "Guideline"), which may represent an important tool in battling the epidemic of prescription drug abuse affecting our nation. New York has been a leader in fighting the abuse of prescription opioids, and I strongly encourage CDC to adopt the Guideline.

As you know, drug overdose rates are at a historic high. Most alarming is the rise in heroin and opioid overdoses. As data released last month by CDC data reflects, 18,893 people in the U.S. died from opioid pain reliever overdoses in 2014, a 16% increase from 2013.[1] In New York, from 2003 to 2012, deaths involving opioid analgesics increased four-fold, from 186 deaths in 2003 to 914 deaths in 2012.[2] At the core of this opioid overdose epidemic is the fact that physicians are writing more prescriptions for opioid pain relievers than ever before. As a result, the use of prescription opioids has increased ten-fold over the past 25 years in the United States.[3] The experience in New York mirrors that of the nation as a whole. In New York City, between 2008 and 2011, the number of opioid painkiller prescriptions filled by New York City residents increased by 31%, from approximately 1.6 million to approximately 2.2 million.[4]

[1] National Center for Health Statistics, National Vital Statistics System, Mortality File, at http://www.cdc.gov/nchs/data/health_policy/AADR_drug_poisoning_involving_OA_Heroin_US_2000-2014.pdf.
[2] New York State Department of Health, Poisoning Deaths Involving Opioid Analgesics in New York State, 2003 - 2012, at https://www.health.ny.gov/statistics/vital_statistics/docs/poisoning_deaths_opioid_analgesics.pdf.
[3] Susan Okie, *A Flood of Opioids, a Rising Tide of Deaths*, New England Journal of Medicine (November 18, 2010).
[4] New York City Department of Health and Mental Hygiene, *Health Department Data Show Increase In Opioid Prescription Painkiller Deaths In New York City* (May 14, 2013), at http://www.nyc.gov/html/doh/html/pr2013/pr013-13.shtml.

The Guideline is addressed to primary care providers treating chronic pain outside of active cancer treatment, thus squarely focusing on an important segment of the medical community. Primary care physicians are the top prescribers of opioid pain medication in the United States. Nevertheless, research suggests that some PCPs may lack a sufficient understanding of how opioid pain medications can result in abuse and addiction. A recent study by the Johns Hopkins Bloomberg School of Public Health suggests that this may be contributing to the ongoing epidemic of prescription opioid abuse and addiction in the United States.[5] Notably, nearly half of the internists, family physicians, and general practitioners surveyed mistakenly believed that "abuse-deterrent" opioid pills were less addictive than their standard counterparts.[6] One-third of these practitioners said they believed that most prescription drug abuse is by means other than swallowing the pills as intended.[7] According to the Food and Drug Administration, however, swallowing capsules or tablets is in fact the most common route of abuse of prescription opioids.[8] Further highlighting the issue, another recent study found that over a median follow-up of 299 days, physicians dispensed opioids to 91% of patients after an overdose, 7% of whom experienced another overdose shortly thereafter.[9] Proper prescribing practice suggests that adverse events, such as overdose, are compelling reasons to cease prescription opioids.[10] Consequently, inconsistencies between proper practice and real-world conduct accentuate the need for health care practitioners to receive more guidance on how to properly prescribe opioid pain medications. While other factors may play a role in the concerning misuse and mismanagement of opioids, health care providers would benefit from stronger and more uniform national guidance on how to properly prescribe opioid pain medication – as set forth in the Guideline.

The nonbinding Guideline is based on solid clinical evidence and contains recommendations that promote the effective treatment of pain and may prevent inappropriate prescribing of opioids, thus saving lives. In particular, Recommendation 9 encourages health care providers to review their patients' history of controlled substance prescriptions using state prescription drug monitoring program ("PDMP") data to determine whether the patient is receiving opioid dosages that put him or her at high risk for overdose. Many states have created PDMPs, and some, such as New York, require prescribers to consult the database before prescribing controlled substances. New York's historic Internet System for Tracking Over Prescribing ("I-STOP") legislation was signed into law on August 27, 2012. This law made New York the first state in the nation to ensure every prescription for a controlled substance is tracked in a real-time database accessed by both prescribers and pharmacists. New York's I-STOP

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[5] Catherine S. Hwang et al., *Primary Care Physicians' Knowledge And Attitudes Regarding Prescription Opioid Abuse and Diversion*, Clinical J. of Pain (Jun. 22, 2015).
[6] *Id*.
[7] *Id*.
[8] Food and Drug Administration, *Abuse-Deterrent Opioids: Evaluation and Labeling Guidance for Industry* (April 2015), at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM334743.pdf.
[9] Marc R. Larochelle, et al., *Opioid Prescribing After Nonfatal Overdose and Association with Repeated Overdose*, Ann. of Intern. Med. (Jan. 5, 2016).
[10] *Id*.

program, which became mandatory in 2013, has helped reduce prescription drug abuse, decreasing doctor shopping by almost 75%.[11]

Thank you for the opportunity to comment on the draft Guideline, and for your commitment to the promotion of public health in our state.

Sincerely,

Eric T. Schneiderman
New York Attorney General

[11] https://www.governor.ny.gov/news/governor-cuomo-announces-progress-states-efforts-crack-down-prescription-drug-abuse.

United States of America

Federal Trade Commission

Diagnosing the Treatments:
Issues in Post-Patent Pharmaceutical Markets

FTC Workshop Opening Remarks from the Federal Trade Commission's
Understanding Competition in Prescription Drug Markets:
Entry and Supply Chain Dynamics

Maureen K. Ohlhausen[1]
Acting Chairman, U.S. Federal Trade Commission

November 8, 2017

Thank you all for coming out bright and early this morning to the FTC's workshop on competition issues in prescription pharmaceuticals. I know from my prior life as the head of the FTC's policy shop just how much work goes into putting together a day like this. So I want to thank both our distinguished group of panelists and the tireless staff of the FTC in putting together what promises to be an extremely valuable program.

We come together today to discuss a topic that has long been a central focus of the agency's competition mission: protecting the markets that develop and produce the lifesaving medicines needed by our citizens. This agency does a lot of important work, but protecting the interests of consumers in the markets for prescription pharmaceuticals is one of our most critical responsibilities.

[1] The views expressed in these remarks are my own and do not necessarily reflect the views of the Federal Trade Commission or any other Commissioner.

The FTC has done countless merger investigations involving prescription pharmaceuticals and also taken aim at some of the biggest and most difficult problems in this space, problems like pay-for-delay agreements and the abuse of government drug approval process through behavior such as sham petitioning.

I am happy to report that we have made much progress on many of these fronts. We have required divestitures that preserve competition and protect consumers in dozens of pharmaceutical merger cases. We fought the issue of pay-for-delay agreements in courts across the country, battling through a series of adverse lower court rulings to eventually obtain a critical victory in the Supreme Court. And we continue the fight, challenging attempts to game the regulatory system for anticompetitive purposes.

It's been a great honor for me to serve at the FTC and be part of these varied and successful efforts to protect competition in the pharmaceutical markets. That said, I realize we have likely not seen the last of pay-for-delay deals, sham petitioning, or problematic, proposed mergers in this space. I fully expect that competition issues involving patented pharmaceuticals will remain a significant focus of the agency's enforcement efforts in the years ahead.

However, today's event has a somewhat different focus. When you consider our pharmaceutical enforcement history in aggregate, it becomes strikingly clear that most of our work in this space has clustered around just one part of the broader Hatch-Waxman Act[2] framework. Many people in this room are intimately familiar with the details of the Hatch-Waxman Act, but most of us spend very little time thinking about the overarching structure of the Act, or the broader policy goals it embodies. So let's take a minute to do just that.

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[2] Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271, 282 (1984)).

This groundbreaking piece of legislation imagined a structure that would protect the important intellectual property rights associated with new medicines, so that firms would retain appropriate economic incentives to develop vital new drugs and to undertake the costly work necessary to demonstrate their safety and efficacy. As I have spoken about many times before, the protection of intellectual property rights is critical to drive innovation, and the Hatch-Waxman framework recognizes and enshrines that essential truth in law.

That said, providing innovation incentives was only the first step in the broader framework envisioned by Hatch-Waxman. Fostering healthy, competitive markets for post-patent pharmaceuticals was another critical policy objective of this legislation. Eventually, patent protections expire, and the legislative framework includes incentives to induce generic entry once patents have run their course.

Rapid generic entry is an important driver of lower pharmaceutical prices. The first generic competitor's product is typically offered at a 20-30% discount to the price charged by the branded product.[3] Subsequent generic entry continues to lower prices, with discounts of 85% or more seen when a large number of generic firms are each competing for business.[4] This evidence suggests that there are few things more effective in lowering the cost of prescription drugs than fostering substantial generic entry upon patent expiration and letting competitive markets drive prices ever lower.

Despite its critical importance in lowering overall spending on pharmaceuticals, this second, vital part of the Hatch-Waxman framework has received far less attention. It was largely

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[3] FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* ii-iii (2011), https://www.ftc.gov/reports/authorized-generic-drugs-short-term-effects-long-term-impact-report-federal-trade-commission.

[4] FTC, *Pay-For-Delay: How Drug Company Pay-offs Cost Consumers Billions* 8 (2010), http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf.

assumed that once patent protections expired, the natural operation of market forces would drive prices down to something approaching marginal cost and that policymakers wouldn't have to do much more than get out of the way to see those 85% reductions in price. Fortunately, for many drugs, particularly those with large demand, that assumption seems correct.

But what we know today is that these assumptions do not necessarily hold in every case. In reality, the markets for pharmaceuticals that have lost patent protection are considerably more diverse and complex than many policymakers originally realized. These markets can involve simple, easily manufactured products that have been sold for decades or highly complex injectable drugs with daunting manufacturing requirements. They can be the big, prototypical markets for blockbuster drugs or small markets for products that treat comparatively rare diseases.

To be clear, the Hatch-Waxman framework has undeniably and dramatically improved access to low-cost generic drugs, and that is a great thing. However, we can also see that this has not occurred in every market. Some pharmaceuticals lose patent protections, but then draw no generic entry, allowing the incumbent firm to maintain high prices. Other medicines may draw some limited generic competition after the patents expire, but not enough generic firms enter to drive prices down to the modest levels that we might otherwise reasonably expect to see. We have also seen some shortages of inexpensive but critical medicines. In some isolated cases that have generated a lot of media attention, speculators have bought up off-patent, single source drugs and raised prices dramatically, without drawing an immediate competitive response.

Whenever any of these situations occurs, we should seek to understand why. Although these issues are complex, I'd suggest there are a few guiding principles we should apply here. Most important among them is the fact that market forces and competition are remarkably

effective mechanisms at driving down prices and improving consumer welfare. Further, the basic laws of supply and demand still apply in this industry. If we are not seeing results that are consistent with well-established, basic economic theory, we need to figure out why.

Fundamentally, that is what today's program is all about. What are the impediments to vigorous competition once pharmaceuticals are no longer protected by intellectual property rights? In other words, where we see that the framework laid out by the Hatch-Waxman Act is failing to deliver the full measure of its expected benefits, what are the root causes and what should the appropriate policy response be?

I recognize that when a law enforcement agency like the FTC identifies an area of concern, some people assume that it is a prelude to a raft of new enforcement actions. That assumption might seem particularly appropriate here, given our substantial enforcement history in this space and the critical nature of these products. Before we go any further here, I would like to caution you about drawing quick conclusions about our future enforcement plans.

We already know that there are many highly complex issues in these markets, and there likely will be no simple, easy solutions to the problems we currently observe. If these problems were straightforward and easy to solve, I would hope that we would have already fixed them.

The complex, multi-faceted nature of these problems strongly suggests that antitrust enforcement is not a cure-all that can fix all the potential problems in this space. Just as there is no single drug to cure every ailment, the antitrust laws are not a panacea for every economic concern. As I have said before, antitrust works best when it focuses its attention on harms to the competitive process and the protection of consumer welfare. We are neither a price regulator nor a sector regulator. We may ultimately determine there is a need for greater antitrust enforcement

in pharmaceutical markets, but that decision will be made on the basis of specific facts and actual market effects, using the familiar methods and processes of antitrust law.

For now, I think we need to learn more about how these markets are working today, with an eye towards not just what antitrust enforcers can do to help, but what changes in the regulatory system as a whole may be appropriate in response to some of the concerns we've identified in these markets.

Here are some of the specific questions we are most interested in understanding:

(1) What are the incentives (and disincentives) that generic manufacturers consider when making the decision to enter or refrain from entering the market for a particular pharmaceutical no longer protected by patents? Should policymakers or market participants alter those incentives to better align with the public interest in robust competition? If so, how?

(2) What strategies, if any, are being undertaken with the intent to reduce generic drug competition today? Are these strategies working and what impact are they currently having on these markets?

(3) What is the current role of intermediaries like group purchasing organizations and pharmacy benefit managers in these markets? What benefits do these intermediaries provide and what costs are they imposing today?

(4) How should all stakeholders evaluate proposals to reduce drug prices and increase consumer access?

These questions aren't going to capture every nuance of these large and complex markets, but they are certainly a good place to start. And the FTC staff has assembled a great set of panels today to begin digging into these important issues in much greater detail.

Finally, I am happy to note that we at the FTC are not the only federal agency paying close attention to these issues. Dr. Scott Gottlieb, the Commissioner of the Food and Drug Administration, and I share a desire to identify and address the hurdles to better generic drug competition, whatever the source. Indeed, today's workshop, bringing together outside experts from academia, industry and both of our agencies is a direct result of our previous discussions. Our two agencies may have different missions and different spheres of responsibility, but we plan to work together closely to ensure that the markets for generic drugs work the way they should, and that U.S. consumers get the safe, efficacious and affordable medicines they deserve.

It is now my pleasure to introduce Dr. Scott Gottlieb. Dr. Gottlieb was sworn in as the 23rd Commissioner of Food and Drugs on May 11, 2017. Dr. Gottlieb is a physician, medical policy expert, and public health advocate who previously served as the FDA's Deputy Commissioner for Medical and Scientific Affairs and before that, as a senior advisor to the FDA Commissioner.

Under his tenure as the head of the agency, the FDA has already taken a number of actions to improve consumer access to generic drugs. These efforts include streamlining the ANDA review process and undertaking various initiatives to significantly improve the transparency of agency actions.

We look forward to having him here today to talk about the vital contribution that access to generic drugs can make to public health and the ways in which our two organizations can work together.

HIGH PRICES & NO EXCUSES: 6 ANTICOMPETITIVE GAMES

MICHAEL A. CARRIER
DISTINGUISHED PROFESSOR
RUTGERS LAW SCHOOL

Crucial Topic

- Important exercise: patents get attention; post-patent entry often does not
- I have comprehensively studied patents and antitrust in pharmaceutical industry
  - Co-author of leading IP/antitrust treatise
  - Author of more than 100 articles (40 on pharmaceutical antitrust law)
  - Author of amicus curiae briefs on behalf of hundreds of professors
  - Frequently cited in media (1000+ times) and courts (including U.S. Supreme Court)

No (or Weak) Patents Delay Generics

- Brand profits from monopoly (each day = millions)
- Regulatory regime used to delay entry: FDA exclusivity, reformulation time, petition process, distribution restrictions
- This behavior and others also follows from patenting of secondary advances
- "Off-patent" not coming as quickly as it used to as brands obtain weaker patents covering developments after active-ingredient patent expires
- **Small molecule example**: Pfizer's strongest Lipitor patents expired in March 2010 & June 2011, but settlement with generics delayed entry until after these periods because of minor patents expiring in 2016
- **Biologic example**: AbbVie's composition-of-matter patent on inflammatory-disease-treating Humira expired in 2016, but patent thicket of 100+ patents (indication/method of treatment (22), formulation (14), manufacturing (24), "other" (15)) extends protection until 2034…53 patents obtained in 2015 and 2016 alone
  - *AbbVie Long-Term Strategy*, Oct. 30, 2015, http://www.biotechduediligence.com/uploads/6/3/6/7/6367956/abbvie_strategy_presentation__1_.pdf;
  - Cynthia Koons, *This Shield of Patents Protects the World's Best-Selling Drug*, BLOOMBERG BUSINESSWEEK, Sept. 7, 2017, https://www.bloomberg.com/news/articles/2017-09-07/this-shield-of-patents-protects-the-world-s-best-selling-drug.

Game 1: Pay-for-delay Settlements

- *FTC v. Actavis*: Settlements by which brands pay generics to delay entering market can have "significant anticompetitive effects" and violate antitrust law
- Parties can settle without payment: 2015 FTC Report shows number of settlements (170) increasing while "pay for delay" deals fall from 40 (FY2012) to 14 (FY2015), with only 5 above $7m litigation costs
- 89% of patents in settled litigation are secondary patents; brand less likely to win on these (32%) than on active-ingredient (92%) patents
    - C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 SCIENCE 1386, 1387 (2013) (drugs first eligible for challenges between 2000 and 2008)
- Most post-*Actavis* cases cover secondary patents: Actos (method of use), AndroGel (formulation), Cephalon (particle size), Effexor (extended release), K-Dur (formulation), Lidoderm (skin application), Loestrin (contraception method), Niaspan (time release), Opana (time release), Solodyn (treatment method), Wellbutrin (extended release)
    - **AndroGel**: Patent for synthetic testosterone expired in 1950s
    - **Loestrin**: FDA approved active ingredients in 1970s
    - **Niaspan**: Active ingredient niacin sold since early 20th century

Game 2: Product Hopping

- Brand firms often switch to new versions of drug products; many switches not connected to generic entry
- But some changes, with patient migration to reformulated product, have one purpose: **delay generics**
  - Prevent operation of state substitution laws and Hatch-Waxman Act
  - Aim to switch market to reformulated version before generic of original version enters market
  - Each switch results in delay from generic reformulation, FDA approval, patent litigation
- **Secondary patents** give extra protection: Prilosec to Nexium = 13 years; Suboxone tablet to film = 14 years; Namenda IR to XR = 14 years
- Even if **no patent**, delay from FDA exclusivity and time it takes to reformulate drug
  - Warner Chilcott engaged in multiple hops on acne-treating Doryx (first available in 1985 as unpatented capsule): (1) capsule to 75- and 100-mg tablets, (2) 150-mg single-scored tablet, (3) 75- and 100-mg single-scored tablets, (4) 150-mg dual-scored tablet
  - Also stopped selling capsules, removed capsules from website, worked with retailers to auto-reference tablet in filling prescriptions, informed purchasers and doctors that capsules replaced by tablets, bought back and destroyed capsules

Game 3: Citizen Petitions

- Citizen petitions are meant to raise legitimate safety concerns with FDA
- But my empirical study of all petitions filed between 2011 and 2015 against pending generics ("505(q)" petitions) found that FDA denies 92%; also 98% of late-filed petitions (within 6 months of expiration of patent or FDA exclusivity), 100% of simultaneous petitions (when FDA resolves petition on same day it approves generic)
  - Michael A. Carrier & Carl J. Minniti III, *Citizen Petitions: Long, Late-Filed, and At-Last Denied,* 66 AMERICAN UNIVERSITY LAW REVIEW 305 (2016)
- **Last-minute petition example**: Bayer's petition on IUD Mirena 1 day before patent expiration
- **Bottleneck example**: Allergan's dry-eye-treating Restasis petitions delay generics
  - Feb. 2014 petition denied Nov. 2014; Dec. 2014 petition denied Feb. 2016; Aug. 2017 petition filed
    - Each petition challenges generics' use of in vitro (as opposed to human) testing protocols
  - In 135-page opinion, Judge Bryson invalidated 6 Restasis patents, but generics Mylan, Teva, Akorn still cannot enter market because of Aug. 2017 petition

Game 4: REMS Restrictions

- REMS serve important purpose in making sure risky drugs reach market
- But brands have used REMS to deny samples generics need for bioequivalence testing
  - 2017 study: REMS restricts 41 drugs with sales exceeding $11 billion
    - Alex Brill, *REMS and Restricted Distribution Programs*, June 2017, https://www.gphaonline.org/media/cms/Alex_Brill_REMS_Study_June_2017.pdf
  - More than 150 generics have informed FDA they cannot obtain samples
- In litigated cases, brands have **denied samples** to generics willing to pay market prices and enter into indemnification agreements
  - And brands have ignored FDA letters showing REMS compliance and protections
    - E.g.: 1) Actelion "would sell" sample upon receiving FDA letter but 2) after Apotex provides FDA letter, Actelion responds: "This changes nothing" and "you don't get [the sample]"
- Brands also have not negotiated in good faith for **shared REMS** programs
  - E.g.: Suboxone allegedly turned down invitations to participate in meetings, insisted on unfavorable conditions, refused to share nonpublic information, demanded veto authority and supermajority vote, engaged in delay tactics
    - *See* Michael A. Carrier, *Sharing, Samples, and Generics: An Antitrust Framework*, CORNELL LAW REVIEW, at 37-42 (forthcoming 2017), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2979565)

Game 5: Non-REMS Distribution Restrictions

- Some companies have imposed distribution restrictions not required by FDA
- 2017 study: Non-REMS programs restrict 33 drugs with sales exceeding $11 billion
  - Alex Brill, *REMS and Restricted Distribution Programs*, June 2017, https://www.gphaonline.org/media/cms/Alex_Brill_REMS_Study_June_2017.pdf
- Martin Shkreli (aka "Pharma Bro") switched Turing's distribution system for infection-treating **Daraprim** from nationwide to single source: Walgreen's Specialty Pharmacy
  - Active ingredient introduced in 1953; distribution limited 62 years later for no safety-related reason
  - Turing official: "would like to do our best to avoid generic competition"; "certainly not going to make it easier" for generics
  - 5000% price increase ($13.50 to $750)
- Retrophin (Shkreli's prior company) also switched to closed distribution, blocking generic access on cholesterol-deficiency-treating **Chenodal** (400% increase) and kidney-stone-treating **Thiola** (1900% increase)
  - Shkreli: "We do not sell Retrophin products to generic companies. . . . The whole model that generics rely upon is turned upside down with specialty pharmacy distribution"

Game 6: Bundling/Rebates

- **Restasis**: Shire sued Allergan for blocking access to dry-eye-disease-treating Xiidra
  - Xiidra can be prescribed to "much larger population" and lacks Restasis's side effects but limited to 10% Medicare Part D market (vs 35% commercial market)
  - Challenge bundling and exclusive dealing (if include Xiidra on formularies, lose substantial discounts/rebates on other Allergan drugs)
    - Even if plan received Xiidra for free, "the numbers still wouldn't work"
- **Remicade**: J&J had only product on market 1998-2016; Pfizer sued, claiming J&J blocked access to arthritis- and Crohn's-treating rival Inflectra
  - Insurers cannot cover Inflectra; otherwise J&J deny rebates (which apply to multiple products)
  - Inflectra has less than 4% of market; J&J raise Remicade list price 9%
- **EpiPen**: Sanofi sued Mylan for offering high ("practically impossible to refuse") rebates to insurers, PBMs, and state Medicaid programs; had effect of blocking coverage of rival Auvi-Q
  - Auvi-Q market share fell roughly 50% after rebates took effect
- **Exclusive dealing law**: Percentage of market foreclosed important. Also: contract duration, industry prevalence, entry barriers, distribution alternatives
- **Rebate law**: Exclusionary effect on competitors (3rd Cir.) vs. attribution test (attribute discount to product on which plaintiff claims exclusion and see if price below cost) (9th Cir.)

Proposals

- **Antitrust enforcement**: Careful scrutiny of thickets and conduct accompanying secondary patents
- **Settlements**: Continued judicial scrutiny and FTC enforcement; consideration of legislation applying presumptive illegality or expanded 180-day exclusivity period
- **Product hopping**: Scrutiny of reformulations that cannibalize profitable drugs, making no economic sense other than by stifling generic entry (can apply to hard **and soft** switches)
  - *See* Michael A. Carrier & Steve Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME LAW REVIEW 167 (2016)
- **REMS**: Antitrust scrutiny for sample denials and delayed negotiations on shared REMS
  - *See* Michael A. Carrier, *Sharing, Samples, and Generics: An Antitrust Framework*, CORNELL LAW REVIEW (forthcoming 2017), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2979565)
  - CREATES Act would provide bipartisan statutory fix for sample denials and blocked negotiations
- **Non-REMS distribution restrictions**: Rigorous antitrust scrutiny (apply no-economic-sense test)
- **Citizen petitions**: Antitrust scrutiny and enforcement (like FTC case against Shire ViroPharma)
  - Also consider: (1) list of 505(q) petitions and delay in annual reports to Congress; (2) determine if simultaneous generic approvals and petition resolutions caused delay; (3) make easier for FDA to summarily dispose of petitions; (4) determine money and time incurred resolving petitions; (5) certify objections filed within one year
    - *See* Michael A. Carrier, *Five Actions to Stop Citizen Petition Abuse*, 118 COLUMBIA LAW REVIEW ONLINE __ (forthcoming 2018), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3043541
- **Bundling/rebates**: Robust antitrust scrutiny of exclusive dealing and bundling

ATTORNEY GENERAL OF THE STATE OF NEW YORK

In the Matter of

ValueOptions, Inc.

Assurance No.: 14-176

ASSURANCE OF DISCONTINUANCE
UNDER EXECUTIVE LAW
SECTION 63, SUBDIVISION 15

Pursuant to the provisions of Section 63(12) of the Executive Law and Article 22-A of the General Business Law, Eric T. Schneiderman, Attorney General of the State of New York, caused an inquiry to be made into certain business practices of ValueOptions, Inc. ("ValueOptions"), relating to its administration of behavioral health benefits. Based upon that inquiry, the Office of the Attorney General ("the OAG") has made the following findings, and ValueOptions has agreed to modify its practices and comply with the following provisions of this Assurance of Discontinuance ("Assurance").

I. BACKGROUND

1. ValueOptions, a for-profit corporation, administers behavioral health benefits for health benefit plans and insurance companies. ValueOptions' principal offices are located at 240 Corporate Boulevard, Norfolk, Virginia 23502. ValueOptions merged with Beacon Health Strategies on December 23, 2014, and is now Beacon Health Options. ValueOptions agrees that its merger does not alter its obligations under this Assurance and any respective successors and assigns are bound herein as set forth in Paragraph 99 below.

2. In the regular course of business, ValueOptions, a managed behavioral health care organization ("MBHO"), administers behavioral health benefits for approximately 2.7 million New Yorkers in fully funded or state and local governmental health plans, who include members of the following health plans: MVP Health Care, Inc. ("MVP"), EmblemHealth, Inc. ("Emblem," which includes Group Health Incorporated ("GHI") and Health Insurance Plan of Greater New York ("HIP")), Oscar Insurance Corporation ("Oscar") (as of January 1, 2014), and the Empire Plan (as of January 1, 2014), the health benefit plan for New York State and certain local governmental employees. In 2013, ValueOptions had revenues of approximately $1.3 billion nationally, and $95 million for its fully insured Emblem and MVP business.

3. MVP and Emblem entered into separate Assurance of Discontinuance agreements with the OAG, effective March 19, 2014, Assurance No. 14-006 ("MVP AOD"), and July 3, 2014, Assurance No. 14-031 ("Emblem AOD"), respectively.

II. THE OAG'S INVESTIGATION AND FINDINGS

4. The Health Care Bureau of the OAG conducted an investigation into ValueOptions' administration of behavioral health benefits following the receipt of dozens of consumer complaints alleging that ValueOptions had improperly denied coverage for behavioral health services. In this Assurance, "behavioral health services" will refer to both mental health and substance use disorder services.

The Need for Adequate Coverage of Behavioral Health Treatment

5. Mental and emotional well-being is essential to overall health. Every year, almost one in four New Yorkers has symptoms of a mental disorder. Moreover, in any year, one in ten adults and children experience mental health challenges serious

enough to affect functioning in work, family, and school life. Lack of access to treatment, which can be caused by health plans' coverage denials, can have serious consequences for consumers, resulting in interrupted treatment, more serious illness, and even death.

6. Mental illness is the leading illness-related cause of disability, a major cause of death (via suicide), and a driver of school failure, poor overall health, incarceration and homelessness.

7. For example, in any given year, one in ten individuals has a diagnosable mood disorder, such as major depression. Three to four percent of women will have an eating disorder, such as anorexia nervosa or bulimia nervosa, at some point in their lives. Individuals with anorexia have a level of mortality up to 18 times greater than the average population without anorexia, the highest mortality rate of any mental illness.

8. The failure of health plans and MBHOs to reimburse members adequately for behavioral health costs, including those for substance abuse treatment, means that plan members who need treatment may not be getting the treatment recommended by their providers. In any given year, 11% of New Yorkers (1.8 million people) have a substance use disorder, but only 11% of these individuals receive any treatment for their condition. In contrast, more than 70% of individuals with hypertension and diabetes receive treatment for those conditions.

ValueOptions' Administration of Behavioral Health Benefits

9. Health plans provide inpatient and outpatient benefits for medical/surgical and behavioral health conditions. Several New York health plans – including MVP, Emblem, Oscar and Empire Plan – subcontract administration of their members'

behavioral health benefits to ValueOptions. These health plans typically pay ValueOptions a fixed fee per member, per month, for ValueOptions to administer behavioral health benefits for their members. Despite the passage of both federal and state laws requiring that plans provide behavioral health coverage "on par" with medical/surgical coverage, most of these health plans – in particular, MVP and Emblem – have not been comparing behavioral health claims approvals and denials with those in the medical/surgical realm.

10. Access to adequate behavioral health care appears to be an issue for health plan members whose benefits are administered by ValueOptions. ValueOptions does not regularly report penetration rate, an important metric that shows the percentage of members accessing behavioral health benefits, to its health plan clients. For some of ValueOptions' contracting health plans, spending on behavioral health benefits has decreased since they outsourced administration of behavioral health benefits to ValueOptions. In particular, Emblem's overall spending on behavioral health care (not including prescription drugs) has declined precipitously from 2011 to 2013, from 3.6% of spending on health care claims to 2.6%. Similarly, of MVP's overall spending on all health claims, approximately 2.6% is directed to behavioral health care, and its payments to ValueOptions for behavioral health benefits management declined more than 20% from 2011 to 2012. In contrast, behavioral health care, including prescription drugs, accounts for approximately 7.3% of all health spending in the U.S. These data suggest that ValueOptions may not be sufficiently covering behavioral health treatment.

ValueOptions' Utilization Review of Behavioral Health Benefits

11. Utilization review is the process by which a health plan (or the MBHO with which it subcontracts) examines plan members' requests or claims for health care services to determine whether the services are medically necessary, and thus eligible for coverage. For services for which preauthorization is required, such as inpatient services, typically a provider will file a request for authorization with the plan (or MBHO) on behalf of the member, and the plan (or MBHO) will review the request to determine whether the services are medically necessary under its medical necessity criteria. If the plan (or MBHO) denies the request, in many cases, the member will not receive the requested service, and will not file a claim for benefits. On the other hand, where services have already been provided, a member or provider will typically submit a claim for benefits, and the plan (or MBHO) will either pay the claim automatically or conduct utilization review for the claim. In the latter situation, the plan (or MBHO) will determine whether the services are medically necessary under its medical necessity criteria.

12. Medically necessary services are those that are reasonable and necessary for the diagnosis or treatment of illness or injury, or to maintain or improve the functioning of an individual. If ValueOptions deems the services to satisfy its criteria, the health plan (or ValueOptions) will pay the claim. If ValueOptions does not deem the services to satisfy its criteria, it will send the member an adverse determination letter, which, under New York law, must contain a detailed explanation of the clinical rationale for the denial and information about the member's appeals rights.

13. A member whose request or claim for behavioral health services ValueOptions denies due to lack of medical necessity (and for certain other reasons) has the right, under New York law, to file: (i) an internal appeal, which ValueOptions decides without any involvement or oversight by the contracting health plan; (ii) in some cases, a second-level, internal appeal, which ValueOptions also decides without any involvement or oversight by the contracting health plan; and (iii) an external appeal, which is reviewed by an independent clinician who has no relationship with ValueOptions or the health plan. ValueOptions, on behalf of the contracting health plan, typically performs utilization review for all inpatient, partial hospitalization and intensive outpatient behavioral health claims, and certain outpatient visits.

14. The OAG's review of consumer complaints, as well as health plans' utilization review data, indicates that ValueOptions applies more rigorous – and frequent – utilization review for behavioral health benefits than the contracting plans apply to medical/surgical benefits. Emblem's Senior Director of Behavioral Health described ValueOptions' approach to utilization review for behavioral health benefits as "aggressive."

15. From January 2011 through mid-2013, 18% of the reviews ValueOptions conducted for requests for behavioral health treatment coverage for Emblem members (for example, requests for preauthorization) resulted in denials, encompassing more than 7,500 denied requests. After many of these denials, the member did not receive the requested care, and did not file a claim for benefits. In contrast, Emblem's medical/surgical reviews resulted in denials only 11% of the time.

16. Additionally, during the same period, ValueOptions denied 22% of behavioral health claims submitted by Emblem members (where services were already provided), whereas Emblem denied only 13% of medical/surgical claims submitted during that period. ValueOptions also denied 38% of all substance abuse treatment claims by Emblem members during that time. From January 2011 through March 2014, ValueOptions denied at least 15,000 requests or claims of Emblem members for behavioral health treatment due to its determination that the treatment was not medically necessary, with billed charges of more than $31,000,000.

17. ValueOptions' denial rates for more intensive levels of behavioral health care – such as inpatient treatment – are especially high. From January 2011 through mid-2013, 26% of ValueOptions' reviews of Emblem members' requests for inpatient psychiatric treatment resulted in adverse decisions, totaling approximately 4,000 denied requests. After many of these denials, the member did not receive the requested care, and did not file a claim for benefits. Additionally, ValueOptions denied 36% of Emblem members' claims for inpatient psychiatric treatment, totaling more than 2,500 denied claims. In the same period, 39% of ValueOptions' reviews of Emblem members' requests for inpatient substance abuse rehabilitation coverage (*e.g.*, preauthorization requests) resulted in adverse decisions, totaling more than 2,300 denied requests, and ValueOptions denied 41% of Emblem members' claims for already-received services for that level of care, totaling almost 2,000 denied claims.

18. In contrast, ValueOptions' contracting health plans conduct utilization review for medical/surgical benefits in a more lenient manner. For example, from 2011 through 2013, only 20% of Emblem's reviews for inpatient medical/surgical treatment

resulted in denials, and only 29% of inpatient medical/surgical claims were denied by Emblem.

19. Similarly, ValueOptions' review of MVP members' behavioral health benefits has been more stringent than MVP's review of its members' medical/surgical claims. From 2011 through 2013, although behavioral health benefits comprised less than 3% of overall benefits paid by MVP, claims for behavioral health benefits comprised 14% of all reviews for claims for health care services. ValueOptions made adverse determinations in 21% of the behavioral health reviews it performed for MVP members, while MVP made adverse determinations in only 15% of the medical/surgical reviews it performed.

20. Over the last three years, ValueOptions has denied almost 40,000 of MVP members' claims for mental health treatment and an additional 11,000 of MVP members' claims for substance use disorder treatment. These numbers include medical necessity denials (which include denials for lack of clinical information and lack of preauthorization) and administrative denials. (An administrative denial is a denial based on a defect in the request or claim, *e.g.*, incomplete claim form, lack of member or provider eligibility, provider contract limitation, or lack of out-of-network benefit, etc.) In particular, over the last three years, ValueOptions has denied 39% of MVP members' claims for inpatient psychiatric treatment, totaling more than 1,200 denied claims. Over the same period, ValueOptions denied 47% of MVP members' claims for inpatient substance use disorder treatment, totaling almost 900 denied claims. In contrast, MVP denied less than 18% of its members' inpatient medical/surgical claims during the same period.

21. Not only does ValueOptions apply more stringent utilization review to behavioral health benefits than the contracting health plans do to medical/surgical benefits, it appears on some occasions to apply medical necessity criteria incorrectly when it reviews behavioral health-related requests and claims. For example, even though substance abuse rehabilitation is not an acute level of care, in denying requests for coverage of rehabilitation, ValueOptions classifies it as acute care, and in certain cases, ValueOptions has denied requests for coverage of substance abuse rehabilitation on the grounds that the member was not experiencing "life-threatening withdrawal," which is not a requirement for such treatment. In fact, individuals who are suffering from life-threatening withdrawal require a more intensive level of care than rehabilitation, such as medically managed inpatient detoxification. For example, in a case in which an MVP member, who was addicted to heroin and prescription painkillers, requested coverage for inpatient substance use disorder rehabilitation treatment, ValueOptions rejected the claim, stating that the member did not have withdrawal symptoms, which is not a criterion for the level of care requested.

22. Although ValueOptions' medical necessity criteria do not contain any "fail first" requirements, in some cases, it has denied requests for coverage of substance abuse rehabilitation treatment through application of "fail first" requirements. For example, ValueOptions denied a request for coverage of substance abuse rehabilitation because the member had not recently failed an outpatient program. This requirement places yet another obstacle in front of members who, suffering from addiction, may have a small window of opportunity to access treatment and embark on the path to recovery. Emblem's own doctors, however, have stated that a member's lack of an attempt at an

outpatient mode of care is not a reason to deny an inpatient stay. Emblem does not apply such a "fail first" requirement to medical/surgical benefits.

23. Persons with mental health and substance use disorders comprise a vulnerable population, and may be reluctant to seek care. Frequent and time-consuming utilization review may pose obstacles preventing them from accessing or completing treatment. Moreover, when ValueOptions approves more intensive levels of care, such as inpatient or partial hospitalization treatment, it will often approve just a few days or visits at a time, requiring members and providers to focus on health coverage rather than treatment. Additionally, in some cases in which ValueOptions has approved a certain number of inpatient days or outpatient visits, it has denied requests for authorization of additional days or visits until claims for all previously authorized days or visits have been exhausted – which may take days or weeks. This also has the effect of interrupting treatment, because the member must wait for ValueOptions to authorize additional care.

24. The utilization review that ValueOptions conducts for behavioral health claims is often intensive and frequent, and providers and members must spend a great deal of time justifying each day or visit. For example, a 14-year old MVP member with an eating disorder was receiving partial hospitalization treatment for her illness, until ValueOptions denied additional days of treatment. As a result, the member had to interrupt treatment while an appeal was lodged on her behalf, exacerbating the symptoms of her illness, and causing her and her family extreme emotional stress. Additionally, although it is not possible to complete substance abuse rehabilitation treatment in one day, in some cases, ValueOptions authorizes one day of inpatient substance abuse rehabilitation treatment at a time.

25. Until recently, ValueOptions, at Empire Plan's direction, required providers of outpatient behavioral health treatment to Empire Plan members to submit "outpatient treatment reports" after ten sessions, before it would authorize further care. Further, ValueOptions required behavioral health providers – even at the outpatient level – to submit treatment and discharge plans, denying coverage if providers failed to do so. For example, ValueOptions required the providers of outpatient behavioral health services to Empire Plan members to submit treatment plans to ValueOptions after ten outpatient visits before it would authorize further care. In contrast, health plans such as Emblem do not typically require medical/surgical providers to develop treatment plans or to demonstrate discharge planning.

26. From 2011 through 2013, in 42% of behavioral health cases of Emblem members that went to external appeal, ValueOptions' denials were reversed, compared with only a 30% reversal rate in medical/surgical cases. After Emblem directed its staff to review behavioral health cases before they went to external appeal, to determine whether the denials were correct, Emblem subsequently reversed the denials in almost 20% of the cases it reviewed. In 2011 and 2012, more than 2,300 MVP members were eligible to file external appeals of MVP's denials of coverage for behavioral health benefits. That is more than twice the number of MVP members eligible to file appeals of medical/surgical denials (1,112). Fewer than 80 of the MVP members eligible for appeals of behavioral health denials – less than 3% of those eligible –actually filed external appeals. MVP's decisions have been overturned in 40% of those cases.

The Outpatient Outlier Model

27. ValueOptions applied a utilization review tool for outpatient behavioral health benefits known as the Outpatient Outlier Model, under which a certain number of member outpatient psychotherapy visits triggers a special form of intensive utilization review whereby additional treatments are more deeply scrutinized, and may be denied. For example, after a member with major depression – a chronic, often life-long, biologically based illness – submitted claims for a certain number of psychotherapy visits, ValueOptions placed that member in the Outpatient Outlier Model, with the expectation that the member will soon terminate treatment. The thresholds are based only on ValueOptions' past claims paid data, not on clinical evidence or research regarding length of treatment for particular mental health conditions.

28. Once ValueOptions places a member in the Outpatient Outlier Model, it requested further information from the member's provider before it would authorize further coverage. ValueOptions has in some cases also recommended a lower frequency of visits as a strategy of working towards treatment termination, even though it cannot point to any literature or evidence supportive of session frequency as a treatment variable.

29. The thresholds in ValueOptions' Outpatient Outlier Model are inconsistent across different members' health plans, depending on the plan design. For example, for GHI members, ValueOptions requires prior approval for the first session of outpatient substance abuse treatment, and another approval prior to the eleventh session of such treatment, whereas other plans have varying thresholds. Additionally, ValueOptions has failed to perform analyses supporting the Outpatient Outlier Model that are required by its own policies, which calls into question the integrity of the model. For example, the

Outpatient Outlier Model policy requires ValueOptions to, on an annual basis: perform an evaluation of population-based utilization and clinical data to determine a set of specific types of potential outlier cases; provide the rationale for inclusion in the outlier program, reporting micromanagement strategies and specific interventions to be followed; and reevaluate the designated national outlier types and the results of the specialized interventions and clinical care management process to assure that the interventions initiated continue to be clinically appropriate. ValueOptions has never taken any of these actions.

30. ValueOptions conducted almost 4,500 reviews of MVP members' treatment under the Outpatient Outlier Model from 2011 through 2013, contributing to the denial of coverage of more than 2,100 sessions of outpatient behavioral health care.

31. MVP and Emblem do not implement a utilization review tool equivalent to the Outpatient Outlier Model in administering medical/surgical benefits.

Inadequate Denial Letters

32. ValueOptions' adverse determination letters denying behavioral health claims are generic and lack specific detail explaining why coverage was denied for particular members. The letters also fail to explain adequately the medical necessity criteria used in making the determinations and why members failed to meet such criteria. For example, each of the denial letters contain boilerplate language such as:

- "[T]he information indicates the patient has made progress toward treatment goals and no longer requires the same frequency of treatment."
- "[T]he review indicates that the treatment plan goals and objectives have been attained and that the signs and symptoms that brought the patient into the treatment have been stabilized."

- "[T]he review does not indicate the presence of biomedical or psychological impairment, or the likelihood of relapse requiring treatment at the acute inpatient hospitalization with 24 hour medical supervision level of care. An appropriate level of care to the current needs of the patient is intensive outpatient services."

Without details of the denial or the criteria used in making the determination, members are without the means to lodge a meaningful appeal of ValueOptions' denials.

33. Emblem has admitted that, in ValueOptions' denial letters, "[c]linical rationales primarily state in general rather than specific terms why the member's condition does not meet medical necessity criteria." Emblem has also admitted that ValueOptions' boilerplate denial reasons in the letters are not sufficient and that denial letters often mischaracterize the level of treatment requested. Such flawed letters call into question the accuracy of ValueOptions' adverse decisions. In contrast, letters issued by MVP and Emblem denying coverage for medical/surgical conditions, are more detailed.

34. Until at least 2012, ValueOptions did not provide sufficiently detailed language regarding the reason for its denial of substance abuse treatment requests and claims. ValueOptions neither cited the medical necessity criteria it used in its denial letters, nor provided the criteria upon request to members, as it is legally required to do.

35. In its denial letters, ValueOptions recommends a less intensive level of care for the member. However, in some cases, after the member has subsequently requested approval for that recommended level of care, ValueOptions has denied the request as well. ValueOptions reported that in one such case, its reviewers failed to take note of the company's own recommendations.

36. Although substance abuse programs in New York State are required to use Guidelines for Level of Care Determinations approved by the New York Office of

Alcoholism and Substance Abuse Services ("OASAS"), ValueOptions uses different criteria, created by ValueOptions, for determining medical necessity for substance abuse treatment, which may result in denial of care, since providers are required to use OASAS-approved criteria.

Lack of Coverage for Residential Treatment for Behavioral Health Conditions

37. Until 2014, MVP and the HIP division of Emblem did not cover residential treatment for behavioral health conditions, and ValueOptions would therefore deny requests by these health plans' members for coverage of such treatment. Residential treatment is a standard, recommended, evidence-based form of behavioral health treatment. Offering medication, counseling and structure, residential treatment facilities for behavioral health disorders provide a critical intermediate level of care between acute inpatient and outpatient treatment, enabling patients to transition back to living with their families. Residential treatment programs provide an intermediate level of care as compared to inpatient services, similar to skilled nursing treatment for medical/surgical conditions.

38. Residential treatment is deemed to be a medically necessary option for treating persons with severe eating disorders, which can require round-the-clock supervision. According to ValueOptions' own treatment guidelines, residential treatment is the standard form of treatment for eating disorders for persons who do not meet the criteria for inpatient hospitalization, but nevertheless are ill enough that they require 24-hour structure and supervision of all meals in order to achieve a healthier weight level, to decrease suicidality, and to develop sufficient motivation to successfully undertake

outpatient treatment. Given the potentially lethal nature of eating disorders, denial of coverage for residential treatment can place members' lives in jeopardy.

39. According to Section 3.301 of ValueOptions' medical necessity criteria:

> Residential Treatment Services are provided to children/adolescents who require 24-hour treatment and supervision in a safe therapeutic environment. RTS is a 24 hour a day/7 day a week facility-based level of care. RTS provides individuals with severe and persistent psychiatric disorders therapeutic intervention and specialized programming in a controlled environment with a high degree of supervision and structure. RTS address the identified problems through a wide range of diagnostic and treatment services, as well as through training in basic skills such as social skills and activities of daily living that cannot be provided in a community setting.

40. Residential treatment is also a standard form of treatment for substance abuse disorders. According to Section 4.301 of ValueOptions' medical necessity criteria:

> Residential treatment is a 24 hour a day/7 day a week facility-based level of care which provides individuals with significant and persistent substance abuse disorders therapeutic intervention and specialized programming in a controlled environment with a high degree of supervision and structure. Residential rehabilitation addresses the identified problems through a wide range of diagnostic and treatment services by reliance on the treatment community setting.

41. ValueOptions' medical director stated that there is evidence to support residential treatment for eating disorders. Moreover, ValueOptions has designated certain residential treatment facilities as diagnostic specialty units, because such units have demonstrated areas of clinical expertise and provide effective treatment. The categorical denial of coverage applied by ValueOptions had a deleterious impact on New Yorkers. In one case, ValueOptions denied residential treatment for a 14-year old Emblem member suffering from anorexia nervosa, even though her doctors in an inpatient facility (where she had been hospitalized with an irregular heartbeat) believed that she needed such care. After a short period of day treatment, the girl relapsed,

necessitating further hospitalization. In another case, ValueOptions denied coverage of residential treatment for a young woman with a severe case of anorexia, even though she was at 72% of ideal body weight – a dangerous condition. As a result, her family paid thousands of dollars out of pocket for room and board so she could be monitored on a 24/7 basis in a residential treatment facility. Even then, ValueOptions denied coverage of therapy services as not medically necessary, until an external reviewer reversed ValueOptions' decision, concluding that ValueOptions had "not acted reasonably, nor with sound medical judgment, and not in the best interest of the patient."

Cost-Sharing for Behavioral Health Services

42. ValueOptions has assessed higher copayments for behavioral health outpatient treatment than health plan members were charged for outpatient medical/surgical treatment. Until 2014, approximately 40% of MVP plans charged a higher copayment for outpatient mental health visits than for outpatient primary care visits. In some MVP plans, the mental health copayment was twice as high as the primary care copayment. Until 2014, approximately 23% of HIP large-group plans charged a higher copayment for outpatient mental health visits than for outpatient primary care visits, in some cases, double the primary care copayment.

Other Problems With ValueOptions' Administration of Behavioral Health Benefits

43. The OAG's investigation has revealed numerous other deficiencies in ValueOptions' administration of behavioral health benefits. The OAG has received numerous complaints with regard to the Empire Plan that ValueOptions' provider network is inadequate, and does not include certain types of providers, such as licensed

mental health counselors, as set forth in the Empire Plan benefits design. Providers and consumers have also complained that ValueOptions has failed to assist providers and members in transitioning between providers, and that ValueOptions' network provider listings are inaccurate and contain the names of providers who are not accepting new patients, calling into question the adequacy of ValueOptions' provider network.

44. In some instances, ValueOptions did not cover treatment for Emblem members, pending completion of internal appeals. Due to numerous deficiencies with ValueOptions' administration of Emblem members' behavioral health benefits, including the issues described above, ValueOptions terminated the director of the office where those benefits are administered. ValueOptions has reduced reimbursement to members for out-of-network behavioral health visits to non-M.D.'s for procedure codes that are typically not billed by M.D.'s. For example, the procedure code for 45 minute psychotherapy (90834) is not intended for use by M.D.'s, thus usual, customary and reasonable ("UCR") rates contained in the FAIR Health database reflect billed charges by social workers and psychologists, not M.D.'s. However, ValueOptions pays only 65% of the UCR rate for procedure code 90834 for visits to social workers, and 75% of that rate to psychologists. As a result, consumers are forced to pay more out-of-pocket for behavioral health care. ValueOptions has also failed to reimburse certain procedure codes that are standard in the mental health field (such as initial evaluation codes), has reimbursed psychiatrists for evaluation and management codes at lower rates than other medical/surgical providers receive, and generally has provided lower reimbursement for in-network psychiatric services in 2014 than in past years.

45. A 2012 Department of Financial Services audit concluded that ValueOptions failed to meet the notification requirements of the New York Utilization Review Law for prospective and concurrent review in almost all cases sampled. Section 4903(b) of the New York Insurance Law states that a utilization review agent must make a utilization review determination involving health care services which require pre-authorization, and provide notice to the insured and their provider thereof, within three business days. In all 15 sampled cases, ValueOptions failed to provide verbal notification to the insured and their provider within the statutorily required timeframe. Section 4903(c) of the New York Insurance Law states that a utilization review agent must make a determination involving continued or extended health care services, and provide notice to the insured and their provider thereof, within one business day. In 11 of 15 sampled cases, ValueOptions failed to provide verbal notification to the insured and their provider within the statutorily required timeframe.

III. RELEVANT LAWS

46. Timothy's Law, enacted in 2006, mandates that New York group health plans that provide coverage for inpatient hospital care or physician services must also provide "broad-based coverage for the diagnosis and treatment of mental, nervous or emotional disorders or ailments, . . . at least equal to the coverage provided for other health conditions." N.Y. Ins. Law §§ 3221(l)(5)(A); 4303(g)(1). Further, all group plans must cover, annually, a minimum of 30 days of inpatient care, 20 visits of outpatient care, and up to 60 visits of partial hospitalization treatment for the diagnosis and treatment of mental, nervous or emotional disorders or ailments. N.Y. Ins. Law §§ 3221(l)(5)(A)(i)&(ii); 4303(g)(1)(A)&(B).

47. Timothy's Law also requires that deductibles, copayments and co-insurance for mental health treatment be consistent with those imposed on other benefits, N.Y. Ins. Law §§ 3221(l)(5)(A)(iii); 4303(g)(1)(C), and that utilization review for mental health benefits be applied "in a consistent fashion to all services covered by [health insurance and health maintenance organization] contracts." 2006 N.Y. Laws Ch. 748, § 1.

48. The New York Insurance Law requires every group plan that provides coverage for inpatient hospital care to cover at least 60 outpatient visits in any calendar year for the diagnosis and treatment of chemical dependence, of which up to twenty may be for family members. N.Y. Ins. Law §§ 3221(l)(7); 4303(l).

49. In 2004, New York enacted legislation creating Comprehensive Care Centers for Eating Disorders (the "CCCED Law"). New York L. 2004, c.114. Pursuant to the CCCED Law, the New York State Department of Health designated three Centers, each of which must provide or arrange for a continuum of care tailored to the specialized needs of individuals with eating disorders, including residential treatment. N.Y. Public Health Law § 2799-g. The CCCED Law prohibits plans from excluding coverage provided by a Comprehensive Care Center for Eating Disorders. N.Y. Ins. Law §§ 3221(k)(14); 4303(dd).

50. The federal Mental Health Parity and Addiction Equity Act ("The Federal Parity Act"), enacted in 2008, prohibits large group, individual, and Medicaid health plans that provide both medical/surgical benefits, and mental health or substance use disorder benefits, from: (i) imposing financial requirements (such as deductibles, copayments, co-insurance, and out-of-pocket expenses) on mental health or substance use

disorder benefits that are more restrictive than the predominant level of financial requirements applied to substantially all medical/surgical benefits; (ii) imposing treatment limitations (such as limits on the frequency of treatment, number of visits, and other limits on the scope or duration of treatment) on mental health or substance use disorder treatment that are more restrictive than the predominant treatment limitations applied to substantially all medical/surgical benefits, or applicable only with respect to mental health or substance use disorder benefits; and (iii) conducting medical necessity review for mental health or substance use disorder benefits using processes, strategies or standards that are not comparable to, or are applied more stringently than, those applied to medical necessity review for medical/surgical benefits. 29 U.S.C. § 1185a; 42 U.S.C. § 300gg-26; 45 C.F.R. § 146.136(c)(4)(i). The essential health benefit regulations under the Affordable Care Act extend the Federal Parity Act's requirements to small and individual plans. 45 C.F.R. § 156.115(a)(3).

51. Timothy's Law and the Federal Parity Act work together, in that Timothy's Law mandates coverage of mental health treatment which is at least equal to coverage for other health conditions, and the Federal Parity Law requires that behavioral health coverage be no more restrictive than coverage of medical/surgical treatment. For example, Timothy's Law requires coverage of at least 20 sessions of outpatient mental health treatment per year. If a health plan does not place visit limits on substantially all outpatient medical/surgical treatment, it may not place visit limits on outpatient mental health treatment.

52. ValueOptions is obligated to comply with the mental health parity laws. ValueOptions has stated that it has "supported over 50 customers in becoming parity

compliant." In administering behavioral health benefits, ValueOptions has prepared mental health parity compliance checklists for its health plan clients. ValueOptions was a member of The Coalition for Parity, Inc., which brought an unsuccessful 2010 lawsuit to block implementation of the Interim Final Rules under the federal Mental Health Parity and Addiction Equity Act ("The Federal Parity Act"), contending that complying with the rules would have a substantial impact on it. Further, the Chief Medical Officer of ValueOptions' Commercial Division testified that ValueOptions must comply with the mental health parity laws.

53. The Affordable Care Act requires health plans to allow enrollees to receive continued coverage pending the outcome of internal appeals. 42 U.S.C. § 300gg-19(a)(1)(C); 29 C.F.R. 2590.715-2719(b)(2)(iii) (group plans); 45 C.F.R. 147.136(b)(3)(iii) (individual plans).

54. The New York General Business Law prohibits "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state." N.Y. G.B.L. § 349(a).

55. The New York State Executive Law authorizes the Attorney General, where there are "repeated fraudulent or illegal acts" or "persistent fraud or illegality in the carrying on, conducting or transaction of business," to seek relief, including enjoining the continuance of such business activity or of any fraudulent or illegal acts, as well as restitution and damages. N.Y. Exec. Law § 63(12).

56. Based on the findings of the Attorney General's investigation, the Attorney General has determined that ValueOptions' conduct has resulted in violations of N.Y. Executive Law Section 63(12), Timothy's Law, the Federal Parity Act, and the

Affordable Care Act. ValueOptions' practices have had the effect of unlawfully limiting members' access to behavioral health services.

NOW, WHEREAS, ValueOptions neither admits nor denies the Attorney General's findings in Paragraphs 4 through 45 above; and

WHEREAS, access to adequate behavioral health treatment is essential for individual and public health; and

WHEREAS, ValueOptions has cooperated with the OAG's investigation; and

WHEREAS, the Attorney General is willing to accept the terms of this Assurance under Executive Law Section 63(15) and to discontinue his investigation; and

WHEREAS, the parties each believe that the obligations imposed by this Assurance are prudent and appropriate; and

WHEREAS, the Attorney General has recently entered into Assurances of Discontinuance with MVP Health Care, Inc. (Assurance No. 14-006) and EmblemHealth, Inc. (Assurance No. 14-031), each of which relates to ValueOptions' administration of New Yorkers' behavioral health benefits; and

WHEREAS, the Attorney General has determined that this Assurance is in the public interest.

IT IS HEREBY UNDERSTOOD AND AGREED, by and between the parties that:

IV. PROSPECTIVE RELIEF

57. Within ninety (90) days of the Effective Date, ValueOptions will implement the reforms set forth below in Paragraphs 58 through 72, for fully funded and state and local governmental health plans in New York.

58. Cost-Sharing Requirements: For outpatient behavioral health visits by members of Emblem and MVP plans, ValueOptions will apply the member's primary care cost-sharing schedule in accordance with the AODs with those entities. For all other plans, ValueOptions will work with and make recommendations to its clients to support their compliance with relevant mental health parity laws, which include applying the member's primary care cost-sharing schedule for outpatient behavioral health visits. If ValueOptions has a good faith belief that applying the specialist cost-sharing schedule for outpatient behavioral health visits is legally permissible for a health plan, it will provide written notice to the OAG regarding its basis for same and will not implement same until thirty (30) days after parties have met and conferred.

59. No visit limits:

a. For members of Emblem and MVP plans, ValueOptions will not apply any day or visit limits for behavioral health services, except for family counseling services, coverage for which may be capped at 20 visits per year, in accordance with the AODs for those entities. For all other plans, ValueOptions will work with and make recommendations to its clients to support their compliance with relevant mental health parity laws, including that they will not apply any day or visit limits for behavioral health services in any health plan it administers, except for

family counseling services, coverage for which may be capped at 20 visits per year, or any other limitations required by law. If ValueOptions has a good faith belief that such limitations are required by law, it will provide written notice to the OAG regarding its basis for same and will not implement same until thirty (30) days after parties have met and conferred.

b. For members of Emblem and MVP plans, ValueOptions will provide coverage for services provided by mental health practitioners licensed under Article 163 of the New York Education Law, in accordance with the AODs for those entities. ValueOptions will work with and make recommendations to its clients to support their compliance with relevant mental health parity laws and the provider non-discrimination provision of the Affordable Care Act, 42 U.S.C. 300gg-5(a), including that they provide coverage for services provided by mental health practitioners licensed under Article 163 of the New York Education Law. If ValueOptions has a good faith belief that excluding coverage for services provided by certain licensures of behavioral health providers is justified, it will provide written notice to the OAG regarding its basis for same and will not implement same until thirty (30) days after parties have met and conferred.

60. Network Adequacy and Transitions:

a. ValueOptions will ensure that its provider network contains an adequate number of behavioral health providers of different types

(including psychiatrists, psychologists, social workers, nurse practitioners, and mental health counselors), within a reasonable distance from members' residences, to meet the treatment needs of such members.

b. ValueOptions will maintain a listing on its website (the "online provider directory"), and make same available to members in hard copy upon request, of the name, address and telephone number of all participating providers, including facilities, and in the case of physicians, board certification. ValueOptions will update the online provider directory within fifteen days of the addition or termination of a provider from ValueOptions' network or a change in a physician's hospital affiliation.

c. When a provider leaves ValueOptions' network, ValueOptions will assist members receiving services from that provider in locating and transitioning to a new network provider, if requested.

d. Before ValueOptions adopts a new fee schedule, it will give providers 30 days written notice, along with a copy of the applicable fee schedule showing the effective date, procedure codes and rates, and indicating the clients/products to which it is applicable.

61. Reimbursement:

a. ValueOptions will reimburse members for out-of-network services at the usual, customary and reasonable rate ("UCR") for the relevant behavioral health service, without applying lowered rates for non-

M.D. providers, unless any such lowered rates are already factored into the UCR data source that ValueOptions employs.

b. ValueOptions will provide reimbursement for standard evaluation and management codes (*e.g.*, 99201, 99202, 99203, 99204, and 99205), and will not require preauthorization of crisis codes.

c. ValueOptions will provide reimbursement for covered behavioral health services by a licensed behavioral health provider for behavioral health treatment of any diagnosis listed in the Diagnostic and Statistical Manual of the American Psychiatric Association (the "DSM") that is covered by the client. ValueOptions will work with and make recommendations to its clients to support their compliance with relevant mental health parity laws, including providing reimbursement for those DSM diagnoses covered under the Empire Plan (the plan provided to public officers and employees pursuant to Article 11 of the Civil Service Law), which currently includes the vast majority of DSM diagnoses.

62. Utilization Review Process Reforms:

a. Preauthorization: ValueOptions will not impose any preauthorization requirements for outpatient behavioral health services, and will discontinue its practice of requiring submission by providers of outpatient treatment reports after a set number of outpatient behavioral health visits, unless comparable requirements are imposed for substantially all outpatient medical/surgical benefits. If ValueOptions

has a good faith belief that it may impose preauthorization requirements for outpatient behavioral health benefits, pursuant to this Paragraph, it will provide written notice to the OAG regarding its basis for same and will not implement same until 30 days after parties have met and conferred.

b. Comparability of Utilization Review Processes: ValueOptions will not use the Outpatient Outlier Model for utilization review purposes. If ValueOptions uses a utilization review tool for behavioral health services that is based on quantity or frequency of outpatient visits, it will develop such tool and update it annually based on clinical evidence, and such tool will be approved by a physician who is board-certified in general psychiatry, or, in the case of substance abuse services, a physician who is board-certified in addiction medicine. ValueOptions will conduct utilization review under such tool only to the extent that the quantity or frequency of visits is inconsistent with clinical evidence. Where, after applying such tool to the requests or claims of a member, ValueOptions denies coverage for services, the member shall be afforded all internal and external appeal rights.

c. Thoroughness of Reviews: Each ValueOptions staff member conducting utilization review will consult the member's entire case file before rendering any utilization review decision, in particular to determine whether ValueOptions has previously recommended a particular level of care.

d. Integration of Utilization Review for Medical/Surgical and Behavioral Health Benefits: ValueOptions will cooperate with measures implemented by its contracting health plans, in particular MVP and Emblem, to promote the integration of administration of medical/surgical and behavioral health benefits.

e. Collection of Information During Utilization Review: ValueOptions will follow a protocol for the collection of information during utilization review, which will include the elements set forth in Exhibit A.

f. Substance Abuse Treatment: ValueOptions will not apply any "fail first" requirement for substance abuse rehabilitation treatment. ValueOptions will administer coverage of outpatient substance abuse treatment received in office settings, including, but not limited to, medication-assisted treatment for opioid addiction.

g. Medical Necessity Criteria: ValueOptions has applied to OASAS for approval of its criteria for determining medical necessity for substance abuse treatment, and will continue to exercise best efforts to secure such approval. ValueOptions will not require that members pose a potential risk of serious harm to self or others in order to satisfy the medical necessity criteria for behavioral health residential treatment or inpatient substance abuse rehabilitation treatment.

h. Continued Treatment: When a member transitions from one level of behavioral health treatment to another, for example from inpatient to

outpatient care, ValueOptions will conduct the review for the second level as a concurrent review, because it concerns continued treatment.

i. Classification of Denials: ValueOptions will process as medical necessity denials any denials of coverage for behavioral health services due to lack of clinical information and/or preauthorization.

j. Duration of Approvals: ValueOptions will not limit the number of days or visits it approves for behavioral health treatment to one day or one visit per approval, and will base such approvals on the treatment needs of the member, unless clinically appropriate.

k. Concurrent Reviews: ValueOptions will conduct clinically appropriate concurrent reviews in accordance with the following, unless a shorter period of time is requested by the provider: (a) with regard to residential treatment care, at least three days in advance of exhaustion of previously approved days or visits, so as not to interfere with treatment; (b) with regard to substance abuse rehabilitation, at least two days in advance of exhaustion of previously approved days or visits, so as not to interfere with treatment; and (c) with regard to outpatient care, at least seven days in advance of exhaustion of previously approved days or visits, so as not to interfere with treatment. Providers may also request authorization of additional days or visits in advance of exhaustion of previously approved days or visits, consistent with the foregoing.

l. Retrospective Reviews: ValueOptions will not conduct retrospective reviews based upon predetermined billing codes or combination codes (*e.g.*, evaluation and management plus psychotherapy, which is a standard combination), unless the coding pattern is unusual or indicates fraud and abuse.

63. Adverse Determination Notification: When making adverse benefit determinations, ValueOptions will provide to the member and provider:

a. Telephonically, with respect to prospective and concurrent determinations and, in writing, with respect to all adverse determinations, the adverse determination.

b. In writing, a detailed explanation of the clinical reason for the denial, citing to specific medical necessity criteria (explaining why they are not met), member-specific facts, and treatment records.

c. In writing, what, if any, additional necessary information must be provided to, or obtained by, ValueOptions to render a decision on the appeal.

d. In writing, a prominent statement regarding the availability, to members and providers, of Behavioral Health Advocates (who are described below in Paragraph 64), with a notation that the provider and member can contact an Advocate to obtain information about facilities and providers able to provide alternative services to the member.

e. In writing, clear, specific information about internal and external appeals (including information as described below in Paragraphs 65 and 66);

f. In writing, the address of a website containing the medical necessity criteria used in making the adverse determination, and notice of the availability, free of charge upon request, of a copy of such criteria.

For all adverse determinations, ValueOptions will also provide the information described above telephonically in a general manner (*e.g.*, ValueOptions will advise that appeal rights are available, but will not describe such rights in detail, unless asked to do so). With respect to Emblem and MVP, adverse determination letters will be reviewed for accuracy by the individual who authorized the adverse determination prior to distribution to members and providers. With respect to all other clients, adverse determination letters will be reviewed for accuracy by a clinical peer reviewer who has the authority to modify or reverse the contents of the letter prior to distribution to members and providers. When ValueOptions recommends or states in an adverse determination letter that a member can be safely treated in a less intensive or restrictive level of care, it will then approve a request for authorization for that level of care, as long as such request is made within ten (10) days of receipt of the adverse determination letter, and will confirm that treatment services are available to the member at such level of care within a reasonable distance from the member's home. ValueOptions will also include in adverse determination letters a short list of alternative providers in the member's area.

64. Behavioral Health Advocates: ValueOptions will cooperate with Behavioral Health Advocates, individuals who are employed to aid MVP and Emblem

members, in particular those whose requests or claims have been denied, by providing accurate and current information regarding utilization review determinations and processes, medical necessity criteria, complaint processes, and appeals, as well as alternative treatment options for the member in the member's area. Behavioral Health Advocates employed by ValueOptions will return member calls within one (1) business day.

65. Internal Appeals: ValueOptions will continue coverage of treatment pending the completion of internal appeals.

66. External Appeals: To facilitate members' timely submission of external appeals, in particular expedited appeals, ValueOptions will cooperate with MVP and Emblem as follows:

a. When ValueOptions renders an adverse determination of a request for coverage of behavioral health services, such determination will be eligible for expedited external review, if it: (i) meets the criteria of New York Insurance Law Section 4914(b)(3) or New York Public Health Law Section 4914(b)(3), *i.e.*, if the member's provider states that a delay in providing the services would pose an imminent or serious threat to the health of the member; (ii) relates to continued or extended behavioral health services; or (iii) relates to inpatient, residential, partial hospital, intensive outpatient mental health or substance use disorder treatment.

b. When a member is eligible for expedited external appeal, as set forth in subpart (a) of this Paragraph, ValueOptions will provide clear and

conspicuous instructions, to the member and provider, orally and in writing, regarding external appeal options, including expedited appeals.

c. A provider may file an external appeal (whether standard or expedited) on behalf of a member for a prospective, concurrent, or retrospective denial of coverage for behavioral health services.

d. For Emblem plans, when a member or such member's provider files an expedited external appeal of a denial of coverage for behavioral health services, ValueOptions must authorize the requested service until the external review agent renders a decision.

e. Effective April 1, 2015, for all members, if a member or his/her health care provider files an expedited internal and external appeal within twenty-four (24) hours from receipt of an adverse determination for inpatient substance use disorder treatment for which coverage was provided while the initial utilization review determination was pending, ValueOptions must provide coverage of the requested service until the external review agent renders a decision.

67. Residential Treatment: ValueOptions will provide coverage for medically necessary residential treatment for behavioral health conditions for members of MVP and Emblem plans, in accordance with the AODs for those entities. As described in ValueOptions' medical necessity criteria, residential treatment facilities provide 24 hours a day/7 days a week treatment and supervision to individuals with severe and persistent psychiatric disorders. Such facilities typically provide therapeutic intervention and

specialized programming in a controlled environment with a high degree of supervision and structure, in the context of a comprehensive, multidisciplinary and individualized treatment plan, with regular physician visits. For all other plans, ValueOptions will work with and make recommendations to its clients to support their compliance with relevant mental health parity laws, which include providing coverage for residential treatment for behavioral health conditions. If ValueOptions has a good faith belief that not providing coverage for residential treatment for behavioral health conditions is legally permissible for a health plan, it will provide written notice to the OAG regarding its basis for same and will not implement same until thirty (30) days after parties have met and conferred.

68. Cooperation With Compliance Administrators: ValueOptions will cooperate with the Compliance Administrators (the "Administrators") appointed pursuant to Assurance of Discontinuance No. 14-006 with MVP Health Care, Inc., and Assurance of Discontinuance No. 14-031 with EmblemHealth, Inc. (the "Assurances"). The Administrators' main tasks are to: (i) evaluate the respective health plans' compliance with the respective Assurances; (ii) evaluate the respective health plans' utilization review system for behavioral health benefits; (iii) provide guidance to the respective health plans and to ValueOptions; and (iv) provide quarterly reports concerning items (i) through (iii) to the respective health plans and the OAG. In particular, ValueOptions will cooperate with reasonable requests by the Administrators for data sufficient for the Administrators to evaluate ValueOptions' administration of the respective health plans' behavioral health benefits. Data to be requested from ValueOptions by the Administrators may include: (i) claims review results; (ii) metrics demonstrating adequate access to effective behavioral health services, including, at a minimum:

adequacy of the provider network; penetration rate; dollar spend on behavioral health services; utilization review results; internal appeals and results thereof; external appeals and results thereof; and member satisfaction with behavioral health coverage; and (iii) adverse determination letters. Such data may be requested in the form of utilization analyses, key indicator reports, population analyses, and/or other reports generated in the normal course of business by ValueOptions.

69. Training: ValueOptions will provide training to all of its utilization review and customer relations staff serving New York members, regarding the requirements of this Assurance, Timothy's Law, New York Insurance Law provisions regarding substance use and eating disorder treatment, the Federal Parity Act, proper application of medical necessity criteria, and appeals processes. ValueOptions will provide a copy of such training materials to the OAG for approval before dissemination.

70. Grievances: For a three (3)-year period, ValueOptions will provide the OAG with a quarterly summary of grievances (as such term is defined in Insurance Law Section 4802) as made to ValueOptions or reported to ValueOptions by its clients regarding behavioral health coverage, without patient-identifying information. A grievance is a member or provider complaint to a health insurance company about a denial based on limitations or exclusions in the contract.

71. Disclosures: ValueOptions will provide to members, in clear and conspicuous language on its website, and by reference to its website in correspondence with members, disclosures regarding behavioral health coverage, as set forth in Exhibit B.

72. Annual Parity Compliance Report: For each of the three (3) years following the Effective Date or until the compliance reporting requirements end under both the MVP and Emblem AODs, whichever is earlier, ValueOptions will file an annual report with the OAG, certifying compliance with the terms of this Assurance and outlining how its administration of behavioral health benefits complies with Timothy's Law, New York Insurance Law provisions regarding substance use and eating disorder treatment, and the Federal Parity Act. Such reports shall include, at a minimum, evidence of the statements set forth in Exhibit B, as well as a completed parity compliance checklist for each of its health plan clients, the form of which ValueOptions will prepare, subject to approval by the OAG. In so doing, ValueOptions will obtain sufficient information from its health plan clients regarding administration of their medical/surgical benefits in order to complete the parity compliance checklists, in particular regarding covered benefits, copayment levels, and request and claim denial rates.

V. RETROSPECTIVE RELIEF

73. ValueOptions will cooperate with the retrospective relief provisions of the MVP AOD and the Emblem AOD. Those retrospective relief provisions call for notice to MVP and Emblem members regarding the opportunity to file independent appeals of medical necessity denials and to file claims for residential treatment for behavioral health conditions, for independent review of claims filed pursuant to such notice, and for restitution to such members determined to have received medically necessary care ("MVP AOD Appeals" and "Emblem AOD Appeals"). In cooperating with the retrospective relief provisions of the MVP AOD and the Emblem AOD, ValueOptions will also take the actions set forth below in Paragraphs 74 and 75.

74. MVP AOD Appeals Process. Effective immediately:

a. ValueOptions will determine, within ten (10) business days of receipt, whether each MVP AOD Appeal application filed by an MVP member or his/her designee ("MVP Claimant") is complete and eligible for independent review, and transmit complete and eligible appeals applications to MCMC, the independent entity conducting such review (the "Reviewer"). The Reviewer is an independent utilization review agent that has been selected by MVP and ValueOptions and has been approved by the OAG. ValueOptions previously provided notice by mail (including appeal applications) to potentially eligible MVP Claimants.

b. All MVP AOD Appeal applications filed by MVP Claimants must be decided within forty-five (45) days of the date that the application was deemed complete and eligible.

c. ValueOptions will make Behavioral Health Advocates (described above) and ValueOptions Appeals Specialists available to assist MVP Claimants in completing their appeal applications, including, where necessary, assisting MVP Claimants in their efforts to submit proof of out-of-pocket expenses and/or unpaid bills and invoices for treatment.

d. Where ValueOptions believes that an MVP AOD Appeal application is incomplete or that an MVP Claimant is ineligible for an appeal, it may not reject such application unless it has communicated to the MVP Claimant with specificity and in writing the reason for such

incompleteness or ineligibility, has reached out to the MVP Claimant telephonically to determine the reason for such incompleteness or ineligibility, reasonably concluded that the application is incomplete and/or the member is not eligible for an MVP AOD Appeal, and communicated the basis for this conclusion to the MVP Claimant and to the OAG. The application may be rejected if it remains incomplete and/or the member does not demonstrate eligibility for the MVP AOD Appeal on or after the thirtieth (30^{th}) day from the date ValueOptions communicates to the MVP Claimant and the OAG the basis for its conclusion.

e. ValueOptions will pay all claims of MVP Claimants eligible for restitution within thirty (30) calendar days of the Reviewer's decision, except for residential treatment claims, which shall be paid within thirty (30) calendar days of the Reviewer's decision or within thirty (30) days from the Effective Date of this Assurance, whichever is later.

f. At the conclusion of the appeals process, ValueOptions will, at its own expense, engage an independent auditor, subject to the approval of the OAG, to confirm that: (i) all complete and eligible MVP AOD Appeal applications have been afforded independent review; and (ii) ValueOptions has distributed restitution payments to eligible MVP Claimants, pursuant to the terms of the MVP AOD.

75. Emblem AOD Appeal Process:

a. ValueOptions will, at its own expense and with the OAG's approval, retain Rust Consulting, Inc. to serve as an independent third-party administrator ("Claims Administrator"), which shall be responsible for: (i) determining the completeness and eligibility of Emblem AOD appeal applications filed pursuant to the Emblem AOD by Emblem members ("Emblem Claimants"); (ii) contacting Emblem Claimants, their providers, ValueOptions and Emblem, as necessary, to obtain information regarding such applications; (iii) transmitting complete and eligible applications to the Reviewer, MCMC (which is an independent utilization review agent that has been selected by Emblem and ValueOptions and has been approved by the OAG); and (iv) ensuring that ValueOptions and Emblem distribute payments to Emblem Claimants pursuant to the terms of the Emblem AOD ("Claims Administrator's Plan").

b. Within ten (10) business days following the execution of this AOD, the Claims Administrator shall provide to the OAG and ValueOptions a written plan reflecting the processes and procedures that the Claims Administrator will follow (the "Claims Administrator's Plan") to: (i) determine the completeness and eligibility of Emblem AOD Appeal applications filed pursuant to the Emblem AOD by Emblem Claimants; (ii) contact Emblem Claimants, their providers, ValueOptions and Emblem, as necessary, to obtain information

regarding such applications (including proof of payment and/or unpaid bills and invoices for treatment); (iii) transmit complete and eligible applications to the Reviewer; and (iv) ensure, by means of an audit, that ValueOptions and Emblem distribute payments to Emblem Claimants pursuant to the terms of the Emblem AOD. Upon the OAG's approval, which shall take into consideration any comments or suggestions made by ValueOptions, the Administrator shall implement the processes and procedures set forth in the Administrator's Plan.

c. ValueOptions, having previously provided notice by mail (including appeal applications) to potentially eligible Emblem Claimants, shall provide to the Claims Administrator all Emblem AOD Appeal applications that it receives from Emblem Claimants, immediately upon receipt of such applications. ValueOptions will also provide to the Claims Administrator the appeal application packages sent by ValueOptions to such claimants.

d. The Claims Administrator will determine, in accordance with the time frame set forth in the Claims Administrator's Plan, whether each Emblem AOD Appeal application is complete and eligible for independent review.

e. All Emblem AOD Appeal applications deemed complete and eligible by the Claims Administrator must be decided by the Reviewer within forty-five (45) days of such determination.

f. ValueOptions will make Behavioral Health Advocates (described above) and ValueOptions Appeals Specialists available to assist Emblem Claimants in completing their appeal applications, including, where necessary, assisting Emblem Claimants in their efforts to submit proof of out-of-pocket expenses and/or unpaid bills and invoices for treatment.

g. Where the Claims Administrator believes that an appeal application is incomplete or that an Emblem Claimant is ineligible for an appeal, it may not reject such application unless it has communicated to the Emblem Claimant with specificity and in writing the reason for such incompleteness or ineligibility, has reached out to the Emblem Claimant telephonically to determine the reason for such incompleteness or ineligibility, reasonably concluded that the application is incomplete and/or the member is not eligible for an Emblem AOD Appeal, and communicated the basis for this conclusion to the Emblem Claimant and to the OAG. The Claims Administrator will provide such information to the OAG on a weekly basis, unless otherwise agreed. The application may be rejected if it remains incomplete and/or the member does not demonstrate eligibility for the Emblem AOD Appeal on or after the thirtieth (30^{th}) day from the date ValueOptions communicates to the Emblem Claimant and the OAG the basis for its conclusion.

h. ValueOptions will pay all claims of Emblem Claimants eligible for restitution, including residential treatment claims, within thirty (30) calendar days of the Reviewer's decision.

i. ValueOptions shall be required to continue to retain the Claims Administrator (or, if necessary, a replacement administrator that is acceptable to the OAG) until all restitution payments have been made to Emblem Claimants.

j. The OAG, at its discretion, shall have the right to require ValueOptions to change the Claims Administrator upon a reasonable and good faith determination that the Claims Administrator has been ineffective in carrying out its duties pursuant to this Assurance.

k. In the event ValueOptions reasonably determines that the Claims Administrator is not performing its duties in an objectively reasonable manner consistent with the terms of this Assurance and the Emblem AOD, ValueOptions shall notify the OAG and the Claims Administrator in writing and the parties shall meet and confer within five (5) days of such written notification in a good faith attempt to resolve the issues.

l. The Claims Administrator shall not be permitted to subcontract its obligations under this Assurance to any other person or entity, except that, after notifying the OAG and subject to the OAG's approval, the Claims Administrator may retain additional persons or entities needed

for the Claims Administrator to carry out its obligations under this Assurance.

m. This Assurance shall be attached to ValueOptions' contract with the Claims Administrator.

n. ValueOptions shall provide a copy of its contract with the Claims Administrator to the OAG within two business days of its execution.

o. ValueOptions shall bear any and all costs associated with retaining the Claims Administrator.

p. ValueOptions shall cooperate with any and all requests by the Claims Administrator or by the OAG to assist in communicating with Emblem Claimants and their providers.

q. The agreement between ValueOptions and the Claims Administrator shall require the Claims Administrator to treat all information provided by the OAG regarding claimants as confidential and not to share such information with any other person or entity.

VI. PENALTIES

76. Within sixty (60) days of the Effective Date, ValueOptions shall pay $900,000 to the OAG as a civil penalty, in lieu of any other action which could be taken by the OAG in consequence of the foregoing. Such sum shall be payable by check to "State of New York Department of Law."

VII. LIQUIDATED DAMAGES

77. If ValueOptions violates any provision of this Assurance, or does not provide requested information specified in Sections IV and V of the Assurance and/or requested by the OAG pursuant to Paragraph 86 below, within thirty (30) days of such request, the OAG may elect as its exclusive remedy in lieu of Paragraphs 90 through 92 below, to demand that ValueOptions pay liquidated damages of $1,000 per day for such non-compliance or failure to provide requested information. Before liquidated damages may be imposed, the OAG shall give ValueOptions written notice that ValueOptions may be subject to liquidated damages under this paragraph. In the event that ValueOptions does not cure the violation or provide the requested information within ten (10) days of receipt of the OAG's written notice, the OAG may impose liquidated damages pursuant to this paragraph. The damages period shall commence on the date that ValueOptions receives the OAG's written notice and end on the date that ValueOptions cures the violation or provides the requested information.

VIII. MISCELLANEOUS

Initial Compliance

78. ValueOptions shall submit to the OAG, within forty-five (45) days of its implementation of the prospective relief measures set forth in paragraphs 57 through 72 above, a letter certifying and setting forth, in detail, such implementation.

ValueOptions' Representations

79. The OAG has agreed to the terms of this Assurance based on, among other

things, the representations made to the OAG by ValueOptions and its counsel and the OAG's own factual investigation as set forth in the above Findings. To the extent that any material representations are later found to be inaccurate or misleading, this Assurance is voidable by the OAG in its sole discretion.

Communications

80. All communications, reports, correspondence, and payments that ValueOptions submits to the OAG concerning this Assurance or any related issues is to be sent to the attention of the person identified below:

Michael D. Reisman, Esq.
Assistant Attorney General
Health Care Bureau
Office of the New York Attorney General
120 Broadway
New York, New York 10271
Michael.reisman@ag.ny.gov

81. Receipt by the OAG of materials referenced in this Assurance, with or without comment, shall not be deemed or construed as approval by the OAG of any of the materials, and ValueOptions shall not make any representations to the contrary.

82. All notices, correspondence, and requests to ValueOptions shall be directed as follows:

Daniel M. Risku, Esq.
Executive Vice President & General Counsel
ValueOptions, Inc.
240 Corporate Boulevard
Norfolk, VA 23502
Daniel.risku@valueoptions.com

Valid Grounds and Waiver

83. ValueOptions hereby accepts the terms and conditions of this Assurance and waives any rights to challenge it in a proceeding under Article 78 of the Civil Practice Law and Rules or in any other action or proceeding.

No Deprivation of the Public's Rights

84. Nothing herein shall be construed to deprive any member or other person or entity of any private right under law or equity.

No Blanket Approval by the Attorney General of ValueOptions' Practices

85. Acceptance of this Assurance by the OAG shall not be deemed or construed as approval by the OAG of any of ValueOptions' acts or practices, or those of its agents or assigns, and none of them shall make any representation to the contrary.

Monitoring by the OAG

86. To the extent not already provided under this Assurance, ValueOptions shall, upon request by the OAG, provide all documentation and information necessary for the OAG to verify compliance with this Assurance. ValueOptions may request an extension of particular deadlines under this Assurance, but OAG need not grant any such request. This Assurance does not in any way limit the OAG's right to obtain, by subpoena or by any other means permitted by law, documents, testimony, or other information.

No Limitation on the Attorney General's Authority

87. Nothing in this Assurance in any way limits the OAG's ability to investigate or take other action with respect to any non-compliance at any time by ValueOptions with respect to this Assurance, or ValueOptions' non-compliance with any applicable law with respect to any matters.

No Undercutting of Assurance

88. ValueOptions shall not take any action or make any statement denying, directly or indirectly, the propriety of this Assurance or expressing the view that this Assurance is without factual basis. Nothing in this paragraph affects ValueOptions' (a) testimonial obligations, or (b) right to take legal or factual positions in defense of litigation or other legal proceedings to which the OAG is not a party.

89. It is the parties' intention that none of the provisions in this Assurance may be used as evidence in any in any litigation or other legal proceedings to which the OAG is not a party. None of the legal and factual statements in this Assurance shall operate as an admission by ValueOptions in any litigation or other legal proceeding to which the OAG is not a party and ValueOptions reserves the right to deny, challenge or refute any such legal or factual assertions in any litigation or other legal proceeding to which the OAG is not a party.

Governing Law; Effect of Violation of Assurance of Discontinuance

90. Under Executive Law Section 63(15), evidence of a violation of this Assurance shall constitute prima facie proof of a violation of the applicable law in any

action or proceeding thereafter commenced by the OAG.

91. This Assurance shall be governed by the laws of the State of New York without regard to any conflict of laws principles.

92. If a court of competent jurisdiction determines that ValueOptions has breached this Assurance, ValueOptions shall pay to the OAG the cost, if any, of such determination and of enforcing this Assurance, including, without limitation, legal fees, expenses, and court costs.

No Presumption Against Drafter; Effect of any Invalid Provision

93. None of the parties shall be considered to be the drafter of this Assurance or any provision for the purpose of any statute, case law, or rule of interpretation or construction that would or might cause any provision to be construed against the drafter hereof. This Assurance was drafted with substantial input by all parties and their counsel, and no reliance was placed on any representation other than those contained in this Assurance.

94. In the event that any one or more of the provisions contained in this Assurance shall for any reason be held to be invalid, illegal, or unenforceable in any respect, in the sole discretion of the OAG such invalidity, illegality, or unenforceability shall not affect any other provision of this Assurance.

Entire Agreement; Amendment

95. No representation, inducement, promise, understanding, condition, or warranty not set forth in this Assurance has been made to or relied upon by ValueOptions in agreeing to this Assurance.

96. This Assurance contains an entire, complete, and integrated statement of each and every term and provision agreed to by and among the parties, and the Assurance is not subject to any condition not provided for herein. This Assurance supersedes any prior agreements or understandings, whether written or oral, between and among the OAG and ValueOptions regarding the subject matter of this Assurance.

97. This Assurance may not be amended or modified except in an instrument in writing signed on behalf of all the parties to this Assurance.

98. The division of this Assurance into sections and subsections and the use of captions and headings in connection herewith are solely for convenience and shall have no legal effect in construing the provisions of this Assurance.

Binding Effect

99. This Assurance is binding on and inures to the benefit of the parties to this Assurance and their respective successors and assigns, provided that no party, other than the OAG, may assign, delegate, or otherwise transfer any of its rights or obligations under this Assurance without prior written consent of the OAG. "Successors" includes any entity which acquires the assets of ValueOptions or otherwise assumes some or all of ValueOptions' current or future business administering behavioral health benefits for fully funded or state and local governmental health plans in New York.

Effective Date

100. This Assurance is effective on the date that it is signed by the Attorney General or his authorized representative (the "Effective Date"), and the document may be executed in counterparts, which shall all be deemed an original for all purposes.

AGREED TO BY THE PARTIES:

Dated:

March 4, 2015

ValueOptions, Inc.

By: _____

DANIEL M. RISKU
Executive Vice President & General Counsel
ValueOptions, Inc.

Dated: New York, New York

March 4, 2015

ERIC T. SCHNEIDERMAN
Attorney General of the State of New York

LISA LANDAU
Health Care Bureau Chief

By: _____

MICHAEL D. REISMAN
Assistant Attorney General
Health Care Bureau

Exhibit A

Protocol for Collecting Information for Medical Necessity Determinations

In making medical necessity determinations regarding requests for coverage of behavioral health treatment, ValueOptions will:

1. Attempt to obtain from members and providers all information necessary for determining whether a request for coverage of treatment meets the medical necessity for the particular level of care at issue. Such information will, at a minimum, include: diagnosis; symptoms; treatment goals; and, where appropriate, risks to the member from not continuing treatment.

2. Inform the provider, and member (where practicable), orally and in writing, of the specific information needed for making the medical necessity determination, the time frame to provide the information, and acceptable methods of submission.

3. Offer to make available to the member and provider a copy of ValueOptions' medical necessity criteria for the level of care at issue, as well as any checklist or questionnaire used by ValueOptions in making medical necessity determinations for the level of care at issue.

4. In a case in which ValueOptions determines that it lacks sufficient information to make a medical necessity determination, ValueOptions will make reasonable efforts to obtain such information from the member and/or provider within the applicable statutory time frames for rendering decisions, including at least one attempt in writing and at least one attempt telephonically.

Exhibit B

Content of Parity Disclosures and Parity Compliance Reports

ValueOptions will disclose to members in writing, and will in its Parity Compliance Reports provide evidence of, the following statements:

1. ValueOptions administers broad-based coverage for the diagnosis and treatment of behavioral health conditions, and works with its clients to ensure that such coverage is at least equal to and no more restrictive than the coverage provided for other health conditions. Behavioral health conditions include mental health and substance abuse disorders.

2. On behalf of its clients, ValueOptions administers, subject to medical necessity, benefits for inpatient and outpatient behavioral health care, which are at least equal to and no more restrictive than medical/surgical benefits under the plan, as well as for residential treatment for behavioral health conditions if its client health plans offer a comparable medical/surgical benefit.

3. For outpatient behavioral health visits, ValueOptions recommends that its client health plans apply the member's primary care cost-sharing schedule.

4. The utilization review conducted by ValueOptions for behavioral health benefits is at least equal to, and no more restrictive than, and applied no more stringently than, the utilization review conducted for medical/surgical benefits by the health plans for which ValueOptions administers behavioral health benefits.

5. Any annual or lifetime limits on behavioral health benefits for plans that ValueOptions administers are no stricter than such limits on medical/surgical benefits.

6. For plans it administers, ValueOptions does not apply any cost-sharing requirements that are applicable only to behavioral health benefits, unless there is a unique behavioral health benefit for which there is no comparable medical/surgical benefit, and ValueOptions has provided notice of same to the Office of the Attorney General.

7. ValueOptions does not apply any treatment limitations that are applicable only to behavioral health benefits, except for family counseling services, which may be capped at twenty (20) visits per year, or any other limitation required by law, for which ValueOptions has provided notice to the Office of the Attorney General.

8. The criteria for medical necessity determinations made by ValueOptions regarding behavioral health benefits are made available on a public website, and, upon request, to any current or potential participant, beneficiary, or contracting provider.

9. Where a plan administered by ValueOptions covers medical/surgical benefits provided by out-of-network providers, the plan covers behavioral health benefits provided by out-of-network providers.

10. ValueOptions members are charged a single deductible for all benefits, whether services rendered are for medical/surgical or behavioral health conditions, with the exception that some plans may charge a separate, combined deductible for prescription drugs.

11. MVP and Emblem, for which ValueOptions administers behavioral health benefits, offer members the services of Behavioral Health Advocates, who are trained to assist members in accessing their behavioral health benefits, by supplying them detailed,

accurate, and current information regarding: treatment options in the member's area; utilization review determinations and processes; medical necessity criteria; and appeals.

ATTORNEY GENERAL OF THE STATE OF NEW YORK

In the Matter of

Purdue Pharma L.P.

Assurance No.: 15-151

ASSURANCE OF DISCONTINUANCE UNDER EXECUTIVE LAW SECTION 63, SUBDIVISION 15

Pursuant to the provisions of Section 63(12) of the Executive Law and Article 22-A of the General Business Law, Eric T. Schneiderman, Attorney General of the State of New York, caused an inquiry to be made into certain business practices of Purdue Pharma L.P. ("Purdue," or the "Company"). Based upon that inquiry, the Office of the Attorney General ("the OAG") has made the following findings, and Purdue has agreed to modify its business practices and comply with the following provisions of this Assurance of Discontinuance ("Assurance").

I. BACKGROUND

1. Purdue is a Delaware limited partnership with its principal place of business at 201 Tresser Blvd., Stamford, Connecticut 06901. Purdue is engaged in the manufacture, marketing and sale of prescription and non-prescription pharmaceutical products, in particular the extended-release, long-acting opioid OxyContin® (oxycodone HCl extended-release tablets), which contain the active ingredient oxycodone.[1] The U.S. Food and Drug Administration (the "FDA") approved OxyContin in 1995, and it is currently indicated for the

[1] Purdue markets and sells other prescription opioid products, including Butrans, Dilaudid, MS Contin and Hysingla.

management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

2. OxyContin, a narcotic painkiller, contains "black box" warnings of serious risks from taking the product, such as addiction and respiratory depression, which can lead to death.

3. According to IMS Health, in 2012 Purdue had U.S. sales of OxyContin totaling $2.78 billion, and in 2013, had U.S. sales of $2.56 billion.

4. To market OxyContin, among other things, Purdue employs an extensive network of sales representatives who establish and maintain relationships with health care providers ("HCPs"), which include medical doctors, doctors of osteopathy, nurse practitioners, pharmacists and physicians' assistants. The Purdue sales reps "detail" HCPs' offices, where they provide informational resources on OxyContin and other Purdue opioid products, with the objective of encouraging these providers to prescribe OxyContin and other Purdue opioid products to their patients under appropriate circumstances.

5. In addition to a yearly salary, Purdue's sales representatives may receive a bonus that is based on the number of prescriptions written by HCPs in their territory, which can create an incentive to encourage more prescribing, including of opioids.

6. Between the 1990s and 2011, prescriptions of oxycodone, an active ingredient in opioid analgesics manufactured by many independent companies including Purdue, more than doubled in the U.S., and sales of the product increased more than tenfold.[2] Between 2008 and 2011, OxyContin accounted for approximately 10% of the total oxycodone prescriptions in New York State. During this time period, according to the New York City Department of Health and Mental Hygiene, the number of opioid painkiller prescriptions filled by New York

[2] *See* http://www.drugabuse.gov/news-events/nida-notes/2014/05/although-relatively-few-doctor-shoppers-skew-opioid-prescribing.

City residents increased by 31%, from approximately 1.6 million to approximately 2.2 million, with oxycodone accounting for 53% of those prescriptions.[3]

7. Between 1997 and 2011, there has also been a sharp increase in the prevalence of opioid addiction, which in turn has been associated with a rise in overdose deaths and heroin use.[4] According to the federal Centers for Disease Control and Prevention, in New York State, from 2003 to 2012, deaths involving opioid analgesics increased five-fold, from 179 in 2003 to 883 in 2012.[5]

II. THE OAG'S INVESTIGATIONS AND FINDINGS

8. In 2014, the OAG commenced an investigation of Purdue, focusing on two areas: (i) Purdue's Abuse and Diversion Detection ("ADD") Program (also known as the "Region Zero" program); and (ii) Purdue's unbranded website www.inthefaceofpain.com, which provides information about how to advocate for patients in pain but does not explicitly reference any specific pharmaceutical product.

A. The ADD Program

9. In 2007, Purdue agreed with a number of states (not including New York) to take steps to reduce the abuse and diversion of OxyContin, in particular by implementing the ADD Program. Purdue's ADD Program requires all Purdue sales representatives and medical liaisons who contact HCPs for the purpose of promoting a Purdue opioid product to report to the Company facts that suggest that an HCP potentially may be involved in the abuse or diversion of such products. After an ADD report is filed, Purdue conducts an internal inquiry of the HCP and determines whether to place that provider on a list, such that the HCP may not be contacted for purposes of promoting Purdue opioid products (the "No-Call List"). If Purdue

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3 *See* http://www.nyc.gov/html/doh/html/pr2013/pr013-13.shtml.

4 *See* http://www.annualreviews.org/doi/pdf/10.1146/annurev-publhealth-031914-122957.

5 *See* http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6414a2.htm.

places an HCP on the No-Call List, no bonus may be earned from prescriptions written by that HCP after such determination.

10. The ADD Program is based on Purdue sales representatives making observations during calls on HCPs. Under the ADD Program, if a Purdue sales representative learns of or observes any of the situations described below, which may suggest that an HCP (or his or her patients) may be involved in the abuse and diversion of opioids, the activities or observations must be reported promptly to the Company. These situations include:

a. An apparent pattern of an excessive number of patients for the practice type. For example, on a consistent basis, a long line of patients waiting to get prescriptions, a waiting room filled to capacity or standing room only, or patient contact with a prescriber that is exceedingly brief or non-existent.

b. An atypical pattern of prescribing techniques or locations. For example, repeated prescribing from an automobile or repeated prescribing at atypical times, such as after usual office hours when the health care professional is not on call.

c. Information from a highly credible source or several sources that an HCP or his/her patients are diverting medication.

d. An HCP who has a disproportionate number of patients who pay cash for office visits and dispensed medication.

e. An HCP with a sudden unexplained change in prescribing or dispensing patterns that are not accounted for by changes in patient numbers or the practice type.

f. An allegation that individuals from a particular HCP's practice have overdosed.

g. A credible allegation that an HCP or his/her staff or patients have abused or are actively abusing substances.

h. An HCP's practice where unauthorized individuals are signing prescriptions or dispensing controlled substances.

i. An HCP's practice with large numbers of patients who travel significant distances, for example across state lines, to obtain and/or fill their prescriptions without a rational explanation.

j. An HCP's practice where there are reports that patients make frequent early requests for new prescriptions significantly in advance of the time the initial prescription would normally have been completed.

k. A credible allegation that an HCP is under active investigation related to diversion or substance abuse by any law enforcement or regulatory authority.

l. An HCP who moves his or her practice from one state to another on more than one occasion within a couple of years without rational explanation.

m. An HCP with an atypical patient population from that customarily observed in such an office based on its location and other attendant circumstances. For example, a disproportionate number of younger patients for the nature of the practice.

11. Between January 1, 2008, and March 7, 2015, Purdue placed 103 New York HCPs on its No-Call List. Purdue's sales representatives had detailed approximately two-thirds of those HCPs, some quite extensively, making more than a total of 1,800 sales calls to their offices over a six-year period. Of the 71 HCPs on the No-Call List upon whom Purdue sales representatives called to promote OxyContin, 64 wrote OxyContin prescriptions. Of the 32 HCPs on the No-Call List never called on by a Purdue sales representative to promote OxyContin, 15 wrote more than 10 OxyContin prescriptions. Purdue spent approximately three thousand dollars in meal expenses for 38 of the 103 HCPs on the No-Call List upon whom its sales representatives called.

12. Some of the HCPs in New York State whom Purdue detailed, and subsequently placed on its No-Call List, were subsequently arrested and/or convicted for illegal prescribing of opioids, including:

- Matthew Bennett, a Buffalo-area physician whom Purdue detailed 46 times between 2009 and 2012, was arrested in August 2012, and pleaded guilty in April 2015 to illegal distribution of oxycodone. Bennett wrote 868 OxyContin prescriptions during the period in which he was detailed by Purdue.

- David Brizer, a Rockland psychiatrist whom Purdue detailed 8 times in 2010 and 2011, was arrested by the OAG in February 2013, and pleaded guilty in March 2013 to illegally selling opioid prescriptions. Brizer wrote 563 prescriptions for OxyContin during the period in which he was detailed by Purdue.

- Richard Cedeno, a Bronx physician's assistant whom Purdue detailed 54 times between 2009 and 2013, was arrested by the OAG in June 2013, and pleaded

guilty in June 2015 to participating in a Medicaid fraud scheme. Cedeno wrote 400 OxyContin prescriptions during the period in which he was detailed by Purdue.

- Rools Deslouches, a Long Island physician's assistant whom Purdue detailed 18 times in 2011, was arrested in June 2012, and pleaded guilty in November 2014 to illegally distributing oxycodone. Deslouches wrote 210 OxyContin prescriptions during the period in which he was detailed by Purdue.

- Eric Jacobson, a Queens physician whom Purdue detailed 18 times in 2010, was arrested in June 2012, and pleaded guilty in 2014 to conspiracy to distribute oxycodone. Jacobson wrote 1,014 OxyContin prescriptions during the period in which he was detailed by Purdue.

- Leonard Marchetta, a Staten Island physician's assistant whom Purdue detailed 27 times between 2008 and 2011, was arrested in September 2014, and pleaded guilty in January 2015 to conspiracy to distribute narcotics. Marchetta wrote 532 OxyContin prescriptions during the period in which he was detailed by Purdue.

- Anand Persaud, a Long Island physician whom Purdue detailed 98 times from 2009 through 2013, and was arrested by the OAG in July 2013 for illegally selling oxycodone prescriptions. Persaud wrote 1,575 prescriptions for OxyContin during the period in which he was detailed by Purdue.

- Frank Telang, a Long Island physician whom Purdue detailed 31 times between 2008 and 2011, was arrested in December 2011, and pleaded guilty in November 2013 to illegally prescribing oxycodone. Telang wrote 701 OxyContin prescriptions during the period in which he was detailed by Purdue.

- Rohan Wijetilaka, a Westchester cardiologist whom Purdue detailed 78 times between 2008 through 2012, was arrested in July 2012, and pleaded guilty in June 2014 to health care fraud. Wijetilaka wrote 3,056 OxyContin prescriptions during the period in which he was detailed by Purdue.

13. While the above charges did not involve OxyContin, and the OAG did not charge that promotion by Purdue played a role in the cases it prosecuted, in certain limited circumstances, Purdue sales representatives may have been aware of red flags regarding some of these prescribers before filing an ADD report as required by the policy, at which point the sales representative should have stopped detailing the HCP sooner. In addition, in three instances, Purdue sales representatives detailed HCPs after HCPs were placed on the No-Call

List. This is due, in part, to the fact that Purdue sales representatives are not currently required to check a No-Call List before contacting a particular HCP.

14. Purdue sales representatives filed ADD reports for 89 of the 103 HCPs on the No- Call List. Of the 14 HCPs for whom an ADD report was not filed and therefore came to Purdue's attention other than through a sales representative, only 5 had been called on within the 6 months prior to the HCP being placed on the No-Call List.

15. Although the ADD Program can be an effective tool in identifying potential abuse and illegal diversion of opioids, these findings demonstrate opportunities for improvement in Purdue's implementation of the program.

B. Purdue's Lack of Disclosure on www.inthefaceofpain.com

16. Purdue maintains an unbranded pain management advocacy website, www.inthefaceofpain.com. From March 2014 to March 2015, the website received a total of 251,648 page views. Much of the video content on www.inthefaceofpain.com is also available on YouTube. A document linked to the site briefly mentions opioid abuse, but the site itself does not.

17. Written and video testimonials from several dozen "Advocates," whose faces appear on the website and many of whom are HCPs, comprise a central component of the site. For example, Dr. Russell Portenoy, the recipient of almost $4,000 from Purdue for meeting and travel costs, was quoted on the website as follows: "The negative impact of unrelieved pain on the lives of individuals and their families, on the healthcare system, and on society at large is no longer a matter of debate. The unmet needs of millions of patients combine into a major public health concern. Although there have been substantive improvements during the past several decades, the problem remains profound and change will require enormous efforts at

many levels. Pressure from patients and the larger public is a key element in creating momentum for change."

18. Although Purdue created the content on www.inthefaceofpain.com, as indicated by the Purdue copyright at the bottom of each page, the site creates the impression that it is neutral and unbiased. However, prior to this investigation, the website failed to disclose that from 2008 to 2013, Purdue made payments totaling almost $231,000, for speaker programs, advisory meetings and travel costs, to 11 of the Advocates whose testimonials appeared on the site. The videos on YouTube also fail to disclose Purdue's payments to the Advocates.[6]

19. Purdue's failure to disclose its financial connections with certain Advocates has the potential to mislead consumers by failing to disclose the potential bias of these individuals.

C. Limitations in HCPs' Knowledge of Appropriate Prescribing Practices

20. Prescriber education has the potential to increase awareness of risks associated with opioids in general and OxyContin in particular. As part of the FDA's mandated Risk Evaluation and Mitigation Strategy ("REMS") in 2010, Purdue conducted a survey of HCPs selected randomly from those that prescribed OxyContin but not all of whom Purdue detailed, That survey indicated deficiencies in certain HCPs' knowledge of appropriate opioid prescribing practices. For example, the survey showed that more than 40% of OxyContin prescribers did not know that individuals who are considered at increased risk of OxyContin abuse include individuals with a personal or family history of mental illness such as major depression, and that more than 30% of prescribers did not know that monitoring for misuse, abuse and addiction may include urine drug testing.[7] Another survey showed that approximately 78% of HCPs who responded knew that individuals with a family history of

[6] In April 2015, a year after the OAG launched its investigation, Purdue removed the profiles of Advocates with whom it has financial relationships from www.inthefaceofpain.com.

[7] *See* http://www.cpdd.org/pages/Meetings/CPDD11AbstractBook.pdf.

mental illness are at increased risk of opioid abuse. Subsequent to that time, each of the prescribers surveyed was sent prescriber education materials pursuant to the OxyContin REMS and the Classwide Extended Release/Long Acting Industry REMS, which has been in place since 2012.

D. Opioid Patients' Need for Information Regarding Addiction Treatment

21. Patients undergoing opioid therapy benefit from information about the risks of addiction and some may need information about addiction treatment resources. One study indicated that opioid use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder.[8] A second study published in 2015, based on computer-assisted review of electronic health records, concluded that 13.5% of patients receiving chronic opioid therapy had either problem opioid use or a diagnosis for opioid abuse or dependence.[9] Although there is presently no consensus regarding the incidence or prevalence of abuse or addiction to opioids among patients treated with chronic opioid therapy, efforts to reduce opioid abuse and overdose deaths should address not only those who abuse opioids such as OxyContin without a prescription, but also those who take the medication as prescribed, yet begin to abuse opioids or become addicted to them.

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8 *See* Joseph A. Boscarino et al., *Risk Factors For Drug Dependence Among Out-Patients On Opioid Therapy In A Large US Health-Care System*, 105 Addiction 1776 (2010); Joseph A. Boscarino et al., *Prevalence of prescription opioid-use disorder among chronic pain patients: comparison of the DSM-5 versus DSM-4 diagnostic criteria*, 30 J. Addictive Diseases 185 (2011).

9 *See* Roy E. Palmer et al., *The Prevalence Of Problem Opioid Use In Patients Receiving Chronic Opioid Therapy: Computer Assisted Review Of Electronic Health Record Clinical Notes*, 156 Pain 1208 (2015).

III. RELEVANT LAW

22. The New York General Business Law prohibits "deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service" in New York State. N.Y. Gen. Bus. Law § 349.

23. The New York General Business Law also prohibits "false advertising in the conduct of any business," or advertising that is misleading in a material respect. Whether an advertisement is materially misleading depends on "the extent to which the advertising fails to reveal facts material in the light of such representations with respect to the commodity to which the advertising relates under the conditions prescribed in said advertisement." N.Y. Gen. Bus. Law § 350.

24. The New York Executive Law prohibits "illegal or fraudulent acts" in the conduct of any business, trade or commerce, and allows the OAG to institute a special proceeding for restitution, damages, and/or injunctive relief against any party which has committed such acts. N.Y. Exec. Law § 63(12).

25. The OAG concludes that Purdue's website www.inthefaceofpain.com (and related content posted by Purdue on YouTube) violates the above-referenced provisions because it fails to disclose Purdue's financial relationships with "advocates," creating a false impression of neutrality.

26. The OAG concludes that Purdue's detailing of certain problematic HCPs, even after Purdue had reason to know through its sales representatives that some of these HCPs may have been engaging in improper prescribing practices violates the above-referenced provisions.

NOW, WHEREAS, Purdue neither admits nor denies the Attorney General's findings in paragraphs 9 through 21 above; and

WHEREAS, New York laws prohibiting deceptive business practices and false and misleading advertising confer important consumer and public health protections; and

WHEREAS, Purdue has cooperated with the OAG's investigation; and

WHEREAS, the Attorney General is willing to accept the terms of this Assurance under Executive Law Section 63(15) and to discontinue his investigation; and

WHEREAS, the parties each believe that the obligations imposed by this Assurance are prudent and appropriate; and

WHEREAS, the Attorney General has determined that this Assurance is in the public interest.

IT IS HEREBY UNDERSTOOD AND AGREED, by and between the parties that:

IV. PROSPECTIVE RELIEF

A. Maintenance of ADD Program

28. Purdue shall continue to maintain its ADD Program consisting of internal procedures designed to ensure that Purdue's interactions with HCPs that reveal observations or circumstances that suggest potential concerns about abuse, diversion, or inappropriate prescribing of opioid medications generate appropriate review and follow-up. Within ninety (90) business days after the Effective Date of this Assurance, Purdue shall implement the modifications set forth below. The ADD Program shall remain in place for as long as Purdue promotes OxyContin to HCPs through sales representatives.

29. The ADD Program applies to Purdue sales representatives and medical liaisons who contact HCPs for the purpose of promoting Purdue opioid products ("ADD Covered Persons"). The Program requires those persons to file a written report (an "ADD Report") with Purdue's Law Department when they observe or learn of the situations described in Paragraph 10 above, which may suggest that an HCP may be involved in the abuse or diversion of

opioids. In addition to those already outlined in the policy, the following situations shall also trigger a report under the ADD Program:

a. That an HCP lacks understanding about the risks associated with prescribing opioids. For example, an HCP who states that he or she does not have basic information about the risks of addiction associated with opioid therapy.

b. Facts that suggest that the HCP's patients are seeking opioids for misuse and abuse, including but not limited to facts that suggest that an HCP has failed to comply with New York's Internet System for Tracking Over-Prescribing/Prescription Monitoring Program (I-STOP/PMP).

30. Purdue shall continue to implement in New York the following elements of the ADD Program as long as it promotes OxyContin to HCPs through sales representatives:

a. Upon identification of potential abuse, diversion, or inappropriate prescribing of opioids involving an HCP with whom ADD Covered Persons interact, Purdue shall conduct an internal inquiry which shall include but not be limited to a review of the HCP's prescribing history and relevant facts about the HCP's practice, and shall take such further steps as may be appropriate based on the facts and circumstances, which shall include ceasing to promote Purdue opioid products to the particular HCP or providing further education to the HCP about appropriate use of opioids.

b. Purdue shall immediately cease promoting Purdue opioid products to an HCP when an ADD Report is filed about that HCP, and shall resume promoting Purdue opioid products to the HCP only after Purdue's Law Department reasonably concludes, based on available information, that it is appropriate to resume sales calls on that HCP.

c. Purdue shall implement and maintain a training and education program with respect to the ADD Program. That training shall cover the details of the revised Program, and Purdue shall require all ADD Covered Persons to complete the training and education program no later than ninety (90) business days after the Effective Date of this Assurance, and to complete the training each year.

d. No sales incentive (bonus) program for sales of Purdue opioid products shall allow incentive credit to be earned for prescriptions by an HCP once that HCP has been placed on the No-Call List.

31. Additionally, Purdue will adopt the following measures as part of the ADD Program:

a. Each week, all ADD Covered Persons shall check whether HCPs they plan to call upon that week are on Purdue's No-Call List. If an ADD Covered Person promotes a Purdue opioid product on a planned call to an HCP on the No-Call List, that individual shall be subject to review for potential disciplinary action, including but not limited to censure, probation and termination.

b. Purdue may resume promoting Purdue opioid products to an HCP about whom an ADD Report has been filed only after its Law Department ***in writing*** reasonably concludes, based on available information, that it is appropriate to resume sales calls on that HCP.

c. On a monthly basis, Purdue shall provide to the OAG the names of any HCPs in New York whom it has placed on the No-Call List, assuming a new HCP has been added.

d. Purdue shall maintain other measures to identify the potential abuse, diversion, or inappropriate prescribing of opioids, including but not limited to: (i)

reviewing news media stories addressing the potential abuse, diversion, or inappropriate prescribing of opioids and/or the governmental investigation and/or arrest of HCPs to whom Purdue has promoted opioids; and (ii) examining data sources, such as HCPs' prescription history, to identify HCPs who should reviewed for potential placement on the No-Call List.

e. Purdue's performance evaluations of persons involved in marketing or promoting Purdue opioid products shall meaningfully take into account that sales persons inform HCPs to whom the sales persons promote opioids about its potential for abuse and diversion, and how to minimize those risks.

f. If an ADD Covered Person fails to file an ADD Report regarding an HCP, and Purdue determines that person knew or should have known that HCP was engaged in conduct covered by the Policy, that person shall be subject to disciplinary action by Purdue, including but not limited to censure, probation and termination.

32. For a minimum of three years, ADD Covered Persons in New York shall enter detailed call notes regarding sales calls to HCPs in which compliance or potential abuse issues are raised, and the Purdue Corporate Compliance department shall, on a quarterly basis, audit and review a sample of such call notes to, *inter alia*, evaluate compliance with the ADD Program and determine whether ADD Reports need to be filed regarding particular HCPs.

33. Purdue shall not employ a compensation structure for persons involved in marketing or promoting Purdue opioid products, in which more than 30% of the individual's total compensation (including bonus) is based on the volume of OxyContin prescriptions.

B. Disclosures Regarding Unbranded Websites

34. If the name, image, audio or video recording of, or a quotation from, a person appears on any unbranded, publicly available web page or social media account controlled or maintained by Purdue, such as the "Voices of Hope" sub-page on www.inthefaceofpain.com, and such name, image, audio or video recording of, or quotation from, the person is accompanied on the web page or social media account by a discussion of the treatment of pain, Purdue shall disclose the existence of individual payments of $10 or more by Purdue to such person, and aggregate payments by Purdue to such person exceeding $100 in a calendar year, as follows:

a. The disclosure shall be designated on the relevant web page with an asterisk accompanying the name of the person. The amount of the aggregate payment to the person for each of the prior three calendar years will be available via one click from the relevant web page. If a person has not been paid by Purdue in the prior three calendar years, the asterisk and aggregate payment amounts previously posted will be removed.

b. If the person is an HCP, the aggregate payment amount will be based on payments in prior calendar years as published in the CMS Open Payments Enterprise Portal or the equivalent for non-physician HCPs. If the person is not an HCP, the aggregate payment amount will be based on payments by Purdue in prior calendar years.

c. Aggregate payment amounts as set forth in this Paragraph will be updated on the relevant web page no later than July 15th of the relevant year.

d. Should any person identified in Paragraph 34 receive a payment from Purdue, for the first time, after the period for reporting described in paragraphs 34 (b)

and (c), Purdue will, within 30 days, include an asterisk denoting that such individual has received a payment. The aggregate payment amount to that individual will be available via one click from the relevant web page no later than July 15th of the following calendar year.

e. Within 90 days after the Effective Date, Purdue will update the relevant web pages with the disclosures set forth in this Paragraph. Prior to executing these updates, Purdue will provide to the OAG a sample of the relevant web pages for review and comment.

f. This Paragraph will remain in effect for as long as the CMS Open Payments provision is in effect. If Purdue determines that its obligations under this Paragraph should no longer be in effect because the CMS Open Payments provision is no longer in effect, it will provide written notice to the OAG regarding its basis for such determination and will comply with this Paragraph for thirty (30) days after providing written notice.

35. On publicly available websites and social media accounts it controls and maintains in which medication to treat pain is referenced, Purdue shall provide, on the site itself, information regarding the risks of opioids, including the risk of addiction, including the information set forth in Paragraph 20 above.

C. <u>Prescriber Training</u>

36. Persons involved in marketing or promoting Purdue opioid products to HCPs shall, at the first visit each year to each New York HCP after the Effective Date, ask the HCP whether he or she completed a training program regarding the appropriate prescribing of opioids, the content of which is compliant with the FDA's REMS for Extended Release/Long-Acting Opioids. If such New York HCP indicates that he or she has not completed such

training, then the sales representative shall provide information about training, in the form of the document set forth as Exhibit A.

D. Treatment Resources

37. Purdue shall make available and provide, upon request, information regarding addiction treatment resources to HCPs to whom it markets or promotes Purdue opioid products. These materials shall be provided to Purdue by the OAG.

V. PENALTIES, FEES AND/OR COSTS

38. Within 30 days of the Effective Date, Purdue shall pay $75,000 by check to the "State of New York Department of Law."

VI. LIQUIDATED DAMAGES

39. If Purdue violates any material provision of this Assurance, the OAG may elect to demand that Purdue pay liquidated damages of $1,000 per episode of non-compliance. Before liquidated damages may be imposed, the OAG shall give Purdue written notice that Purdue may be subject to liquidated damages under this Paragraph. In the event that Purdue does not cure the violation or provide the requested information within thirty (30) days of receipt of the OAG's written notice, the OAG may impose liquidated damages pursuant to this Paragraph. The damages period shall commence on the date after the period to cure has lapsed.

VII. COMPLIANCE

40. Initial Compliance: Within ninety (90) days of the Effective Date, Purdue shall submit a letter, along with supporting documentation, certifying its compliance with Paragraphs 28 through 38 of this Assurance. Purdue shall then, on an annual basis for three years, certify its continuing compliance with the provisions of this Assurance.

41. Auditor: to evaluate the ADD Program, Purdue shall appoint an auditor (the "Auditor"), an independent individual or entity selected by Purdue and paid for and contracted by Purdue as follows:

a. Within 30 days of the Effective Date, Purdue shall select the Auditor, subject to OAG approval.

b. Each year, for three years, Purdue shall provide the Auditor with information about its implementation of the ADD Program along with ADD Reports filed during that year and the Company's determination regarding each report. The Auditor shall evaluate Purdue's compliance with Section IV.A. above and the reasonableness of Purdue's decisions regarding whether to continue marketing or promoting opioid products to the HCP at issue in each ADD Report.

c. The Auditor shall present its findings in a written report (the "Auditor's Report") to the OAG and Purdue. The first Auditor's Report shall be due one (1) year after the Effective Date.

VIII. GENERAL PROVISIONS

42. Purdue's Representations: The OAG has agreed to the terms of this Assurance based on, among other things, the representations made to the OAG by Purdue and its counsel and the OAG's own factual investigation as set forth in the above Findings. To the extent that any material representations are later found to be inaccurate or misleading, this Assurance is voidable by the OAG in its sole discretion.

43. Communications: All communications, reports, correspondence, and payments that Purdue submits to the OAG concerning this Assurance or any related issues is to be sent to the attention of the person identified below:

Michael Reisman, Esq.
Assistant Attorney General Health Care Bureau
Office of the New York State Attorney General
120 Broadway
New York, New York 10271

44. Receipt by the OAG of materials referenced in this Assurance, with or without comment, shall not be deemed or construed as approval by the OAG of any of the materials, and Purdue shall not make any representations to the contrary.

45. All notices, correspondence, and requests to Purdue shall be directed as follows:

Robin E. Abrams
Vice President, Associate General Counsel
Purdue Pharma L.P.
201 Tresser Blvd.
Stamford, Connecticut 06901

46. Valid Grounds and Waiver: Purdue hereby accepts the terms and conditions of this Assurance and waives any rights to challenge it in a proceeding under Article 78 of the Civil Practice Law and Rules or in any other action or proceeding.

47. No Deprivation of the Public's Rights: Nothing herein shall be construed to deprive any member or other person or entity of any private right under law or equity.

48. No Blanket Approval by the Attorney General of Purdue's Practices: Acceptance of this Assurance by the OAG shall not be deemed or construed as approval by the OAG of any of Purdue's acts or practices, or those of its agents or assigns, and none of them shall make any representation to the contrary.

49. Monitoring by the OAG: To the extent not already provided under this Assurance, Purdue shall, upon request by the OAG, provide all documentation and information necessary for the OAG to verify compliance with this Assurance. Purdue may request an extension of particular deadlines under this Assurance, but OAG need not grant any such

request. This Assurance does not in any way limit the OAG's right to obtain, by subpoena or by any other means permitted by law, documents, testimony, or other information.

50. No Limitation on the Attorney General's Authority: Nothing in this Assurance in any way limits the OAG's ability to investigate or take other action with respect to any non-compliance at any time by Purdue with respect to this Assurance, or Purdue's noncompliance with any applicable law with respect to any matters.

51. No Undercutting of Assurance: Purdue shall not take any action or make any statement denying, directly or indirectly, the propriety of this Assurance or expressing the view that this Assurance is without factual basis. Nothing in this paragraph affects Purdue's testimonial obligations, or right to take legal or factual positions in defense of litigation or other legal proceedings to which the OAG is not a party. This Assurance is not intended for use by any third party in any other proceeding and is not intended, and should not be construed, as an admission by Purdue of any liability or finding set forth herein.

53. This Assurance shall apply only in and be governed by the laws of the State of New York without regard to any conflict of laws principles.

54. If a court of competent jurisdiction determines that Purdue has breached this Assurance, Purdue shall pay to the OAG the cost, if any, of such determination and of enforcing this Assurance, including, without limitation, legal fees, expenses, and court costs.

55. None of the parties shall be considered to be the drafter of this Assurance or any provision for the purpose of any statute, case law, or rule of interpretation or construction that would or might cause any provision to be construed against the drafter hereof. This Assurance was drafted with substantial input by all parties and their counsel, and no reliance was placed on any representation other than those contained in this Assurance.

56. In the event that any one or more of the provisions contained in this Assurance shall for any reason be held to be invalid, illegal, or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provision of this Assurance.

57. No representation, inducement, promise, understanding, condition, or warranty not set forth in this Assurance has been made to or relied upon by Purdue in agreeing to this Assurance.

58. This Assurance contains an entire, complete, and integrated statement of each and every term and provision agreed to by and among the parties, and the Assurance is not subject to any condition not provided for herein. This Assurance supersedes any prior agreements or understandings, whether written or oral, between and among the OAG and Purdue regarding the subject matter of this Assurance.

59. This Assurance may not be amended or modified except in an instrument in writing signed on behalf of all the parties to this Assurance.

60. The division of this Assurance into sections and subsections and the use of captions and headings in connection herewith are solely for convenience and shall have no legal effect in construing the provisions of this Assurance.

61. Binding Effect: This Assurance is binding on and inures to the benefit of the parties to this Assurance and their respective successors and assigns, provided that no party, other than the OAG, may assign, delegate, or otherwise transfer any of its rights or obligations under this Assurance without prior written consent of the OAG.

62. Effective Date**:** This Assurance is effective on the date that it is signed by the Attorney General or his authorized representative (the "Effective Date"), and the document may be executed in counterparts, which shall all be deemed an original for all purposes.

AGREED TO BY THE PARTIES:

Dated: Stamford, CT
Aug. 17th, 2015

Purdue Pharma L.P.

By: Robin E Abrams
Robin E. Abrams
Vice President, Associate General Counsel

Dated: New York, New York
August 19, 2015

ERIC T. SCHNEIDERMAN
Attorney General of the State of New York

LISA LANDAU
Health Care Bureau Chief

By: Michael Reisman
MICHAEL D. REISMAN
Assistant Attorney General
Health Care Bureau

EXHIBIT A

ER/LA Opioid Analgesics REMS

The Extended-Release and Long-Acting (ER/LA) Opioid Analgesics Risk Evaluation and Mitigation Strategy (REMS)

REMS-Compliant Prescriber Training

In 2007, Congress granted the FDA the authority to require manufacturers of medicinal products to implement a Risk Evaluation and Mitigation Strategy (REMS) if the FDA determines a REMS is necessary to ensure that a drug's benefits outweigh its risks. A REMS is a safety strategy required by the FDA from manufacturers to manage a known or potential serious risk associated with a medication and to enable patients to have continued access to such medications by managing their safe use.

FDA has required a shared REMS for all extended-release (ER) and long-acting (LA) opioid medications called the "ER/LA Opioid Analgesics REMS".

If you prescribe ER/LA opioid analgesics, FDA strongly encourages you to complete a REMS-compliant continuing education (CE) program that provides updated training on the risks and safe use of ER/LA opioids. Numerous CE activities that meet REMS standards (also known as "REMS-compliant CE") are currently available in both live and online formats. These activities are offered by accredited providers of CE at nominal or no cost to you. A listing of the ER/LA Opioid Analgesics REMS-compliant CE activities supported by the REMS Program Companies (RPC), a consortium of ER/LA opioid companies, can be found at: **https://search.er-la-opioidrems.com/**.

Providers of REMS-compliant CE adhere strictly to the accreditation standards of the Accreditation Council for Continuing Medical Education® (ACCME) or other CE accrediting bodies.

The REMS also includes a one-page document that prescribers can use to counsel patients on the risks and safe use of ER/LA opioid analgesics. This patient counseling document can be accessed at:
http://www.er-la-opioidrems.com/IwgUI/rems/pcd.action

Additional information/resources may be found at **http://www.er-la-opioidrems.com**.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ALLERGAN, INC.,	§	
	§	
Plaintiff,	§	
	§	
v.	§	Case No. 2:15-cv-1455-WCB
	§	
TEVA PHARMACEUTICALS USA, INC., et al.,	§	
	§	
	§	
Defendants.	§	

MEMORANDUM OPINION AND ORDER

Before the Court is Plaintiff's Opposed Motion to Join Party Pursuant to Federal Rule of Civil Procedure 25(c). Dkt. No. 517. The Court GRANTS the motion.

BACKGROUND

On September 8, 2017, following the trial of this case, plaintiff Allergan, Inc., filed a letter with the Court announcing that Allergan had assigned its rights to the patents at issue in this case, to the Saint Regis Mohawk Tribe and that the Tribe had granted Allergan an exclusive license to the patents. Allergan added that it "expects to join the Tribe as a co-plaintiff in due course." Dkt. No. 480-1. Under the terms of the agreements between Allergan and the Tribe, the Tribe will receive $13.5 million upon execution of the agreement and will be eligible to receive $15 million in annual royalties. Dkt. No. 510-3.

On September 11, defendants Mylan Pharmaceuticals Inc. and Mylan Inc. filed a response stating that Allergan "has admitted in other forums that the intent is to employ Native American sovereign immunity and attempt to cut-off pending validity challenges with the Patent Office."

Dkt. No. 481, at 1. Mylan argued that "Allergan is attempting to misuse Native American sovereignty to shield invalid patents from cancellation." Id. at 2.

The Saint Regis Mohawk Tribe has made a special appearance in the inter partes review ("IPR") proceedings pending before the Patent and Trademark Office ("PTO"), and has moved to dismiss those proceedings based on the assertion of the Tribe's sovereign immunity. Dkt. No. 510-7.

After waiting a month for Allergan to file the promised motion to join the Tribe, the Court on October 6 entered an order directing Allergan, by October 13, to submit information regarding the assignment to the Tribe and directing the parties by the same date to file briefs addressing the question whether the Tribe should be added as a co-plaintiff or whether the assignment transaction should be disregarded as a sham. Dkt. No. 503.

Later that day, the defendants filed what they styled Defendants' Notice Regarding Allergan's Document Production According to the Court's October 6, 2017 Order (Dkt. No. 503). Dkt. No. 504. In that filing, the defendants sought to ensure that they would receive copies of the materials submitted by Allergan. In addition, the defendants listed nine categories of documents that they believed Allergan should produce in response to the Court's October 6 order and stated that, "in the event evaluation of Allergan's production reveals the necessity," they would be requesting leave to conduct depositions directed to the nature of Allergan's transaction with the Tribe. Id. at 2. The defendants also requested "leave to file a letter seeking relief from the October 13 filing and allowing Defendants to conduct such depositions on an expedited basis." Id.

On October 9, Allergan filed Plaintiff's Response to Defendants' Notice Regarding Document Production According to the Court's October 6, 2017 Order. Dkt. No. 505. Allergan stated that it had sought the defendants' consent to a motion to add the Tribe as a co-plaintiff

pursuant to Federal Rule of Civil Procedure 25(c), but that the defendants had not consented to such a motion. Dkt. No. 505, at 2. Allergan represented that it would produce "all the materials identified in the Court's October 6 order by October 10, and produce to the Court contemporaneously with this filing the assignment and license documents already provided to Defendants." Id. at 2-3. Allergan also represented that it would file an opposed motion to add the Tribe as a co-plaintiff by October 13. Id.

The following day, the Court entered an order that (1) directed Allergan to provide to the defendants all of the materials provided to the Court in response to the Court's October 6 order; (2) directed Allergan to tell the Court what consideration was given to Allergan in exchange for the purported assignment of the patents-in-suit to the Tribe; (3) denied the defendants' requests for the production of additional materials from Allergan and for the opportunity to conduct depositions regarding the issue of whether the Tribe should be added as a co-plaintiff; and (4) denied the defendants' request to submit a letter seeking relief from the October 13 date for filing briefs addressing the question whether the Tribe should be added as a co-plaintiff. Dkt. No. 509.

Allergan subsequently provided additional materials related to the assignment and license transactions between Allergan and the Tribe. Dkt. Nos. 510, 511. Allergan also answered the Court's question about consideration by stating that the consideration for the assignment of the patents to the Tribe was the Tribe's promise not to waive its sovereign immunity with respect to any IPR or other administrative action in the PTO related to the patents. Dkt. No. 510, at 2-4.

The parties' briefs were timely filed on October 13. Dkt. Nos. 513, 514. In addition, Allergan moved to substitute the Tribe as the plaintiff in this action pursuant to Federal Rule of Civil Procedure 25(c), which the defendants opposed. Dkt. No. 517. Allergan represented that the

Tribe consents to being joined as a plaintiff in this action. Dkt. No. 513, at 6 n.1. The Court advised the parties that the issue would be resolved without a hearing. Dkt. No. 519.

DISCUSSION

The Court has reviewed the information and briefs filed in response to the Court's order. From that information, it is clear that Allergan's motivation for the assignment was to attempt to avoid the IPR proceedings that are currently pending in the PTO by invoking the Tribe's sovereign immunity as a bar to those proceedings.

The Court has serious concerns about the legitimacy of the tactic that Allergan and the Tribe have employed. The essence of the matter is this: Allergan purports to have sold the patents to the Tribe, but in reality it has paid the Tribe to allow Allergan to purchase—or perhaps more precisely, to rent—the Tribe's sovereign immunity in order to defeat the pending IPR proceedings in the PTO. This is not a situation in which the patentee was entitled to sovereign immunity in the first instance. Rather, Allergan, which does not enjoy sovereign immunity, has invoked the benefits of the patent system and has obtained valuable patent protection for its product, Restasis. But when faced with the possibility that the PTO would determine that those patents should not have been issued, Allergan has sought to prevent the PTO from reconsidering its original issuance decision. What Allergan seeks is the right to continue to enjoy the considerable benefits of the U.S. patent system without accepting the limits that Congress has placed on those benefits through the administrative mechanism for canceling invalid patents.

If that ploy succeeds, any patentee facing IPR proceedings would presumably be able to defeat those proceedings by employing the same artifice. In short, Allergan's tactic, if successful, could spell the end of the PTO's IPR program, which was a central component of the America Invents Act of 2011. In its brief, Allergan is conspicuously silent about the broader consequences

of the course it has chosen, but it does not suggest that there is anything unusual about its situation that would make Allergan's tactic "a restricted railroad ticket, good for this day and train only." Smith v. Allwright, 321 U.S. 649, 669 (1944) (Roberts, J., dissenting).

Although sovereign immunity has been tempered over the years by statute and court decisions, it survives because there are sound reasons that sovereigns should be protected from at least some kinds of lawsuits. But sovereign immunity should not be treated as a monetizable commodity that can be purchased by private entities as part of a scheme to evade their legal responsibilities. It is not an inexhaustible asset that can be sold to any party that might find it convenient to purchase immunity from suit. Because that is in essence is what the agreement between Allergan and the Tribe does, the Court has serious reservations about whether the contract between Allergan and the Tribe should be recognized as valid, rather than being held void as being contrary to public policy. See generally Restatement of the Law (Second) Contracts §§ 178-179, 186.

The defendants point out that the assignment-and-licensing transaction in this case is similar in some respects to other transactions that have been held ineffective, such as abusive tax shelter transactions, in which courts have looked behind the face of the transactions to determine whether the transactions have economic substance or are simply a method of gaming the tax system to generate benefits that were not intended to be available. See, e.g., Salem Fin., Inc. v. United States, 786 F.3d 932 (Fed. Cir. 2015); Coltec Indus., Inc. v. United States, 454 F.3d 1340 (Fed. Cir. 2006).

Allergan argues that the transactions are legitimate because the Tribe has offered consideration in the form of its agreement not to waive its sovereign immunity before the PTO and in exchange has received much-needed revenue from Allergan. But such circumstances are

frequently encountered in sham transactions, such as abusive tax shelters. The straw parties who perform the service of making the transaction appear to have economic substance, when it actually does not, are providing a service, for which they are ordinarily well compensated. Nonetheless, the transaction is disregarded if it is contrary to the policies underlying the relevant laws.

Another roughly analogous example cited by the defendants is People ex rel. Owen v. Miami Nation Enterprises, 386 P.3d 357 (Cal. 2016). In that case, two tribal entities ran payday loan businesses. When the lending entities were sued by the State for improper lending practices, the entities asserted sovereign immunity. The California Supreme Court determined that, despite the formal agreements between the lending entities and the tribes, the tribes had no operational control over the businesses and received only a small percentage of the profits of the businesses. After examining all of the circumstances, the court concluded that the arrangement between the lenders and the Tribes was such that the businesses were not entitled to assert the tribes' sovereign immunity.

The concern of the courts in both of those examples is the same: whether the party invoking a particular legal protection has engaged in a bona fide transaction of the sort for which that legal protection was intended. In both the abusive tax shelter cases and the Owen case, the answer was no. In this case, as indicated, the Court has serious doubts that the transaction in which Allergan has sought to obtain immunity from inter partes review by the PTO in exchange for payments to the Tribe is the kind of transaction to which the Tribe's sovereign immunity was meant to extend.

There is a second significant issue presented by Allergan's motion: whether after the Tribe's grant of an exclusive license in the Restasis patents to Allergan, the Tribe has transferred all substantial rights in the patents back to Allergan, so that Allergan, and not the Tribe, is properly

considered the patentee. See, e.g., Diamond Coating Techs., LLC v. Hyundai Motor Am., 823 F.3d 615, 618 (Fed. Cir. 2016). Even assuming that the initial assignment was valid, the Tribe would not be considered the owner of the patents if, through the exclusive license agreement, it has transferred all substantial rights in the patents except for the right to receive royalties on the sale of Restasis. In that event, Allergan would be entitled to maintain this action on its own, and it would not be necessary to add the Tribe as a co-plaintiff. On the other hand, if the Tribe has retained substantial rights in the patents, even after the grant of the exclusive license to Allergan, the Tribe would be a necessary party to this infringement action.

Allergan argues that the Tribe retained substantial rights, including the right to practice the patents for research, education, and other non-commercial uses, and the first right to sue third parties not related to Restasis bioequivalents. Dkt Nos. 518, at 2; Dkt. No. 510-7, at 17-18. The Court has examined the documents provided by Allergan and regards the question as a close one. Some provisions of the exclusive license, such as the limitations on Allergan's rights to as particular field of use—specifically, to practice the patents in the United States for all FDA-approved uses—give the Tribe at least nominal rights with regard to the Restasis patents. It is, however, questionable whether those rights have any practical value. There is no doubt that at least with respect to the patent rights that protect Restasis against third-party competitors, Allergan has retained all substantial rights in the patents, and the Tribe enjoys only the right to a revenue stream in the form of royalties.

The questions as to the validity of the assignment and exclusive license transaction and whether the Tribe is an owner of the Restasis patents within the meaning of the Patent Act may be dispositive in the IPR proceedings. But those issues do not bear on this Court's power to hear this case. Regardless of whether Allergan's tactic is successful in terminating the pending

IPR proceedings, it is clear that the assignment does not operate as a bar to this Court's continued exercise of its jurisdiction over this matter.

This case was brought by Allergan, the Tribe's predecessor in interest, seeking affirmative relief, and thus any possible immunity from suit that might be applicable to avoid litigation brought against the Tribe has no application to this action. See Competitive Techs., Inc. v. Fujitsu Ltd., 374 F.3d 1098, 1102-03 (Fed. Cir. 2004) ("[W]hen a state files suit in federal court to enforce its claims to certain patents, the state shall be considered to have consented to have litigated in the same forum all compulsory counterclaims, i.e., those arising from the same transaction or occurrence that gave rise to the state's asserted claims." (quoting Regents of the Univ. of N.M. v. Knight, 321 F.3d 1111, 1126 (Fed. Cir. 2003))); see also Texas v. Caremark, Inc., 584 F.3d 655, 659 (5th Cir. 2009) ("When a state initiates a lawsuit, it waives its sovereign immunity to the extent required for the lawsuit's complete determination." (citing Clark v. Barnard, 108 U.S. 436, 448 (1883))); United States v. Oregon, 657 F.2d 1009, 1014-16 (9th Cir. 1981) (holding that tribe waives sovereign immunity by intervening in lawsuit).

While the sovereign immunity issue is not presented in this case, the question whether Allergan's assignment of its patent rights to the Tribe is valid nonetheless has a bearing on this case, because the validity of the assignment contract between Allergan and the Tribe affects whether the Court should grant Allergan's motion to add the Tribe as a co-plaintiff. If the assignment to the Tribe is valid, the Tribe should be added as a co-plaintiff. If the assignment to the Tribe is invalid, it would not be necessary to add the Tribe as a co-plaintiff.

This is more than a housekeeping matter of determining which names belong in the caption. If the Court declines to join the Tribe as a co-plaintiff and it is later determined that the Tribe is a valid owner of the patents, any judgment entered by the Court could be subject to

challenge on the ground that the owner of the patents was not a party to the action. See Indep. Wireless Tel. Co. v. Radio Corp. of Am., 269 U.S. 459, 468 (1926); Diamond Coating Techs., 823 F.3d at 618-19; Propat Int'l Corp. v. RPost, Inc., 473 F.3d 1187, 1189 (Fed. Cir. 2007); Abbott Labs. v. Diamedix Corp., 47 F.3d 1128, 1131 (Fed. Cir. 1995).

While it is important to ensure that any judgment in this case will not be subject to challenge based on the omission of a necessary party, the Court is not required to decide whether the assignment of the patent rights from Allergan to the Tribe was valid in order to resolve the question whether to add the Tribe as a co-plaintiff. Instead, the Court will adopt the safer course of joining the Tribe as a co-plaintiff, while leaving the question of the validity of the assignment to be decided in the IPR proceedings, where it is directly presented.

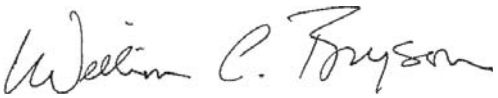
Allergan has moved for the Court to add the Tribe as a co-plaintiff under Rule 25(c) of the Federal Rules of Civil Procedure. That Rule provides that "[i]f an interest is transferred" during the course of litigation, "the action may be continued by or against the original party unless the court, on motion, orders the transferee to be substituted in the action or joined with the original party." Because the Tribe is at least the nominal transferee of the Restasis patents, and because failure to join the Tribe could render any judgment rendered by this Court invalid, the Court invokes its discretion under Rule 25(c) to order the Tribe joined as a co-plaintiff. Importantly, the Court's decision to permit joinder of the Tribe does not constitute a ruling on the validity of the assignment of the Restasis patents or the Tribe's status as a "patentee" for purposes of the Patent Act, 35 U.S.C. § 281. Instead, it is "merely a discretionary determination by the trial court that the transferee's presence would facilitate the conduct of the litigation." 7C Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, Federal Practice and Procedure § 1958, at 196-98 (2007).

Although the defendants have filed a lengthy and thorough brief in opposition to Allergan's motion to have the Tribe joined as a co-plaintiff in this action, they have not argued that they would be prejudiced in any way by the joinder of the Tribe. The Tribe has consented to joinder, Dkt. No. 513, at 6 n.1; id. at 7, and in light of the fact that the trial and the post-trial briefing in the case has been completed, the presence of the Tribe as a co-plaintiff will not interfere with the prompt entry of the Court's findings of fact and conclusions of law, and the Court's the final judgment in this case. Allergan has represented that "the joinder will not otherwise impact the substantive issues in the litigation. Id. at 6. And, as the successor-in-interest to Allergan, the Tribe would be bound by any judgment. See Kloster Speedsteel AB v. Crucible Inc., 793 F.2d 1565, 1582 (Fed. Cir. 1986). For that reason, substitution of a successor-in-interest is appropriate even when the substitution occurs after trial. Panther Pumps & Equip. Co. v. Hydrocraft, Inc., 566 F.2d 8 (7th Cir. 1977).

Accordingly, in order to ensure that any judgment entered in this case will be protected against challenge on the ground that the proper parties were not all joined as plaintiffs, the Court hereby orders the joinder of the Tribe as a co-plaintiff in this action under Federal Rule of Civil Procedure 25(c). In so doing, the Court does not hold that the assignment of the patent rights to the Tribe is valid, but instead proceeds on the ground that the assignment may at some point be held valid, and that joining the Tribe as a party in this action is necessary to ensure that the judgment in this case is not rendered invalid because of the absence of a necessary party.

IT IS SO ORDERED.

SIGNED this 16th day of October, 2017.



WILLIAM C. BRYSON
UNITED STATES CIRCUIT JUDGE

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., TEVA PHARMACEUTICALS USA, INC., and AKORN INC.,
Petitioners,

v.

ALLERGAN, INC.,
Patent Owner.

Case IPR2016-01127 (8,685,930 B2)
Case IPR2016-01128 (8,629,111 B2)
Case IPR2016-01129 (8,642,556 B2)
Case IPR2016-01130 (8,633,162 B2)
Case IPR2016-01131 (8,648,048 B2)
Case IPR2016-01132 (9,248,191 B2)

AMICUS CURIAE BRIEF OF JAMES R. MAJOR, D.PHIL. IN SUPPORT OF PETITIONERS' OPPOSITION TO ST. REGIS MOHAWK TRIBE'S MOTION TO DISMISS

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TREATISE

Amicus Curiae James R. Major, D.Phil. ("Amicus") hereby submits this brief in support of Petitioners' Opposition to St. Regis Mohawk Tribe's Motion to Dismiss (Paper 87) to Corrected Patent Owner's Motion to Dismiss for Lack of Jurisdiction Based on Tribal Sovereign Immunity (Paper 81) (the "Motion").

Amicus takes no position as to the applicability, if any, of tribal sovereign immunity in *inter partes* review proceedings and is submitting this brief to provide arguments that may assist the Board in deciding the Motion. The arguments herein do not necessarily reflect the views of: (i) Major IP Law PLLC or its clients; (ii) Lucas & Mercanti, LLP or its clients; or (iii) any associations of which Amicus is a member. Amicus has no direct financial or controlling interests in any of the parties to the above-identified proceedings.

ARGUMENT

I) The Express Rights that the Tribe Retains Are Illusory

Under the Patent License Agreement between Saint Regis Mohawk Tribe and Allergan, Inc. Dated as of September 8, 2017 (the "Agreement"), Saint Regis Mohawk Tribe (the "Tribe") "retains all rights under the Licensed Patents not expressly granted hereunder . . . ." Agreement (Ex. 2087) ¶ 2.4. The expressly-retained rights "includ[e] the right to use and practice the Licensed Patents for research, scholarly use, teaching, education, patient care incidental to the foregoing, sponsored research for itself and in collaborations with

Non-Commercial Organizations ('Non-Commercial Uses') . . . ." *Id.*

At first blush, the Tribe has apparently retained the right to practice, for example, the method of claim 1 of U.S. Patent No. 8,633,162 B2 (the "'162 Patent") in caring for patients incidental to a research study. *See* '162 Patent cl. 1 ("A method of treating dry eye disease . . . comprising topically administering to the eye of a human in need thereof an emulsion . . . .") *and* Agreement, Schedule 1.32(a) (lising the '162 Patent as a "Licensed Patent[]."). However, if taken at its word, the Tribe *already had* the right to practice the Licensed Patents. This is because, as the Tribe urges, the Tribe has "inherent sovereign immunity." Paper 81, 8. Even when Allergan, Inc. ("Allergan") was the assignee of the Licensed Patents, the Tribe could, if taken at its word, assert sovereign immunity to defeat *any* suit of Allergan's alleging infringement of the Licensed Patents.

Of course, the patent laws do not exist in a vacuum and there may be other laws and regulations that prevent the Tribe from practicing the Licensed Patents. Allergan assigned to the Tribe all rights in the Licensed Patents by way of a Patent Assignment Agreement dated September 8, 2017. Ex. 2086. However, Allergan *could not* exempt the Tribe from any law or regulation at least on the principle of *nemo dat quod non habet*: a party cannot give what it does not have.

Because the Tribe already had the express rights that the Tribe purportedly "retained" in the Agreement, the express rights that the Tribe retains are illusory.

II) The Right of the Tribe to Enforce the Licensed Patents in Infringement Suits Unrelated to a Generic Equivalent Is Nugatory

"With regard to any Infringement that does not relate to a Generic Equivalent, as between the Parties, [the Tribe] shall have the first right, but not the obligation, to control and prosecute any past, present or future Infringement with respect to the Licensed Patents . . . ." Agreement ¶ 5.2.3. Therefore, "the Tribe has the first right to enforce the [Licensed Patents] for all infringement unrelated to generic equivalents of Restasis®." Patent Owner's Reply to Opp'n to Mot. to Dismiss for Lack of Jurisdiction Based on Tribal Sovereign Immunity (Paper 93), 2. While these rights appear important, they are nominal on closer inspection.

While the Tribe purportedly retains some rights under the Agreement, the Tribe has agreed "not [to] directly or indirectly develop, market or license any Competing Product or engage in or license activities that would and/or are intended to result in a Competing Product." Agreement ¶ 2.4. A "'Competing Product' means any Generic Equivalent or any product other than a Licensed Product that is developed or approved by the FDA for any indication that includes or is the same as any indication for which any Licensed Product is approved by the FDA." Agreement ¶ 1.10 (emphasis in original omitted). Written slightly differently, a Competing Product "means ~~any Generic Equivalent or~~ any product ~~other than a Licensed Product~~ that is developed ~~or approved by the FDA~~ for any

indication that includes or is the same as any indication for which any Licensed Product is approved by the FDA." An example of one such Competing Product would be a compounded, non-FDA-approved product for an indication for which the FDA has approved a Licensed Product such as Restasis® (cyclosporine ophthalmic emulsion). *See* Paper 93, 2. However, the Tribe has agreed to refrain from activities that would result in such a product. And this would doom any possible suit against the producer of a Competing Product.

Remedies for infringement of a patent include injunctions, lost profits, or damages no less than a reasonable royalty. *See* 35 U.S.C. §§ 283-84 (2012). However, the Tribe could not successfully seek any of these remedies.

Lost profits would be unavailable because the Tribe has agreed to refrain from activities that would result in a Competing Product. Additionally, the reasonable royalty would be zero. "[I]t seems unlikely that a willing licensor and willing licensee would agree to a zero royalty payment in a hypothetical negotiation, where both infringement and validity are assumed." *Apple Inc. v. Motorola, Inc.*, 757 F.3d 1286, 1328 (Fed. Cir. 2014). However, this is one such case. Shorn of any ability to license activities that would result in a Competing Product, the Tribe would not be a "licensor" in the hypothetical negotiation and no rational licensee would seek a license when none was available. *See Apple*, 757 F.3d at 1330 (citing 7 DONALD S. CHISUM, CHISUM ON PATENTS § 20.07[3][a]

(2011) ("The premise of the reasonable royalty measure is that a holder of a valid and infringed patent has inherently suffered legal damage *at least to the extent of a lost license royalty opportunity*.") (emphasis added)).

To obtain a permanent injunction:

> A plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006). However, the Tribe would have suffered no injury in equity because the *eBay* Court rejected the proposition that infringement of a valid patent was injury *per se*. *eBay*, 547 U.S. at 393-94. The Tribe would have also suffered no monetary damages as described above, and the balance of the hardships would certainly favor an alleged infringer for the same reasons. Finally, the public interest would certainly not be served by enjoining the alleged infringer without good reason.

In sum, any infringement suit that the Tribe has the first right to bring would fail. Therefore, the right of the Tribe to enforce the Licensed Patents in infringement suits unrelated to a Generic Equivalent is nugatory.

III) The Rights that the Tribe Do Retain Are Insufficient to Support a Holding that the Tribe Retains All Substantial Rights in the Licensed Patents

Despite the arguments above, the Tribe does retain some rights, such as the right to enforce the Licensed Patents in connection with Generic Equivalents if Allergan does not do so. Agreement ¶ 5.2.2. However, that right is *contingent*. In any event, there would be no remedy in light of the Tribe's agreement to refrain from activities that would result in a Competing Product. *See infra* § II. Another right is to provide written consent to Allergan before Allergan can settle an infringement suit related to a Generic Equivalent. Agreement ¶ 5.2.2. But that consent is all but meaningless, given that the Tribe would receive no financial benefit from any such settlement. *See* Agreement ¶¶ 4.1 and 4.2 (providing for payments of flat fees). Merely holding title to the Licensed Patents and having a mixture of other, inconsequential rights is insufficient to support a holding that the Tribe retains all substantial rights in the Licensed Patents.

CONCLUSION

Because the Agreement has stripped the Tribe of any meaningful rights in the Licensed Patents, the Board should hold that Allergan is the true owner of the Licensed Patents and deny the Motion.

Date: December 1, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(3)(4) and 42.205(b), the undersigned certifies that on December 1, 2017, a complete entire copy of the *Amicus Curiae* Brief of James R. Major, D.Phil. in Support of Petitioners' Opposition to St. Regis Mohawk Tribe's Motion to Dismiss was provided, via electronic service, to the persons named below at their address of record, viz:

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Case IPR2016-01130 (8,633,162 B2)
Case IPR2016-01131 (8,648,048 B2)
Case IPR2016-01132 (9,248,191 B2) [1]

BRIEF OF AMICI SCHOLARS IN SUPPORT OF
PATENT OWNER THE ST. REGIS MOHAWK TRIBE

[1] Cases IPR2017-00576 and IPR2017-00594, IPR2017-00578 and IPR2017-00596, IPR2017-00579 and IPR2017-00598, IPR2017-00583 and IPR2017-00599, IPR2017-00585 and IPR2017-00600, and IPR2017-00586 and IPR2017-00601 have respectively been joined with the captioned proceedings.

INTRODUCTION AND INTEREST OF AMICI

Pursuant to the Board's Order of November 3, 2017, the undersigned scholars submit this brief amici curiae in support of the St. Regis Mohawk Tribe, the Patent Owner in this proceeding. Amici are legal scholars with expertise in the U.S. Constitution, the separation of powers, and the proper role of governmental agencies such as the Patent Trial and Appeal Board ("PTAB").

Amici submit that, where a patent owner establishes a prima facie showing of tribal sovereign immunity, the Board should accept that showing at face value and decline to entertain the kind of arguments against tribal sovereign immunity that Petitioners seek to raise here. Congress, not the Board (nor Article III courts), is the arbiter of tribal immunity and the proper forum for considering the policy arguments and objections raised by Petitioners.

ARGUMENT

Petitioners Mylan Pharmaceuticals, Inc. *et al*. contend that "[c]ourts and agencies have the power and duty" to deny assertions of tribal sovereign immunity to prevent what they call "abuses." Petrs. Opp. to Motion to Dismiss, Paper 87, IPR2016-01127 (Oct. 13, 2017), at 10. Petitioners maintain that "[s]overeign immunity does not require respect for an agreement designed to protect patents from review." *Id*. at 13. They describe the Tribe's assertion of immunity as being part of a "sham" (*id.* at 2, 10, 11, 12, 13), a "contrivance" (*id.* at 3), a "manipulation" (*id.* at

15), and a "rent-a-tribe" scheme. *Id.* at 10 (internal quotation marks and citation omitted). They urge the Board to withhold tribal immunity to protect "the integrity of the patent system" (*id*. at 13) and to prevent patent owners from "reap[ing] a windfall at the public's expense." *Id*. at 11 (citation and internal quotation marks omitted); *id*. at 12 ("private gain at public expense . . . is no justification for extending tribal immunity").

Petitioners' contentions miss the mark. Tribal sovereignty is not a "sham" or a "contrivance," even when it produces results Petitioners do not like. There is no dispute that the St. Regis Mohawk Tribe is what the Supreme Court has termed a "domestic dependent nation[]" (*Cherokee Nation v. Georgia*, 30 U.S. 1, 17 (1831) (Marshall, C.J.)) entitled to tribal sovereign immunity and that its agreement with Allergan is a legitimate contract. Further, the Tribe has explained that the contract serves its sovereign interests and represents an important part of its technology development plan, a project that is saturated with sovereign importance, in part because it complements the Tribe's modest tax base. *See Michigan v. Bay Mills Indian Community*, 134 S. Ct. 2024, 2043-45 (2014) (Sotomayor, J., concurring).

Moreover, Petitioners' objections are being raised in the wrong forum. Congress – rather than the Board, the Article II executive, or even the Article III courts – controls the availability of tribal sovereign immunity. As the Supreme Court has explained, "it is fundamentally Congress's job, not ours, to determine

whether or how to limit tribal immunity. The special brand of sovereignty the tribes retain—both its nature and its extent—rests in the hands of Congress." *Bay Mills Indian Community*, 134 S. Ct. at 2037. Congress has not withdrawn tribal immunity in patent cases. Where a patent owner makes a prima facie showing of tribal sovereign immunity, the Board should recognize that showing and decline to consider the kind of challenges to immunity that Petitioners seek to raise. There is no warrant for the Board to entertain Petitioners' policy objections to the Tribe's assertion of sovereign immunity, and doing so would interfere with Congress's plenary and exclusive responsibility for setting the boundaries of tribal immunity.

The Board has already adopted a similar approach in recognizing the sovereign immunity of three state universities. *See Covidien LP v. Univ. of Fla. Research Found. Inc.*, IPR2016-01274, Paper 21 at 39 (Jan. 25, 2017); *Neochord, Inc. v. Univ. of Md., et al.*, IPR2016- 00208, Paper 28 at 20 (May 23, 2017); *Reactive Surface Ltd., LLP v. Toyota Motor Corp.*, IPR2016-01914, Paper 36 at 17 (July 13, 2017). The Board should follow the same approach with respect to tribal sovereign immunity.

The Supreme Court's decision in *Republic of Philippines v. Pimentel*, 553 U.S. 851 (2008), provides instruction for the proper resolution of this proceeding. In *Pimental*, the Supreme Court held that an interpleader action could not proceed in the absence of the Republic of the Philippines and a government-created

commission, which were protected by sovereign immunity. The Court explained that, once a tribunal recognizes that an assertion of sovereign immunity is "not frivolous," it is "error" for the tribunal to proceed further to address the merits. *Id.* at 864. "[W]here sovereign immunity is asserted, and the claims of the sovereign are not frivolous," the tribunal should accept those claims. *Id.* at 867. The Board should follow that approach here and decline to consider Petitioners' policy objections to tribal sovereign immunity.

I. Congress, Not The Board, is the Arbiter of Tribal Sovereign Immunity.

"Indian tribes are 'domestic dependent nations' that exercise 'inherent sovereign authority.'" *Michigan v. Bay Mills Indian Community*, 134 S. Ct. 2024, 2030 (2014) (citations omitted). "As dependents, the tribes are subject to plenary control by Congress," although "they remain 'separate sovereigns pre-existing the Constitution.'" *Id.* (citation omitted). "Thus, unless and 'until Congress acts, the tribes retain' their historic sovereign authority." *Id.* (citation omitted). The Supreme Court has "time and again treated the 'doctrine of tribal immunity [as] settled law' and dismissed any suit against a tribe absent congressional authorization (or a waiver)." *Id.* at 2030-31 (quoting and following *Kiowa Tribe of Okla. v. Manufacturing Technologies, Inc.*, 523 U.S. 751, 756 (1998)).

"Among the core aspects of sovereignty that tribes possess— subject, again, to congressional action—is the 'common-law immunity from suit traditionally enjoyed by sovereign powers.'" *Bay Mills Indian Community*, 134 S. Ct. at 2030 (quoting *Santa Clara Pueblo v. Martinez*, 436 U.S. 49, 58 (1978)). That immunity, the Supreme Court has explained, is "a necessary corollary to Indian sovereignty and self-governance." *Three Affiliated Tribes of Fort Berthold Reservation v. Wold Engineering, P.C.*, 476 U.S. 877, 890 (1986). Immunity from suit reflects a logical corollary of sovereignty (protection from suit in court absent consent), the governance needs of the sovereign in protecting the public fisc and allocating resources according to the political needs of its population, and a dignitary interest in the form of respect from other governments as a matter of comity. [2]

The Supreme Court has repeatedly stressed that ***Congress*** plays the exclusive role in setting the bounds of tribal sovereign immunity. Neither Article III courts nor administrative agencies (nor even the Article II Executive) may disregard an

[2] *See Washington v. Confederated Tribes of Colville Reservation*, 447 U.S. 134, 154 (1980); *Santa Clara Pueblo v. Martinez*, 436 U.S. 49, 56 (1978); *Puyallup Tribe, Inc. v. Department of Game of Wash.*, 433 U.S. 165, 167-68, 172-73 (1977); *United States v. United States Fidelity & Guaranty Co.*, 309 U.S. 506, 512 (1940); *Turner v. United States*, 248 U.S. 354, 358 (1919); *Parks v. Ross*, 52 U.S. (11 How.) 362, 374 (1850); David H. Getches, Charles F. Wilkinson, Robert A. Williams Jr., Matthew L.M. Fletcher, and Kristen A. Carpenter, Cases and Materials on Federal Indian Law 415-65 (7th ed. 2017); Catherine T. Struve, Tribal Immunity and Tribal Courts, 36 Ariz. St. L.J. 137, 139-45 (2004) (providing a deep account of tribal sovereign immunity in Supreme Court precedents).

assertion of tribal immunity that Congress has seen fit to retain. As the Supreme Court has explained, "it is fundamentally Congress's job, not ours, to determine whether or how to limit tribal immunity. The special brand of sovereignty the tribes retain—both its nature and its extent—rests in the hands of Congress." *Bay Mills Indian Community*, 134 S. Ct. at 2037. "[A] fundamental commitment of Indian law is judicial respect for Congress's primary role in defining the contours of tribal sovereignty." *Id.* at 2039. Congress "has the greater capacity 'to weigh and accommodate the competing policy concerns and reliance interests' involved in the issue." *Id.* at 2037-38 (citation omitted).[3]

The baseline condition is one of tribal immunity. As long ago as *Talton v. Mayes*, 163 U.S. 376, 425 (1896), the Supreme Court recognized the "powers of self-government enjoyed by the Cherokee nation existed prior to the Constitution." Thus, the Court's decisions establish that any congressional abrogation of tribal sovereign immunity "must be clear. The baseline position, we have often held, is

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[3] *See also United States v. Lara*, 541 U.S. 193, 200 (2004) (Congress's power is "plenary and exclusive") (citations omitted); *Kiowa*, 523 U.S. at 758 ("we defer to the role Congress may wish to exercise in this important judgment"); *Oklahoma Tax Comm'n v. Citizen Band Potawatomi Indian Tribe of Oklahoma*, 498 U.S. 505, 510 (1991) (because "Congress has always been at liberty to dispense with" or limit tribal immunity, "we are not disposed to modify" its scope); *Santa Clara Pueblo*, 436 U.S. at 60 ("[A] proper respect ... for the plenary authority of Congress in this area cautions that [the courts] tread lightly"); Felix Cohen, Handbook of Federal Indian Law § 2.01[1], at 110 (1982 ed.), ("Judicial deference to the paramount authority of Congress in matters concerning Indian policy remains a central and indispensable principle of the field of Indian law").

tribal immunity; and '[t]o abrogate [such] immunity, Congress must 'unequivocally' express that purpose.'" *Bay Mills Indian Community*, 134 S. Ct. at 2031 (quoting *C&L Enterprises, Inc. v. Citizen Band Potawatomi Tribe of Okla.*, 532 U.S. 411, 418 (2001)). "That rule of construction reflects an enduring principle of Indian law: Although Congress has plenary authority over tribes, courts will not lightly assume that Congress in fact intends to undermine Indian self-government." *Id*. at 2031-32.

Congress has exercised its power by choosing to adjust tribal immunity in some contexts but not others. In *Kiowa*, for example, the Court noted that Congress had restricted tribal immunity "in limited circumstances" (including in 25 U.S.C. § 450f(c)(3) (mandatory liability insurance); § 2710(d)(7)(A)(ii) (gaming activities)), while "in other statutes" declaring an "intention not to alter" the doctrine. 523 U.S. at 758; *see also Oklahoma Tax Comm'n v. Citizen Band Potawatomi Indian Tribe of Oklahoma*, 498 U.S. 505, 510 (1991) (discussing Indian Financing Act of 1974, 88 Stat. 77, 25 U.S.C. § 1451 *et seq.*). "Congress should make the call whether to curtail a tribe's immunity," and "the Court should accept Congress's judgment." *Bay Mills Indian Community*, 134 S. Ct. at 2038 (enforcing tribal sovereign immunity even though Congress, in the Indian Gaming Regulatory Act, had abrogated tribal immunity in certain circumstances)

Here, the critical fact is that Congress did not expressly abrogate tribal sovereign immunity in the America Invents Act, or any other statute, for purposes

of *inter partes* review. In fact, tribes are not mentioned in any statute governing patents. *See Home Bingo Network v. Multimedia Games, Inc.*, No. 1:05-CV-0608, 2005 WL 2098056, at *1 (N.D.N.Y. Aug. 30, 2005) ("Plaintiff points to no authority that Congress has expressly waived tribal immunity with respect to the enforcement of patents."); *Specialty House of Creation, Inc. v. Quapaw Tribe*, No. 10-CV-371-GKF-TLW, 2011 WL 308903, at *1 (N.D. Okla. Jan. 27, 2011) (noting lack of "authority that Congress has expressly abrogated tribal sovereign immunity with respect to the enforcement of patents").

Indeed, legislation has been introduced in Congress to address the very issue of tribal sovereign immunity in *inter partes* review. *See, e.g.*, S. 1948, 115th Cong., 1st Sess. (2017). The pendency of that proposal reinforces our point: that the decision is Congress's (and not the Board's) to make. As the Supreme Court has observed, Congress's consideration of legislative proposals restricting tribal sovereign immunity is a powerful reason for other branches not to interfere. *See Bay Mills Indian Community*, 134 S. Ct. at 2038-39 ("Following *Kiowa*, Congress considered several bills to substantially modify tribal immunity in the commercial context . . . But instead of adopting those reversals of *Kiowa*, Congress chose to enact a far more modest alternative . . . [W]e act today against the backdrop of a congressional choice: to retain tribal immunity (at least for now) in a case like this one."). In fact, the Court noted that failing to recognize tribal immunity where

Congress has not actually enacted legislation abrogating it "would scale the heights of presumption: Beyond upending 'long-established principle[s] of tribal sovereign immunity,' that action would replace Congress's considered judgment with our contrary opinion." *Id.* at 2039 (citation omitted). The Court's commitment to the primacy of Congress "gains only added force when Congress has already reflected on an issue of tribal sovereignty, including immunity from suit, and declined to change settled law." *Id.* That principle is squarely applicable here.

II. The Issues Raised By Petitioners Are Beyond The Board's Statutory Purview and Institutional Expertise.

The Board should reject Petitioners' policy arguments against tribal sovereign immunity for a further reason: The Supreme Court has established that administrative agencies should not decide questions — especially complex and sensitive questions, such as those arising from Petitioners' arguments against tribal sovereign immunity — beyond their statutory purview and institutional competence. In such situations, agencies lack the expertise to resolve broader policy issues and risk interference with Congress's legislative prerogatives. Further, an agency acting beyond its purview lacks legitimacy and accountability. Controversial measures such as Petitioners' proposed restrictions on tribal sovereign immunity require a broader national democratic debate than an agency like the Board can provide.

In *Hampton v. Mow Sun Wong*, 426 U.S. 88, 116 (1976), for example, the Supreme Court invalidated a Civil Service Commission regulation denying federal employment to non-citizens — even though the agency was ***not*** found to have acted beyond its statutory mandate — simply because the decision to bar aliens from federal employment was not one with which Civil Service Commission officials were specifically charged, nor one they were competent to make. The Court noted that the Civil Service Commission "performs a limited and specific function" and that its "only concern" was "the promotion of an efficient federal service." *Id.* at 114. The Court held that the Commission could not justify its rule because it "has no responsibility for foreign affairs, for treaty negotiations, for establishing immigration quotas or conditions of entry, or for naturalization policies. Indeed, it is not even within the responsibility of the Commission to be concerned with the economic consequences of permitting or prohibiting the participation by aliens in employment opportunities in different parts of the national market." *Id.*

Similarly, in *Greene v. McElroy*, 360 U.S. 474 (1959), the Supreme Court refused to find an implicit congressional delegation of authority to the Department of Defense to administer a security clearance program that had far-reaching legal implications: "Without explicit action by lawmakers, decisions of great constitutional import and effect would be relegated by default to administrators who, under our system of government, are not endowed with authority to decide them."

Id. at 507*; see also King v. Burwell*, 135 S. Ct. 2480, 2489 (2015) (Internal Revenue Service not equipped to resolve questions of "deep 'economic and political significance" arising under Affordable Care Act).

This principle applies squarely here. The Board has no expertise or experience that would enable it to second-guess prima facie assertions of tribal sovereign immunity. Its statutory jurisdiction over IPRs is limited to challenges based on prior art and obviousness. 35 U.S.C. § 311(b). The problematic objections to tribal sovereign immunity that Petitioners seek to raise involve sensitive legal questions that are far different from the patent issues that Congress has charged the Board with resolving. As Petitioners concede, an "agency can only do what Congress permits." Petrs. Opp. to Motion to Dismiss, Paper 87, IPR2016-01127 (Oct. 13, 2017), at 24.

The Board is not competent to evaluate or balance the legitimacy of the Allergan-Mohawk contract from Congress's policy perspective. Far from being a scheme to shield patents from review, the agreement from the Tribe's perspective is part of its economic development plan. The Tribe, as sovereign, adopted a Tribal Resolution endorsing the creation of a technology and innovation center for the commercialization of existing and emerging technologies. The enterprise is known as the Office of Technology, Research and Patents and is part of the Tribe's Economic Development Department. Hence, the Allergan-Mohawk contract

reflects exactly the sort of economic entrepreneurship that Congress has been urging upon Tribes — to pursue economic development based on new businesses (such as gaming and energy ventures), contracts with off-reservation partners, and other market-based solutions, rather than federal handouts. *See Bay Mills Indian Community*, 134 S. Ct. at 2043-45 (Sotomayor, J., concurring).[4]

Petitioners' objections boil down to the claim that the Allergan/Mohawk contract is a "sham agreement" (Petrs. Opp. to Motion to Dismiss, Paper 87, IPR2016-01127 (Oct. 13, 2017), at 2, 10), a "sham assignment" (*id.* at 11, 12, 13), a "scheme[] to buy tribal immunity for dubious activities" (*id.* at 10), and even an example of "rent-a-tribe" schemes (*id.* at 10 (internal quotation marks and citation omitted). Not only are these arguments highly disrespectful to the sovereign Tribe, but adjudicating them will embroil the Board in an intrusive and politically charged inquiry into tribal motivations and the policy wisdom of tribal economic freedom. These are issues for Congress, not the courts, and not an agency.

Accordingly, the Board should decline to entertain Petitioners' arguments against tribal sovereign immunity.

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[4] *See also* Stephen Cornell & Joseph Kalt, "American Indian Self-Determination: The Political Economy of a Successful Policy" (Working Paper, Harvard Project on Native American Indian Economic Development 2010), excerpted in David H. Getches, Charles F. Wilkinson, Robert A. Williams Jr., Matthew L.M. Fletcher, and Kristen A. Carpenter, Cases and Materials on Federal Indian Law 721-27 (7th ed. 2017).

CONCLUSION

The Patent Owner's Motion to Dismiss should be granted.

Respectfully submitted.

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115TH CONGRESS
1ST SESSION

S. 974

To promote competition in the market for drugs and biological products by facilitating the timely entry of lower-cost generic and biosimilar versions of those drugs and biological products.

IN THE SENATE OF THE UNITED STATES

APRIL 27, 2017

Mr. LEAHY (for himself, Mr. GRASSLEY, Ms. KLOBUCHAR, Mr. LEE, Mrs. FEINSTEIN, Mrs. MCCASKILL, Ms. COLLINS, Mr. MCCAIN, Mr. BLUMENTHAL, Mr. WHITEHOUSE, Mr. COTTON, and Mr. DURBIN) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

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A BILL

To promote competition in the market for drugs and biological products by facilitating the timely entry of lower-cost generic and biosimilar versions of those drugs and biological products.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Creating and Restoring Equal Access To Equivalent Samples Act of 2017'' or the ''CREATES Act of 2017''.

SEC. 2. FINDINGS.

Congress finds the following:

(1) It is the policy of the United States to promote competition in the market for drugs and biological products by facilitating the timely entry of low-cost generic and biosimilar versions of those drugs and biological products.

(2) Since their enactment in 1984 and 2010, respectively, the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417; 98 Stat. 1585) and the Biologics Price Competition and Innovation Act of 2009 (Subtitle A of title VII of Public Law 111–148; 124 Stat. 804), have provided pathways for making lower-cost versions of previously approved drugs and previously licensed biological products available to the people of the United States in a timely manner, thereby lowering overall prescription drug costs for patients and taxpayers by billions of dollars each year.

(3) In order for these pathways to function as intended, developers of generic drugs and biosimilar biological products (referred to in this section as ''generic product developers'') must be able to obtain quantities of the reference listed drug or biological product with which the generic drug or biosimilar biological product is intended to compete (referred to

in this section as a ''covered product'') for purposes of supporting an application for approval by the Food and Drug Administration, including for testing to show that—

(A) a prospective generic drug is bioequivalent to the covered product in accordance with subsection (j) of section 505 of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 355), or meets the requirements for approval of an application submitted under subsection (b)(2) of that section; or

(B) a prospective biosimilar biological product is biosimilar to or interchangeable with its reference biological product under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)), as applicable.

(4) For drugs and biological products that are subject to a risk evaluation and mitigation strategy, another essential component in the creation of low-cost generic and biosimilar versions of covered products is the ability of generic product developers to join the manufacturer of the covered product (referred to in this section as the ''license holder'') in a single, shared system of elements to assure safe use and supporting agreements, or secure a variance

therefrom, as required by section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1).

(5) Contrary to the policy of the United States to promote competition in the market for drugs and biological products by facilitating the timely entry of lower-cost generic and biosimilar versions of those drugs and biological products, certain license holders are preventing generic product developers from obtaining quantities of the covered product necessary for the generic product developer to support an application for approval by the Food and Drug Administration, including testing to show bioequivalence, biosimilarity, or interchangeability to the covered product, in some instances based on the justification that the covered product is subject to a risk evaluation and mitigation strategy with elements to assure safe use under section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1).

(6) The Director of the Center for Drug Evaluation and Research at the Food and Drug Administration has testified that some manufacturers of covered products have used REMS and distribution restrictions adopted by the manufacturer on their own behalf as reasons to not sell quantities of a cov-

ered product to generic product developers, causing barriers and delays in getting generic products on the market. The Food and Drug Administration has reported receiving significant numbers of inquiries from generic product developers who were unable to obtain samples of covered products to conduct necessary testing and otherwise meet requirements for approval of generic drugs.

(7) The Chairwoman of the Federal Trade Commission has testified that the Federal Trade Commission continues to be very concerned about potential abuses by manufacturers of brand drugs of REMS or other closed distribution systems to impede generic competition.

(8) Also contrary to the policy of the United States to promote competition in the market for drugs and biological products by facilitating the timely entry of lower-cost generic and biosimilar versions of those drugs and biological products, certain license holders are impeding the prompt negotiation and development on commercially reasonable terms of a single, shared system of elements to assure safe use, which may be necessary for the generic product developer to gain approval for its drug or licensing for its biological product.

(9) While the antitrust laws may address the refusal by some license holders to provide quantities of a covered product to a generic product developer, a more tailored legal pathway would help ensure that generic product developers can obtain necessary quantities of a covered product in a timely way for purposes of developing a generic drug or biosimilar biological product, facilitating competition in the marketplace for drugs and biological products.

(10) The antitrust laws may address actions by license holders who impede the prompt negotiation and development of a single, shared system of elements to assure safe use, and the Food and Drug Administration has some authority to waive the requirement of a single, shared system. Clearer regulatory authority to approve different systems that meet the statutory requirements to ensure patient safety, however, would limit the effectiveness of bad faith negotiations over single, shared systems to delay generic approval. At the same time, clearer regulatory authority would ensure all systems protect patient safety.

SEC. 3. ACTIONS FOR DELAYS OF GENERIC DRUGS AND BIOSIMILAR BIOLOGICAL PRODUCTS.

(a) DEFINITIONS.—In this section—

(1) the term ''covered product''—

(A) means—

(i) any drug approved under subsection (b) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or biological product licensed under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262);

(ii) any combination of a drug or biological product described in clause (i); or

(iii) when reasonably necessary to demonstrate sameness, biosimilarity, or interchangeability for purposes of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), or section 351 of the Public Health Service Act (42 U.S.C. 262), as applicable, any product, including any device, that is marketed or intended for use with such drug or biological product; and

(B) does not include any drug or biological product that the Secretary has determined to be currently in shortage and that appears on the drug shortage list in effect under section 506E

of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356e), unless the shortage will not be promptly resolved—

(i) as demonstrated by the fact that the drug or biological product has been in shortage for more than 6 months; or

(ii) as otherwise determined by the Secretary;

(2) the term ''device'' has the meaning given the term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321);

(3) the term ''eligible product developer'' means a person that seeks to develop a product for approval pursuant to an application for approval under subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or for licensing pursuant to an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k));

(4) the term ''license holder'' means the holder of an application approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or the holder of a license under subsection (a) or (k) of section 351 of

the Public Health Service Act (42 U.S.C. 262) for a covered product;

(5) the term ''REMS'' means a risk evaluation and mitigation strategy under section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1);

(6) the term ''REMS with ETASU'' means a REMS that contains elements to assure safe use under section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1);

(7) the term ''Secretary'' means the Secretary of Health and Human Services;

(8) the term ''single, shared system of elements to assure safe use'' means a single, shared system of elements to assure safe use under section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1); and

(9) the term ''sufficient quantities'' means an amount of a covered product that allows the eligible product developer to—

(A) conduct testing to support an application—

(i) for approval under subsection (b)(2) or (j) of section 505 of the Federal

Food, Drug, and Cosmetic Act (21 U.S.C. 355); or

(ii) for licensing under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)); and

(B) fulfill any regulatory requirements relating to such an application for approval or licensing.

(b) CIVIL ACTION FOR FAILURE TO PROVIDE SUFFICIENT QUANTITIES OF A COVERED PRODUCT.—

(1) IN GENERAL.—An eligible product developer may bring a civil action against the license holder for a covered product seeking relief under this subsection in an appropriate district court of the United States alleging that the license holder has declined to provide sufficient quantities of the covered product to the eligible product developer on commercially reasonable, market-based terms.

(2) ELEMENTS.—

(A) IN GENERAL.—To prevail in a civil action brought under paragraph (1), an eligible product developer shall prove, by a preponderance of the evidence—

(i) that—

(I) the covered product is not subject to a REMS with ETASU; or

(II) if the covered product is subject to a REMS with ETASU—

(aa) the eligible product developer has obtained a covered product authorization from the Secretary in accordance with subparagraph (B); and

(bb) the eligible product developer has provided a copy of the covered product authorization to the license holder;

(ii) that, as of the date on which the civil action is filed, the product developer has not obtained sufficient quantities of the covered product on commercially reasonable, market-based terms;

(iii) that the eligible product developer has requested to purchase sufficient quantities of the covered product from the license holder; and

(iv) that the license holder has not delivered to the eligible product developer sufficient quantities of the covered product

on commercially reasonable, market-based terms—

(I) for a covered product that is not subject to a REMS with ETASU, by the date that is 31 days after the date on which the license holder received the request for the covered product; and

(II) for a covered product that is subject to a REMS with ETASU, by 31 days after the later of—

(aa) the date on which the license holder received the request for the covered product; or

(bb) the date on which the license holder received a copy of the covered product authorization issued by the Secretary in accordance with subparagraph (B).

(B) AUTHORIZATION FOR COVERED PRODUCT SUBJECT TO A REMS WITH ETASU.—

(i) REQUEST.—An eligible product developer may submit to the Secretary a written request for the eligible product developer to be authorized to obtain suffi-

cient quantities of an individual covered product subject to a REMS with ETASU.

(ii) AUTHORIZATION.—Not later than 90 days after the date on which a request under clause (i) is received, the Secretary shall, by written notice, authorize the eligible product developer to obtain sufficient quantities of an individual covered product subject to a REMS with ETASU for purposes of—

(I) development and testing that does not involve human clinical trials, if the eligible product developer has agreed to comply with any conditions the Secretary determines necessary; or

(II) development and testing that involves human clinical trials, if the eligible product developer has—

(aa)(AA) submitted protocols, informed consent documents, and informational materials for testing that include protections that provide safety protections comparable to those pro-

vided by the REMS for the covered product; or

(BB) otherwise satisfied the Secretary that such protections will be provided; and

(bb) met any other requirements the Secretary may establish.

(iii) NOTICE.—A covered product authorization issued under this subparagraph shall state that the provision of the covered product by the license holder under the terms of the authorization will not be a violation of the REMS for the covered product.

(3) AFFIRMATIVE DEFENSE.—In a civil action brought under paragraph (1), it shall be an affirmative defense, on which the defendant has the burden of persuasion by a preponderance of the evidence—

(A) that, on the date on which the eligible product developer requested to purchase sufficient quantities of the covered product from the license holder—

(i) neither the license holder nor any of its agents, wholesalers, or distributors

was engaged in the manufacturing or commercial marketing of the covered product; and

(ii) neither the license holder nor any of its agents, wholesalers, or distributors otherwise had access to inventory of the covered product to supply to the eligible product developer on commercially reasonable, market-based terms; or

(B) that—

(i) the license holder sells the covered product through agents, distributors, or wholesalers;

(ii) the license holder has placed no restrictions, explicit or implicit, on its agents, distributors, or wholesalers to sell covered products to eligible product developers; and

(iii) the covered product can be purchased by the eligible product developer in sufficient quantities on commercially reasonable, market-based terms from the agents, distributors, or wholesalers of the license holder.

(4) REMEDIES.—

(A) IN GENERAL.—If an eligible product developer prevails in a civil action brought under paragraph (1), the court shall—

(i) order the license holder to provide to the eligible product developer without delay sufficient quantities of the covered product on commercially reasonable, market-based terms;

(ii) award to the eligible product developer reasonable attorney fees and costs of the civil action; and

(iii) award to the eligible product developer a monetary amount sufficient to deter the license holder from failing to provide other eligible product developers with sufficient quantities of a covered product on commercially reasonable, market-based terms, if the court finds, by a preponderance of the evidence—

(I) that the license holder delayed providing sufficient quantities of the covered product to the eligible product developer without a legitimate business justification; or

(II) that the license holder failed to comply with an order issued under clause (i).

(B) MAXIMUM MONETARY AMOUNT.—A monetary amount awarded under subparagraph (A)(iii) shall not be greater than the revenue that the license holder earned on the covered product during the period—

(i) beginning on—

(I) for a covered product that is not subject to a REMS with ETASU, the date that is 31 days after the date on which the license holder received the request; or

(II) for a covered product that is subject to a REMS with ETASU, the date that is 31 days after the later of—

(aa) the date on which the license holder received the request; or

(bb) the date on which the license holder received a copy of the covered product authorization issued by the Secretary in ac-

cordance with paragraph (2)(B); and

(ii) ending on the date on which the eligible product developer received sufficient quantities of the covered product.

(C) AVOIDANCE OF DELAY.—The court may issue an order under subparagraph (A)(i) before conducting further proceedings that may be necessary to determine whether the eligible product developer is entitled to an award under clause (ii) or (iii) of subparagraph (A), or the amount of any such award.

(c) LIMITATION OF LIABILITY.—A license holder for a covered product shall not be liable for any claim arising out of the failure of an eligible product developer to follow adequate safeguards to assure safe use of the covered product during development or testing activities described in this section, including transportation, handling, use, or disposal of the covered product by the eligible product developer.

(d) RULE OF CONSTRUCTION.—

(1) DEFINITION.—In this subsection, the term ''antitrust laws''—

(A) has the meaning given the term in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12); and

(B) includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that such section applies to unfair methods of competition.

(2) ANTITRUST LAWS.—Nothing in this section shall be construed to limit the operation of any provision of the antitrust laws.

SEC. 4. REMS APPROVAL PROCESS FOR SUBSEQUENT FILERS.

Section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1) is amended—

(1) in subsection (g)(4)(B)—

(A) in clause (i) by striking ''or'' after the semicolon;

(B) in clause (ii) by striking the period at the end and inserting ''; or''; and

(C) by adding at the end the following:

''(iii) accommodate different approved risk evaluation and mitigation strategies for a reference drug product and a drug that is the subject of an abbreviated new drug application.''; and

(2) in subsection (i)(1), by striking subparagraph (B) and inserting the following:

"(B) Elements to assure safe use, if required under subsection (f) for the listed drug.

"(i) Subject to clause (ii), a drug that is the subject of an abbreviated new drug application may use—

"(I) a single, shared system with the listed drug under subsection (f); or

"(II) a different, comparable aspect of the elements to assure safe use under subsection (f).

"(ii) The Secretary may require a drug that is the subject of an abbreviated new drug application and the listed drug to use a single, shared system under subsection (f), if the Secretary determines that no different, comparable aspect of the elements to assure safe use could satisfy the requirements of subsection (f).".

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