UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PACIRA PHARMACEUTICALS, INC., DR. LOREN J. HARRIS, and DR. JOSEPH W. BELL,

Plaintiffs,

v.

UNITED STATES FOOD & DRUG ADMINISTRATION; UNITED STATES OF AMERICA; DR. STEPHEN OSTROFF, in his official capacity as Acting Commissioner of Food and Drugs; UNITED STATES DEPARTMENT OF HEALTH & HUMAN SERVICES; and SYLVIA MATHEWS BURWELL, in her official capacity as Secretary of the Department of Health & Human Services,

Defendants.

Civil Action No. 15-cv-7055-RA

MEMORANDUM OF LAW IN SUPPORT OF
MOTION FOR PRELIMINARY INJUNCTION

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PRELIMINARY STATEMENT

Plaintiffs Pacira Pharmaceuticals, Inc. ("Pacira") and Drs. Loren Harris and Joseph Bell (the "Doctor Plaintiffs") seek a preliminary injunction to enable Pacira to share truthful information about its product, EXPAREL, with sophisticated physicians.

In direct contravention of the Second Circuit's holding in *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012), the Food and Drug Administration ("FDA") directed Pacira to "immediately cease" sharing truthful information about EXPAREL on the ground that such speech violated the Food, Drug and Cosmetic Act ("FDCA"). As the Supreme Court made clear in *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653, 2659, 2667 (2011), content- and speaker-based restrictions on commercial speech, such as those imposed by FDA on Pacira, are subject to heightened judicial scrutiny and will, "[i]n the ordinary case," fail such scrutiny. In keeping with *Sorrell* and *Caronia*, the U.S. District Court for the Southern District of New York recently entered an injunction against FDA confirming that a pharmaceutical manufacturer's truthful, non-misleading speech about its product may not form the basis of a misbranding prosecution. *See Amarin Pharma, Inc. v. FDA*, No. 15-cv-3588, slip op. at 69 (S.D.N.Y. Aug. 7, 2015).

Pacira's case is even stronger, for while the speech at issue in *Amarin* and *Caronia* concerned "*off*-label" drug uses, the speech Pacira desires to engage in concerns *on*-label information about use of EXPAREL for its FDA-approved indication. In 2011, FDA approved EXPAREL for general use in any "surgical site" to control postsurgical pain. Three years later, FDA attempted, through a Warning Letter, to rewrite the label and to limit Pacira's speech to two specific surgical procedures: bunionectomies and hemorrhoidectomies. FDA likewise directed Pacira to stop making claims about EXPAREL's ability to control pain for up to 72 hours, even though a pivotal trial for EXPAREL supports precisely that conclusion. FDA's attempts to limit Pacira's truthful and non-misleading speech warrant injunctive relief, just as in *Amarin*.

Pacira is a young company that (together with its predecessors) developed EXPAREL at significant cost over many years. EXPAREL is an innovative product that combines a well established local non-opioid anesthetic (bupivacaine) with a novel controlled-release delivery platform (DepoFoam). In contrast to opioids, EXPAREL works with a single administration into the surgical site to block the generation and conduction of pain from the nerves in and around that location. *See* Declaration of Dr. Alex Cahana ("Cahana Decl.") ¶ 19.

Consistent with long-established FDA practice, Pacira sought a broad approval for controlling postsurgical pain on the basis of two controlled clinical studies that demonstrated EXPAREL's safety and efficacy in two distinct types of surgeries: hemorrhoidectomy, which involves highly vascular, soft-tissue; and bunionectomy, which involves a surgical site comprised primarily of bone and joint. As recognized by FDA's historical practice and regulatory guidance, discussed below, the safety and effectiveness of EXPAREL in these two well-established pain models provide a clear scientific and medical rationale for concluding that the drug's clinical benefits are generalizable to other surgical sites.

Relying on these studies, FDA approved EXPAREL in 2011 for the general control of postsurgical pain. The "Indications and Usage" section of the FDA-approved label states: "EXPAREL is a liposome injection of bupivacaine, an amide-type local anesthetic, indicated for administration into the surgical site to produce postsurgical analgesia." This section of the label does not reference bunionectomy or hemorrhoidectomy or otherwise limit the surgical sites for which EXPAREL has been approved. Declaration of Julian Helisek ("Helisek Decl.") Ex. 1 at 1.

Since its approval and launch, EXPAREL has been used extensively by physicians, who were quick to recognize its value as an innovative non-opioid product. Doctors, including Doctor Plaintiffs, frequently administer EXPAREL to produce postsurgical analgesia for

procedures other than hemorrhoidectomy and bunionectomy. Regardless of whether administration of EXPAREL in these surgical sites is on-label, as Pacira has reasonably believed since receiving approval, or off-label, as FDA now claims, these uses are lawful and common. Even the United States uses EXPAREL in procedures other than hemorrhoidectomy and bunionectomy: the Department of Defense regularly uses EXPAREL because military doctors have concluded that it has important benefits for servicemember patients, including treating battlefield injuries. And while EXPAREL is used extensively beyond bunionectomies and hemorrhoidectomies, after over 1.3 million uses, it has a safety record similar to a placebo.[1]

Physicians desire, and deserve, accurate, up-to-date information about EXPAREL so they can provide safe and effective pain management for their patients. Since EXPAREL's approval, Pacira has communicated with physicians about its approved indication: "administration into the surgical site to produce postsurgical analgesia." Pacira has been fully transparent with FDA. It worked with FDA to develop clinical study protocols so that EXPAREL could get a broad indication approved. Pacira then promoted within the FDA-approved indication and provided copies of promotional materials for EXPAREL to FDA, as FDA requires.

Given its efforts to comply with FDA's regulatory framework, Pacira was surprised when, on September 22, 2014—three years after EXPAREL's approval, and after having provided FDA for three years with promotional materials that marketed EXPAREL according to its indication—the Company received a "Warning Letter" from FDA's Office of Prescription Drug Promotion ("OPDP") objecting to these promotional materials and asserting, for the first time, that they violated criminal provisions of the FDCA. The letter stated that as part of FDA's "routine monitoring and surveillance program" it had come across certain "violations." Helisek Decl. Ex. 2 at 2 ("Warning Letter"). FDA objected to certain information Pacira had provided to

[1] Declaration of Richard Scranton ("Scranton Decl.") ¶ 6.

some doctors about how other doctors use EXPAREL on the ground that this information concerned surgical sites other than bunionectomy and hemorrhoidectomy, *id.* at 2, notwithstanding that FDA had approved EXPAREL for general control of postsurgical pain. Based on a *post hoc* analysis of EXPAREL's pivotal hemorrhoidectomy study, FDA also challenged Pacira's claims that EXPAREL was effective for controlling postsurgical pain for up to 72 hours, *id.* at 4, despite the fact that the study's successful primary endpoint (and secondary endpoints) showed that EXPAREL provided a statistically significant advantage over placebo for 72 hours post-surgery.

The Warning Letter demanded that Pacira "immediately cease" the speech that FDA considered unlawful. It directed Pacira to respond within two weeks "stating whether you intend to comply" and instructed Pacira to issue "corrective messages" to health care providers. The Warning Letter closed by stating that "[f]ailure to correct the violations discussed above may result in FDA regulatory action, including seizure or injunction, without further notice." *Id.* at 4-5. Notwithstanding the value of EXPAREL to patients, FDA has now attempted retroactively to narrow EXPAREL's label, after three years on the market, asserting that Pacira's truthful speech about the indication expressly stated in the FDA-approved label is "off-label" and constitutes a crime, without regard to whether the information conveyed is truthful.

To avoid further enforcement action, Pacira agreed to take certain steps specified by FDA and ceased distribution of the materials cited in the Warning Letter. Declaration of George Wagner ("Wagner Decl.") ¶ 23. Pacira continued to request a meeting with FDA to discuss the scope of the EXPAREL approval and support for its 72-hour claim. But FDA declined to meet with Pacira and largely ignored Pacira's submissions. Lacking other options, Pacira brought this suit to vindicate its rights under the Administrative Procedure Act and First Amendment.

STATEMENT OF FACTS

A. FDA Approved EXPAREL, An Innovative Non-Opioid Analgesic, For Postsurgical Pain Control Without Limitation To Particular Surgeries

Pacira markets one principal product: EXPAREL. Pacira developed EXPAREL to provide postsurgical pain relief generally, without limitation to specific surgical sites. EXPAREL uses Pacira's DepoFoam technology to deliver the drug bupivacaine, a local anesthetic that has been used for decades in a wide variety of surgical procedures. EXPAREL is injected into the surgical site to produce postsurgical analgesia by the controlled, gradual release of bupivacaine. Declaration of Vladimir Kharitonov ¶¶ 6-15.

On September 28, 2010, Pacira filed its NDA for EXPAREL. In support of its application, Pacira submitted data from two multicenter, randomized, double-blinded clinical trials, one in bunionectomy and one in hemorrhoidectomy. Pacira, with FDA approval and oversight, designed and selected these clinical trials in two distinct types of surgical sites in order to obtain a broad indication for postsurgical analgesia. The Company's approach to EXPAREL's clinical development was consistent with scientific and medical knowledge about the etiology of pain and how analgesic medications work; it also accounted for the challenges associated with studying drugs to treat pain. Scientists, doctors, and FDA concur that it is both undesirable and infeasible to require clinical studies in every pain model in which the drug will be used. As Larry Goldkind, former Deputy Director and Acting Director of FDA's Division of Anti-Inflammatory, Analgesic, and Ophthalmologic Drug Products ("DAAODP"), explains in his declaration, FDA has long relied on extrapolation and favored broad indications for analgesic drugs wherever possible, based on the view that a pain drug demonstrated to be safe and effective in two pain models can reasonably be expected to perform in other models without the

need for a separate clinical study. Declaration of Dr. Lawrence Goldkind ("Goldkind Decl.") ¶¶ 13-23.

Experts agree that two key factors determine whether a medication will effectively control pain. First is the type of the pain, as characterized by its temporal features, intensity, and cause. If, for example, the pain is caused by trauma to the skin or underlying tissue because of a surgical incision, as with postsurgical pain, then the same pain control medication will address that source of pain regardless of where it occurs. Second is the drug's mechanism of action and pharmacodynamic properties. Goldkind Decl. ¶¶ 14-16. When a drug is well understood its clinical benefit can reasonably be predicted across a wide range of pain models. *Id*.

FDA has long touted the benefits of extrapolation for analgesic drugs and made clear that an applicant need not prove safety and efficacy with clinical data in every pain model for which a drug may be used. Dr. Bob Rappaport, the Director of the Division of Anesthesia, Analgesia, and Addiction Products at FDA's Center for Drug Evaluation and Research at the time EXPAREL was approved, emphasized the importance of extrapolation and stated that the medical community needs "to have analgesics with broader indications."[2] Rappaport's position is consistent with FDA policy and practice. Recent FDA guidance states that for "general acute pain indications"—an extraordinarily broad category that includes *any* type of pain requiring treatment for no more than a few weeks—only two clinical trials are required so long as one trial is in a visceral pain model (*i.e.*, pain related to the internal organs) and one is in a non-visceral model (*i.e.*, bone, joint, or musculoskeletal pain). *See* FDA, *Draft Guidance for Industry: Analgesic Indications: Developing Drugs and Biological Products* 2, 5, 15 (Feb. 2014). FDA's

[2] *See* Bob A. Rappaport, M.D., *Regulatory Issues Related to the Development of Drugs to Treat Painful Peripheral Neuropathy*, Presentation at the 2012 Foundation for Peripheral Neuropathy National Research Symposium (Mar. 15, 2012), http://www.acttion.org/static/docs/Rappaport_slide_presentation.pdf.

reliance on extrapolation in the analgesic context is borne out by its practice of approving analgesics with broad indications based on more limited clinical trials. Goldkind Decl. ¶ 22.

The extrapolation rationale undergirded the clinical development program for EXPAREL. Consistent with what FDA confirmed in its 2014 Draft Guidance, Pacira conducted two clinical studies to support a postsurgical analgesia indication, a subcategory of acute pain. The models Pacira studied are as dissimilar as two surgeries could be within the indication Pacira sought. The bunionectomy study, the "gold standard" for pain models, demonstrated safety and effectiveness in a surgical site comprised primarily of bone and joint, while the hemorrhoidectomy study demonstrated that EXPAREL was safe and effective in a highly vascular, soft-tissue site. The success of EXPAREL across both types of surgical sites, as well as what is known about the pharmacology of EXPAREL, provided clear support for extrapolation to other surgical sites, *id.* ¶¶ 26-30, as has been validated by three-plus years of safe and effective EXPAREL use in a broad range of surgical sites.

FDA approved EXPAREL with a general postsurgical indication after a thorough review of Pacira's application. This was no accident. During FDA's review, a Medical Officer recommended that the Indications and Usage section of the Prescribing Information ("PI," or "label") be narrowed to approval only for "postoperative analgesia following hemorrhoidectomy and bunionectomy." *Id.* ¶ 43. But FDA ultimately overruled this suggestion and approved EXPAREL for use generally in surgical sites. Per FDA's own regulations, EXPAREL's approved Indications and Usage cannot be limited by statements elsewhere in the FDA-approved label, and EXPAREL's broad approval thus reflected a conscious decision. *Id.* ¶ 34.[3]

[3] The references to bunionectomy and hemorrhoidectomy in the Dosage and Administration section, for example, are preceded by a *general* dosing instruction applicable to all surgeries stating that "[t]he recommended dose of EXPAREL is based on the surgical site and the volume to cover the area." Helisek Decl. Ex. 1 at 1. The references that follow to the areas specifically studied provide examples and a range for physicians to consider when using

FDA's application of the Pediatric Research Equity Act ("PREA") to EXPAREL further confirms the broad approval. PREA authorizes FDA to require NDA holders to conduct pediatric studies in on-label uses of their product. 21 U.S.C. § 355c(a)(2)(A). Given that under PREA, FDA may only require pediatric studies for on-label indications, and that bunionectomies and hemorrhoidectomies rarely occur in children and teenagers, FDA could only have concluded that pediatric studies were required for EXPAREL if FDA understood the indication to broadly cover postsurgical pain relief. Furthermore, Pacira proposed various studies to satisfy its PREA obligation, and at no point did FDA object that such surgeries were outside the scope of EXPAREL's approved indication; if EXPAREL's indication were limited to bunionectomy and hemorrhoidectomy, as FDA now claims, testing the drug in children for *other* uses would raise ethical concerns. *See* Goldkind Decl. ¶¶ 48-55; Helisek Decl. Ex. 3 at 1 (FDA letter requiring PREA studies of EXPAREL in pediatric patients "undergoing multiple surgical procedures").

B. FDA Has Threatened Enforcement Action Against Pacira For Communicating In A Manner Consistent With EXPAREL's Indication

Nearly three years after FDA approved EXPAREL with a broad postsurgical indication, FDA sent Pacira the Warning Letter. FDA regulations state that the Indications and Usage section describes the conditions for which a drug is approved, 21 C.F.R. § 201.57(c)(2)(iv), yet the Warning Letter highlighted passages in the Dosage and Administration and Clinical Studies sections, and incorrectly asserted that such references limited the drug's approval. FDA claimed that Pacira was promoting EXPAREL "for new uses for which it lacks approval" and that these "violations . . . are serious." Helisek Decl. Ex. 2 at 1, 4. FDA also asserted that it was "false or

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EXPAREL in other procedures given the significant differences between the two studied surgical sites. Goldkind Decl. ¶ 37. This approach is consistent with FDA regulations, which require that the Dosage and Administration section provide "[t]he dosage range" and "[a]n upper limit beyond which safety and effectiveness have not been established," 21 C.F.R. § 201.57(c)(3)(i), and recognizes that physicians must rely on their medical judgment when determining how to dose and administer a local anesthetic. The Clinical Studies section similarly cannot be viewed as limiting the indication, as that section is designed only to provide information about the studies submitted in support of the NDA approval. *Id.* § 201.57(c)(15); *see* Goldkind Decl. ¶ 42.

misleading" for Pacira to suggest that EXPAREL provides "pain control that lasts for up to 72 hours"—ignoring that the pivotal study's primary endpoint and pre-specified secondary endpoints demonstrated this duration of effectiveness. *See* Declaration of Dr. Lee-Jen Wei ("Wei Decl.") ¶¶ 25-30.

The Warning Letter drew on FDA regulations that criminalize manufacturer speech about off-label uses of drugs. Under the FDCA, manufacturers face criminal penalties if they introduce a "new drug" without FDA approval or "misbrand" their products by making violative claims in advertising or labeling. 21 U.S.C. §§ 331(a), (d), 355(a). However, because FDA has adopted an exceedingly broad interpretation of which communications constitute labeling and advertising, the Agency effectively bans nearly *all* communications that reference off-label uses, irrespective of the accuracy or importance of the information. Under Sections 201(p) and 505(a) of the statute, for example, if a drug's "labeling" "prescribe[s], recommend[s], or suggest[s]" a use for the drug not indicated in the approved NDA, then it constitutes a "new drug" for which the manufacturer must seek separate approval or risk criminal penalties. 21 U.S.C. § 331(d). A drug is deemed misbranded if, *inter alia*, "its labeling is false or misleading in any particular" or the labeling does not bear "adequate directions for use." *Id.* § 352(a), (f). Additionally, FDA has deemed products misbranded if their advertising or labeling "recommend[s] or suggest[s] any use that is not in the labeling accepted in [the drug's] approved new-drug application" or are otherwise "false or misleading." 21 C.F.R. § 202.1(e)(4)(i)(a), (e)(6).

FDA has adopted a cramped reading of the FDCA to conclude that a drug lacks adequate directions for use when its labeling—a term broadly interpreted by FDA to cover most manufacturer communications—departs from what FDA approved. *Id.* § 201.100(c)(1).[4] The

[4] Although the FDCA explicitly exempts prescription drugs from the "adequate directions for use" requirement, the Agency circumvents this exemption by regulation that applies it *only if* the product labeling has "adequate

regulations further erode the FDCA by providing that a drug's "intended use" is any use "for which it is advertised or represented," *id.*, regardless of whether such use is mentioned on the drug's label. Thus, the Agency considers manufacturer speech about an off-label use as supporting a new "intended use" of the product, *id.*, and when the manufacturer's "intended use" differs from FDA's approved labeling, FDA considers that speech a criminal act.

FDA's interpretation of "false or misleading" does not hinge on whether information is true. The Agency has instead declared that manufacturer claims concerning safety or efficacy or comparing the drug to another are "false or misleading" whenever those claims or information are outside of the label or not supported by "substantial evidence"—an exceedingly high standard required by the FDCA for drug *approval* that FDA has, without authority, insisted upon for communications about approved drugs. 21 U.S.C. § 355(d); 21 C.F.R. § 202.1(e)(6). In the absence of two clinical trials, FDA deems any such speech by the company criminal, even when about the FDA-approved indication. 21 C.F.R. § 202.1(e)(6); *see* 21 U.S.C. §§ 331(a), 352(a).

The severe constraints on manufacturer speech imposed by FDA's "substantial evidence" regulation are evident here, where FDA challenged as "false or misleading" claims about the effectiveness of EXPAREL for up to 72 hours that are directly supported by EXPAREL's pivotal hemorrhoidectomy study. As Dr. Lee-Jen Wei, a Harvard statistician, explains, that study "clearly demonstrated a reduction in pain intensity for up to 72 hours after surgery as compared to placebo." Wei Decl. ¶ 6. This conclusion is supported by the study's pre-specified primary endpoint, the results of which "were highly statistically significant and indicate that EXPAREL was effective for up to 72 hours," *id.* ¶ 7, and by other analyses from that study, including a "'time-to-event' analysis of one of the pre-specified secondary endpoints, . . . which assessed the

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information" to instruct medical professionals on how to use the product safely and for "the purposes for which it is intended." 21 C.F.R. § 201.100(c)(1).

amount of time elapsed after surgery before subjects took 'rescue medication,'" and which "clearly demonstrate[d] EXPAREL's highly statistically significant advantage over placebo for the entire 72-hour follow-up period." *Id.* ¶ 9. FDA nonetheless challenged Pacira's claims regarding 72-hour efficacy based on the "substantial evidence" regulation and FDA's own *post hoc* analyses, which, as Dr. Wei observes, are "not appropriate for use in casting doubt on the durability of EXPAREL's treatment effect," because they purport to detect differences between EXPAREL and placebo that the study was not large enough to detect, and because FDA applied "an unfair statistical adjustment." *Id.* ¶ 8.

Invoking a litany of its regulations on manufacturer speech, FDA demanded that Pacira cease "violating" the FDCA or it would face "FDA regulatory action, including seizure or injunction, without further notice." Helisek Decl. Ex. 2 at 4-5. Pacira submitted a comprehensive response on October 6, 2014, expressing strong disagreement with FDA's claims and retroactive attempt to alter EXPAREL's approved indication. Helisek Decl. Ex. 4 at 1. FDA persisted in demanding that Pacira take corrective action, and Pacira was compelled to comply. In a letter to health care providers "correcting" Pacira's speech, the Company noted that while "EXPAREL was approved for administration into the surgical site to produce postsurgical analgesia," FDA required it to state that "[a]pproval was based on studies of bunionectomy and hemorrhoidectomy, and the drug has not been demonstrated to be safe and effective for any other specific type of surgery." Helisek Decl. Ex. 5 at 1. While Pacira complied due to its fear of enforcement action, it continued to point out the inconsistencies in FDA's position and sought a meeting with FDA. Helisek Decl. Ex. 6 ("White Paper"). Rather than meet with Pacira to discuss these unresolved issues, FDA *sua sponte* issued a "close-out" letter on July 24, 2015,

referring again to Pacira's "violative" speech, while ignoring Pacira's repeated requests to meet with FDA. Helisek Decl. Ex. 7 at 1-2.

C. The Government's Speech Restrictions Have Harmed Pacira And Chill Pacira's Ability To Communicate In A Truthful And Non-Misleading Way

Prior to receipt of the Warning Letter, Pacira felt free to share truthful, non-misleading, on-label information about EXPAREL with health care providers. Based on FDA regulations and guidance, and the FDA-approved label, Pacira promoted EXPAREL for administration to the surgical site. To assist doctors, Pacira developed and distributed educational technique guides summarizing the individual experiences of, and techniques preferred by, physicians using EXPAREL. These guides offered doctors the ability to review the professional choices made by their peers when administering EXPAREL to produce postsurgical pain relief.

As a result of FDA's changed interpretation of the EXPAREL indication, and the application of its speech-limiting regulations through the Warning Letter, Pacira has been forced to censor its speech and to undertake the "corrective actions" required by FDA. Wagner Decl. ¶ 25. These restrictions on its speech have harmed Pacira's sales, spawned confusion and uncertainty among physicians and hospitals, and inhibited the Company from advancing its mission of providing non-opioid pain medications.

Pacira now seeks to overcome the government's attempts to suppress its speech and to communicate with physicians in a truthful and non-misleading manner about EXPAREL. Pacira seeks to engage in a dialogue with health care professionals (including the Doctor Plaintiffs) about the following truthful, non-misleading messages and content:

- EXPAREL is indicated for use in surgical sites generally, including but not limited to: total knee arthroplasty; hip replacement; bariatric surgery; hernia repair; colectomy; cholecystectomy; ileostomy reversal; breast reconstruction; and urologic surgeries.
- Published studies and reports regarding EXPAREL's administration into surgical sites.

- Experiences that other doctors have had administering EXPAREL in these surgical sites, and different methods by which EXPAREL can be administered in surgical sites, including by infiltration of EXPAREL into the *Tranversus Abdominis Plane* ("iTAP").

- EXPAREL has demonstrated effectiveness in some patients for up to 72 hours following surgery.

- Pacira would also like to respond in a truthful and non-misleading way to speech from other companies comparing EXPAREL to other methods of treating postsurgical pain.

Doctor Plaintiffs, meanwhile, seek to exercise their First Amendment right to receive this type of information. Physicians believe, based on their medical judgment, that access to this information would enable them to provide better care to their patients, that Pacira is the best situated party to share this information, and that receiving this information would be of great value to patients experiencing postsurgical pain.[5]

Pacira would ensure that the speech is not misleading by providing appropriate disclosures. Under FDA's current interpretation of its regulations, however, even if Pacira's speech is truthful and non-misleading, accompanied by appropriate disclaimers, and made to a sophisticated audience, it is categorically prohibited if it does not conform to FDA's current views of what is "on label" or supported by FDA's views about "substantial evidence."

ARGUMENT

Plaintiffs seek a preliminary injunction to protect Pacira's right to share truthful and non-misleading information about EXPAREL. To obtain a preliminary injunction, Plaintiffs must establish that they are likely to succeed on the merits, they are likely to suffer irreparable harm absent preliminary relief, the balance of equities tips in their favor, and an injunction is in the public interest. *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008).[6] Plaintiffs

[5] Declaration of Dr. Loren Harris ("Harris Decl.") ¶ 14; Declaration of Dr. Joseph Bell ("Bell Decl.") ¶ 12.
[6] Where a plaintiff seeks an injunction to alter the status quo, it must show a "substantial" likelihood of success. *New York Progress & Prot. PAC v. Walsh*, 733 F.3d 483, 486 (2d Cir. 2013). Here it is FDA, rather than Pacira, that seeks to alter the status quo regarding the scope of EXPAREL's approved indication. But even if Pacira were required to show a "substantial" likelihood of success, it would satisfy that standard. *See Amarin*, slip op. at 49

amply satisfy that standard here, where Pacira's desired speech is not only truthful and non-misleading, but also consistent with EXPAREL's FDA-approved label.

I. PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS

Given the recent precedent in *Caronia* and *Amarin*, Plaintiffs are very likely to establish that the restraints imposed by FDA on Pacira's speech fail First Amendment scrutiny. But even before reaching that constitutional issue, Plaintiffs are highly likely to show FDA's unilateral reinterpretation of the scope of EXPAREL's label, years after it was approved, and without following agency procedures, violates the Administrative Procedure Act and Fifth Amendment.

A. FDA's Retroactive Attempt To Limit The Scope Of EXPAREL's Approved Indication Violates The Administrative Procedure Act

As discussed below, *see infra* I.B., Pacira would have a right to speak truthfully about lawful uses of EXPAREL even if FDA had not approved those uses. Here, however, FDA has approved EXPAREL for use in surgical sites generally, not merely for two specific procedures. FDA's attempt to narrow that approved indication through the Warning Letter independently violates the APA, and the Court may therefore avoid this important constitutional issue.

1. Because EXPAREL Was Approved For Use In Surgical Sites Generally, Pacira's Desired Speech Is "On-Label"

Under the FDCA, applicants must seek FDA approval for a "new drug" through FDA's approval regime. 21 U.S.C. §§ 331, 333, 355. The outcome of this process is the FDA-approved label, which includes the Indications and Usage section that describes the indications for which the drug has been approved, and any limitations thereto. 21 C.F.R. § 201.57(a)(6), (c)(2). Other sections of the FDA-approved label provide additional information, but do not limit the approved

("Where the speech at issue consists of truthful and non-misleading speech promoting the off-label use of an FDA-approved drug, such speech, under *Caronia*, *cannot* be the act upon which an action for misbranding is based.").

indications stated in the "Indications and Usage" section of the label. 21 C.F.R. § 201.57(a)(6); 21 C.F.R. § 201.57(c)(2).[7]

The Indications and Usage section of EXPAREL's label states, in no uncertain terms, that it is approved for "administration into the surgical site to produce postsurgical analgesia." Helisek Decl. Ex. 1 at 1. Unlike other pain medications, EXPAREL's Indications and Usage section contains no limitation as to the type or location of the surgical site where EXPAREL is approved for use. *See* Goldkind Decl. ¶ 47 (describing labels for SUFENTA, DEPODUR, and VICOPROFEN). As discussed above, *supra* 5-6, and in the declaration of Dr. Goldkind, the former Acting Director of DAAODP, approval of EXPAREL for a broad indication was consistent with FDA's longstanding practice and the science, which strongly supports extrapolating from successful studies of an analgesic relating to two distinct tissue types and pain models to approve a broad indication. *Id.* ¶¶ 13-23.

Consistent with scientific understandings and FDA guidance, Pacira submitted its NDA with two studies demonstrating that EXPAREL was broadly effective in the management of postsurgical pain. In the Indications and Usage section of EXPAREL's label, FDA awarded the general postsurgical analgesic indication Pacira sought, without limitation to a specific surgery type. If FDA had believed that the bunionectomy and hemorrhoidectomy models did not support the general postsurgical analgesic indication, it would have limited the Indications and Usage section accordingly. *Id.* ¶ 35. To the contrary, the final decision-maker rejected a suggestion that the label be limited. *Id.* ¶¶ 43-44. FDA's application of PREA to EXPAREL confirms that the Agency understood other surgical sites to be within the approved indication. *See supra* 8. Had EXPAREL been approved only for bunionectomy and hemorrhoidectomy, FDA would have

[7] "Contraindications" can limit the Indication, but as relevant here EXPAREL's do not. 21 C.F.R. § 201.57(c)(5).

waived pediatric studies altogether, and certainly not have required studies of EXPAREL concerning uses in children that were unapproved, which would be unethical.

For three years following EXPAREL's approval, Pacira correctly promoted it consistent with its broadly worded Indications and Usage, and provided FDA copies of those promotional materials, as FDA requires. Wagner Decl. ¶ 11; *see* 21 C.F.R. §§ 314.81(b)(3)(i), 601.12(f)(4). FDA's assertion, for the first time, in the September 2014 Warning Letter that EXPAREL was approved only for use in connection with bunionectomy and hemorrhoidectomy constituted a dramatic and unauthorized attempt to rewrite the label.

2. Given EXPAREL's Excellent Safety Profile, FDA Would Have No Basis Under Applicable Law To Narrow EXPAREL's Approved Indication

FDA would have no basis under the FDCA or its own regulations to narrow EXPAREL's approved indication, much less do so retroactively. FDA may only revise, amend, or otherwise order changes to a product's label post-approval if the Agency meets substantive standards and observes designated procedures. To initiate procedures for revising a drug's approved label, FDA must typically identify "new safety information." 21 U.S.C. §§ 355(o)(4)(A), 355-1(a)(2)(A).[8] If, in light of such information, FDA believes a labeling change is necessary to protect the public health, the Agency must make a formal determination to that effect and provide notice to the NDA holder, allowing time to respond. 21 U.S.C. § 355(o)(4)(B); *id.* at § 355(o)(4)(F). In all instances, including where FDA desires to act based on an "imminent hazard to the public health," FDA must afford notice and opportunity for a hearing. 21 U.S.C. § 355(e); 21 C.F.R. § 314.150(b)(3). This did not and could not happen here.

[8] Under the FDCA, "[n]ew safety information" means "information derived from a clinical trial, an adverse event report, a postapproval study . . . or peer-reviewed biomedical literature; data derived from the postmarket risk identification and analysis system under section 355(k) of [the FDCA]; or other scientific data deemed appropriate by the Secretary about . . . a serious risk or an unexpected serious risk associated with use of the drug that the Secretary has become aware of (that may be based on a new analysis of existing information) since the drug was approved." 21 U.S.C. §§ 355-1(b)(3), 355(o)(2)(C).

There is no "new safety information" to justify a formal change to EXPAREL's label as required by Section 355. To the contrary, EXPAREL has a remarkable safety record, similar to that of a placebo, with an adverse event rate of approximately one-third of one-tenth of one percent. Nor has FDA taken any of the procedural steps that would be necessary to amend EXPAREL's indications. FDA's declaration, through the Warning Letter, that EXPAREL's approved indication was being limited, in a manner inconsistent with the statutory requirements and without following applicable procedures, is "not in accordance with law," is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," and is "without observance of procedure required by law." 5 U.S.C. § 706(2)(A), (C), (D). It is also arbitrary and capricious and an abuse of the agency's discretion. *Id.* § 706(2)(A). As such, FDA's attempt to enforce its narrowed interpretation of EXPAREL's label violates the APA.

B. FDA's Restriction Of Pacira's Speech Violates The First Amendment

The Supreme Court and Second Circuit have recently confirmed that the First Amendment protects pharmaceutical manufacturers' ability to speak about their products. "[S]peech in aid of pharmaceutical marketing . . . is a form of expression protected by the Free Speech Clause of the First Amendment." *Sorrell*, 131 S. Ct. at 2659. The First Amendment prevents the government from "interfer[ing] with the ability of physicians and patients to receive potentially relevant treatment information" from manufacturers that will allow physicians to make "informed and intelligent treatment decisions." *Caronia.*, 703 F.3d at 166-67. *Sorrell* makes clear that where a law restricts truthful, non-misleading speech on the basis of its content and the identity of the speaker, that law "must be subjected to heightened judicial scrutiny," even for "commercial" speech. 131 S. Ct. at 2659, 2664. Content- and speaker-based restrictions on commercial speech fail this heightened scrutiny "[i]n the ordinary case." *Id.* at 2667.

FDA has imposed two distinct speaker- and content-based restrictions on Pacira's ability to speak about EXPAREL, each of which impermissibly infringes these First Amendment interests. First, FDA has threatened enforcement action against Pacira for discussing with doctors use of EXPAREL in surgeries other than bunionectomy or hemorrhoidectomy, on the theory that such speech is a criminal violation of the FDCA. Second, FDA has, by regulation and in the Warning Letter, asserted that Pacira may not make statements about the effectiveness of EXPAREL, or comparisons between it and other products, unless its statements are supported by two well-controlled clinical trials, the incredibly demanding standard Congress has established for *drug approval* that reaches far beyond what is necessary to make a statement truthful and non-misleading, and which no other speaker is required to satisfy. Each of these restrictions violates the First Amendment.

1. Whether On- Or Off-Label, Pacira's Truthful And Non-Misleading Speech About Uses Of EXPAREL Beyond Bunionectomy And Hemorrhoidectomy Is Protected By The First Amendment

Caronia holds that FDA cannot, consistent with the First Amendment, restrict manufacturer speech simply because it promotes off-label uses of a drug. As the Second Circuit explained, "off-label drug usage is not unlawful," and therefore promotion of drugs for off-label uses is "not in and of itself false or misleading." 703 F.3d at 165-66. To the extent the government has legitimate interests in ensuring the integrity of the drug approval process or preventing misleading claims about a drug, *Caronia* noted that "[t]he government's interests could be served equally well by more limited and targeted restrictions on speech." *Id.* at 168.

In *Amarin*, this Court recently rejected the government's characterization of *Caronia* as a "fact-bound decision," and confirmed that FDA may not prohibit truthful, non-misleading pharmaceutical manufacturers' speech about their products. *Amarin*, slip op. at 44-45. As Judge Engelmayer explained, when "the speech at issue consists of truthful and non-misleading speech

promoting the off-label use of an FDA-approved drug, such speech, under *Caronia*, *cannot* be the act upon which the action for misbranding is based." *Id.* at 48-49. *Caronia* applies "across-the-board to *all* truthful and non-misleading promotional speech." *Id.* at 51.

Under *Caronia* and *Amarin*, even if FDA could retroactively limit EXPAREL's approval to use in bunionectomy and hemorrhoidectomy, Pacira's truthful and non-misleading speech to physicians about administration of EXPAREL in connection with other surgeries would be constitutionally protected. Doctors, scientists, and FDA, routinely extrapolate from clinical studies in limited models to more general use of an analgesic to control pain. Bell Decl. ¶ 8; Goldkind Decl. ¶¶ 13-23. In the case of EXPAREL, which is based on a well-understood pain medication, extrapolation is particularly appropriate. Goldkind Decl. ¶¶ 24-30. Accordingly, it is truthful and non-misleading for Pacira to discuss with healthcare professionals how EXPAREL's trials, and approval, demonstrate its safety and efficacy in other surgical sites.

FDA's close-out letter makes explicit FDA's view that this truthful speech about uses of EXPAREL beyond bunionectomy and hemorrhoidectomy is "violative" of the FDCA. Helisek Decl. Ex. 7, at 1. There is no question that FDA regards Pacira's speech itself as the criminal act. *See Amarin*, slip op. at 45. But the FDCA, as construed in light of the First Amendment, neither criminalizes, nor authorizes FDA to restrict, manufacturers' speech about lawful use of their products, even if FDA has not approved that use. *Caronia*, 703 F.3d at 168-69.

Just as Pacira has a right, under the First Amendment, to speak to healthcare professionals about the lawful use of EXPAREL in other surgical sites, those professionals, including the Doctor Plaintiffs, have a right to receive this information. *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 756 (1976). Listeners' interests in such information are especially important "in the fields of medicine and public health, where

information can save lives." *Sorrell*, 131 S. Ct. at 2664. *See id.* (observing that a "consumer's concern for the free flow of commercial speech often may be far keener than his concern for urgent political dialogue" (citation omitted)). One type of communication Pacira desires to engage in is to share with physicians materials describing the experiences of other doctors using EXPAREL in sites other than hemorrhoidectomy and bunionectomy. Compl. ¶ 163. Such use is lawful, and the First Amendment would protect doctors' right to describe, in a truthful, non-misleading way, their experiences administering EXPAREL. That same speech does not become false or misleading simply because Pacira facilitates the dissemination of that information, such as by distributing printed or digital materials that the Company has prepared in collaboration with those doctors. FDA's prohibition is the very definition of a speaker-based restriction on speech, subject to stringent scrutiny under the First Amendment. *Caronia*, 703 F.3d at 164-65.

2. FDA Cannot Limit Speech About The Effectiveness Of EXPAREL Or Comparisons Between It And Other Products To Claims Supported By Two Clinical Trials

Second Circuit precedent also confirms that FDA may not restrict pharmaceutical manufacturers from discussing the effectiveness of their products, or the relative merits of their drug compared to another product, by imposing arbitrary prerequisites before the manufacturer may speak. As the Second Circuit has held in the false advertising context, "to the extent a speaker or author draws conclusions from non-fraudulent data, based on accurate descriptions of the data and methodology underlying those conclusions, on subjects about which there is legitimate ongoing scientific disagreement," the government cannot, by fiat, simply declare those statements "false" and thus outside the First Amendment because it does not meet some arbitrary standard of support. *ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490, 498 (2d Cir. 2013); *see Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 67 (D.D.C. 1998). The First Amendment precludes such categorical rules where adequate disclosure by the speaker about the

nature of the support for the claim can prevent the speech from being potentially misleading. *Pearson v. Shalala*, 164 F.3d 650, 657-59 (D.C. Cir. 1999); *Amarin*, slip op. at 57-61.

FDA may not, therefore, simply declare, as a categorical matter, that all claims regarding efficacy or comparative claims are false or misleading unless supported by two clinical trials, as FDA purports to do.[9] FDA based its Warning Letter, as it related to Pacira's speech regarding EXPAREL's effectiveness for up to 72 hours, upon this very regulation. Helisek Decl. Ex. 2 at 4 (citing 21 C.F.R. § 202.1(e)(6)(i)).

Pacira's pivotal trial of hemorrhoidectomies provides a basis for making truthful and non-misleading claims that EXPAREL is effective to control pain for up to 72 hours. As Dr. Wei explains in his declaration, *see supra* 10-11, this claim is supported by the primary endpoint of the hemorrhoidectomy study. Wei Decl. ¶¶ 7, 13-20. That conclusion is further supported by several pre-specified secondary endpoints, one of which demonstrated with a high degree of statistical significance that nearly three times the number of patients in the EXPAREL arm than the placebo arm of the study (28% vs. 10%) took no opioids for 72 hours. *Id.* ¶ 37. FDA discounted those study results, but Dr. Wei explains that FDA's bases for doing so were statistically inappropriate. *Id.* ¶¶ 21-30. FDA cannot categorically ban Pacira from making truthful claims about the scientific evidence suggesting effectiveness up to 72 hours, with whatever disclosures and caveats are necessary to make them non-misleading, simply because the claim is not supported by *two* clinical trials. The two-clinical-trial standard is an exceptionally high one, involving multi-year studies and hundreds of millions of dollars in investment, that Congress requires before FDA may approve a new drug, *see* 21 U.S.C. 355(d),

[9] *See* 21 U.S.C. § 355(d) (defining "substantial evidence" to require "adequate and well-controlled investigations"); FDA, *Guidance for Industry, Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products* 3 (May 1998) (reflecting FDA's view that "Congress generally intended to require at least two adequate and well-controlled studies, each convincing on its own, to establish effectiveness"); *see also* 21 C.F.R. § 202.1(e)(6)(i)-(ii) (deeming false or misleading claims lacking "substantial evidence"); *supra* 10.

but a claim about a drug that FDA has already approved can be truthful and non-misleading even when its evidentiary support does not meet that high bar. *See Amarin*, slip op. at 62-66 (holding that qualified health claim was truthful and non-misleading even when supported by less rigorous evidence than required for a new drug approval).

FDA's insistence that pharmaceutical manufacturers must have two clinical trials to support any claim of effectiveness or comparison is a disfavored speaker-based restriction. No other speaker is limited to making a claim only after amassing two clinical trials to support it. This case illustrates the point. Halyard, the maker of the ON-Q pump, is under no such explicit restriction because it sells a "device" rather than a drug. And, indeed, Halyard has made comparative claims of very dubious validity. *See* Compl. ¶ 130; Helisek Decl. Exs. 8, 9. But, even though there are various advantages of EXPAREL over ON-Q, *see* Harris Decl. ¶ 12; Bell ¶ 7, Pacira is categorically precluded from making those comparative claims, because it does not have two clinical trials to support them. *See* 21 C.F.R. § 202.1(e)(6)(ii). The First Amendment does not tolerate such speaker-based restrictions on truthful, non-misleading speech.

C. FDA's Speech Restrictions As Applied To Pacira Violate The Due Process Clause Of The Fifth Amendment

The illegal nature of FDA's restrictions of Pacira's speech is further confirmed by the non-retroactivity and fair notice principles of the Fifth Amendment. As discussed, FDA's assertion that Pacira's speech is "off-label" depends on FDA's unilateral reinterpretation, long after the fact, of the scope of EXPAREL's indication.[10] FDA approved EXPAREL for administration into the surgical site without limitation, confirmed that understanding through the PREA process, and was on notice that Pacira promoted EXPAREL consistent with that indication. After three years, the Agency reversed course. For the Agency to suddenly and

[10] *See Schorr v. Menifee*, No. 04 Civ. 1863, 2004 WL 1320898, at *5 (S.D.N.Y. June 14, 2004) ("A changed agency policy can violate the Ex Post Facto Clause where it has the effect of changing substantive law.").

dramatically alter course in a Warning Letter and decide that the Company's once permissible speech had somehow become impermissible off-label speech operates as a retroactive ex post facto prohibition. Given these circumstances, any enforcement action taken against Pacira for promoting EXPAREL for use in surgical sites other than bunionectomy and hemorrhoidectomy would constitute an unconstitutional, retroactive ex post facto penalty.

Additionally, when speech rights are at stake, the Due Process Clause requires the government to establish clear rules giving "fair notice of what is prohibited," and "rigorous adherence to [these] requirements is necessary to ensure that ambiguity does not chill protected speech." *FCC v. Fox Television Stations, Inc.*, 132 S. Ct. 2307, 2317 (2012). After *Caronia*, FDA cannot "criminaliz[e] the simple promotion of a drug's off-label use" without violating the First Amendment. 703 F.3d at 162. While FDA may have "take[n] issue with the [*Caronia*] majority's" approach, "the proper forum for that critique was a petition for rehearing or certiorari in *Caronia*," *Amarin*, slip op. at 50 n.57, which the government did not pursue. Yet, FDA has so far failed to clarify its rules, leaving manufacturers to discern FDA policy from a mosaic of non-binding draft guidance documents. Pacira has no way of knowing, based on FDA's highly restrictive regulations, to what extent promotion deemed off-label will still be subject to jail time and potentially massive fines. This uncertainty is "particularly treacherous" in cases like this where criminal penalties "deter those who seek to exercise protected First Amendment rights." *Buckley v. Valeo*, 424 U.S. 1, 76-77 (1976). At the very least, FDA could not take enforcement action against Pacira based on Pacira's reasonable understanding that EXPAREL's FDA-approved indication was a general one for postsurgical pain relief, not limited to particular surgical procedures. Where, as here, free speech rights are at stake, FDA must regulate with clarity to the extent it purports to criminalize manufacturer speech.

II. PLAINTIFFS WILL SUFFER IRRERPARABLE INJURY ABSENT A PRELIMINARY INJUNCTION

"Where infringement of free speech is claimed, irreparable harm may normally be presumed." *Am. Freedom Def. Initiative v. Metro. Transp. Auth.*, 880 F. Supp. 2d 456, 465-66 (S.D.N.Y. 2012) (citation omitted). "The 'loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury.'" *N.Y. Magazine v. Metro. Transp. Auth.*, 136 F.3d 123, 127 (2d Cir. 1998) (quoting *Elrod v. Burns*, 427 U.S. 347, 373 (1976)). Pacira's First Amendment speech rights have been chilled by the threat of government enforcement, and the Doctor Plaintiffs' First Amendment rights to receive Pacira's speech have been similarly infringed upon. Without relief, that infringement will continue.

In *Amarin*, the court noted that because plaintiffs showed that their First Amendment rights would be chilled absent preliminary relief, they had "articulated a specific present objective harm or threat of a specific future harm so as to establish a cognizable claim based on the chilling of [F]irst [A]mendment rights." *Amarin*, slip op. at 66 (quoting *Am. Postal Workers Union, AFL-CIO v. U.S. Postal Serv.*, 766 F.2d 715, 722 (2d Cir. 1985)). As in *Amarin*, FDA has threatened to bring action against Pacira under various regulations. Helisek Decl. Ex. 2 at 4-5. Accordingly, there is here, a "genuine threat that the alleged unconstitutional law is about to be enforced against [Pacira]." *Brache v. Cty. of Westchester*, 658 F.2d 47, 51 (2d Cir. 1981).

III. THE BALANCE OF EQUITIES FAVORS PLAINTIFFS, AND A PRELIMINARY INJUNCTION IS IN THE PUBLIC INTEREST

The balance of equities and the public interest also strongly support preliminary relief. "[S]ecuring First Amendment rights is in the public interest." *New York*, 733 F.3d at 488; *see also Amarin*, slip op. at 67. As a physician quoted by the Supreme Court in *Sorrell* explained: "[w]e have a saying in medicine, information is power. And the more you know, or anyone knows, the better decisions can be made." *Sorrell*, 131 S. Ct. at 2671. Protecting core liberties,

particularly when those liberties help doctors make better decisions for patients, enhances the public interest.

The public interest in Pacira's speech is even greater. EXPAREL is an alternative to opioids, which can cause severe health problems, including heart and lung problems, overdose, addiction, and death. EXPAREL has the potential to reduce the need for patients to use opioids during post-surgical recovery, thereby avoiding these adverse effects and possibly preventing future addiction for those exposed to opioids in the post-operative period. Cahana Decl. ¶ 34; Bell Decl. ¶¶ 5-6. Patients who avoid opioids are more attentive and alert, which is particularly meaningful for members of the U.S. military. Scranton Decl. ¶¶ 11-14. Pacira's desired speech is, in short, important and valuable to physicians, patients and the public health.

The government has no legitimate countervailing interest. The Government itself uses EXPAREL for procedures outside of bunionectomy and hemorrhoidectomy. *Id.* ¶ 10. While the government argued in *Amarin* that permitting off-label speech would undermine the drug approval process, *see* slip op. at 49-50, 67, the government can advance no such argument here, as Pacira did observe that process and secured a labeled indication for EXPAREL that encompasses the uses about which it desires to speak. Beyond that, just as the court found in *Amarin* that "there is no basis to fear that promoting Vascepa for [an] off-label purpose would endanger the public health. . . . [Vascepa] is already widely-prescribed to treat patients with persistently high triglycerides," *id.* at 67, the same is true of EXPAREL, which is already widely used because of its significant clinical benefits. And EXPAREL has an outstanding safety record. The only interest the government has—defending its own regulatory regime—is no basis for violating Pacira's and the Doctor Plaintiffs' constitutional rights.

CONCLUSION

The motion for a preliminary injunction should be granted.

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