

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. 1:15-cv-07055-RA

DECLARATION OF LOREN J. HARRIS, M.D.

I, Loren J. Harris, M.D., declare as follows:

1. I currently serve as the Director of General Thoracic Surgery at Maimonides Medical Center in Brooklyn, New York. In that role, I perform numerous surgeries every year. My clinical work focuses primarily on general thoracic surgical oncology, including lung and esophageal malignancies, as well as tumors of the mediastinum and chest wall. I am licensed to practice medicine in the state of New York and am a resident of New York County.

2. I am board certified in thoracic surgery. I hold academic appointments at New York Medical College and SUNY Downstate Medical Center, and I serve as Assistant Clinical Professor of Cardiothoracic Surgery at New York University Medical Center. I am a member of

numerous professional associations including the New York Society of Thoracic Surgery, the American College of Surgery, the American College of Chest Physicians, and the ACCP Thoracic Oncology Network Steering Committee, among others.

3. Previously, I served as Chairman of the Department of Surgery and the Director of the Division of Thoracic Surgery at Richmond University Medical Center in Staten Island. I am a graduate of New York University School of Medicine, where I also completed a fellowship in general surgery and cardiothoracic surgery. I have published extensively throughout my career, on topics including general surgery and lung cancer, and I have been practicing medicine for nearly 30 years.

4. My *curriculum vitae* is attached hereto as Exhibit A.

5. I submit this declaration in support of plaintiffs' motion for a preliminary injunction in the above-captioned matter.

**I regularly administer EXPAREL to patients
to provide safe and effective post-surgical pain relief.**

6. As a thoracic and cardiothoracic surgeon, I perform several hundred operations each year, and I regularly administer EXPAREL to my patients to provide post-surgical analgesia.

7. I have administered EXPAREL for thoracotomies (*i.e.*, an incision into the pleural space of the chest); median sternotomies (*i.e.*, an incision along the sternum); and video-assisted thoracic surgery, known as "VATS." Specifically, I have administered EXPAREL for patients who have undergone lobectomies (*i.e.*, surgery to remove one lobe of the lung that contains cancerous cells); pneumonectomies (*i.e.*, surgery to remove an entire lung); surgical procedures to remove portions of the esophagus (containing malignant tumors) and reconstruct the

gastrointestinal tract; lung transplants; and many other procedures. I can and do administer EXPAREL without the assistance of an anesthesiologist.

8. Over the past several years, I have administered EXPAREL to my patients in approximately 250-300 surgeries. When I first began using EXPAREL, I administered it directly into the wound or surgical site only. Today, depending on the particulars of a given patient and surgical procedure, I will administer EXPAREL in different ways to provide post-surgical analgesia.

9. It is my understanding that EXPAREL uses liposomes to deploy the drug bupivacaine, a common local anesthetic. Based on my experience and medical training as a surgeon, I am familiar with how to administer a local anesthetic for different surgical procedures.

10. In my experience, EXPAREL is safe and effective. My patients who receive a single-dose infiltration of EXPAREL following surgery tend to report at least 1-2 days of post-operative pain relief, and the pain relief can last up to or beyond 72 hours. I am aware of very few adverse events occurring in my patients who are given EXPAREL, and the drug is generally well tolerated.

11. I use EXPAREL as part of a multi-modal approach to controlling post-operative pain. Following a surgical procedure, I may prescribe a temporary course of opioids on an outpatient basis, but in my experience, EXPAREL tends to reduce the need for pain-relieving narcotics. The availability of alternatives to opioids is critical for some patients, because opioids are associated with many adverse events, including severe constipation. Opioid use in elderly patients also presents unique challenges. In particular, opioid use in elderly patients may cause drowsiness, decreasing a patient's breathing rate, and thus potentially leading to pneumonia.

I would like to receive additional information about EXPAREL from Pacira.

12. I am aware that there are opioid alternatives on the market, including EXPAREL, NAROPIN, elastomeric pumps that can infuse non-opioid analgesics on a continuous basis (*e.g.*, ON-Q), and others. These products all have advantages and disadvantages in different situations. My patients, the majority of whom are elderly, generally experience better results with EXPAREL than with elastomeric pumps like ON-Q, which carry greater risks of infection, device malfunction, and migration or dislodgment of catheters. I recognize that those devices may be suitable for use in certain other patient populations. Still, it would be helpful for me to receive more information comparing the various available drug and device therapies currently on the market, so that I can choose the right one for my patients.

13. As a surgeon, I use my experience and judgment when administering anesthetics to provide post-operative pain relief. A scalable dosing regimen is a common feature of drugs that I often prescribe to relieve pain, and for EXPAREL I calculate the dose based on a patient's body weight. I know how to administer local anesthetics for post-surgical analgesia based on my medical training, decades of experience as a practicing surgeon, and discussions with my fellow surgeons and other health care professionals. Prior to EXPAREL becoming available, I regularly used MARCAINE (bupivacaine) and so am very familiar and experienced with the active ingredient in EXPAREL, which is also bupivacaine. My ability to properly dose EXPAREL draws on this extensive experience with bupivacaine, which has been widely used since before I began practicing medicine.

14. I understand that Pacira, the manufacturer of EXPAREL, has developed administration technique guides describing individual physician experiences using EXPAREL.

Although I have never seen or received such a guide, I would be interested to read them to learn more about other physicians' use of EXPAREL.

15. As a general matter, I am interested in receiving information about EXPAREL, including information about the drug's safety and effectiveness when used in the types of surgical procedures I regularly perform, or as compared to other treatment options like pain pumps or narcotics.

FDA regulations that prevent Pacira from sharing truthful, non-misleading information with me frustrate my ability to practice medicine and may harm patients.

16. I have reviewed the FDA-approved prescribing information for EXPAREL. As a physician who regularly uses EXPAREL, I understand the approved indication—namely, “for administration into the surgical site to produce postsurgical analgesia”—to mean that EXPAREL is FDA-approved for administration into any surgical site to produce postsurgical analgesia. As I read the prescribing information for EXPAREL, the approved indication does not limit the drug's use to bunionectomies and hemorrhoidectomies. In my experience, if a drug is indicated for only limited uses (*e.g.*, indicated for use in only one or two particular types of surgeries), the drug's prescribing information will say so specifically.

17. To the extent that FDA regulations prevent Pacira from sharing with me and my colleagues truthful, non-misleading information about EXPAREL's uses in certain surgeries, those regulations are frustrating my ability to practice good medicine and are harming my patients and the public health.

18. For example, I understand that Pacira has information and data, including medical and scientific research articles and papers addressing the use of EXPAREL to create a field block in the surgical site in the abdomen. Receiving that information would be highly valuable to me

and to my patients, and I am interested in learning more about EXPAREL's uses in the abdomen. I see no reason why Pacira ought not to be permitted to share such truthful, non-misleading information and data with physicians, myself included.

19. Moreover, I devote a great deal of time to patient care. I understand that pharmaceutical manufacturers, like Pacira, may respond to "unsolicited requests" about their products, but that they are not permitted to respond to broad, standing requests for information about their products that is not incorporated into the FDA-approved prescribing information, and can only respond to specific questions. As a practical matter, because of the constraints on my time, I simply cannot prepare and send specific questions for each of the numerous pharmaceutical manufacturers whose products might be valuable to my patients, much less do so on a monthly or even quarterly basis to ensure that I am receiving the most recent information.

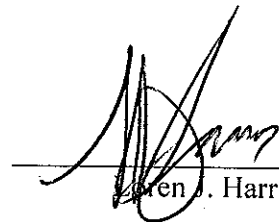
20. I further understand that pharmaceutical manufacturers are permitted to discuss information about their products that is not incorporated into the FDA-approved prescribing information as part of presentations or discussions at scientific or medical conferences. Because of the financial cost of attending such conferences and the significant time commitment required, I can only attend, at most, two national conferences per year, and I cannot rely on that approach to keep abreast of developments about the products I use to care for my patients.

21. One of the most important ways that I learn new information is by speaking with colleagues. But given the time I spend devoted to patient care, the universe of colleagues with whom I am regularly able to discuss surgery techniques and the use of pain-control medications can be limited to those other surgeons in my hospital. I have a strong desire to learn more about how other surgeons, in other hospitals, use EXPAREL in surgical sites.

22. I must rely on information that comes my way. Pharmaceutical manufacturers often know more about their products than anyone else, but restrictions on manufacturers' truthful speech prevent them from sharing with me the most up-to-date information available. Truthful, non-misleading information helps me optimize decision-making when I treat my patients. I, and my patients, would benefit from receiving more information from Pacira.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on September 1, 2015.


Loren J. Harris, M.D.