

If you paid for Lupron[®]—used to treat prostate cancer, endometriosis, uterine fibroids, and precocious puberty—you could get a payment from a legal settlement.

A federal court authorized this notice. This is not a solicitation from a lawyer.

- A nationwide settlement has been proposed in class action litigation about the cost of Lupron[®]. This notice is for:
 - **Consumers who paid for Lupron[®], for example, as part of their treatment for prostate cancer, endometriosis, uterine fibroids, or precocious puberty.**
 - **Private and certain governmental insurers, employee welfare benefits plans, and governmental employers that paid for Lupron[®].**
- The settlement will pay cash to those who submit valid claims. It will also pay fees for the lawyers appointed by the Court, plus expenses and the costs of the notice and settlement administration.

— This does not involve the safety or effectiveness of Lupron[®] —

YOUR LEGAL RIGHTS AND OPTIONS IN THIS SETTLEMENT:	
SUBMIT A CLAIM FORM	The only way to get a payment.
EXCLUDE YOURSELF	Get no payment. This is the only option that allows you to start, or remain part of any other lawsuit against the Defendants about the cost of Lupron [®] or other legal claims in this case.
OBJECT	Write to the Court about why you don't like the settlement.
GO TO A HEARING	Ask to speak in Court about the settlement.
DO NOTHING	Get no payment. Give up your rights to be part of any other lawsuit against the Defendants about the cost of Lupron [®] or other legal claims in this case.

- These rights and options—**and the deadlines to exercise them**—are explained in this notice.
- The Court in charge of this case has to decide whether to approve the settlement. Payments will be made if the Court approves the settlement, and after any appeals are resolved. Please be patient.

QUESTIONS? CALL 1-866-410-7650 TOLL FREE, OR VISIT WWW.LUPRONCLAIMS.COM

PARA UNA NOTIFICACIÓN EN ESPAÑOL, VISITE NUESTRO SITIO DE INTERNET

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BASIC INFORMATION

1. Why was this notice issued?

A Court authorized this notice because you have a right to know about a nationwide proposed settlement of this class action, including the right to claim money, and about all of your options, before the Court decides whether to give “final approval” to the settlement. If the Court approves the settlement, and after any appeals are resolved, payments will be made to everyone who submitted a valid claim. This notice explains the lawsuit, the settlement, your legal rights, what benefits are available, who may be eligible for them, and how to get them.

Judge Richard G. Stearns of the United States District Court for the District of Massachusetts is overseeing this class action. The case is known as *In re Lupron[®] Marketing and Sales Practices Litigation*, No. 01-CV-10861-RGS, MDL 1430. The people who sued are called the “Plaintiffs,” and the companies they sued, TAP Pharmaceutical Products Inc. (“TAP”), Abbott Laboratories, and Takeda Pharmaceutical Company Limited (formerly known as Takeda Chemical Industries, Ltd.), are called the “Defendants.”

2. What is the litigation about?

There are lawsuits about the cost of Lupron[®], an injectable drug usually given by a doctor to treat prostate cancer in men, endometriosis and uterine fibroids in women and precocious puberty in children. The litigation is about whether people or entities were unlawfully overcharged and defrauded by the Defendants. **This does not involve the safety or effectiveness of Lupron[®].** The Plaintiffs say that there was a fraudulent scheme by the Defendants about the marketing, sale and distribution of Lupron[®], and that the alleged scheme caused people to overpay for Lupron[®]. They say the scheme involved: 1) artificially inflating the average wholesale price (“AWP”) so that doctors could charge more for Lupron[®]; 2) giving free samples to doctors knowing they would charge patients and insurers for them; and 3) giving valuable gifts to doctors as incentives to prescribe Lupron[®] instead of other less costly alternatives.

The Defendants deny all of these claims. Specifically, the Defendants say they have many defenses, that they are not liable to the Plaintiffs, and that the Plaintiffs are not entitled to any money or benefits from the litigation. The Defendants say the federal government created and still uses AWP instead of cost-to-acquire as a basis for reimbursing physicians, despite decades of knowledge and criticism that AWP does not necessarily reflect the actual cost-to-acquire. Defendants also believe that the Plaintiffs cannot prove they lost any money or had “damages” from free samples given by TAP to certain doctors.

3. Why is this a class action?

In a class action, one or more people or entities like you, called Class Representatives, sue on behalf of people who have similar claims. All these people are a “Class” or “Class Members.”

One court resolves the issues for all Class Members, except for those who exclude themselves from the Class.

4. Why is there a settlement?

Both sides agreed to a settlement to avoid the cost and risk of a trial, and so that the people affected can get compensation, in exchange for releasing the Defendants from all liability. The settlement does not mean the Defendants did anything wrong or that they violated any laws. The Class Representatives and the lawyers representing them think the settlement is best for all Class Members.

WHO IS IN THE SETTLEMENT?

To see if your rights will be affected by this settlement or if you will get money from the settlement, you first have to determine if you are a Class Member.

5. How do I know if I am part of the settlement?

The Court decided that Class Members in the settlement include: *All individual persons or entities who paid for Lupron[®] from January 1, 1985 through March 31, 2005.*

Note: This includes all formulations of Lupron[®], including Lupron Depot[®].

6. Are there exceptions to being included?

Excluded from the class are several large insurers called “Settling Health Plans” who are settling separately (*See* Question 10), the Defendants, their respective present and former, direct and indirect, parents, subsidiaries, divisions, partners and affiliates; and the United States government, its officers, agents, agencies and departments, and all other government entities’ claims, to the extent that they previously released their claims pursuant to the 2001 [Settlement Agreement](#) and Release resolving the matter of *United States of America v. TAP Pharmaceutical Products Inc.* (D. Mass.) and related litigation.

7. How are consumers included?

Consumers, i.e., people who paid any amount for Lupron[®], including co-pays and deductibles, are included in the settlement. Lupron[®] is not the typical prescription drug that is “paid for” at a pharmacy. Instead, your doctor usually injects it—to treat prostate cancer in men, endometriosis and uterine fibroids in women, or precocious puberty in children—and includes a charge for it on your bill. You may have paid for a portion of the cost of Lupron[®] if your insurance company did not pay your doctor his/her full charge for Lupron[®] (e.g. you paid a “copay”). If you have no insurance, or your insurance does not cover Lupron[®], you may have paid more.

8. Which entities are included?

Entities, also known as “third party payors,” could include health insurers (other than the Settling Health Plans) that paid part or all of the cost of Lupron[®] for their insured patients. Entities may also include employee welfare benefit plans, governmental plans or union plans that paid some portion of the cost of Lupron[®] for insureds, employees or family members of employees insured under these plans.

9. What if I’m not sure whether I’m included in the settlement?

If you are not sure whether you or your company is included in the Class, you may call the toll-free number 1-866-410-7650 with questions. You may also write with questions to Lupron Settlement Administrator, P.O. Box 24604, West Palm Beach, FL 33416.

THE SETTLEMENT BENEFITS—WHAT YOU GET

10. What does the settlement provide?

Up to \$150 million will be paid by TAP, on behalf of all the Defendants. After allocating \$55 million to a separate settlement with the Settling Health Plans, a \$95 million fund will be set up for the Class Members in this settlement. After deducting certain amounts, including attorneys’ fees, expenses, and payments to Class Representatives (*See* Question 20), the net fund will be distributed in cash to consumers who submit valid claim forms, as well as to third party payors. Consumers will receive up to 42.1% of the net fund, and up to 57.9% will go to third party payors. The amount of money for third party payors may be reduced if the Settling Health Plans show that their claims entitle them to more than the \$55 million currently allocated to them.

If you are a third party payor and want to get out of the settlement (*See* the section called “Excluding Yourself From the Settlement” below), the third party payor settlement fund will be reduced by the amount of money you could have received if you had filed a valid claim. More details are available in the [Settlement Agreement](#) at www.lupronclaims.com.

11. How much will my payment be?

Your share of the settlement fund will be based on how much Lupron[®] you paid for and on how many Class Members file valid claims. Consumers will get \$100 each or 30% of their Lupron[®] purchases from January 1, 1985 through March 31, 2005, whichever is greater. If the amount of claims received is too great to allow payment of either of these amounts, consumers will get a *pro rata* share (based on what each consumer paid in proportion to what all consumers paid). Third party payors’ payments will be *pro rata*, based on how much Lupron[®] third party payors paid for, and the January 1, 2000 through December 31, 2001 time period will be used to determine each *pro rata* share.

The Defendants will not be involved in deciding how much money you may receive.

12. What am I giving up as part of the settlement?

If the settlement becomes final, consumer and third party payor Class Members will be releasing the Defendants and other people and entities for all the claims described and identified in paragraphs 2(y) and 18 of the [Settlement Agreement](#). The Settlement Agreement is available at www.lupronclaims.com. The Settlement Agreement describes the released claims with specific descriptions, in necessarily accurate legal terminology, so read it carefully. The release does not cover any legal claims about the safety or effectiveness of Lupron[®]. Even if you registered with, or excluded yourself from, a different Lupron[®] lawsuit about similar claims, you'll be giving up rights described in [this](#) Settlement Agreement.

HOW DO YOU GET A PAYMENT—SUBMITTING A CLAIM FORM

13. How can I get a payment?

To ask for a payment, you must complete and submit a [claim form](#). You can get a claim form at www.lupronclaims.com or by calling the Settlement Administrator at 1-866-410-7650 or writing to the address below. If you are a consumer Class Member you need to include the dates you used Lupron[®] and send proof that you paid for Lupron[®] sometime from January 1, 1985 through March 31, 2005 (only one proof of purchase is required), and any amount paid during that period. Proof may be in the form of: 1) a written prescription for Lupron[®], 2) a receipt, cancelled check, or credit card statement that shows that you paid for Lupron[®], 3) an EOB (explanation of benefits) that shows you made a co-pay for Lupron[®], 4) a letter from your doctor saying he or she prescribed and that you paid part of the cost of Lupron[®] at least once, including the amount paid or 5) a notarized statement saying you paid a co-pay or cash payment for Lupron[®] from January 1, 1985 through March 31, 2005 and noting the total out-of-pocket payments you made during that time. Third party payors need to provide all of the information required on the [claim form](#), including the amount paid for Lupron[®] from January 1, 2000 through December 31, 2001. On third party payors' claims for purchases over \$300,000, more information must be provided.

[Claim forms](#) must be postmarked by **May 15, 2005**, and mailed to:

Lupron Settlement Administrator
P.O. Box 24604
West Palm Beach, FL 33416

QUESTIONS? CALL 1-866-410-7650 TOLL FREE, OR VISIT WWW.LUPRONCLAIMS.COM

14. When would I get my payment?

Payments will be mailed to Class Members after the Court grants “final approval” of the settlement and any appeals are resolved. Send in your [claim form](#) postmarked by **May 15, 2005**. The Court is scheduled to consider final approval at a hearing on **April 13, 2005** (See section called “The Court’s Fairness Hearing” below).

EXCLUDING YOURSELF FROM THE SETTLEMENT

If you don’t want a payment from this settlement, but you want to keep the right to sue or continue to sue Defendants over the legal issues in this case, then you must take steps to get out. This is called asking to be excluded from—or sometimes called “opting out” of—the Class. The deadline for exclusions to be received is **April 1, 2005**.

15. If I exclude myself, can I get money from this settlement?

No. If you exclude yourself, you cannot get money from this settlement, and should not send in a claim form to request a payment. If you ask to be excluded, you will not get any settlement payment, and you cannot object to the settlement. But you may sue, continue to sue, or be part of a different lawsuit against Defendants in the future. You will not be bound by anything that happens in this lawsuit or settlement. If a third party payor excludes itself, the share of the money it could have received if it had stayed in will be removed from the \$55 million set aside for third party payors and given back to TAP.

16. What about the other cases involving Lupron®?

You may have received or seen other notices about other class actions about the cost of Lupron[®], including a national case in a North Carolina court, *Stetser v. TAP Pharmaceutical Products, Inc.*, and a statewide case in a New Jersey court, *Walker v. TAP Pharmaceutical Products, Inc.* If you registered with, or if you excluded yourself from, one of those or other cases, you need to exclude yourself from [this](#) case if you want to sue, continue to sue, or be part of a different lawsuit against the Defendants about the cost of Lupron[®] or any other legal issues in this case, ever again. The courts overseeing those cases may dismiss those cases, but they may not, so check with your lawyer about how this case will affect your rights.

17. If I don’t exclude myself, can I sue later?

No. Unless you exclude yourself, you give up the right to sue the Defendants for all the claims that this settlement resolves. You must exclude yourself from this Class to start or continue your own lawsuit, or to be part of any different lawsuit relating to these claims.

18. How do I get out of the settlement?

If you wish to be excluded from the settlement you must, in writing, state that you want to be excluded from *In re Lupron*[®] *Marketing and Sales Practices Litigation*, provide the time period (month/year to month/year) during which you paid for Lupron[®], include your name, address, taxpayer identification number, telephone number, fax number (if any), and your signature.

Third party payor Class Members must include the total amounts paid for Lupron[®] from January 1, 2000 through December 31, 2001. If you are submitting an exclusion request on behalf of a third party payor Class Member, you must also provide a signed certification with the following wording, indicating that the Class Member has given you the authority to submit the exclusion:

“The undersigned individual hereby represents that he/she has authority to sign and submit this notice of exclusion on behalf of the above-named class member. The undersigned also certifies that he/she has not received any advice from the parties to this litigation or their attorneys concerning his/her or the class member’s fiduciary obligations under the Employee Retirement Income Security Act of 1974, 29 U.S.C. § 1100, et seq., or other laws governing their obligations to any class member. The undersigned understands that by submitting this notice of exclusion, the class member identified above will not be entitled to receive any proceeds of the Class Settlement Fund. By affixing my signature below, I certify under penalty of perjury that the foregoing is true and correct. 28 U.S.C. § 1746.”

Any exclusion requests must be received on or before **April 1, 2005** at this address:

Lupron Settlement Administrator
P.O. Box 24604
West Palm Beach, FL 33416

THE LAWYERS REPRESENTING YOU

19. Do I have a lawyer in the case?

The Court has appointed the law firms of Cohen, Milstein, Hausfeld, & Toll, P.L.L.C., of Washington, DC; Foote Meyers Mielke & Flowers, of Geneva, IL; Hagens Berman LLP, of Cambridge, MA; Lieff Cabraser Heimann & Bernstein, LLP, of San Francisco, CA; and Spector Roseman & Kodroff, of Philadelphia, PA to represent you and other Class Members as “Class Counsel.” You will not be charged for these lawyers. If you want to be represented by your own lawyer, you may hire one, at your own cost.

20. How will the lawyers be paid?

Class Counsel will ask the Court for attorneys' fees not to exceed 30% of the \$95 million settlement fund (after deducting any amount that TAP gets back from any third party payor exclusions—*See* Question 15) plus reimbursement of their expenses. The Defendants have agreed not to oppose these fees and a request for reasonable expenses. Class Counsel will also ask for a payment for the Class Representatives, who helped the lawyers on behalf of the whole Class. The Court may award less than these amounts to Class Counsel or to the Class Representatives.

OBJECTING TO THE SETTLEMENT

You can tell the Court that you don't agree with the settlement or some part of it.

21. How do I tell the Court if I don't like the settlement?

If you are a Class Member and you do not exclude yourself, you can object to the settlement if you don't like any part of it. If you decide to object to the settlement you should give reasons why you think the Court should not approve it. The Court will consider your views. To object, you must do so in writing. Be sure to include your name, address, telephone number, your signature, and the reasons why you object to the settlement, and any documentation supporting your objection. Send the objection to these three different places postmarked no later than **March 15, 2005**:

COURT	CLASS COUNSEL	DEFENSE COUNSEL
Clerk of Court John Joseph Moakley U. S. Courthouse 1 Courthouse Way Boston, MA 02210	Edward Notargiacomo Hagens Berman, LLP 225 Franklin Street, 26th Floor Boston, MA 02110	Jason G. Winchester Jones Day 77 West Wacker, Suite 3500 Chicago, Illinois 60601-1692

22. What's the difference between objecting and excluding?

Objecting is simply telling the Court that you don't like something about the settlement. You can object only if you stay in the Class. Excluding yourself is telling the Court that you don't want to be part of the Class. If you exclude yourself, you cannot object to the settlement or to the attorneys' fees because the case no longer affects you, and you will not receive any settlement payment.

THE COURT'S FAIRNESS HEARING

The Court will hold a hearing to decide whether to approve the settlement. You may attend, but you don't have to. You may also ask to speak at the hearing.

23. When and where will the Court decide whether to approve the settlement?

The Court will hold a Fairness Hearing at 2:30 p.m. on Wednesday, **April 13, 2005** at the United States District Court for the District of Massachusetts, Court Room No. 21, 1 Courthouse Way, Boston, MA. At this hearing the Court will consider whether the settlement is fair, reasonable, and adequate. The Court will consider whether to approve the settlement and the request for attorneys' fees, expenses, and awards for Class Representatives and others. If there are objections, the Court will consider them. The hearing may be moved to a different date without additional notice, so it is a good idea to check www.lupronclaims.com for updated information.

24. Do I have to come to the hearing?

No. Class Counsel will answer any questions the Court may have. But you are welcome to attend the hearing at your own expense. If you send a written objection, you don't have to come to Court to talk about it. As long as you mailed your written objection on time, the Court will consider it. You may also pay your own lawyer to attend, but it is not necessary.

25. May I speak at the hearing?

To speak at the Fairness Hearing, you must send a letter or other written document saying that the letter or document is your "Notice of Intention to Appear" in *In re Lupron[®] Marketing and Sales Practices Litigation*, No. 00-CV-10861-RGS, MDL 1430. Be sure to include your name, address, telephone number, and your signature. You must also include the information on what you intend to say at the hearing. You must send your "Notice of Intention to Appear" to the three addresses listed in Question 21 above. It must be postmarked no later than **March 15, 2005**. The Court will decide if you will be allowed to speak at the hearing.

IF YOU DO NOTHING

26. What happens if I do nothing at all?

If you do nothing, you will not get any payment from this settlement. And, unless you exclude yourself from this Class, you will not be able to start a lawsuit, continue with a lawsuit, or be part of any other lawsuit, including any other class action lawsuit, against the Defendants about the cost of Lupron® or any other legal issues in this case.

GETTING MORE INFORMATION

27. How do I get more information?

This notice summarizes the proposed settlement. You can get a copy of the [Settlement Agreement](#) at www.lupronclaims.com. You may also write with questions to Lupron Settlement Administrator, P.O. Box 24604, West Palm Beach, FL 33416. You can get a [claim form](#) at the website or by calling the toll free number below.