

2nd Civil No. B170828
(LASC Case No. BS 083758)

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA
SECOND APPELLATE DISTRICT
DIVISION EIGHT

SERONO, INC., a Massachusetts corporation,

Appellant,

vs.

**DEPARTMENT OF HEALTH SERVICES, a public agency, DIANE
M. BONTÁ, in her official capacity as Director of the Department of
Health Services,**

Respondent.

ON APPEAL FROM THE SUPERIOR COURT,
COUNTY OF LOS ANGELES
HONORABLE DAVID P. YAFFE, JUDGE

***AMICUS CURIAE* BRIEF OF JOSEPH PALESKI
IN SUPPORT OF APPELLANT**

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I. Introduction

It is undisputed that before “delisting” a drug from the Medi-Cal List of Contract Drugs (the “List”), the Respondent, California Department of Health Services’ (“CDHS”), must comply with certain statutorily required notice and hearing procedures. This appeal concerns whether CDHS’ implementation of a 100% prior authorization requirement for Serostim® is tantamount to a delisting of Serostim®, thus triggering the requirement for notice and hearing procedures.

CDHS’s implementation of a 100% prior authorization requirement for Serostim® has indeed effectively removed Serostim® from the Medi-Cal List of Contract Drugs. There is absolutely no difference -- and CDHS has articulated no plausible difference -- between a drug like Serostim®, which is on the List (in name only) with a 100% prior authorization requirement, and a drug that is not on the List at all.

Because CDHS has removed Serostim® from the List, this Court should reverse the Superior Court and require CDHS to comply with the statutory notice and hearing procedures required prior to delisting.

II. Parties Other Than Serono, Inc. Are Concerned By the Outcome of This Appeal.

CDHS claims that Appellant Serono, Inc. is the only party with an interest in the outcome of this case. (Respondent Brief at 4.) But this is false.

Mr. Paleski and thousands of similarly situated Medi-Cal beneficiaries across California are substantially affected by this appeal. *First*, Mr. Paleski has been subject to and has been adversely affected by the very prior authorization requirements that are the subject of this appeal. *Second*, Mr. Paleski has a pending lawsuit in Los Angeles Superior Court, challenging those same prior authorization requirements. *Third*, as a beneficiary of Medi-Cal, Mr. Paleski is interested in protecting his due process rights by ensuring that medically necessary drugs are not delisted without the requisite statutory notice and hearing.

A. Mr. Paleski Needs Access to Serostim®.

Mr. Paleski is a resident of West Hollywood, California, and a beneficiary of the Medi-Cal program. Mr. Paleski suffers from multiple chronic, severe life-threatening conditions, including AIDS and AIDS related wasting. For his wasting symptoms, Mr. Paleski's physician has prescribed the drug Serostim®. Serostim® has effectively treated Mr. Paleski's condition in the past, providing relief from debilitating symptoms and slowing and/or reversing the effects of wasting. In the case of Mr. Paleski, Serostim® has greatly improved his quality of life and is necessary to sustain his health and his life.

Nevertheless, since about Summer 2003, CDHS has repeatedly denied treatment authorization requests ("TARs") submitted by Mr. Paleski

for Serostim®. By limiting access to Serostim®, DHS has put the health of Mr. Paleski and many others similarly situated at risk.

B. Mr. Paleski's Pending Lawsuit May Be Affected by this Appeal.

Not only is Mr. Paleski interested in this appeal as a Medi-Cal beneficiary for whom Serostim® treatment is medically necessary, but also Mr. Paleski is the petitioner/plaintiff in a pending suit in Los Angeles Superior Court that may be affected by the outcome of this appeal, *Paleski v. Department of Health Services*, No. BS088330 (filed Feb. 10, 2004) (trial June 20, 2005) (Yaffe, J.).

Mr. Paleski's suit charges that CDHS's procedures and criteria for authorizing Serostim® TARs under its prior authorization program are fatally inconsistent with controlling federal and state law. Mr. Paleski's suit alleges that CDHS's procedures and criteria are arbitrary and capricious, and have the effect of significantly -- and unlawfully -- reducing the ability of Mr. Paleski and other beneficiaries with AIDS wasting access to Serostim®, even in circumstances where such treatment is medically necessary.

C. Mr. Paleski's Due Process Rights May Be Affected by this Appeal.

The Superior Court's ruling in this case allowed Medi-Cal to circumvent the notice and hearing requirements required by law. The Court

has deprived Mr. Paleski and other recipients of Serostim® of their due process rights to be notified and heard before an adverse action is taken. If that ruling is allowed to stand, no recipient of CDHS services can be certain that they will be afforded due process before life-sustaining medications are removed from the List of contract drugs.

The primary mission of CDHS is to protect and improve the health of all Californians, and one of the paramount duties of those who administer Medi-Cal is to protect the public by ensuring access to medically necessary medication. The California Legislature created notice and public hearing requirements to ensure that Medi-Cal beneficiaries, and the rights of those affected by changes in the List of contract drugs, will be adequately protected. *See* Cal. Welf. & Inst. Code § 14105.38. The Superior Court's ruling allowed Medi-Cal to effectively delist Serostim® without complying with the mandated notice and hearing requirements. If allowed to stand, this ruling endangers not only Mr. Paleski, but all present and future Medi-Cal recipients who receive contract drugs.

III. A 100% Prior Authorization Requirement for Serostim® Is Tantamount to Delisting It.

The central issue in this appeal is whether CDHS's 100% prior authorization requirement for Serostim® is tantamount to delisting that drug within the meaning of Welfare & Institutions Code § 14105.38.

CDHS argues that its prior authorization requirement does not constitute such a delisting because “Serostim® continued to be on the Medi-Cal list, to maintain the need for access to an important drug.” (Respondent Brief at 4.)

But the fallaciousness of CDHS’s assertion exposes the duplicity in its position. Nowhere does CDHS plausibly articulate how Serostim®’s inclusion on the List (in name only) maintains access to it in any way greater than for a drug not on the List at all. The absence of such an explanation demonstrates that while Serostim® may remain on the List *in name*; CDHS has removed Serostim® from the List *in all force, significance, and effect*, by requiring 100% prior authorization.

CDHS argues that “there are distinct advantages to being on the List, even for those drugs on the List that require prior authorization.” (Respondent Brief at 39, 14.) However, CDHS has failed to identify any such advantages, leaving the distinction between Serostim® and a drug not on the List as non-existent. In fact, the three supposed advantages are false and non-existent. The only real advantage of being on the List is just the one that CDHS has removed: the absence of a 100% prior authorization requirement.

A. Serostim®’s Inclusion on the List Does Not Facilitate Providers’ Determinations that It Is Covered.

CDHS argues that because Serostim® is on the List, providers can readily ascertain that it is a drug that is covered by Medi-Cal. (Respondent Brief at 9.) This argument is belied by well known Medicaid law and standards because CDHS must already cover all FDA-approved prescription drugs. Accordingly, this “advantage” is no real advantage at all.

While CDHS need not include prescription drugs as a covered benefit within the Medi-Cal program, since it has chosen to cover FDA-approved prescription drugs, it must cover *all of them* – both those on and off the List. *See* 42 U.S.C. § 1396r-8(d)(4)(D).¹ Therefore, the provision of information about coverage cannot, as CDHS asserts, be any benefit of or advantage to being on the List, because that information is *already* known and understood by providers.

¹ *See also* H.R. Rep. No. 101-881, at 96-97 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2108-09; *Doe v. Chiles*, 136 F.3d 709 (11th Cir. 1998); Kaiser Commission on Medicaid and the Uninsured, *Model Prescription Drug Prior Authorization Process for State Medicaid Programs* 5 (April 2003); National Health Policy Forum, *Medicaid Prescription Drug Coverage: State Efforts to Control Costs* 3 (May 2003); Tim Westmoreland, *Medicaid & HIV/AIDS Policy: A Basic Primer* 41 (July 1999).

B. Serostim®’s Inclusion on the List Does Not Make TAR Approval Any Quicker or More Likely.

CDHS next argues that because Serostim® is on the List, “approval under the prior authorization program for Serostim® would be quicker and more likely” and “available to those who legitimately need it.” (Respondent Brief at 10, 40.) This argument is also illusory because federal law requires prior authorization for drugs on and off the List to be processed in the same period; and approval for Serostim® is actually *less* likely than for drugs not on the List.

Federal Medicaid law *already* requires Medi-Cal to turn-around TARs (including those for unlisted drugs) within 24 hours. *See* 42 U.S.C. § 1396r-8(d)(1)(A); Cal. Welf. & Inst. Code § 14133.37. So, being on the List adds nothing in terms of how “quickly” a TAR is reviewed. CDHS cannot be claiming that it is processing TARs for Serostim® any faster than 24 hours.

Furthermore, in the case of Serostim®, its inclusion on the List (in name only) has hardly made approval of TARs for the drug more likely. As Appellant argues, the TAR process for Serostim® has often resulted in deferrals and delays. (Appellant Brief at 15-18.) And even more seriously, CDHS’s TAR review for Serostim® often results in outright denials. While, 87% of TARs (for unlisted drugs) are approved upon initial

submission,² according to CDHS' own statistical records, during 2003, only 54% of Serostim® TARs were approved. 18% of Serostim® TARs were deferred and 27% were denied.³

Rather than making approval "quicker and more likely," Serostim®'s record demonstrates that its approvals are slower and less likely than drugs that are not on the List. CDHS's 100% prior authorization requirement has significantly curtailed indigent AIDS patients' access to Serostim®, and being on the List (in name only) fails to mitigate that decreased access.

C. Because it is on the List in Name Only, Serostim® Must Satisfy All the Medical Necessity Requirements.

Finally, CDHS argues that "because Serostim® is on the Medi-Cal List, it does not have to meet some of the specific medical necessity requirements in the regulation. . . . Assuming that the Department has determined that the patient has the appropriate condition, a prior authorization for Serostim®, because it is on the Medi-Cal List, should be approved." (Respondent Brief at 10.) But this argument is false because CDHS requires Serostim® to satisfy all medical necessity requirements.

² Kaiser Commission on Medicaid and the Uninsured, *Prior Authorization for Medicaid Prescription Drugs in Five States: Lessons for Policy Makers* 21 (April 2003).

³ Documents Bates-stamped CDHS- 000941-000966, produced by CDHS in *Paleski v. Department of Health Services*, LASC No. BS088330.

If a Medi-Cal patient has AIDS wasting, then Medi-Cal is already legally required to approve Serostim® -- *whether or not* it is on the List. *See Holmes v. Kizer*, 11 Cal. App. 4th 395 (1992). Furthermore, it is precisely at the level of what constitutes AIDS wasting that CDHS builds in its medical necessity requirements. While CDHS agrees to approve Serostim® for a beneficiary with AIDS wasting, it demands satisfaction of an exhaustive and medically arbitrary list of specific criteria to establish that the beneficiary has the condition.⁴ (*See, e.g.* Lee Decl. ¶¶ 7-13, Appendix at 542-43.) Notably, of the more than 1200 Serostim® TARs that CDHS has denied since 2003, *CDHS denied more than 900 for reasons related to the diagnosis of AIDS wasting.*⁵

IV. Conclusion

None of the alleged advantages by CDHS are real advantages. But this is to be expected. The essential and only genuine advantage to being on the List is the absence of prior authorization requirements. And it is just this advantage that CDHS has taken away.

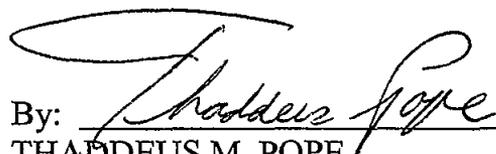
⁴ For example, the authorization criteria require beneficiaries' medical conditions to significantly deteriorate before authorizing treatment, consequently causing significant strain to the liver and kidneys from losing lean body weight, regaining it when Serostim® is approved, and losing it again when the Serostim® treatment is exhausted.

⁵ Defendants' Amended Responses to Plaintiff's Second Set of Special Interrogatories in *Paleski v. Department of Health Services* (Oct. 27, 2004) (Responses 10 & 11).

Because CDHS has effectively delisted Serostim® without complying with the statutorily-required delisting procedures, this Court should reverse the Superior Court's erroneous ruling and require CDHS to give notice and hold a public evidentiary hearing, as required by Medi-Cal law, before continuing to enforce a 100% prior authorization requirement for Serostim®.

Dated: February 4, 2005

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PROOF OF SERVICE

I am a resident of the State of California and am employed in the County of Los Angeles, State of California. I am over the age of 18 years and not a party to the within action. My business address is 777 South Figueroa Street, 44th Floor, Los Angeles, California 90017-5844.

On February 4, 2005, I served the foregoing document described as:

***AMICUS CURIAE BRIEF OF JOSEPH PALESKI
IN SUPPORT OF APPELLANT***

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- by placing the original and a true copy thereof enclosed in sealed envelope(s) addressed as follows: **SEE ATTACHED SERVICE LIST**
- BY MAIL** I placed such envelope with postage thereon prepaid in the United States Mail at 777 South Figueroa Street, 44th Floor, Los Angeles, California 90017-5844. Executed on February 4, 2005 at Los Angeles, California.
- BY PERSONAL SERVICE** I caused such envelope to be delivered by hand to the office of the addressee. Executed on _____ at Los Angeles, California.
- BY FACSIMILE** The above-referenced document (together with all exhibits and attachments thereto) was transmitted via facsimile transmission to the addressee(s) as indicated on the attached mailing list on the date thereof. The transmission was reported as completed and without error. Executed on _____ at Los Angeles, California.
- BY FEDERAL EXPRESS** I am readily familiar with Arnold & Porter LLP's business practices of collecting and processing items for pickup and next business day delivery by Federal Express. Under said practices, items to be delivered the next business day are either picked up by Federal Express or deposited in a box or other facility regularly maintained by Federal Express in the ordinary course of business on that same day with the cost thereof billed to Arnold & Porter LLP's account. I placed such sealed envelope for delivery by Federal Express to the offices of the addressee(s) as indicated on the attached mailing list on the date hereof following ordinary business practices. Executed on _____ at Los Angeles, California.
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- FEDERAL** I declare that I am employed in the office of a member of the bar of this court at whose direction the service was made.

Teri Beck

Signature

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