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Washington State
Court of Appeals
Division Two

October 26, 2021

IN THE COURT OF APPEALS OF THE STATE OF WASHINGTON

DIVISION II

SAREPTA THERAPEUTICS, INC., Appellant/Cross-Respondent v. STATE OF WASHINGTON, HEALTH CARE AUTHORITY, and MARYANNE LINDEBALD, in her official capacity as Director of Washington State Health Care Authority, Respondent/Cross-Appellant.	No. 54870-4-II PUBLISHED OPINION

LEE, C.J. — Sarepta Therapeutics, Inc., appeals the superior court's order denying its petition for judicial review under the Washington Administrative Procedure Act (APA), chapter 34.05 RCW, wherein Sarepta challenged the Washington Health Care Authority's (HCA) application of its prior authorization rules to Sarepta's drug, EXONDYS 51 (Exondys). The HCA cross-appeals the superior court's order denying its motion to dismiss Sarepta's petition for lack of standing. We hold that Sarepta lacks standing to file its petition for judicial review. Therefore, the superior court erred by denying the HCA's motion to dismiss. Accordingly, we reverse the superior court's order denying Sarepta's motion to dismiss for lack of standing and dismiss Sarepta's appeal.

FACTS

A. BACKGROUND—APPROVAL OF EXONDYS

Duchenne Muscular Dystrophy (DMD) is a "genetic disorder characterized by the progressive loss of skeletal muscle and degeneration." Clerk's Papers (CP) at 131. DMD primarily affects young boys. "The primary symptoms of [DMD] are caused by a lack of dystrophin in the muscle. Children with [DMD] lose the ability to walk independently and most become reliant on wheelchairs for mobility by the age of 13." CP at 131.

On September 19, 2016, the Food and Drug Administration (FDA) approved Sarepta's new drug application for Exondys pursuant to its accelerated approval regulations. Exondys is a drug that treats patients with specific mutations of DMD. "The provision of EXONDYS 51 has been shown to result in the production of truncated dystrophin, which hopes to have a positive effect on muscle degeneration [by] slowing or halting the progression of [DMD]." CP at 131 (boldface omitted). Only 13 percent of all DMD patients have the specific mutation which Exondys treats.

B. MEDICAID DRUG REBATE PROGRAM AND HCA'S PRIOR AUTHORIZATION REQUIREMENT

"Congress created the Medicaid program in 1965 by adding Title XIX to the Social Security Act." *Pharmaceutical Research & Mfrs. of America v. Walsh*, 538 U.S. 644, 650, 123 S. Ct. 1855, 155 L. Ed. 2d 889 (2003). However, before 1990, Medicaid did not specifically address outpatient prescription drug coverage. *Id*. at 651. Instead, the Secretary of the Health and Human Services would approve individual State plans regulating the coverage of outpatient prescription drugs as part of controlling Medicaid costs. *Id*. These individual state plans controlled the coverage of outpatient prescription drugs through the use of formularies excluding specific drugs from coverage or through prior authorization requirements. *Id*. at 651-52.

In 1990, Congress included the Medicaid Drug Rebate Program (MDRP) in the Omnibus Reconciliation Act of 1990. 42 U.S.C. § 1396r-8; *Walsh*, 538 U.S. at 652. Under the MDRP, drug manufacturers must enter into rebate agreements in order for their drugs to be eligible for coverage by Medicaid. 42 U.S.C. § 1396r-8(a)(1). Once a drug manufacturer enters into a rebate agreement with either the Secretary or a state, their drugs are considered "covered outpatient drugs" and are reimbursable under State Medicaid programs. 42 U.S.C. § 1396r-8(a)(1), (k)(2). Reimbursement for covered outpatient drugs is subject to various limitations. 42 U.S.C. § 1396r-8(d). Congress specifically included the use of formularies under certain circumstances and the use of prior authorization programs. 42 U.S.C. § 1396r-8(d)(1), (4), (5).

"A State may subject to prior authorization any covered outpatient drug." 42 U.S.C. § 1396r-8(d)(1)(A). 42 U.S.C. § 1396r-8(d)(5) provides:

> A State plan under this subchapter may require, as a condition of coverage or payment for a covered outpatient drug . . . the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6)) only if the system providing for such approval—
>
> (A) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and
>
> (B) except with respect to the drugs on the list referred to in paragraph (2), provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

The purpose of creating the MDRP was to reduce the cost of prescription drugs to the Medicaid program and to ensure that Medicaid recipients had access to a variety of prescription drug choices:

> The Committee believes that Medicaid, the means-tested entitlement program that purchases basic health care for the poor, should have the benefit of the same discounts on single source drugs that other large public and private purchasers enjoy. The Committee bill would therefore establish a rebate mechanism in order

> to give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser. Because the Committee is concerned that Medicaid beneficiaries have access to the same range of drugs that the private patients of their physicians enjoy, the Committee bill would require States that elect to offer prescription drugs to cover all of the products of any manufacturer that agrees to provide price rebates.

H.R. REP. NO. 101-881 at 96-97 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2108-09. The House Bill report states, "[T]he bill would not affect any authority States have under current law to impose prior authorization controls on prescription drugs." 1990 U.S.C.C.A.N. 2017, 2110. The report further explained,

> States that elect to offer prescription drug coverage under their Medicaid programs would be required to cover all of the drugs of any manufacturer entering into and complying with such an agreement with the Secretary. This requirement would take effect April 1, 1991. As under current law, States would have the option of imposing prior authorization requirements with respect to covered prescription drugs *in order to safeguard against unnecessary utilization and assure that payments are consistent with efficiency, economy, and quality of care*. However, the Committee does not intend that States establish or implement prior authorization controls that have the effect of preventing competent physicians from prescribing in accordance with their medical judgment. This would defeat the intent of the Committee bill in prohibiting States from excluding coverage of prescription drugs of manufacturers with agreements—i.e., *assuring access by Medical beneficiaries to prescription drugs where medically necessary*.

1990 U.S.C.C.A.N. 2017, 2110. "Congress effectively ratified the Secretary's practice of approving state plans containing prior authorization requirements when it created its rebate program." *Walsh*, 583 U.S. at 652.

The legislature has delegated the authority of administering Washington's Medicaid program to the HCA. RCW 74.09.530(1)(a). As a part of its administration, the HCA is required to "take any necessary actions to control costs without reducing the quality of care when reimbursing for or purchasing drugs." RCW 70.14.050(1). To further this purpose, the legislature

requires the HCA to establish "an evidence-based prescription drug program." RCW 70.14.050(1).

The HCA has implemented regulations in the Washington Administrative Code (WACs) establishing an evidence-based prior authorization program for health care services and equipment, including prescription drugs.[1] WAC 182-501-0165(3). Prior authorization determinations are based on findings of medical necessity. WAC 182-501-0165(3). Specifically, WAC 182-501-0165(3) provides that "[t]he [HCA] authorizes, on a case-by-case basis, [prescription drug requests] when [the HCA] determines the service or equipment is medically necessary as defined in WAC 182-500-[0]070." "Medically necessary" is defined as

> a term for describing requested service which is reasonably calculated to prevent, diagnose, correct, cure, alleviate or prevent worsening of conditions in the client that endanger life, or cause suffering or pain, or result in an illness or infirmity, or threaten to cause or aggravate a handicap, or cause physical deformity or malfunction. There is no other equally effective, more conservative or substantially less costly course of treatment available or suitable for the client requesting the service. For the purposes of this section, "course of treatment" may include mere observation or, where appropriate, no medical treatment at all.

WAC 182-500-0070 (medical necessity rule).

Medical necessity determinations are based on submitted medical evidence[2] and an evidence-based rating system. WAC 182-501-0165(3). The evidence-based rating system is

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[1] Prescription drugs are considered health care services. WAC 182-501-0050 ("For the purposes of this section, health care services includes treatment, equipment, related supplies, and drugs.").

[2] The HCA considers the following medical evidence:

> (4) The agency reviews available evidence relevant to a medical, dental, or behavioral health service or equipment to:
> (a) Determine its efficacy, effectiveness, and safety;
> (b) Determine its impact on health outcomes;

codified under WAC 182-501-0165(6) (hierarchy of evidence rule). Under the hierarchy of evidence rule, "[t]he [HCA] uses a hierarchy of evidence to determine the weight given to available data." WAC 182-501-0165(6)(a). And "[b]ased on the quality of available evidence, the [HCA] determines if the requested service is effective and safe for the client by classifying it as an **'A,' 'B,' 'C,'** or **'D'** level of evidence." WAC 182-501-0165(6)(b).

An "A" level classification "[s]hows the requested service or equipment is a proven benefit to the client's condition." WAC 182-501-0165(6)(b)(i). A "B" level classification "[s]hows the requested service or equipment has some proven benefit." WAC 182-501-0165(6)(b)(ii). A "C" level classification "[s]hows only weak and inconclusive evidence regarding safety, or efficacy, or both." WAC 182-501-0165(6)(b)(iii). And a "D" level classification "[i]s not supported by any

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> (c) Identify indications for use;
> (d) Evaluate pertinent client information;
> (e) Compare to alternative technologies; and
> (f) Identify sources of credible evidence that use and report evidence-based information.
>
> (5) The agency considers and evaluates all available clinical information and credible evidence relevant to the client's condition. The provider responsible for the client's diagnosis, or treatment, or both, must submit with the request credible evidence specifically related to the client's condition including, but not limited to:
>
> (a) A physiological description of the client's disease, injury, impairment, or other ailment;
> (b) Pertinent laboratory findings;
> (c) Pertinent X-ray and/or imaging reports;
> (d) Individual patient records pertinent to the case or request;
> (e) Photographs, or videos, or both, if requested; and
> (f) Objective medical/dental/behavioral health information such as medically/dentally acceptable clinical findings and diagnoses resulting from physical or behavioral health examinations.

WAC 182-501-0165(4), (5).

evidence regarding its safety and efficacy, for example that which is considered investigational or experimental." WAC 182-501-0165(6)(b)(iv). Based on the evidence classification, the agency:

> (i) Approves **"A"** and **"B"** rated requests if the service or equipment:
> (A) Does not place the client at a greater risk of mortality or morbidity than an equally effective alternative treatment; and
> (B) Is not more costly than an equally effective alternative treatment.
> (ii) Approves a **"C"** rated request only if the provider shows the requested service is the optimal intervention for meeting the client's specific condition or treatment needs, and:
> (A) Does not place the client at a greater risk of mortality or morbidity than an equally effective alternative treatment;
> (B) Is less costly to the agency than an equally effective alternative treatment; and
> (C) Is the next reasonable step for the client in a well-documented tried-and-failed attempt at evidence-based care.
> (iii) Denies **"D"** rated requests unless:
> (A) The requested service or equipment has a humanitarian device exemption from the [FDA]; or
> (B) There is a local institutional review board (IRB) protocol addressing issues of efficacy and safety of the requested service that satisfies both the agency and the requesting provider.

WAC 182-501-0165(6)(c).

C. HCA'S MEDICAL NECESSITY DETERMINATIONS FOR EXONDYS

In May and June 2019, the HCA received requests for prior authorization for Exondys from three Medicaid patients with DMD. In June 2019, the HCA denied each of the requests for prior authorization because it determined that Exondys was not medically necessary for the three patients. The HCA concluded that Exondys had a level "D" evidence rating and that "[g]iven the lack of effectiveness noted in the FDA label, the low quality of the clinical trials, an unchanged trajectory of change for the 6MWT, and continued significant functional decline in multiple functional domains, the best available evidence does not support the efficacy of and therefore medical necessity of [Exondys]." CP at 147. In other words, because each of the three Medicaid

patients failed to show clinical responsiveness to Exondys, and because they continued to decline while taking the drug, the HCA concluded that Exondys was not medically necessary.

On August 27, 2019, the HCA amended its earlier denial letters by changing the evidence rating of Exondys to "C." The HCA also explained that the denials were based on each patient's failure to show clinical responsiveness to Exondys.

In October 2019, the Medicaid patients' treating physician requested a peer-to-peer consultation with the HCA's medical officer who made the initial medical necessity determinations. The treating physician provided new information demonstrating that the Medicaid patients were obtaining minor therapeutic benefits from using Exondys. Based on this information, the HCA's medical officer determined that Exondys was medically necessary for the three patients and provided instructions to the HCA to approve the requests for prior authorization.

D. PROCEDURAL HISTORY

On July 12, 2019, Sarepta filed a petition for judicial review under the APA. Specifically, Sarepta sought declaratory judgment invalidating the HCA's hierarchy of evidence rule as it applies to reimbursement for Exondys.[3] Later, Sarepta amended the petition to also include a challenge to the validity of the medical necessity rule.

The HCA filed a motion to dismiss Sarepta's petition for judicial review, arguing that Sarepta lacked standing under the APA. The superior court denied the HCA's motion to dismiss for lack of standing. The superior court also denied Sarepta's petition for judicial review on the merits.

[3] RCW 34.05.570(2)(a) provides, "A rule may be reviewed by petition for declaratory judgment filed pursuant to this subsection."

Sarepta appeals and the HCA cross-appeals.

ANALYSIS

The HCA cross-appeals the superior court's order on the amended petition,[4] arguing that the superior court erred by denying the HCA's motion to dismiss because Sarepta lacked standing to bring its petition for judicial review under the APA. We agree.

A. LEGAL PRINCIPLES

We review standing de novo. *Center for Biological Diversity v. Dep't of Fish & Wildlife*, 14 Wn. App. 2d 945, 981, 474 P.3d 1107 (2020). The petitioner bears the burden of establishing standing. *KS Tacoma Holdings, LLC v. Shorelines Hr'gs Bd.*, 166 Wn. App. 117, 127, 272 P.3d 876, *review denied*, 174 Wn.2d 1007 (2012).

Judicial review of an agency action is governed by the APA. *Patterson v. Segale*, 171 Wn. App. 251, 257-58, 289 P.3d 657 (2012). A party has standing to obtain judicial review of an agency action if that person is aggrieved or adversely affected by the agency action. RCW 34.05.530. A party is aggrieved or adversely affected when three conditions are present:

> (1) The agency action has prejudiced or is likely to prejudice that person;
> (2) That person's asserted interests are among those that the agency was required to consider when it engaged in the agency action challenged; and
> (3) A judgment in favor of that person would substantially eliminate or redress the prejudice to that person caused or likely to be caused by the agency action.

[4] The HCA's cross-appeal alleges that the superior court erred by denying its motion to dismiss of lack of standing. Because standing is required for a party to obtain judicial review under the APA, we address the HCA's cross-appeal before Sarepta's appeal on the merits of the petition. *See* RCW 34.05.530.

RCW 34.05.530(1)-(3).[5] All three requirements must be established for a person to have standing. *Allan v. Univ. of Wash.*, 140 Wn.2d 323, 326-27, 997 P.2d 360 (2000).

The first and third requirements of this standing test are collectively referred to as the "'injury-in-fact' test." *Patterson*, 171 Wn. App. at 258 (quoting *Allan*, 140 Wn.2d at 327). Under the "injury-in-fact" test, the petitioner must show that the agency decision caused some specific and perceptible harm. *Freedom Found. v. Bethel School Dist.*, 14 Wn. App. 2d 75, 86, 469 P.3d 364 (2020), *review denied*, 196 Wn.2d 1033 (2021). In other words, there must be an invasion of a legally protected interest. *Snohomish County Pub. Transp. Benefit Area v. Pub. Emp't Relations Comm'n*, 173 Wn. App. 504, 513, 294 P.3d 803 (2013).

Where "a party alleges a threatened injury, 'as opposed to an existing injury,' the party must prove that the threatened injury is 'immediate, concrete, and specific'" in order to have standing under the APA. *City of Burlington v. Liquor Control Bd*., 187 Wn. App. 853, 869, 351 P.3d 875, *review denied*, 184 Wn.2d 1014 (2015) (quoting *Trepanier v. City of Everett*, 64 Wn. App. 380, 383, 824 P.2d 524 (1992)). "Conjectural or hypothetical injuries are insufficient to confer standing." *Freedom Found.*, 14 Wn. App. 2d at 86. Finally, the petitioner must show that

[5] In addition to the standing requirements under RCW 34.05.530, RCW 34.05.570(2)(b)(i) requires a person challenging an agency rule to show that the rule or its threatened application "interferes with or impairs or immediately threatens to interfere with or impair the legal rights or privileges of the petitioner." Furthermore, challenges to agency rules are brought through a declaratory judgment action. RCW 34.05.570(2)(a). A justiciable controversy is required to bring a declaratory judgment action. *To-Ro Trade Shows v. Collins*, 144 Wn.2d 403, 410-11, 27 P.3d 1149 (2001), *cert. denied*, 535 U.S. 931 (2002). A justiciable controversy requires (1) an actual, present, and existing dispute, (2) between parties with opposing interests, (3) involving direct and substantial interests, and (4) for which a judicial determination will be final and conclusive. *Id.* at 411. Neither party argues these additional standards should apply or that they would compel a different result. And under any of the applicable standards, Sarepta has failed to establish standing to bring this action challenging the HCA's rules.

a favorable decision will likely—not merely speculatively—redress the injury. *Patterson*, 171 Wn. App. at 259.

The second requirement is referred to as the "zone of interests" test. *Allan*, 140 Wn.2d at 327. "The zone of interest test limits judicial review of an agency action to litigants with a viable interest at stake, rather than individuals with only an attenuated interest in the agency action." *City of Burlington*, 187 Wn. App. at 862. In order to satisfy the "zone of interests" test, the party seeking standing must demonstrate that "the Legislature intended the agency to protect the party's interests when taking the action at issue." *St. Joseph Hosp. and Health Care Ctr. v. Dep't of Health*, 125 Wn.2d 733, 739-40, 887 P.2d 891 (1995); *City of Burlington*, 187 Wn. App. at 863.

B. SAREPTA'S STANDING—ZONE OF INTERESTS

The HCA argues that Sarepta fails to establish standing because Sarepta has not met its burden to show that the zone of interests test is satisfied. Specifically, the HCA contends that the legislature did not intend to protect a drug manufacturer's financial interests in establishing the administration of Washington's Medicaid program. Sarepta argues that because it has entered a Medicaid Drug Rebate Agreement under the MDRP, its interest in having its drugs reimbursed by the HCA is established under the terms of the MDRP. We agree with the HCA.

As an initial matter, the Washington legislature clearly did not intend to protect the interests of drug manufacturers when it directed the HCA to establish an evidence-based prescription drug program under RCW 70.14.050. The legislature directed the HCA to "take any necessary actions to control costs without reducing the quality of care when reimbursing for or purchasing drugs." RCW 70.14.050(1). Based on the plain language of the statute, the legislature's intent was for the HCA to balance controlling costs with ensuring quality of care. The legislature did not intend for

the HCA to protect Sarepta's financial interests when making rules to administer the prescription drug program. Therefore, Sarepta has failed to satisfy the zone of interests test under the Washington statutes. *See St. Joseph Hosp.*, 125 Wn.2d at 739-40.

However, Sarepta argues that its standing derives from the MDRP, not the Washington statutes. Sarepta contends that the MDRP guarantees coverage when a drug manufacturer enters into a rebate agreement under the terms of the MDRP. Because the HCA is responsible for ensuring the state Medicaid program complies with federal Medicaid requirements, Sarepta asserts that the HCA was required to protect Sarepta's interests under the MDRP when administering its prescription drug program.

Sarepta misinterprets the effect of an agreement under the MDRP and conflates coverage of drugs with reimbursement of drugs. And Sarepta's argument fails to acknowledge Congress's legislative intent when establishing the MDRP. Sarepta's financial interests are no more protected under the MDRP than they are under RCW 70.14.050. Because Congress did not intend for prescription drug programs to protect the financial interests of drug manufacturers, Sarepta is not within the zone of interests protected by the MDRP.

First, Sarepta's argument fails to acknowledge Congress's legislative intent when establishing the MDRP. The text of the MDRP does not contain an explicit statement of purpose or intent like that contained in RCW 70.14.050. Therefore, the plain language of the statute is ambiguous in establishing Congress's intent in passing the legislation. However, the legislative history is not ambiguous. The house bill report clearly shows that Congress's intent in establishing the MDRP was to control Medicaid costs by reducing the costs of prescription drugs. 1990 U.S.C.C.A.N. 2017, 2108 ("The Committee believes that Medicaid, the means-tested entitlement

program that purchases basic health care for the poor, should have the benefit of the same discounts on single source drugs that other large public and private purchasers enjoy."). Congress further intended to ensure Medicaid patients have access to the same range of drugs as patients that do not require Medicaid. 1990 U.S.C.C.A.N. 2017, 2108-09. The legislative history of the MDRP does not establish Congress's intent to protect the drug manufacturer's financial interests when establishing the MDRP.

Second, despite Congressional intent, Sarepta argues that agreements under the MDRP entitle Sarepta to reimbursement for its drugs, which creates a protected interest for drug companies who have agreements under the MDRP. Sarepta's argument conflates the concepts of coverage and reimbursement under the MDRP. Furthermore, Sarepta's argument misrepresents the effect of a rebate agreement under the MDRP.

Sarepta's argument is that because state prescription drug programs are required to *cover* all of a drug manufacturer's prescription drugs, the state prescription drug program is required to *pay* for all covered drugs prescribed for its intended use. This is an incorrect reading of the MDRP.

The MDRP does not specifically define the meaning of "covered" and the definition of a "covered outpatient drug" does not contain any language related to reimbursement or payment for a drug. *See* 42 U.S.C. § 1396r-8(k)(2). However, reading the MDRP as a whole shows there is a difference between coverage of a drug and reimbursement/payment for a drug. For example, 42 U.S.C. § 1396 r-8(d)(5) references prior authorization as a condition of "coverage or payment," indicating that there is a difference between coverage of a drug and payment for a drug. Sections of the MDRP also reference "upper payment limits" and "maximum allowable cost limitation" established by State programs, implying that there is a point at which the State would not be

required to pay for covered drugs. *See* 42 U.S.C. § 1396r-8(e)(3) ("This section shall not supersede or affect provisions . . . relating to any maximum allowable cost limitation established by a State for payment by the State for covered outpatient drugs, and rebates shall be made under this section without regard to whether or not payment by the State for such drugs is subject to such a limitation or the amount of such a limitation."); *see also* 42 U.S.C. § 1396r-8(e)(4), (e)(5).

The language of the MDRP does not establish that coverage for prescription drugs requires payment for prescription drugs. The MDRP only establishes that the covered prescription drugs are *eligible* for reimbursement or payment under Medicaid programs. Therefore, Sarepta has incorrectly interpreted the MDRP to guarantee payment for prescription drugs; the MDRP only allows coverage for prescription drugs.

Third, Sarepta argues that its agreement under the MDRP creates an interest that must be protected because drug manufacturers agree to provide rebates in exchange for a guarantee that that State Medicaid programs cover their drugs. As explained above, coverage is not the same as payment. And rebate agreements under the MDRP are not the equivalent of negotiated contracts as Sarepta implies. Rebate agreements under the MDRP are a mandatory prerequisite for prescription drugs to be eligible for Medicaid coverage. 42 U.S.C. § 1396r-8(a)(1). In other words, to the extent that a rebate agreement is akin to a contract, drug manufacturers enter into rebate agreements in exchange for their drugs being eligible for Medicaid coverage, not to guarantee payment for their drugs.

Because the MDRP only makes the drugs covered and does not guarantee drug manufacturers payment for their drugs under Medicaid, the MDRP does not establish that Sarepta has an interest that the HCA was required to protect when it established rules for the administration

of its Medicaid prescription drug program. Therefore, Sarepta has failed to establish that the MDRP places Sarepta's financial interests within the zone of interests required to be considered by the HCA.

Sarepta's MDRP agreement does not establish standing to petition for judicial review under the APA. Therefore, Sarepta has failed to establish standing under the APA to bring its petition for judicial review of the HCA's application of its hierarchy of evidence rule in determining reimbursement for Exondys.

CONCLUSION

Sarepta does not have standing to petition for judicial review of HCA's prior authorization rules under the APA because Sarepta has failed to satisfy the zone of interests requirement. Therefore, the superior court erred by denying the HCA's motion to dismiss for lack of standing. Accordingly, we reverse the superior court's order denying the HCA's motion to dismiss for lack of standing and dismiss Sarepta's appeal.

Lee, C.J.

We concur:

Maxa, J.

Cruser, J.