

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

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UNITED STATES OF AMERICA	)	
EX REL. PETER ROST,	)	
	)	
Plaintiffs,	)	Docket Number: 1:03-CV-11084-PBS
	)	
-v.-	)	The Honorable Patti B. Saris
	)	
PFIZER INC AND	)	
PHARMACIA CORPORATION,	)	
	)	
Defendants.	)	
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**REPLY MEMORANDUM IN SUPPORT OF REQUEST FOR JUDICIAL NOTICE**

Relator opposes defendants' request for judicial notice, claiming that judicial notice of the contents of the DRUGDEX compendium is improper because there are disputes about this compendium. In fact, the only relevant disputes between the parties involve questions of law, not questions of fact. Rost does not contend that the DRUGDEX excerpts provided with Pfizer's opening memorandum misstate the contents of DRUGDEX. Instead, the parties dispute the legal effect to be given to the statements contained in DRUGDEX. But Rost offers no reason why the Court cannot take judicial notice of statements that appear in DRUGDEX simply because the parties disagree on how the Medicaid statute applies to those undisputed facts.

A district court in this Circuit has taken judicial notice of DRUGDEX excerpts in a similar case. *See United States ex rel. McDermott v. Genentech, Inc.*, No. 05-147, 2006 WL 3741920, \*13 n.8 (D. Me. Dec. 14, 2006). As in this case, the relator argued that he had alleged

false claims by identifying reimbursement claims for “off-label” uses of a prescription drug. *Id.*

\*13. In moving to dismiss the complaint, Genentech included excerpts from DRUGDEX to show that these “off-label” uses were supported by this compendium, and that the reimbursements were therefore not false claims. *Id.* Like the court in *McDermott*, this Court should take judicial notice of the DRUGDEX excerpts.

### ARGUMENT

#### **I. THE COURT SHOULD TAKE JUDICIAL NOTICE OF THE “SHORT STATURE” DISCUSSION OF SOMATROPIN IN DRUGDEX.**

Federal Rule of Evidence 201(b)(2) provides that “[a] judicially noticed fact must be one not subject to reasonable dispute in that it is . . . capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned.” Fed. R. Evid. 201(b)(2). This rule further provides that judicial notice is *mandatory* “if requested by a party and [the court is] supplied with the necessary information.” Fed. R. Evid. 201(d). Because these requirements are met in this case, the Court should take judicial notice of the DRUGDEX excerpts submitted in support of the motion to dismiss.

#### **A. THE CONTENTS OF DRUGDEX ARE NOT SUBJECT TO REASONABLE DISPUTE.**

Rost argues that judicial notice of DRUGDEX is improper because “[c]ourts are barred from taking judicial notice of disputed matters,” and “[t]he parties dispute whether Drugdex’s critical commentary required Medicaid to pay prescriptions of Genotropin used to treat ‘short stature.’” Rost Opp. at 2, 3. But Pfizer is not asking the Court to take judicial notice of Medicaid’s requirement of reimbursement for certain “off-label” prescriptions. That is a question of law, not a question of fact. As the briefs in support of the motion to dismiss illustrate, whether Medicaid requires reimbursement for “short stature” claims turns on the

proper interpretation of the Medicaid statute's definition of "medically accepted indication," in particular, the meaning of the phrase "supported by one or more citations included in" certain compendia. 42 U.S.C. § 1396r-8(k)(6).

Pfizer requests only that the Court take judicial notice of the statements contained in DRUGDEX relating to use of somatropin for "short stature." This includes the entry for "short stature" in the "Therapeutic Uses" section of the December 2000-2002 volumes of DRUGDEX, which states that "[s]everal studies show that increases in growth velocity can be attained, particularly if somatropin is given prior to onset of puberty." Pfizer Mem. in Supp. of Mot. to Dismiss, Exs. A-C. Judicial notice of this and other statements in DRUGDEX is appropriate because their inclusion in this compendium is not subject to dispute. Rost appears to concede that Pfizer's DRUGDEX excerpts accurately reflect the contents of DRUGDEX; he relies on these exhibits to support his assertion that DRUGDEX is critical of the use of Genotropin for "short stature." See Pl.'s Mem. in Opp. to Mot. to Dismiss 11-12 (quoting "Exhibits A, B, and C, attached to Motion to Dismiss").

Contrary to Rost's assertions, Pfizer does not ask the Court to adopt its interpretation of the Medicaid statute through judicial notice. Instead, it requests that the Court take judicial notice of the statements contained in DRUGDEX, and then apply the terms of the statute to determine the legal significance of these statements. Rule 201 prevents a court from taking judicial notice of "disputed *factual* propositions." *United States v. Hoyts Cinema Corp.*, 380 F.3d 558, 570 (1st Cir. 2004) (emphasis added). It does not prevent a court from taking judicial notice of undisputed facts simply because the parties dispute the legal significance of those facts.

**B. THE CONTENTS OF DRUGDEX ARE CAPABLE OF ACCURATE AND READY DETERMINATION.**

The Court should take judicial notice of the contents of DRUGDEX because they are “capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned.” Fed. R. Evid. 201(b)(2). Because Pfizer has provided a copy of the actual pages from the DRUGDEX compendium as the source for determining the contents of DRUGDEX, this requirement is satisfied almost by definition.

Rost questions the accuracy of DRUGDEX, arguing that its “description of Genotropin’s efficacy is disputed.” Rost Opp. at 5. Indeed, he suggests that he could offer expert evidence to disprove statements made in DRUGDEX. *Id.* But Rost fails to account for the purpose for which the DRUGDEX excerpts are being offered. Pfizer has not asked the Court to take judicial notice of Genotropin’s efficacy for “short stature”; it does not need to prove this fact to show that “short stature” is a “medically accepted indication” for Genotropin.<sup>1</sup> Instead, the Medicaid statute requires only that DRUGDEX include a citation supporting this indication. Thus, Pfizer asks the Court to take judicial notice of the statements contained in DRUGDEX – not to prove that these statements are true as a matter of scientific fact – but to establish the contents of DRUGDEX so that the Court can determine as a matter of law whether use of Genotropin for “short stature” is “supported by one or more citations in” that compendium. No source could be better suited for this purpose.

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<sup>1</sup> For example, Pfizer does not request that the Court take judicial notice that somatropin leads to greater growth velocity in children with idiopathic short stature based on DRUGDEX’s citation to (and discussion of) a study that reached that conclusion. *See* Pfizer’s Mem. in Supp. of Mot. to Dismiss, Ex. A. Instead, Pfizer requests judicial notice of the fact that DRUGDEX includes a citation to a study that reaches that conclusion.

In any event, Rost is not entitled to present expert evidence on Genotropin's efficacy in an attempt to disprove citations that appear in DRUGDEX. The Medicaid statute makes clear that a particular use is a "medically accepted indication" if it is supported by a DRUGDEX citation, and it does not create a process for disputing the decisions made by DRUGDEX's publisher. As one court recently explained, a party is not entitled to argue that a particular use is not a "medically accepted indication" based on disagreement with a compendium's analysis. *See Edmonds v. Levine*, 417 F. Supp. 2d 1323, 1339 (S.D. Fla. 2006) ("In essence, [defendant] is attacking the motives and methodology of the editors of all of the compendia. However, Congress has already stamped its imprimatur on these compendia by including them in § 1396r-8(g)(1)(B)(i). [Defendant] may not substitute its own judgment for that of Congress.").

Rost's other arguments on this point are also unpersuasive. He argues that the Court should not take judicial notice of DRUGDEX because "it is not from available government records, but must be purchased from a private company and is expensive." Rost Opp. at 5. These factors are not relevant under Rule 201. Courts have previously taken judicial notice of DRUGDEX and other scientific texts. *See McDermott*, 2006 WL 3741920, \* 13 n.8 (judicial notice of DRUGDEX); *In re: Vicuron Pharmaceuticals, Inc.*, 2005 WL 2989674, \* 3 (E.D. Pa. July 1, 2005) (judicial notice of pharmacology reference materials). More generally, courts take judicial notice of a wide range of facts under Rule 201(b)(2), without regard to the involvement of a private company or the cost of purchasing the source. *See, e.g.*, 29 Am. Jur. 2d Evidence § 34 (2008) ("Numerous cases can be found in which courts judicially notice historical, scientific, geographical and topographical facts, phenomena of nature, seasons and plants, time, customs and usages of businesses and professions, and actions of government bodies and

agencies.”) (citations omitted). There is no basis for refusing to take judicial notice of the contents of DRUGDEX.

**II. THE COURT MAY ALSO CONSIDER THE CONTENTS OF DRUGDEX BECAUSE THE AMENDED COMPLAINT INCORPORATES THE COMPENDIUM.**

Rost concedes – as he must – that he references “the drug compendia identified in the Medicaid Statute” in the Amended Complaint. Rost Opp. at 6 (quoting Am. Compl. ¶43). He nonetheless argues that the Amended Complaint does not incorporate DRUGDEX, and thus does not provide a basis for the Court to consider its contents, because the discussion of compendia was “simply . . . an indirect passing reference” in a “paragraph that is not an integral part of the complaint.” Rost Opp. at 6. Rost’s attempt to downplay the reference in the Amended Complaint is belied by the briefs filed in connection with the motion to dismiss.

The contents of DRUGDEX are central to the principal argument in the motion to dismiss. If “short stature” is a “medically accepted indication” for Genotropin in the circumstances of this case, then Rost’s Amended Complaint, like his original complaint, fails to identify any false claims. Both parties’ arguments on this point rely on DRUGDEX’s commentary on use of Genotropin for “short stature.” Rost argues that critical comments in DRUGDEX show that “short stature” is not a “medically accepted indication” for Genotropin. *See* Pl.’s Mem. in Opp. to Mot. to Dismiss 10-19. The reference to DRUGDEX in the Amended Complaint therefore is clearly more than a passing reference. It is tied to whether Medicaid reimbursement of the claims Rost alleges is required (as Pfizer argues) or whether it can form the basis for a violation of the False Claims Act (as Rost argues).

Rost also argues that a document is not incorporated into a complaint if the authenticity of that document is at issue. But he does not contend that the DRUGDEX excerpts provided with the motion to dismiss fail to reflect the contents of DRUGDEX. Indeed, he quotes

directly from these excerpts in his opposition to the motion to dismiss. *See* Pl.'s Mem. in Opp. to Mot. to Dismiss 11-12 (quoting "Exhibits A, B, and C, attached to Motion to Dismiss").

Because Rost references DRUGDEX in the Amended Complaint and the contents of DRUGDEX are central to the viability of this case, the Court should treat DRUGDEX as incorporated in the Amended Complaint. *See Beddall v. State St. Bank and Trust Co.*, 137 F.3d 12, 17 (1st Cir. 1998) ("When, as now, a complaint's factual allegations are expressly linked to – and admittedly dependent upon – a document (the authenticity of which is not challenged), that document effectively merges into the pleadings and the trial court can review it in deciding a motion to dismiss under Rule 12(b)(6).").

#### CONCLUSION

For the foregoing reasons, the Court should take judicial notice of the excerpts of DRUGDEX attached as exhibits to Pfizer's memorandum in support of its motion to dismiss.

Respectfully submitted,

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