IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA ex rel. PETER ROST,	Docket No. 1:03-CV-11084-PBS
Plaintiff,	The Honorable Patti B. Saris
v.	
PFIZER, INC. and PHARMACIA CORPORATION,	
Defendants.	

BRIEF OF WASHINGTON LEGAL FOUNDATION
AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANTS'
MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED COMPLAINT

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INTERESTS OF *AMICUS CURIAE*

The interests of *amicus curiae* Washington Legal Foundation (WLF) are more fully set forth in the accompanying motion for leave to file this brief. In brief, WLF is a public interest law and policy center with members and supporters in all 50 States. It seeks to defend the rights of individuals and businesses against interference from excessive government regulation. WLF's members include physicians who seek to receive truthful information about potential "off-label" uses of FDA-approved products, and medical patients who want their doctors to have such information. WLF successfully challenged the constitutionality of certain FDA restrictions on speech about off-label uses and has in place a permanent injunction against enforcement of those restrictions. *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dism'd*, 202 F.3d 331 (D.C. Cir. 2000).

WLF also has regularly participated in litigation regarding the scope of the civil False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.* *See, e.g., Allison Engine Co. v. United States ex rel. Sanders*, U.S. Sup. Ct. No. 07-214 (U.S., dec. pending); *Rockwell Int'l Corp. v. United States ex rel. Stone*, 127 S. Ct. 1397 (2007); *Riley v. St. Luke's Episcopal Hosp*., 196 F.3d 514 (5th Cir. 1999). WLF is concerned that, over the last two decades, excessive FCA activity has spawned abusive punitive litigation against businesses, both large and small, to the detriment of those businesses, their employees, their shareholders, and the public at large.

WLF is filing this brief because of its concern that Plaintiff's action, if allowed to proceed, could harm public health by reducing public knowledge regarding beneficial off-label uses of FDA-approved products. Plaintiff's opposition brief focuses on the First Amended

Complaint's allegations that Defendants engaged in improper promotional activities. But the issue in this case is whether Defendants violated the FCA, not whether they improperly promoted Genotropin. WLF is concerned that imposing liability in the absence of credible allegations that Defendants violated the FCA would lead to the chilling of truthful manufacturer speech that could have significant adverse public health consequences.

STATEMENT OF THE CASE

The First Circuit recently affirmed Judge Tauro's decision that the initial complaint was subject to dismissal under Fed.R.Civ.P. 9(b) and 12(b)(6) for failure to state a claim upon which relief could be granted. *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 731 (1st Cir. 2007) ("*Rost I*"). This Court must now determine whether the First Amended Complaint cures the deficiencies identified by the First Circuit in the initial Complaint.

Plaintiff/Relator Peter Rost alleges that Defendants violated the FCA by causing others to file "false" claims with federal officials for the use of Genotropin by individuals covered by a federal medical insurance program. Rost does not allege that Defendants themselves said anything false. Rather, he alleges that Defendants' promotional activities encouraged doctors to prescribe Genotropin for off-label uses, that at least some of those off-label uses were not covered by Medicaid and/or other federal programs, and that it was foreseeable that doctors would nonetheless seek reimbursement for at least some of the nonreimburseable uses for which Defendants had encouraged them to prescribe Genotropin.

The First Circuit upheld Judge Tauro's determination that Rost, in the initial Complaint, "failed to plead his fraud claims with sufficient specificity" under Fed.R.Civ.P. 9(b). *Id.* The court noted that in the FCA context, Rule 9(b) "requires relators to 'provide

details that identify particular false claims for payment that were submitted to the government.'" *Id*. (quoting *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 232 (1st Cir. 2004)). The court held that the Complaint failed to meet the requirements of Rule 9(b) because it failed to identify any particular claims for payment that were "false," *i.e.*, that were not properly reimbursable. *Id*. at 732-33. While Rost alleged that, as a direct result of Defendants' marketing activities, more than one-half of all adult and one-quarter of all pediatric sales of Genotropin were for off-label uses, the court held that Rost had done no more than "raise[] facts that suggest fraud was possible; . . . the complaint contained no factual or statistical evidence to strengthen the inference of fraud beyond possibility." *Id.* at 733.

The First Amended Complaint is largely similar to the initial Complaint. Defendants again moved to dismiss on the grounds, *inter alia*, that Rost still has not met the Rule 9(b) pleading standard. In opposition to the motion to dismiss, Rost points to one new set of allegations: that 200 claims for reimbursement were submitted to Medicaid officials in Indiana for the cost of Genotropin prescribed off-label to children to treat "short stature" during 2001-2006. Opp. Br. 17-18. Rost alleges that these 200 claims were "false" because they were not properly reimbursable under federal Medicaid law and that Defendants "caused" these false claims to be submitted, and thus that the First Amended Complaint meets the Rule 9(b) pleading standards. *Id.* Defendants reply that Rost has failed to provide sufficient specificity with respect to the 200 claims to satisfy Rule 9(b) and, moreover, that those 200 claims were reimbursable as a matter of law. Def. Reply Br. 3, 9. Defendants also assert that the First Amended Complaint does not adequately allege a causal connection between their activities

and the "false" claims allegedly presented to the federal government. Def. Br. 12-14.

SUMMARY OF ARGUMENT

WLF agrees with Defendants that the First Amended Complaint fails to state a claim upon which relief can be granted and fails to meet the pleading standards of Rule 9(b). WLF writes separately to emphasize the important role that off-label use of FDA-approved drugs and medical devices plays in our Nation's health care, and to urge that Court not interpret the FCA in a manner that unnecessarily interferes with such uses.

The medical community's knowledge regarding the safety and efficacy of FDA-approved drugs and devices inevitably outpaces FDA-approved labeling. Physicians who regularly work with such drugs and devices learn of safe and efficacious uses for the drugs/devices that are not included within the labeling (generally referred to as "off-label" uses). In some fields such as oncology, a significant portion of all medically-accepted treatments involves off-label uses of FDA-approved drugs and medical devices. Accordingly, were doctors limited to using therapeutic products only as labeled, doctors would be providing sub-optimal care to their patients. In many cases, doctors simply could not treat their patients properly without resort to off-label uses. Indeed, the U.S. Supreme Court has officially recognized off-label treatments as an important part of medical care in this country. *See Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 350, 351 n.5 (2001) ("'[O]ff-label' usage of medical devices (use of a device for some other purpose than that for which it has been approved by the FDA) is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine. . . . Off-label use is widespread in the medical community and often is essential to giving patients optimal

medical care, both of which medical ethics, FDA, and most courts recognize."). FDA and Congress similarly recognize the importance of off-label uses; for example, in 1997, Congress explicitly prohibited efforts to limit the authority of physicians to put FDA-approved products to off-label uses. *See* 21 U.S.C. § 396 (providing that nothing in the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 *et seq.*, "shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship."). To ensure that doctors learn about safe and effective off-label uses, the courts, Congress, and FDA have all recognized that there are circumstances under which it is entirely appropriate for manufacturers to disseminate information about off-label uses of their medical products.

In light of that history, it is inconceivable that Congress simultaneously intended that the FCA should be interpreted in a manner that would greatly discourage off-label uses. Yet that would be the effect of Rost's proposed interpretation. When a manufacturer discusses (in a truthful and balanced manner) potential off-label uses of its product, it is always foreseeable that someone *might* be induced thereby to put the product to that use and to seek Medicaid reimbursement for the use, even when the use is not properly reimbursable. If the manufacturer could under those circumstances be held liable for "causing" a false claim to be asserted even in the absence of evidence that it did anything to encourage the filing of nonreimburseable claims, then manufacturers would be more reluctant to say anything at all about those off-label uses. The result would be that fewer patients would have access to the latest medical advances.

A much more plausible interpretation of the FCA is the one espoused by Defendants and by numerous other federal courts. A drug or device manufacturer cannot be held liable under the FCA for having "caused" the false claim to be submitted in the absence of pleaded facts suggesting that the defendants' actions were both the actual and proximate cause of the submission. No such facts have been pleaded here. Even assuming that the Indiana claims cited by Rost could be deemed false, he has not pleaded facts suggesting that Defendants took any steps to encourage their submission. Indeed, there is not even an allegation that those submitting the claims ever had any contact with sales representatives who are alleged to have been promoting off-label uses of Genotropin. Given the numerous potential sources of information about off-label uses of FDA-approved products, and the absence of statistical evidence demonstrating a direct correlation between Defendants' promotional activity in Indiana and a subsequent spike in submissions of "short stature" reimbursement claims to Indiana Medicaid officials, there is no factual predicate for inferring such a causal connection.

Moreover, the FCA imposes a strict scienter requirement; liability is limited to those who "knowingly" present or cause to be presented a false claim, or "knowingly" make or cause to be made a false statement to get a false claim paid. 31 U.S.C. § 3729(a)(1) & (2). WLF fully concurs with Defendants' assertion that the 200 Indiana "short stature" submissions cannot, as a matter of law, be deemed "false" claims. The *very most* that can be said for Rost's allegations regarding "short stature" reimbursement claims is that the reimbursability of such claims is a matter over which reasonable people could disagree. Under those circumstances, Rost has not adequately alleged that either Defendants or those who actually submitted the "short stature" claims acted with the requisite scienter.

ARGUMENT

I. OFF-LABEL USE OF FDA-APPROVED MEDICAL PRODUCTS IS AN ESSENTIAL COMPONENT OF OPTIMAL MEDICAL CARE AND VERY OFTEN IS REIMBURSABLE BY MEDICAID AND OTHER FEDERAL PROGRAMS

Plaintiff's First Amended Complaint and his opposition brief attempt to maintain an exclusive focus on his allegations that Defendants engaged in improper promotional activity. But the issue in this case is whether Defendants violated the FCA (*i.e.*, whether they caused others knowingly to submit nonreimburseable claims for Genotropin prescriptions), not whether they improperly promoted Genotropin. Moreover, in determining whether Rost has stated a claim for violation of the FCA, the Court should not allow Rost's rhetoric to create the impression that there is something nefarious about off-label pharmaceutical sales in general, or off-label sales of Genotropin in particular.

As noted above, off-label uses of FDA-approved medical products play a vital role in health care delivery in the United States. The U.S. Supreme Court has recognized the importance of that role, *Buckman Co.*, 531 U.S. at 350, and Congress in 1997 explicitly prohibited efforts to limit the authority of physicians to put FDA-approved products to off-label uses. 21 U.S.C. § 396. Numerous studies confirm that drugs prescribed for an off-label use are a significant (and increasing) percentage of all pharmaceutical prescriptions. *See, e.g.*, David C. Radley, *et al.*, *Off-Label Prescribing Among Office-Based Physicians*, 166 ARCH. INTERNAL MED. 1021, 1023 (2006) (over 20% of all prescriptions are off-label; 46% of cardio-vascular prescriptions are off-label); Shane M. Ward, *WLF & the Two-Click Rule: The First Amendment Inequity of the Food & Drug Administration's Regulation of Off-Label Drug Use Information on the Internet*, 56 FOOD & DRUG L.J. 41, 45-46 (2001) (off-label use is over 30%

for cancer, 40% for AIDS, 80% for children, and 90% for patients with rare diseases); James M. Beck & Elizabeth Azari, *FDA, Off-Label Use, & Informed Consent: Debunking Myths & Misconceptions*, 53 FOOD & DRUG L.J. 71, 80 (1998) (off-label use represents 25-60% of all drug prescriptions, more in many specialties); U.S. General Accounting Office, *Off-Label Drugs: Reimbursement Policies Constrain Physicians in Their Choice of Cancer Therapies*, at 13-14 (1991) (65% of cancer treatments are off-label). FDA itself recognizes that its approval of new labeling for approved drugs cannot keep up with the rapid development of new therapies, and even recognizes that "in some specific and narrow areas of medical practice, practitioners consider off-label use to constitute the standard of good medical care." *WLF v. Friedman*, 13 F. Supp. 2d at 56. *See also* FDA, *Draft Guidance for Industry on Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices* (hereinafter, "*Draft Guidance*") 73 Fed. Reg. 9342 (Feb. 20, 2008) ("These off-label uses or treatment regimens may be important and may even constitute a medically recognized standard of care.").

A corollary to the need for doctors to employ safe and effective off-label uses of therapeutic products is that they must be able to learn which such uses are medically recognized. The need for knowledge does not stop with graduation from medical school; new drugs and devices are constantly entering the market, and new uses for these products are constantly being discovered. The discovery that an approved product is beneficial in treating an off-label condition is of no help to a patient unless his/her physician knows about that use. Accordingly, it is highly important to effective health care delivery that information about new

uses be widely disseminated within the medical community. Doctors acquire that information from a variety of sources, including continuing medical education (CME) symposia, peer-reviewed medical journal articles, and medical textbooks (including DRUGDEX and the other medical compendia discussed in the parties' briefs).

FDA, Congress, and the U.S. Constitution authorize manufacturers to play a role in disseminating such information, subject to certain restraints. For example, because FDA recognizes that a manufacturer is likely to be highly knowledgeable regarding recognized off-label uses of its products, FDA authorizes manufacturers to provide off-label information to doctors who make unsolicited requests for such information. 21 C.F.R. § 99.1(b). FDA encourages manufacturers to provide financial support for CME symposia, even when the presentations are likely to include discussion of off-label uses of the manufacturers' products. A federal court decision has recognized that manufacturers have a First Amendment right to distribute peer-reviewed medical journal articles to doctors, even when the articles include discussion of off-label uses. *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 56 (D.D.C. 1998), *appeal dism'd*, 202 F.3d 331 (D.C. Cir. 200). As a result of the *Friedman* decision, FDA is permanently enjoined from preventing manufacturer distribution of such articles. FDA has not attempted to prevent such distribution and instead recently issued a draft guidance that purports to establish ground rules regarding how manufacturers should go about conducting such distribution. *See Draft Guidance, supra*, 73 Fed. Reg. 9342 (Feb. 20, 2008).

Rost alleges that Defendants went beyond the permissible steps outlined above and engaged in illegal off-label promotion of Genotropin. Nonetheless, one can draw two significant conclusions relevant to this case from the regulatory background cited above. First,

there are numerous sources – other than Defendants' alleged illegal promotion – from which physicians who prescribed Genotropin for off-label uses may have learned about the efficacy of those uses, and it is eminently plausible that it was information from one of those other sources that prompted the off-label prescriptions and reimbursement claims of which Rost complains. Accordingly, in light of the strict pleading requirements of Fed.R.Civ.P. 9(b), the Court ought to require Rost to plead facts demonstrating that any "false" claim on which he relies was directly attributable to the alleged illegal off-label promotion and not to one of the numerous alternative sources of that same information.

Second, the courts, Congress (*see* 21 U.S.C. § 360aaa *et seq.* (1997)), and FDA have all recognized that there are circumstances under which it is entirely appropriate for a manufacturer to disseminate information about off-label uses of its medical products – because they recognize the importance of ensuring that physicians and their patients obtain the most up-to-date information about a medical product's safety and effectiveness. It is, of course, entirely foreseeable that if some of that information involves off-label uses that are not currently reimbursable under Medicaid and other federal programs, some of those who put the product to the suggested off-label use may seek reimbursement even though reimbursement is not authorized. Given Congress's recognition of the importance of off-label uses and its endorsement of dissemination of truthful information about such uses, it is not plausible that Congress intended to impose broad FCA liability under such circumstances simply because an FCA relator can demonstrate a vague statistical correlation between the dissemination of off-label information and the subsequent filing of reimbursement claims for nonreimburseable off-

label uses.[1] Any such interpretation of the FCA would significantly undercut the willingness of manufacturers and others to engage in authorized information-dispensing activities and thus would ensure that fewer patients would have access to the latest medical advances.

II. PLAINTIFF HAS NOT ADEQUATELY ALLEGED A CAUSAL CONNECTION BETWEEN DEFENDANTS' PROMOTIONAL ACTIVITIES AND THE SUBMISSION OF ANY FALSE CLAIMS

A much more plausible interpretation of the FCA is the one espoused by Defendants and by numerous other federal courts. A drug or device manufacturer cannot be held liable under the FCA for having "caused" a false claim to be submitted in the absence of pleaded facts suggesting that the defendants' actions were both the actual and proximate cause of the submission. Rost has not adequately alleged facts suggesting such a causal connection.

Rost alleges that Defendants are liable under §§ (a)(1) and (a)(2) of the FCA, which impose liability on any person who:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; [or]
>
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government.

31 U.S.C. § 3729(a)(1) & (2).

Rost does not allege that Defendants presented false claims to the federal government, nor does he allege that they made or used a false record or statement. Rather, he seeks to

[1] Indeed, under Rost's theory, FCA liability would not be limited to *manufacturers* that disseminate information about off-label uses. Liability could attach even to an independent researcher who has conducted a well-controlled clinical trial and later gives a speech about new, off-label uses for an FDA-approved medical product.

impose liability based on allegations that they "cause[d]" others to take such actions. Fed.R.Civ.P. 9(b) provides that such allegations of causation are insufficient to state an FCA claim unless they are "stated with particularity." *United States ex rel. Karvelas,* 360 F.3d at 226-228. Nor is it sufficient, when alleging causation, to allege facts demonstrating that the defendant's actions were a but-for cause of the presentment of the false claim (or the but-for cause of the making/using of a false record/statement). Rather, as this Court has held, an FCA relator must also establish proximate cause – *i.e.*, that it was foreseeable to a drug manufacturer engaged in off-label marketing that its conduct "would ineluctably result in false Medicaid claims" and "played a key role in setting in motion a chain of events that led to false claims." *United States ex rel. Franklin v. Parke-Davis*, 2003 U.S. LEXIS 15754, at *15 - *16 (D. Mass. 2003).

The First Amended Complaint (FAC) falls far short of alleging "with particularity" that Defendants "played a key role in setting in motion a chain of events" that led to submission of the 200 Indiana "short stature" claims upon which Rost relies. While the FAC alleges that Defendants promoted off-label use of Genotropin to treat "short stature" in pediatric populations, it makes no allegations that Defendants conducted such activities anywhere in Indiana – let alone that Defendants had any contact whatsoever with those responsible for presenting the 200 "short stature" claims to the federal government.

Moreover, the FAC does not allege that Defendants ever suggested that those physicians prescribing Genotropin for "short stature" should do anything to facilitate federal reimbursement of the costs of the drug. The absence of such an allegation is in sharp contrast to the allegations in *Franklin*, in which the defendant pharmaceutical company allegedly

bribed doctors to prescribe its drug off-label, *id.*, 2003 U.S. LEXIS 15754, at *20, and then instructed its medical liaisons, when addressing reimbursability issues, "to coach doctors on how to conceal the off-label nature of the prescription." *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 39, 46 (D. Mass. 2001). In the absence of an allegation of that nature, a drug company cannot be deemed to have done anything to "set in motion" the submission of false claims. In affirming dismissal of the initial complaint for failure to meet Rule 9(b)'s heightened pleading standards with respect to causation, the First Circuit relied on the absence of any such "coaching" allegations. *Rost I*, 507 F.3d at 732-33 & n.9. The FAC does nothing to correct the deficiencies – noted by the First Circuit – in the complaint's allegations regarding causation. Indeed, as the appeals court pointed out, the April 2007 criminal information regarding improper off-label promotion of Genotropin for anti-aging uses stated that patients taking Genotropin for those uses "in most, if not all, instances" paid for the drug "out-of-pocket without reimbursement from any public or private third-party payors." *Id.* at 732. That evidence strongly suggests, in the absence of contrary allegations stated with particularity, that Defendants did nothing to "set in motion" the filing of false claims with respect to any off-label uses of Genotropin.

The causation allegations are particularly deficient when one considers the numerous sources of information that might have prompted Indiana physicians to prescribe Genotropin to children to treat "short stature." They might, for example have learned about the safety and effectiveness of this treatment from attending a CME presentation, from reading peer-reviewed medical literature, or from reading medical texts such as DRUGDEX. The rapidly expanding use of Genotropin to treat "short stature," followed by FDA's eventual recognition of such use

as a labeled indication, indicates that the medical community became increasingly convinced of the safety and efficacy of this off-label use throughout the past decade. In the absence of evidence indicating that the Indiana physicians wrote their prescriptions in direct response to Defendants' alleged illegal marketing activities, and not in response to other potential causes, the FAC is subject to dismissal for failure to allege causation with the particularity required by the Rule 9(b) pleading standards.

III. PLAINTIFF HAS NOT ADEQUATELY ALLEGED SCIENTER

The FCA does not impose strict liability on those who file (or cause to be filed) false claims with the federal government. Rather, liability is limited to those who act "knowingly." The First Amended Complaint is subject to dismissal for the additional reason that it does not adequately allege a "knowing" violation of the FCA.

The parties agree that many off-label uses of FDA-approved products are reimbursable under Medicaid and other federal programs, and thus that submission of a reimbursement claim for off-label uses is not a "false" claim under the FCA in those instances. State Medicaid programs are generally required to reimburse Medicaid-eligible individuals for the costs of a "covered" drug used for a "medically accepted indication." A "medically accepted indication" is defined as including the prescription of an FDA-approved drug for a use "supported by one or more citations" included in "any of the compendia" listed in the Medicaid laws. 42 U.S.C. § 1396r-8(k)(6). The three listed compendia are: (1) the American Hospital Formulary Service Drug Information; and (2) United States Pharmacopeia - Drug Information; and (3) DRUGDEX Information System. 42 U.S.C. § 1396r-8(g)(1)(B)(i).

Moreover, it is uncontested that, during the years covered by the FAC, DRUGDEX

included a number of citations to the use of Genotropin to treat "short stature" in children. The only disagreement between the parties is whether those citations are sufficiently positive to justify a determination that such off-label use of Genotropin is "supported" by the DRUGDEX citations.[2] For the reasons stated in Defendants briefs, WLF agrees that the use of Genotropin to treat "short stature" in pediatric populations was "supported" by DRUGDEX as a matter of law during the years in question.

But regardless how the Court resolves that dispute, the existence of that dispute amply demonstrates that Rost has not adequately pleaded scienter. The *very most* that can be said for Rost's allegations regarding "short stature" reimbursement claims is that the reimbursability of such claims is a matter over which reasonable people could disagree. Under those circumstances, Rost's allegations that Defendants "knowingly" caused others to file "false" claims fails as a matter of law. The FCA defines "knowingly" as meaning that a defendant:

> [W]ith respect to information --
>
> (1) has actual knowledge of the information

---

[2] If one concludes that use of Genotropin to treat "short stature" is "supported" by DRUGDEX, there is no doubt that Indiana Medicaid officials were required to reimburse the costs of such use. Although Medicaid law permits States to take steps to eliminate reimbursement for certain "medically accepted indications," it is uncontested that Indiana has not taken such steps with respect to Genotropin. A State may establish a "formulary committee," which may in turn develop a "drug formulary," a list of Medicaid-eligible drugs for which the State will provide reimbursement when prescribed for medically accepted indications. 42 U.S.C. § 1396r-8(d)(4)(A) & (B). The committee may remove a Medicaid-eligible drug (such as Genotropin) from the drug formulary for some or all of its accepted uses (and thereby bar reimbursement for such uses of the drug) if it determines that the drug "does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome" over other drugs included in the formulary. 42 U.S.C. § 1396r-8(d)(4)(C). *See Edmonds v. Levine*, 417 F. Supp. 2d 1323, 1328 (S.D. Fla. 2006). The provisions of § 1396r-8(d)(4)(C) are inapplicable here because Indiana Medicaid officials have not taken steps to bar reimbursement for otherwise-reimbursable off-label uses of Genotropin.

(2) acts in deliberate ignorance of the truth or falsity of the information; or

(3) acts in reckless disregard of the truth or falsity of the information.

31 U.S.C. § 3729(b).

Based on DRUGDEX's extensive citations to use of Genotropin to treat "short stature" during the years in question, Defendants cannot as a matter of law be deemed to have acted with the requisite scienter. In light of Rost's acknowledgment of those citations, case law is clear that Defendants did not *knowingly* cause the presentment of false claims as that term has been understood by the FCA case law. Thus, for example, in *Hagood v. Sonoma County Water Agency*, 81 F.3d 1465 (9th Cir. 1996), the appeals court dismissed as a matter of law an FCA claim that was based on a disagreement over how a government contractor allocated its costs. The court said that "a disputed legal issue" over how to allocate costs, even if sufficient to support a reasonable inference that the allocation was false, was insufficient to support a claim that the contractor "knowingly" violated the FCA. *Id.* at 1478. While acknowledging that the contractor may have sought to "take advantage of a disputed legal issue" to increase its billing to the government, such conduct was insufficient to establish scienter because "to take advantage of a disputed legal question . . . is to be neither deliberately ignorant nor recklessly disregardful." *Id.* The court explained:

> The False Claims Act, to repeat, requires a showing of knowing fraud. The requisite intent is the knowing presentation of what is known to be false, as opposed to innocent mistake or mere negligence. . . . Likewise, the statutory phrase "known to be false" does not mean incorrect as a matter of proper accounting methods, it means a lie.

Id. (citations omitted). *See also United States ex rel. Riley v. St. Luke's Episcopal Hospital*, 355 F.3d 370, 376 (5th Cir. 2004) (submission of reimbursement claims based on a good-faith belief that medical services were "necessary" is not actionable under FCA; "the FCA requires

a statement known to be false, which means a lie is actionable but not an error."); *cf. United States ex rel. O'Keeffe v. Sverdup Corp.*, 131 F. Supp. 2d 87, 100 (D. Mass. 2001) (dismissing FCA claim against government contractor because defendant introduced unrebutted evidence that those trained in the field would not necessarily have considered the disputed claim to be "false").

Thus, even if the FAC could be deemed to have adequately pleaded that Defendants "caused" others to present "false" claims to the federal government (which it cannot), the FAC is still subject to dismissal because Rost has not adequately pleaded scienter. Given the numerous DRUGDEX citations to the use of Genotropin to treat "short stature," Defendants cannot as a matter of law be deemed to have caused the filing of claims that they *knew* to be false (*i.e.*, not properly reimbursable). Defendants cannot as a matter of law be deemed to have lied about the reimbursability of such claims merely because Rost disagrees with Defendants about just how positive the DRUGDEX citations actually are.

CONCLUSION

Amicus curiae WLF respectfully requests that the Court grant Defendants' motion to dismiss.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 1st day of May, 2008, copies of the foregoing *amicus curiae* brief of the Washington Legal Foundation, filed through the Electronic Case Filing system, were sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEC) and paper copies were sent to those indicated as nonregistered participants via U.S. Mail as follows:

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