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## False Claims Act Settlements: Catch-22 Tax Implications

George Mikhail\*

### Part I. Introduction

A pharmaceutical company promotes a drug for an unapproved off-label use, and in turn triggers the False Claims Act (FCA), when physicians prescribe the drug and patients submit a claim for Medicare and/or Medicaid.<sup>1</sup> When it comes time to settle the case, the government refuses to characterize the purpose of a portion of the damages. The settlement agreement includes (1) single damages, which are directly compensating the government, (2) civil penalties, which are paid as a punitive measure, and (3) excess payments that are uncharacterized damages. These uncharacterized, large sums have significant tax implications depending on their purpose.

While the pharmaceutical company can attempt to characterize the excess payment during the settlement negotiations, the government often refuses to include any characterization in the settlement agreement. The company then claims these damages as a tax deduction, but the IRS denies the deduction because the settlement agreement does not clearly characterize the purpose of the damages. This is the catch-22 situation the government has created which leads the courts to grapple with different approaches in determining the purpose of the payments. The government refuses to characterize the damages in the settlement agreement and then argues that the damages are not deductible because the agreement does not state their purpose.

The characterization issue turns on whether these payments are considered to be compensatory or punitive.<sup>2</sup> Compensatory damages are deductible under the Tax Code;<sup>3</sup> if the

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<sup>1</sup> 31 U.S.C. § 3729 (2012).

<sup>2</sup> 26 U.S.C. § 162(f) (2012).

<sup>3</sup> 26 C.F.R. § 1.162-21(b)(2) (2011).

payments are considered punitive, however, the damages are not deductible.<sup>4</sup> Although courts have applied different approaches to determine the purpose of these payments,<sup>5</sup> this Comment argues that the economic realities approach adopted by the First Circuit is more effective in determining the actual purpose of the payment and thus extricates the pharmaceutical companies from the catch-22 created by the government. The Ninth Circuit approach and a refined, hierarchical approach proposed by F. Philip Manns, fail to properly determine the actual intentions of the parties. In addition to the adoption of the economic realities approach, this Comment proposes that the burden to prove the purpose of the damages should be placed on the government. Currently, courts are in agreement that the burden to show the purpose of the payment is on the violator.<sup>6</sup> This Comment will argue, however, that the government should be the one to show that these damages are actually punitive, which will be problematic because this Comment finds that the purpose of these payments is likely compensatory rather than punitive.

Part II of this Comment provides an overview of the FCA and explains the development of the relevant sections of the Tax Code. Part III illustrates two approaches adopted by circuit courts and provides a detailed analysis of the relevant cases. Part IV argues that the Ninth Circuit approach and the hierarchy approach are faulty, and proposes that the economic realities approach coupled with burden shifting to the government provides the highest likelihood of determining the true purpose of the payments.

## Part II. FCA Overview and Development of Relevant Tax Law

### A. FCA Overview

Congress originally passed the FCA during the Civil War to protect the US Army from

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<sup>4</sup> § 162(f).

<sup>5</sup> *Talley Indus. v. Comm'r*, 116 F.3d 382 (9th Cir. 1997); *Fresenius Med. Care Holdings, Inc. v. United States*, 763 F.3d 64 (1st Cir. 2014).

<sup>6</sup> *Fresenius*, 763 F.3d at 68 (citation omitted)

false contracts.<sup>7</sup> In addition to using the FCA to protect against fraud from government contractors in various industries, the FCA is used in the life sciences industry to counter fraudulent activity.<sup>8</sup> The FCA prohibits fraudulent claims from being submitted to the government, and holds liable anyone who “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval.”<sup>9</sup> Violators are “liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000 . . . plus 3 times the amount of damages which the Government sustains because of the act of that person.”<sup>10</sup>

Essentially, the FCA is in place to punish anyone who attempts to defraud the government.<sup>11</sup> The FCA affects the pharmaceutical industry in two common situations: unlawful promotion of drugs and illegal kickbacks.<sup>12</sup> Unlawful drug promotion occurs when a pharmaceutical company instructs its sales force to promote drugs to physicians for uses that are not approved (i.e. off-label), and the physicians prescribe for the off-label use.<sup>13</sup> For example, if a drug has been approved for diabetes, sales representatives cannot promote the drug to physicians for treating cholesterol. If they do this off-label promotion and physicians prescribe the drug for cholesterol, any claims submitted for payment from government health insurance is a false claim.<sup>14</sup> Traditionally the Food, Drug & Cosmetic Act (FD&C Act) served as the primary enforcement mechanism against unlawful promotion;<sup>15</sup> however, the “potential for greater civil

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<sup>7</sup> United States v. Griswold, 24 F. 361 (D. Or. 1885).

<sup>8</sup> Robert N. Rabecs, *Kickbacks as False Claims: The Use of the Civil False Claims Act to Prosecute Violations of the Federal Health Care Program's Anti-Kickback Statute*, 2001 L. REV. MICH. ST. U. DET. C.L. 1, 3 (2001).

<sup>9</sup> 31 U.S.C. § 3729 (2012).

<sup>10</sup> *Id.*

<sup>11</sup> § 3729(a)(1)(B).

<sup>12</sup> Rabecs, *supra* note 8, at 3–4.

<sup>13</sup> Vicki W. Girard, *Punishing Pharmaceutical Companies for Unlawful Promotion of Approved Drugs: Why the False Claims Act Is the Wrong Rx*, 12 J. HEALTH CARE L. & POL'Y 119, 121 (2009).

<sup>14</sup> 31 U.S.C. § 3729 (2012).

<sup>15</sup> Girard, *supra* note 13 at 121.

finer under the False Claims Act” and its whistleblower provision made the FCA a more attractive enforcement tool.<sup>16</sup>

The FCA is also used to enforce violations of unlawful kickbacks under the Anti-Kickback Statute (AKS).<sup>17</sup> The AKS is a criminal statute that punishes whoever “knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate)” in exchange for referring a person to someone that gets paid from federal healthcare programs.<sup>18</sup> Violating the AKS may result in a fine of up to \$25,000 and imprisonment for up to five years.<sup>19</sup>

Additionally, a violation under the AKS may result in exclusion from participation in federal healthcare programs.<sup>20</sup> This permissive exclusion provides the government with substantial leverage in suits against pharmaceutical companies, because exclusion from federal healthcare programs is akin to corporate suicide for pharmaceutical companies.<sup>21</sup> This is because the government is the largest payer for pharmaceuticals through Medicare and Medicaid.<sup>22</sup> Rational companies will not take their chances to litigate an AKS claim with the risk of being excluded from government programs. As mentioned, this is especially the case in claims against pharmaceutical companies, where the government is the largest payer for their products.<sup>23</sup> The risks attendant to litigation lead to what are in essence automatic settlements between pharmaceutical companies and the government.<sup>24</sup> This leverage allows the government

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<sup>16</sup> *Id.* at 136.

<sup>17</sup> 42 U.S.C § 1320a-7b(g)(2012).

<sup>18</sup> § 1320a-7b.

<sup>19</sup> § 1320a-7b(b).

<sup>20</sup> § 1320a-7(b)(7).

<sup>21</sup> Christopher D. Zalesky, *Pharmaceutical Marketing Practices: Balancing Public Health and Law Enforcement Interests; Moving Beyond Regulation-Through-Litigation*, 39 J. HEALTH L. 235, 241 (2006).

<sup>22</sup> Centers for Medicaid and Medicare Review Services, *CMS Roadmaps for the Traditional Fee-for-Service (FFS) Program: Overview*, CMS.gov, [http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/downloads/RoadmapOverview\\_OEA\\_1-16.pdf](http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/downloads/RoadmapOverview_OEA_1-16.pdf) (last visited Jan. 16, 2015).

<sup>23</sup> *Id.*

<sup>24</sup> Zalesky, *supra* note 21, at 241.

to refuse to characterize damages in the settlement agreement.<sup>25</sup>

The FCA not only allows the government to initiate action, but it has a qui tam provision.<sup>26</sup> A qui tam claim arises when a “realtor”, a citizen, sues on behalf of the government.<sup>27</sup> The courts have reasoned that Congress included a whistleblower provision in the FCA as an effective means to stop fraud initiated by private citizens.<sup>28</sup> As an incentive to whistleblowers, the FCA awards qui tam plaintiffs a percentage of the recovery.<sup>29</sup> This can range from 15 to 25 percent of the amount the government recovers, which can be quite significant.<sup>30</sup> For example, whistleblowers in a recent FCA claim against Abbott Labs received \$84 million dollars as a part of the settlement.<sup>31</sup> The qui tam provision is designed to allow the Department of Justice to intervene and prosecute the case;<sup>32</sup> however the realtor is also free to continue the action if the Department of Justice does not intervene.<sup>33</sup> This private right of action, however, does not apply to AKS claims.<sup>34</sup>

The FCA requires a \$5,000 to \$10,000 penalty for each violation, and also allows the government to request treble damages, three times the amount of losses caused by the violation.<sup>35</sup> The FCA does have a provision limiting the treble damages to double damages in cases in which the court determines that the violator cooperated.<sup>36</sup> The civil penalties, treble damages, and qui tam provision make the FCA a very attractive tool for combating fraud. The government can

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<sup>25</sup> See *Fresenius Med. Care Holdings, Inc. v. United States*, 763 F.3d 64 (1st Cir. 2014).

<sup>26</sup> See 31 U.S.C. § 3730 (2012) (“A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government.”).

<sup>27</sup> *Id.*

<sup>28</sup> *United States ex rel. Springfield Terminal Ry. v. Quinn*, 14 F.3d 645, 649 (D.C. Cir. 1994).

<sup>29</sup> Girard, *supra* note 13, at 135-36.

<sup>30</sup> 31 U.S.C. § 3730(d) (2012).

<sup>31</sup> *Abbott Labs to Pay \$1.5 Billion to Resolve Criminal & Civil Investigations of Off-label Promotion of Depakote*, JUSTICE.GOV, (May 7, 2012), <http://www.justice.gov/opa/pr/abbott-labs-pay-15-billion-resolve-criminal-civil-investigations-label-promotion-depakote>.

<sup>32</sup> 31 U.S.C. § 3730(b), (c) (2012).

<sup>33</sup> § 3730(b)(4)(B).

<sup>34</sup> *United States ex rel. Barrett v. Columbia/HCA Healthcare Corp.*, 251 F. Supp. 2d 28, 37 (D.D.C. 2003).

<sup>35</sup> § 3729(a)(1).

<sup>36</sup> § 3729(a)(2).

rely on citizens to identify the fraud, and the Act allows for hefty damages on the violator.

The stakes are quite high for pharmaceutical companies with FCA claims against them, considering that they have been paid out very large figures to settle. For example, the government recovered \$1.5 billion from Abbott Labs after settling a suit for off-label promotion violations.<sup>37</sup> Pfizer Inc. paid the government \$1 billion in 2009 for FCA violations.<sup>38</sup> These examples help put in perspective the scope and size of FCA settlements against pharmaceuticals. The magnitude of these settlements has grave tax implications for the violators.

## B. Tax Code Development

Depending on payment characterization, companies can deduct business expenses.<sup>39</sup> Currently the Tax Code allows deductibility of “ordinary and necessary expenses paid or incurred during the taxable year in carrying on any trade or business.”<sup>40</sup> “Ordinary” has been defined as an “expense [] that is normally to be expected, in view of the circumstances facing the business”<sup>41</sup>, and a necessary expense as one “that is appropriate and helpful to the business.”<sup>42</sup> The “ordinary and necessary” standard has been applied quite broadly<sup>43</sup> and can even include one-time occurrences.<sup>44</sup> Under this principle, a settlement or court judgment should be considered an “ordinary and necessary” business expense for the purposes of deductibility.<sup>45</sup> However, § 162(f) of the Tax Code does not allow deductions for any “fine or penalty that is

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<sup>37</sup> *Abbott Labs to Pay \$1.5 Billion to Resolve Criminal & Civil Investigations of Off-label Promotion of Depakote*, JUSTICE.GOV, (May 7, 2012), <http://www.justice.gov/opa/pr/abbott-labs-pay-15-billion-resolve-criminal-civil-investigations-label-promotion-depakote>.

<sup>38</sup> *Justice Department Announces Largest Health Care Fraud Settlement in Its History: Pfizer to Pay \$2.3 Billion for Fraudulent Marketing* (Sept. 2, 2009), HHS.GOV, <http://www.hhs.gov/news/press/2009pres/09/20090902a.html>. (last visited Jan. 16, 2015).

<sup>39</sup> 26 U.S.C. § 162(a) (2012).

<sup>40</sup> *Id.*

<sup>41</sup> *Palo Alto Town & Country Village, Inc. v. Commissioner*, 565 F.2d 1388, 1390 (9th Cir. 1977) (citing *Commissioner v. Heininger*, 320 U.S. 467, 471 (1943)).

<sup>42</sup> *Id.*

<sup>43</sup> *M. L. Eakes Co. v. C. I. R.*, 686 F.2d 217, 220–21 (4th Cir. 1982).

<sup>44</sup> Arthur W. Andrews, *Rule 11 and the Nondeductibility of Monetary Sanctions Imposed Upon Attorneys*, 32 ARIZ. L. REV. 279, 304 (1990).

<sup>45</sup> 26 U.S.C. § 162(a) (2012).

paid to the government for the violation of law.”<sup>46</sup> Before the enactment of §162(f), courts could not rely on the Tax Code to refuse deductions of criminal fines or civil penalties.<sup>47</sup> Courts did, however, rely on public policy, reasoning that expenses accrued in violation of the law are not “ordinary and necessary.”<sup>48</sup> The courts explained that deductions should be disallowed if they directly violate national and state public policy.<sup>49</sup> Allowing tax deductions on payments that are made to deter and punish the violator did not seem logical. This led to the enactment of §162(f), prohibiting deductions for “fines or penalties” paid to the government.<sup>50</sup>

The Senate Finance Committee Report on the Tax Reform Act of 1969 explained that §162(f)’s scope is limited to criminal cases where the taxpayer was required to make payment.<sup>51</sup> The Treasury, however, interpreted §162(f) broadly in regulation § 1.162–21(b), to include “civil penalties” and amounts “paid in settlement of the taxpayer’s actual or potential liability for a fine or penalty.”<sup>52</sup> Without the Treasury regulation, only payments related to criminal cases were within the scope of §162(f). The Treasury regulation did not stop taxpayers from challenging the inclusion of civil penalties under §162(f) “fines or penalties”, seeking a narrower interpretation.<sup>53</sup> In *South Pacific Transportation Co. v. Commissioner*, the tax court held that the Treasury’s interpretation is in line with Congress’s intent.<sup>54</sup>

Jury awards are labeled as punitive or compensatory; however, in a settlement context, parties need to determine the portion that is punitive or compensatory. This leads to further

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<sup>46</sup> § 162(f).

<sup>47</sup> F. Philip Manns, Jr., *Internal Revenue Code Section 162(f): When Does the Payment of Damages to A Government Punish the Payor?*, 13 Va. TAX REV. 271, 276 (1993).

<sup>48</sup> *Id.* at 277.

<sup>49</sup> Andrews, *supra* note 44, at 310 (quoting *Tank Truck Rentals, Inc. v. C.I.R.*, 356 U.S. 30, 33–34 (1958)).

<sup>50</sup> Manns, *supra* note 47, at 277.

<sup>51</sup> *Id.* (citing Senate Comm. on Finance, Tax Reform Act of 1969, S. Rep. No. 552, 91st Cong., 1st Sess. 274 (1969), reprinted in 1969 U.S.C.C.A.N. 2027, 2311–12).

<sup>52</sup> 26 C.F.R. § 1.162–21(b) (2011).

<sup>53</sup> *S. Pac. Transp. Co. v. Comm’r*, 75 T.C. 497 (1980).

<sup>54</sup> *Id.*



issues. Currently, §162(f) limits the deductibility of any portion of a settlement that is punitive.<sup>55</sup> Section 1.162-21 also made it clear that compensatory damages do not fall within the limitations of §162(f) and are deductible.<sup>56</sup>

These tax principles are relevant in the context of FCA settlements because if a settlement is properly characterized, compensatory payments to the government are deductible and punitive payments are nondeductible.<sup>57</sup> The line separating compensatory and punitive damages in settlements is gray, particularly when the settlement agreement does not characterize the payments. The parties are free to characterize the payments in the settlement agreement, which limits the problems violators are having. The key issue that determines deductibility is the intent or purpose of the payment, i.e., whether it is made to compensate or punish.<sup>58</sup> Depending on how courts approach the issue of intent, large payments can be tax deductible.

### Part III. First Circuit and Ninth Circuit Disagreement

Violators find themselves in a catch-22 situation where the government refuses to characterize the damages in the agreement, and then argues that the damages are not deductible because the agreement does not state their purpose. The Ninth and First Circuits disagree over how to approach this situation,<sup>59</sup> and the issue turns on the employed method to characterizing the damages as compensatory or punitive.<sup>60</sup> In *Talley Industries v. Commissioner*, the Ninth Circuit relied heavily on the settlement agreement to determine the characterization of the damages and held that the burden is on the violator to show the purpose of the settlement money

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<sup>55</sup> 26 U.S.C. § 162(f) (2012).

<sup>56</sup> 26 C.F.R. § 1.162-21(b)(2) (2011).

<sup>57</sup> *Id.*

<sup>58</sup> *Manns*, *supra* note 47, at 277 (citing *Stephens v. Commissioner*, 905 F.2d 667, 673 (2d Cir. 1990)); *True v. United States*, 894 F.2d 1197, 1204 (10th Cir. 1990); *Mason and Dixon Lines, Inc. v. United States*, 708 F.2d 1043, 1047 (6th Cir. 1983); *Southern Pacific Transp. Co. v. Commissioner*, 75 T.C. 497, 652 (1980); Rev. Rul. 88-46, 1988-1 C.B. 76).

<sup>59</sup> *Talley Indus. v. Comm'r*, 116 F.3d 382 (9th Cir. 1997); *Fresenius Med. Care Holdings, Inc. v. United States*, 763 F.3d 64 (1st Cir. 2014).

<sup>60</sup> 26 U.S.C. § 162(f) (2012).

in question.<sup>61</sup> Conversely, in *Fresenius Medical Care Holdings, Inc. v. United States*, the First Circuit held that the court should consider other factors beside the lack of characterization in the settlement agreement<sup>62</sup>

#### A. Ninth Circuit Analysis

In *Talley*, three senior employees maintained fraudulent timecards with the number of hours worked, and these records were used to determine the costs of production and were submitted as part of the bill for the government.<sup>63</sup> The defendant also altered employee time cards so that labor costs which should have been allocated to fixed-price contracts were allocated to government contracts that did not have a fixed price.<sup>64</sup> These activities directly resulted in FCA violations.<sup>65</sup> The defendant agreed to settle, and in exchange, the government agreed not to prosecute the senior employees and to dismiss the other claims.<sup>66</sup> Throughout the settlement negotiation process, the parties had several disputes as to the actual damages of the claims, and the settlement agreement did not characterize the excess payments.<sup>67</sup> Tally paid a total of \$2.5 million as part of the settlement, characterized as \$1.56 million of estimated loss, \$1,855 as a penalty, but with \$940,000 remaining uncharacterized.<sup>68</sup>

The Tax Court held that the uncharacterized damages were compensatory because the government did not characterize the payment, and because the \$2.5 million settlement was “significantly lower than double the estimated amount of actual damages of \$1.56 million.”<sup>69</sup> The Tax Court also reasoned that if the excess payments were punitive, in addition to the civil

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<sup>61</sup> *Talley*, 116 F.3d at 387–88.

<sup>62</sup> *Fresenius*, 763 F.3d at 67.

<sup>63</sup> *Talley*, 116 F.3d at 384.

<sup>64</sup> *Id.*

<sup>65</sup> 31 U.S.C. § 3729 (2012).

<sup>66</sup> *Talley*, 116 F.3d at 385.

<sup>67</sup> *Id.* at 384.

<sup>68</sup> *Id.* at 385.

<sup>69</sup> *Id.*

penalties, which are clearly punitive, then there could be an implication of the double jeopardy clause.<sup>70</sup>

On appeal, the Commissioner argued that the uncharacterized payment constituted double damages under the FCA, which are considered punitive.<sup>71</sup> Talley, on the other hand, argued that the \$940,000 was intended to compensate for actual or unknown damages, and thus it was not intended to be a double damage.<sup>72</sup> Both parties presented conflicting evidence of intent by showing previous statements as to how much the actual damages were.<sup>73</sup> Because of the ambiguity of the intent, the Circuit Court reversed the Tax Court, finding that this was a genuine issue of fact for the trier-of-fact.<sup>74</sup>

In doing so, the Circuit Court followed the relevant tax principle stating, “[i]f a civil penalty is imposed for purposes of enforcing the law and as punishment for the violation thereof, [the payment is not deductible].”<sup>75</sup> But if the payments are compensating the government, the “expenses incurred as a result of the violation, [are deductible because it] it does not serve the same purpose as a criminal fine and is not ‘similar’ to a fine within the meaning of section 162(f).”<sup>76</sup> The Court reasoned that multiple damages can have dual purposes, stating “[t]he double damage provision of the FCA has both compensatory and deterrence purposes.”<sup>77</sup>

The Ninth Circuit concluded that the Tax Court erred because the violator has the burden to demonstrate the purpose of the damages, and there is no requirement to reach the maximum damages, particularly because the parties needed to settle quickly in these circumstances.<sup>78</sup>

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<sup>70</sup> *Id.* at 388.

<sup>71</sup> *Talley*, 116 F.3d at 386.

<sup>72</sup> *Id.* at 386–7.

<sup>73</sup> *Id.*

<sup>74</sup> *Id.* at 387.

<sup>75</sup> *Id.* at 385.

<sup>76</sup> *Talley*, 116 F.3d at 385–86.

<sup>77</sup> *Id.* at 387 (citing *United States v. McLeod*, 721 F.2d 282, 285 (9th Cir. 1983)).

<sup>78</sup> *Id.* at 387–388.

Talley is a manufacturer for the military and is one of a few companies that can satisfy the government's need.<sup>79</sup> In addition, the court rejected the argument that double damages implicated the double jeopardy clause and held "whether a payment is deemed compensatory for double jeopardy purposes does not determine whether the payment is deductible under the Tax Code."<sup>80</sup> If the "payment ultimately serves each of these purposes, i.e., law enforcement (nondeductible) and compensation (deductible)," the tax court must "determine which purpose the payment was designed to serve."<sup>81</sup>

The court remanded the case, finding that there were genuine issues of material fact, and that "[n]either the characterization nor purpose of the payment is clarified by the settlement agreement."<sup>82</sup> On remand, the Tax Court stated "[t]he record shows that the parties did not agree whether the portion of the settlement in excess of the Government's "singles" damages would constitute compensation to the Government for its losses or a penalty against Stencel [which is a subsidiary of defendant], thus follows that petitioner has failed to establish entitlement to a deduction for the disputed portion of the settlement."<sup>83</sup> The court on remand focused on the fact that the parties did not characterize the payments, and held that the defendant did not meet the burden of proving the payment's purpose.

#### B. First Circuit Analysis: Economic Realities Approach

In *Fresenius*, the defendant's subsidiaries "engaged in a conspiracy to defraud Medicare and other federal healthcare programs by double billing, paying kickbacks, ordering unnecessary laboratory tests, and retaining Medicare overpayments."<sup>84</sup> The global settlement agreement

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<sup>79</sup> *Id.* at 384.

<sup>80</sup> *Id.* at 388.

<sup>81</sup> *Id.* at 386 (citing *Waldman v. Commissioner*, 88 T.C. 1384, 1387 (1987), *aff'd*, 850 F.2d 611 (9th Cir. 1988)).

<sup>82</sup> *Talley*, 116 F.3d at 387.

<sup>83</sup> *Talley Indus., Inc. v. C.I.R.*, 77 T.C.M. (CCH) 2191 (T.C. 1999) *aff'd*, 18 F. App'x. 661 (9th Cir. 2001).

<sup>84</sup> *Fresenius Med. Care Holdings, Inc. v. United States*, No. 08-12118, 2013 WL 1946216, at \*1 (D. Mass. May 9, 2013) *aff'd*, 763 F.3d 64 (1st Cir. 2014).

contained eight agreements that all included a term stating that, “[n]othing in this Agreement constitutes an agreement by the United States concerning the characterization of the amounts paid hereunder for purposes of any proceeding under Title 26 of the Internal Revenue Code.”<sup>85</sup>

The settlement agreement stated that Fresenius would pay a total of \$486,334,232; \$101,186,898 was characterized as criminal fines and the remaining \$385,147,334 was the price for “Fresenius's absolution from civil liability.”<sup>86</sup> At the trial level, the court placed the burden of proof on the defendant and asked the jury to determine the deductibility of the \$385 million, considering the economic realities of the transaction.<sup>87</sup> The jury found that \$95,000,000 were compensatory, and thus deductible.<sup>88</sup> The trial court reasoned that the payment’s purpose could be proven through evidence of interest calculations, calculations of attorney billable hours, and expense records.<sup>89</sup>

On appeal, the government argued that under *Talley*, any FCA damages that exceed single damages should be considered punitive, unless the defendant can prove other intentions by presenting evidence of tax characterization.<sup>90</sup> The government went on to claim that the absence of characterization in the agreement defeats the defendant’s claim.<sup>91</sup> Essentially the government argued that because the burden is on the violator and they agreed not agree on a characterization, the violator cannot show the damages were compensatory.

The First Circuit held “that in determining the tax treatment of an FCA civil settlement, a court may consider factors beyond the mere presence or absence of a tax characterization

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<sup>85</sup> *Id.*

<sup>86</sup> *Fresenius*, 763 F.3d at 67.

<sup>87</sup> *Id.* at 69.

<sup>88</sup> *Id.*

<sup>89</sup> *Fresenius*, No. 08-12118, 2013 WL 1946216, at \*20.

<sup>90</sup> *Fresenius Med. Care Holdings, Inc. v. United States*, 763 F.3d 64, 69–70 (1st Cir. 2014).

<sup>91</sup> *Id.* at 69.

agreement between the government and the settling party.”<sup>92</sup> The court began by finding that “some amounts in excess of single damages generally are regarded as compensatory.”<sup>93</sup> The court went on to say “this makes good economic sense: an enforcement action following a fraud brings new costs and delays and requires a recovery of more than single damages to make the government whole.”<sup>94</sup> Judge Selya explained that these additional costs might include expenses of prosecuting the case and compensating for the delay in getting single damages.<sup>95</sup>

While the court agreed that the burden is on the defendant to prove the intent, the court stated “[a] rule that requires a tax characterization agreement as a precondition to deductibility focuses too single-mindedly on the parties' manifested intent in determining the tax treatment of a particular payment.”<sup>96</sup> Here, the court refused to focus on the settlement agreement as the single source of intent, realizing the practical effect of the situation.<sup>97</sup> The Court explained, “[s]uch an exclusive focus would give the government a whip hand of unprecedented ferocity: it could always defeat deductibility by the simple expedient of refusing to agree—no matter how arbitrarily—to the tax characterization of a payment.”<sup>98</sup> The court struggled to define the application of *Talley*, explaining “[t]he case is distinguishable on its facts and its message is unclear . . . . If *Talley* stands for the proposition asserted by the government, then *Talley* is incorrectly decided and does not deserve our allegiance.”<sup>99</sup>

The court clarified that the party’s intent is not irrelevant, stating “[i]f the government and a defendant settle an FCA claim and specifically agree as to how the settlement will be

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<sup>92</sup> *Fresenius*, 763 F.3d at 67.

<sup>93</sup> *United States ex rel. Chandler*, 538 U.S. 119, 130–31 (2003).

<sup>94</sup> *Fresenius*, 763 F.3d at 68 (citing *United States ex rel. Chandler*, 538 U.S. 119, 130–31 (2003)); *United States v. Bornstein*, 423 U.S. 303, 315 (1976).

<sup>95</sup> *Id.* at 69 (citing *Chandler*, 538 U.S. at 131, 123); *Fresenius*, 2013 U.S. Dist. LEXIS 66234 at \*5-6.

<sup>96</sup> *Id.* at 70.

<sup>97</sup> *Id.*

<sup>98</sup> *Fresenius*, 763 F.3d at 70.

<sup>99</sup> *Id.* at 71.

treated for tax purposes, it is hard to envision any reason why a reviewing court should not honor that agreement.”<sup>100</sup> Here, however, the parties agreed not to agree on characterization of the payments.<sup>101</sup> This prompted the court to eschew the *Talley* standard in favor of looking at the “economic realities” of the transaction.<sup>102</sup>

FCA characterization issues are not solely related to settlements. The *Fresenius* court explained that characterization issues arise from court awards in FCA claims as well.<sup>103</sup> “When an FCA claim is tried rather than settled, there will perforce be no characterization agreement available to guide the tax treatment of awarded damages.”<sup>104</sup> Just because there is a court award, it does not mean that the payments exceeding single damages are automatically punitive.<sup>105</sup> The same logic should apply in the settlement context. This is why having tax characterization agreement as precondition produces an “infelicitous asymmetry.”<sup>106</sup>

The government also argued that the jury instructions were flawed because the instructions stated that payments can only be considered punitive if they are “above what is necessary” to compensate the government.”<sup>107</sup> The government contended that this residual approach to damages is not proper because discounts in settlement agreements “require some level of compromise.”<sup>108</sup> The court does not address this issue because the argument was presented too late.<sup>109</sup>

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<sup>100</sup> *Id.* at 70.

<sup>101</sup> *Id.*

<sup>102</sup> *Id.*

<sup>103</sup> *Id.* at 71.

<sup>104</sup> *Fresenius*, 763 F.3d at 71(citing *Cook County v. United States ex rel. Chandler*, 538 U.S. 119, 130–31 (U.S. 2003) *United States v. Bornstein*, 423 U.S. 303, 315 (U.S. 1976).

<sup>105</sup> *Id.*

<sup>106</sup> *Id.*

<sup>107</sup> *Id.*

<sup>108</sup> *Id.*

<sup>109</sup> *Id.*

Essentially, the First Circuit rejected the Ninth Circuit's approach that allowed the government to place violators in a catch-22 situation, and instead adopted an approach that looks at the true purpose, or economic realities, of the payments.<sup>110</sup> The Ninth Circuit, on the other hand, relied heavily on the settlement agreement to determine the characterization of the damages, which has supported the government's plan to place violators in a catch-22 situation.<sup>111</sup>

Part IV. An Economic Realities Approach Coupled with the Burden Shifting to the Government Provides the Highest Likelihood of Determining the True Purpose of the Payments

The First Circuit economic realities approach is the better than the Ninth Circuit approach and the hierarchy approach proposed by F. Philip Manns in determining the characterization of settlements because it gets at the true purpose of the damages. This Comment argues, however, that the First Circuit approach standing alone is insufficient. Instead, courts should apply the economic realities approach and place the burden of proof to prove that the damages are punitive on the government, instead of requiring the violator to show that the damages are compensatory. Because the payments are likely to be compensatory, the burden should be properly placed on the government.

A. The Ninth Circuit Approach Is Flawed

The approach in *Talley* lacks clarity, a problem which the *Fresenius* court took issue with when the government argued in reliance on *Talley*.<sup>112</sup> One way to read *Talley*, as the government in *Fresenius* did,<sup>113</sup> is that the Ninth Circuit created a rule making settlement amounts for FCA cases in excess of single damages and punitive fees non-deductible, unless the settlement agreement expressly states that the payments are compensatory.<sup>114</sup>

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<sup>110</sup> *Fresenius*, 763 F.3d at 67.

<sup>111</sup> *Talley Indus. v. Comm'r*, 116 F.3d 382 (9th Cir. 1997).

<sup>112</sup> *Id.* at 71.

<sup>113</sup> *Id.* at 69–70.

<sup>114</sup> *Talley Indus., Inc. v. C.I.R.*, 77 T.C.M. (CCH) 2191 (T.C. 1999) *aff'd*, 18 F. App'x 661 (9th Cir. 2001).



Focusing on the settlement agreement without considering the reality of the transaction, which can clearly compensate the government, directly violates § 162 of the Tax Code because compensatory payments are deductible.<sup>115</sup> The practical effect is that parties need to express clear intent and characterize the excess damages, because courts focus mainly on the settlement agreement as the source of intent. As mentioned *supra*, this can be a challenge when considering the leverage the government has in many FCA cases. Another way to read *Talley* is that the court will allow the petitioner to show intent outside the agreement, but the lack of characterization in the agreement will likely be determinative.<sup>116</sup> Under either reading, these approaches fail to consider the “economic reality” of the settlement and the situation that FCA violators are in.

As outlined *supra*, many of the claims brought under the FCA include actions against pharmaceutical companies’ abuse of federal programs.<sup>117</sup> The hammer that forces the defendants to settle with the government is the risk of litigating and losing, which can result in their exclusion from billing federal health programs.<sup>118</sup> Such a result would likely lead pharmaceutical companies to go bankrupt, as the government is the largest payer for pharmaceuticals.<sup>119</sup> This type of leverage allows the government to refuse characterization of payments in the settlement agreement. The Ninth Circuit essentially approves of this catch-22 situation.<sup>120</sup> Focusing on solely the settlement agreement to determine the intentions of the parties does not consider the purpose of the payments if the government refuses to characterize the payments.

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<sup>115</sup> 26 C.F.R. § 1.162–21(b)(2) (2011).

<sup>116</sup> 77 T.C.M. (CCH) 2191 (T.C. 1999).

<sup>117</sup> Rabecs, *supra* note 8, at 3.

<sup>118</sup> 42 U.S.C. § 1320a-7(a)

<sup>119</sup> Centers for Medicaid and Medicare Review Services, *CMS Roadmaps for the Traditional Fee-for-Service (FFS) Program: Overview*, CMS.gov, [http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/downloads/RoadmapOverview\\_OEA\\_1-16.pdf](http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/downloads/RoadmapOverview_OEA_1-16.pdf). (last visited Jan. 16, 2015)

<sup>120</sup> *Talley Indus. v. Comm’r*, 116 F.3d 382, 387-88(9th Cir. 1997).

## B. The Economic Realities Approach is Better Reasoned

Focusing on the economic realities of the transaction is a logical approach because it takes the defendant out of the catch-22 situation, and the courts can look at the true purpose of the payments.<sup>121</sup> Under this approach, the entirety of the record surrounding the settlement becomes relevant.<sup>122</sup> The *Fresenius* court understood that payments exceeding single damages could easily have been compensating the government, stating “an enforcement action following a fraud brings new costs and delays.”<sup>123</sup> Compensating for unknown damages stemming from the violation is quite reasonable, and the economic realities test would properly identify the true purpose, whether compensatory or punitive.

The trial court in *Fresenius* reasoned that the parties’ intent could be proven through evidence of interest calculations, calculations of attorney billable hours, and expense records.<sup>124</sup> “While the parties’ negotiations also may provide evidence of the compensation due to the government, these negotiations and the eventual settlement agreement will seldom be the sole evidence available to foresighted parties.”<sup>125</sup> Pharmaceutical companies settling with the government in an FCA claim now need to gather other evidence to show the intent of the payments. They cannot rely on a settlement agreement that does not characterize the payments because of the government’s refusal to do so. The First Circuit appreciated this catch-22 and adopted an approach that looks at the true purpose of the payments, including evidence outside the settlement agreement.<sup>126</sup>

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<sup>121</sup> *Fresenius Med. Care Holdings, Inc. v. United States*, 763 F.3d 64, 69 (1st Cir. 2014).

<sup>122</sup> *Fresenius Med. Care Holdings, Inc. v. United States*, No. 08-12118, 2013 WL 1946216, at \*7 (D. Mass. May 9, 2013) *aff’d*, 763 F.3d 64 (1st Cir. 2014).

<sup>123</sup> *Fresenius*, 763 F.3d at 68 (citing *United States ex rel. Chandler*, 538 U.S. 119, 130–31 (2003); *United States v. Bornstein*, 423 U.S. 303, 315 (1976) (describing FCA multiple damages as “necessary to compensate the Government completely for the costs, delays, and inconveniences occasioned by fraudulent claims”).

<sup>124</sup> No. CIV.A. 08-12118, 2013 WL 1946216, at \*20.

<sup>125</sup> *Id.*

<sup>126</sup> *Id.*

Applying the economic realities approach to the facts in *Tally*, the First Circuit approach would look beyond the lack of characterization of payments in the settlement agreement.<sup>127</sup> This includes looking at evidence of how the payments were calculated and any evidence that would indicate what the parties were intending during the negotiations.<sup>128</sup> These negotiations are likely complex and contain evidence showing the break down of the payment purposes.

In *Talley*, the court focused on the ambiguity in the agreement and did not consider the economic reality of the transaction.<sup>129</sup> Thus, on remand the *Talley* court allowed both parties to produce evidence to show intention, which included counsel negotiations, however, the court concluded by stating “[p]etitioner did not clarify the matter . . . . The parties executed a settlement agreement that is silent on the subject of the characterization of the settlement payment.”<sup>130</sup>

Under the economic realities test, however, the burden of producing the evidence of intent remains on the defendant, but the court would not focus exclusively on the presence or lack of express intent.<sup>131</sup> The defendant presented evidence that the government suffered losses exceeding the settlement, which were “incidental losses, such as the costs associated with the investigation, the suspension and debarment proceedings, [and] the grounding of Navy aircraft for lack of replacement parts.”<sup>132</sup> The defendant also submitted an offer that characterized the payments as compensatory, but the government sent a counteroffer leaving the payments uncharacterized.<sup>133</sup>

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<sup>127</sup> *Fresenius*, 763 F.3d at 70.

<sup>128</sup> No. CIV.A. 08-12118, 2013 WL 1946216, at \*20.

<sup>129</sup> *Talley Indus., Inc. v. C.I.R.*, 77 T.C.M. (CCH) 2191 (T.C. 1999) *aff'd*, 18 F. App'x 661 (9th Cir. 2001).

<sup>130</sup> *Id.* at 7.

<sup>131</sup> *See Fresenius*, 763 F.3d 64.

<sup>132</sup> 77 T.C.M. (CCH) 2191 \*6 (T.C. 1999).

<sup>133</sup> *Id.* at 3-4.

The government did not take the opportunity to characterize the payments as punitive, despite characterizing the payments as punitive within in-house communications.<sup>134</sup> The government could have simply included the characterization of these payments as punitive, but they had no impetus to, given their superior bargaining power.<sup>135</sup> The economic reality of the transaction is likely to be compensatory based on those facts; however, the trial court on remand followed the Ninth Circuit approach.<sup>136</sup>

Courts need to understand the reality of the catch-22 situation the government imposes and focus on the actual basis of the transaction to avoid giving the government unprecedented power. This approach will force the government to characterize settlement payments, or else the court will look at the actual intent of the transaction. This is especially the case where the government refuses to characterize the payments. Allowing the government to create a catch-22 situation defeats the purpose of § 162 of the Tax Code, because the violator is not able to prove the intent.

### C. Hierarchy Approach

F. Philip Manns proposes a refined hierarchy approach that courts should use when considering whether payments are punitive or compensatory.<sup>137</sup> This approach looks at the “(1) legislative intent, (2) the particular circumstances at hand, and (3) the nature of the remedy.”<sup>138</sup> In applying this approach, court would start by looking observing the legislative intent, then consider the facts surrounding the case, and finally consider the remedies nature. Manns argues that

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<sup>134</sup> *Id.* at 7.

<sup>135</sup> *Id.*

<sup>136</sup> *See id.*

<sup>137</sup> *See Manns, supra* note 47.

<sup>138</sup> *Id.* at 288.

courts and administrative agencies have accepted attenuated declarations of punitive purpose, . . . have arrogated power to ‘substance over form’ analysis in derogation of the purpose of section 162(f), . . . and improperly have required the taxpayer to prove that the exaction was compensatory rather than that it was merely not-punitive.<sup>139</sup>

Manns proposes that courts expressly adopt this hierarchy, which he claims has been implied in courts analyses.<sup>140</sup>

The hierarchy approach presents valid arguments and identifies the issue the First Circuit expressed with the Ninth Circuit’s approach; however, it fails to consider its practical application to cases involving the FCA. While considering the legislative intent, the circumstances, and the nature of the remedy<sup>141</sup> are reasonable ways to address whether damages are punitive or compensatory, the economic realities approach properly focuses on the core issue. For example, the government should not rely on the legislative intent of a statute to tax a violator when the economic reality of the transaction is to compensate the government for other damages caused by the violation. This would directly violate the Tax Code, which allows compensatory damages to be deducted.<sup>142</sup> The legislative intent should be irrelevant if the parties’ intentions are to compensate the government.

The economic realities approach looks at the true intentions of the damages, instead of having the parties make arguments as to the legislative intent. The third element of this hierarchy—the nature of the remedy—is essentially the focus of the economic reality approach; however, looking at the “nature of the remedy” is too general. The economic realities approach, on the other hand, has practical application and looks at the whole transaction. While the

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<sup>139</sup> *Id.* at 293.

<sup>140</sup> *Id.* at 289.

<sup>141</sup> *Id.* at 288.

<sup>142</sup> 26 C.F.R. § 1.162–21(b)(2) (2011).

hierarchy approach is better than looking solely at the settlement agreement, the economic realities approach is more practical and focused on the main issue.

#### D. The Burden to Show the Purpose Should be on Plaintiff

Placing the burden on the plaintiff to show the purpose is better reasoned when considering the likelihood of the payments to have been compensatory. By placing the burden on the violator, there is a presumption that the payments are punitive, especially in cases where the government refuses to characterize the payments. The Supreme Court has held that “an income tax deduction is a matter of legislative grace and that the burden of clearly showing the right to the claimed deduction is on the taxpayer.”<sup>143</sup> Courts have relied on this to place the burden on the violator.

The Supreme Court in *United States ex rel. Marcus v. Hess*, however, stated “[w]e think the chief purpose of the statutes here was to provide for restitution to the government of money taken from it by fraud, and that the device of double damages plus a specific sum was chosen to make sure that the government would be made completely whole . . . This conclusion is consistent with a statement made immediately before final passage of the bill.”<sup>144</sup> While the Court reasoned that the burden should be on the taxpayer,<sup>145</sup> it still held that the FCA double or treble damages are likely compensating the government.<sup>146</sup>

In addition, some commentators have indicated that the Supreme Court’s decision in *Hudson v. United States* has “defended punitive damages as a measure required to combat fraud.”<sup>147</sup> The Court in *Hudson* held that civil penalties did not implicate the double jeopardy

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<sup>143</sup> *INDOPCO, Inc. v. Comm’r*, 503 U.S. 79, 84 (1992).

<sup>144</sup> *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 551–552 (1943).

<sup>145</sup> *INDOPCO*, 503 U.S. at 84.

<sup>146</sup> *Hess*, 317 U.S. at 551–552.

<sup>147</sup> Dennis Oscar Vann, Jr., *Stemming the Federal Tort Fountain: Why Federal Courts Should Maintain Implied Certification Limitations on Qui Tam Suits Against Nonclaimant Defendants*, 47 GA. L. REV. 999, 1005 (2013).

clause.<sup>148</sup> The Court was addressing issues concerning double jeopardy implications with criminal prosecution and civil penalties.<sup>149</sup> Here, the issue is different because the treble and double damages are not clearly defined as punitive, while the civil penalties are. This Comment does argue, however, that the treble and double damages are more likely to be compensatory rather than punitive.

The court in *Cook County* held that the purpose of the damages can be compensatory stating, “[i]n qui tam cases the rough difference between double and triple damages may well serve not to punish, but to quicken the self-interest of some private plaintiff who can spot violations and start litigating to compensate the Government, while benefiting himself as well.”<sup>150</sup> The court also explained that “[h]aving a whistleblower provision and allowing for treble damages indicates the purpose of promoting citizens to sue on behalf of the government, while the government is being properly compensated for the fraud and any unknown damages as a result.”<sup>151</sup> The court in *Bornstein* also mentioned “some liability beyond the amount of fraud is usually ‘necessary to compensate the government completely for costs, delays, and inconveniences occasioned by fraudulent claims.’”<sup>152</sup>

In addition, the plain statutory text of the FCA indicates that the treble or double damages are actually compensating the government rather than punishing the violator. The FCA allows the government to claim “three times the damages which the Government sustains because of the act of that person.”<sup>153</sup> Based on this language, it seems logical to conclude that the damages claimed are to compensate the government. This makes more sense when considering that the

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<sup>148</sup> *Hudson v. United States*, 522 U.S. 93 (1997).

<sup>149</sup> *Hudson*, 522 U.S. at 93 (1997).

<sup>150</sup> *Cook Cnty., Ill. v. U.S. ex rel. Chandler*, 538 U.S. 119 (2003) (citing *Hess*, 317 U.S. at 547).

<sup>151</sup> *Id.* (citing *United States v. Bornstein*, 423 U.S. 303, 315 (1976)).

<sup>152</sup> *Bornstein*, 423 U.S. at 315.

<sup>153</sup> 31 U.S.C. § 3729(a)(1) (2012).

FCA already puts in place civil penalties to punish the violator.<sup>154</sup> While it is conceivable that the intentions would be to punish the violator, the civil penalties are already in place to achieve that.

While the First Circuit realizes the likelihood that treble and double damages are compensatory,<sup>155</sup> the court does not go as far as creating a rule making them automatically compensatory.<sup>156</sup> The court will simply use the economic realities approach in determining the intent.<sup>157</sup> In comparison, the Ninth Circuit is practically presuming that the double damages are punitive by putting emphasis on the characterization of the damages.<sup>158</sup> The First Circuit would not need to go to such an extreme if the burden was properly placed on the plaintiff to show that the payments are actually punitive.

Because the damages are likely to be compensatory, it would make logical sense to have the burden on the government to show otherwise. The burden of proof traditionally rested on the plaintiff,<sup>159</sup> and this situation does not warrant any change to this tradition. As mentioned earlier, Manns proposes that the violator should still have the burden, but only to show that the damages were non-punitive.<sup>160</sup> While this approach does make more sense than having the burden to show that the damages were compensatory, having the burden on the government will eliminate any issues of agreeing to uncharacterized damages in the settlement agreement. The government will not be able to hide behind the agreement anymore because the burden will be on it to show that the damages were actually in place to punish.

#### E. Policy Reasons to Place the Burden on Government and Adopt the Economic Realities Approach

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<sup>154</sup> *Id.*

<sup>155</sup> *Fresenius Med. Care Holdings, Inc. v. United States*, 763 F.3d 64, 68 (1st Cir. 2014).

<sup>156</sup> *Id.*

<sup>157</sup> *Id.* at 67.

<sup>158</sup> *Talley Indus. v. Comm'r*, 116 F.3d 382, 387 (9th Cir. 1997).

<sup>159</sup> *See Hooper v. Robinson*, 98 U.S. 528, 540 (1878).

<sup>160</sup> Manns, *supra* note 47, at 288.



While the FCA is a great tool for the government to tackle the issue of fraudulent activity by pharmaceutical companies, the overall impact is ultimately hurting consumers. This Comment is not proposing that the FCA is detrimental and should be abandoned, but rather that the government is abusing its power. As mentioned *supra*, the FCA is already costing many pharmaceutical companies billions of dollars.<sup>161</sup> Allowing the government to take a second bite at the apple by refusing to characterize damages, and in turn refusing to allow violators to deduct the payments, is shifting costs to the general public. Undoubtedly, this issue is making drugs more costly. A counterargument can be made that the government is the one who is injured when consumers submit claims to the government despite their not being injured. Also, even if the FCA is affecting drug costs, the government is the largest payer.<sup>162</sup> This reasoning is flawed because consumers who are not being supported by government healthcare programs are being hurt the most. The costs are just shifting to consumers.

In discussing this cost shifting issue, one commentator found that “[f]unds recovered through health care fraud enforcement are distributed to the Medicare Trust Fund, to the federal agencies that investigate and prosecute health care fraud, and to private parties who initiate suits on the government's behalf.”<sup>163</sup> The utilization of the FCA to combat fraud is not benefiting the consumers that are actually hurt by the fraud.<sup>164</sup> This commentator proposes that “direct compensation of injured patients or a broader co-payment fund” would address this issue.<sup>165</sup>

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<sup>161</sup> See *Abbott Labs to Pay \$1.5 Billion to Resolve Criminal & Civil Investigations of Off-label Promotion of Depakote*, JUSTICE.GOV, (May 7, 2012), <http://www.justice.gov/opa/pr/abbott-labs-pay-15-billion-resolve-criminal-civil-investigations-label-promotion-depakote>.

<sup>162</sup> *CMS Roadmaps for the Traditional Fee-for-Service (FFS) Program: Overview*, CMS.gov, [http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/downloads/RoadmapOverview\\_OEA\\_1-16.pdf](http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/downloads/RoadmapOverview_OEA_1-16.pdf). (last visited Jan. 16, 2015)

<sup>163</sup> Joan H. Krause, *A Patient-Centered Approach to Health Care Fraud Recovery*, 96 J. CRIM. L. & CRIMINOLOGY 579 (2006).

<sup>164</sup> *Id.*

<sup>165</sup> *Id.* at 619.

While this approach puts the proper focus on patients, the measures proposed in this Comment would also lessen the cost shifting impact via a more simplistic application. By simply placing the burden on the government to show the intent of the damages and utilizing the economic realities approach, the costs can be greatly reduced. Although the economic realities approach coupled with burden shifting does not address the larger issue of how the FCA fails to actually help the injured, the ease of application by the courts will allow pharmaceutical companies to properly characterize damages. This would likely lead to cheaper drug costs.

#### Part V. Conclusion

The FCA is already burdening the pharmaceutical industry, and the government is abusing the situation by refusing to characterize settlement payments. The First Circuit approach to determine whether payments that exceed single damages and civil penalties are compensatory or punitive for tax purposes gets to the actual purpose of the funds.<sup>166</sup> The court correctly rejects the argument that because the settlement agreement does not indicate the characterization of payment, then the defendant has not met its burden to show that the payments were compensatory.<sup>167</sup> Focusing on the economic reality of the transaction is proper because it gets to the real intent of the party and avoids the catch-22 situation that the government creates by not characterizing the payments in the settlements prior to litigation.<sup>168</sup> This is particularly important in many FCA cases that include the possibility of exclusion from government programs.<sup>169</sup> In those situations, the government has the ultimate leverage in avoiding characterization. In addition, the burden of proving the purpose of the payments should be placed on the government because these payments are likely compensatory. These proposals are supported by

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<sup>166</sup> *Fresenius Med. Care Holdings, Inc. v. United States*, 763 F.3d 64, 67 (1st Cir. 2014).

<sup>167</sup> *Id.* at 70.

<sup>168</sup> *Id.*

<sup>169</sup> 42 U.S.C. § 1320a-7(a) (2012).

congressional intent and the plain statutory text, and they help address the cost shifting to consumers.