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FRAUD AND THE MEDICAID DRUG REBATE PROGRAM

Kyle Mitchell

Introduction

Among the numerous drug manufacturers that have been recently charged with violating the Medicaid Drug Rebate Program, Mylan Pharmaceuticals and their product, EpiPen, has been one of the most highly publicized. The issue arises when considering the distinction between a drug product being classified as an innovator or a non-innovator drug for rebate purposes. While the distinction at first may seem to be a simple matter of nomenclature, the amount of correlated rebate payments is substantial. As of January 2016, The Center for Medicare and Medicaid Services (“CMS”) has enacted its Covered Outpatient Drugs final rule with comments.¹ This final rule was aimed to clarify the discrepancy between the classification of innovator and non-innovator drugs for manufacturers involved in the Medicaid Drug Rebate Program. While this rule has helped to distinguish the two classifications, it has left a void where companies such as Mylan have products that can fall into either category. Manufacturers have developed products that contain aspects of both innovator and non-innovator status and will be further known as drug-device combination products (“DDCP”)². These products have been mislabeled in the past, and will continue to be mislabeled until a proper rule is implemented to clarify the confusion.³

¹ *Medicaid Drug Rebate Program*, MEDICAID.GOV: KEEPING AMERICA HEALTHY, <https://www.medicaid.gov/medicaid/prescription-drugs/covered-outpatient-drug-policy/index.html>, (last visited Mar. 25, 2017).

² *About Combination Products*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES: U.S. FOOD & DRUG ADMINISTRATION, <https://www.fda.gov/CombinationProducts/AboutCombinationProducts/default.htm> (last updated Sept. 08, 2016).

³ James Matthews et al., *The EpiPen Controversy Signals Intensifying Scrutiny of Drug Classification Under Medicaid Rebate Program*, HEALTHCARE LAW TODAY, (Sept. 07, 2016), <https://www.healthcarelawtoday.com/2016/09/07/the-epipen-controversy-signals-intensifying-scrutiny-of-drug-classification-under-medicaid-rebate-program/>, (last visited Mar. 22, 2017).

The purpose of this paper is to introduce a proposed legislative solution to be implemented by CMS to help resolve the aforementioned issue. The first section will define what the Medicaid Drug Rebate Program is, the process a manufacturer must go through to enroll, and what an innovator and non-innovator classification entail. The second section goes through varying examples of drug manufacturers who have misclassified their products for rebate purposes and have consequently paid significant financial penalties. The third section discusses CMS's final rule with comments and its' narrow exception. The fourth section contains a proposed legislative solution to the categorization issue caused by DDCPs. The final section discusses how manufacturer misclassification may be actionable under the False Claims Act.

I. Medicaid Drug Rebate Program

The Medicaid Drug Rebate Program (“MDRP”), was established by Congress in 1990 as part of the Omnibus Budget Reconciliation Act and authorized by Section 1927 of the Social Security Act.⁴ The purpose of the enactment was to control the cost of prescription drugs covered under Medicaid by offsetting federal and state costs.⁵ The program encompasses CMS, State Medicaid Agencies, and the drug manufacturers in participation.⁶ There are approximately 600 drug manufacturers in participation, and currently all fifty states cover prescription drugs under the program.⁷

⁴ Stefanie Berman, *A Legislative History of the Medicaid Drug Rebate Law: The Drug Industry and the Crusade of Senator David Pryor*, HARVARD UNIVERSITY DASH, (Mar. 19, 2004) <https://dash.harvard.edu/bitstream/handle/1/8965555/Berman.pdf?sequence=1>.

⁵ *Medicaid Drug Rebate Program*, MEDICAID.GOV: KEEPING AMERICA HEALTHY, <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html>, (last updated June 16, 2016).

⁶ *Id.*

⁷ *Id.*

a. Enrollment Process

The first step to admission is a requirement that the drug manufacturer enters into a national rebate agreement with the Secretary of the Department of Health and Human Services (“HHS”) in exchange for state Medicaid coverage.⁸ This has the potential to include a large proportion of the manufacturer’s drugs. Second, when the manufacturer markets a new covered drug, it must provide the drug’s product and pricing data to CMS via the Drug Data Reporting (“DDR”).⁹ Third, manufacturers must pay a certain rebate amount for which payment was made under the state plan.¹⁰ The rebates are to be paid on a quarterly basis to the states, which then share with the federal government, to help offset the price.¹¹ Finally, in addition to signing a national rebate agreement, drug manufacturers are required to enter into two other federal program agreements in order to have their drugs covered.¹² The two agreements include a pricing agreement for the Section 340B Drug Pricing Program¹³ and a Master agreement with the Secretary of Veteran Affairs for the Federal Supply Schedule.¹⁴

b. Innovator v. Non-Innovator

The drugs are then classified into two categories: innovator and non-innovator. A statutory formula is used to determine the amount rebate due for each unit of the drug.¹⁵ Innovator drugs either owe 23.1% of the Average Manufacturer Price (“AMP”) per unit or the

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.*

¹¹ *Medicaid Drug Rebate Program*, MEDICAID.GOV: KEEPING AMERICA HEALTHY, <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html>, (last updated June 16, 2016).

¹² *Id.*

¹³ 340B Program is an agreement by a manufacturer to provide outpatient drugs to covered entities at reduced prices. *340B Drug Pricing Program*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICE: HEALTH RESOURCES AND SERVICES ADMINISTERED, <https://www.hrsa.gov/opa/>, (last reviewed Mar. 2017).

¹⁴ *Medicaid Drug Rebate Program*, MEDICAID.GOV: KEEPING AMERICA HEALTHY, <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html>, (last updated June 16, 2016).

¹⁵ *Id.*

difference between the AMP and the best price per unit (this is adjusted by the Consumer Price Index-Urban (“CPI-U”) based on launch date and current quarter AMP).¹⁶ The cap on the total rebate amount for each innovator drug is at 100% of the AMP.¹⁷ Non-innovator drugs owe 13% of the AMP per unit.¹⁸ This 10% distinction can be crucial between having a product classified as an innovator or non-innovator. In the case of large pharmaceuticals companies, this has the potential to cost the states and their tax payers millions of dollars.¹⁹ Following the passage of the Affordable Care Act, generic drugs have been exempted from the additional inflationary rebate applied to brand drugs for which AMP increases faster than the rate of inflation.²⁰

II. MDRP and Fraud

Based on the large discrepancy in rebate amounts, numerous pharmaceutical companies have attempted to classify their products as non-innovators. Whether these acts are intentional or not, companies such as Mylan Pharmaceuticals, Dava Pharmaceuticals, KV Pharmaceuticals, UDL Laboratories, Inc., AstraZeneca Pharmaceuticals LP, and Ortho McNeil Pharmaceutical, Inc., each has faced adverse judgments for misclassification. When determining whether a drug should be classified as an innovator or non-innovator, there are two key factors to evaluate. The first factor is whether the active pharmaceutical ingredient (“API”) is an innovator or non-innovator medication. The FDA defines APIs as follows:

[A]ny substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production

¹⁶ *Id.*

¹⁷ *Medicaid Drug Rebate Program*, MEDICAID.GOV: KEEPING AMERICA HEALTHY, <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html>, (last updated June 16, 2016).

¹⁸ *Id.*

¹⁹ Ed Silverman, *Feds slam Mylan for misclassifying EpiPen, with 'financial consequences' to Medicaid*, STAT, (Sept. 29, 2016), <https://www.statnews.com/pharmalot/2016/10/05/mylan-overcharged-medicaid-epipen/>.

²⁰ James Matthews et al., *The EpiPen Controversy Signals Intensifying Scrutiny of Drug Classification Under Medicaid Rebate Program*, HEALTHCARE LAW TODAY, (Sept. 07, 2016), <https://www.healthcarelawtoday.com/2016/09/07/the-epipen-controversy-signals-intensifying-scrutiny-of-drug-classification-under-medicaid-rebate-program/>.

of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.²¹

An example of a generic API can be demonstrated as follows: if you had a headache, you would take Tylenol or Advil. The generic active ingredient found in both is acetaminophen.

a. New Drug Application v. Abbreviated New Drug Application

The second factor is whether the drug is marketed under an abbreviated new drug application (“ANDA”) or a new drug application (“NDA”). A NDA is a submission by a drug manufacturer, to the FDA, when the sponsor of a new drug believes enough evidence on the drug’s safety and effectiveness has been obtained to meet FDA’s requirements for marketing approval.²² The application must contain data from specific technical viewpoints for review. These include: chemistry, pharmacology, medical, biopharmaceutics, and statistics.²³ If the NDA is granted approval, the product is permitted marketing rights in the United States.²⁴

In contrast, an ANDA is submitted to the FDA’s Center for Drug Evaluation and Research. The ANDA must be accompanied with data that provides for review and ultimate approval of a generic drug product.²⁵ ANDAs are abbreviated because they are generally not required to include preclinical (animal) and clinical (human) testing data to demonstrate safety and effectiveness.²⁶ Instead, a generic applicant must establish that its’ product is bioequivalent

²¹ Edward Lamb, *What Are Active Pharmaceutical Ingredients, or APIs?*, THE BALANCE, <https://www.thebalance.com/what-are-active-pharmaceutical-ingredients-or-apis-2663827>, (last updated July 28, 2016).

²² Types of Applications, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES: U.S. FOOD & DRUG ADMINISTRATION, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications> (last updated Oct. 23, 2014).

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*

(i.e., performs in the same manner as the innovator drug).²⁷ Once approved, the generic product can be marketed as a safe, effective, and lower costing alternative to a brand name drug.²⁸ While it may seem this distinction makes the classifications between NDAs and ANDAs rather black and white, a shade of grey is added when dealing with DDCPs. These products include both a brand name administering device and a generic drug. To elaborate on this point, The New York Times reported that many old medications are being delivered in new packages. These medications include asthma inhalers, insulin injectors, and emergency rescue drugs like GlucaGen and Narcan, both utilize generic APIs administered by new intramuscular auto-injectors.²⁹

b. Illustrations of Past Misclassifications

Mylan Pharmaceuticals has come under fire in recent media for the significant price increase of its EpiPen product. The price has dramatically increased 548% over the past decade to \$608 for a two-pack device.³⁰ This was further exacerbated by the fact that Mylan had been misclassifying its product as a non-innovator drug, relying on a 1997 letter from CMS. This letter was written to Dey Laboratories, which Mylan purchased in 2007, noting that it was “fitting and proper” to classify EpiPen as a “non-innovator” or generic drug product.³¹ The letter reads,

²⁷ *Id.*

²⁸ Types of Applications, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES: U.S. FOOD & DRUG ADMINISTRATION, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications> (last updated Oct. 23, 2014).

²⁹ James Matthews et al., *The EpiPen Controversy Signals Intensifying Scrutiny of Drug Classification Under Medicaid Rebate Program*, HEALTHCARE LAW TODAY, (Sept. 07, 2016), <https://www.healthcarelawtoday.com/2016/09/07/the-epipen-controversy-signals-intensifying-scrutiny-of-drug-classification-under-medicare-rebate-program/>.

³⁰ Ed Silverman, *Mylan overcharged Medicaid for EpiPen for years, despite warnings*, STAT, (Oct. 05, 2016), <https://www.statnews.com/pharmalot/2016/10/05/mylan-overcharged-medicare-epipen/>.

³¹ Ed Silverman, *Mylan to pay \$465 million to settle claims of shortchanging Medicaid*, STAT, (Oct. 07, 2016), <https://www.statnews.com/pharmalot/2016/10/07/mylan-465-million-settlement-epipen-medicare/>.

[I]n order to determine the Drug Category . . . to use when reporting [EpiPen] to the MDRP. Because these products are included in a package with a new delivery system, they are listed by the FDA under a NDA (New Drug Application), HCFA stated; however, “[t]he products themselves . . . are listed under an ANDA (Abbreviated New Drug Application) because they are very old products and made by many generic drug companies. HCFA concluded, even though the current NDCs of these products . . . are listed under an NDA, *it is entirely fitting and proper . . . to report them to the Drug Rebate Program with a Drug Category of ‘N’ (Non-innovator, Multiple Source)* and be subject to the lowest rebate amount of 11% of quarterly AMP.³²

From 2011 to 2015, Medicaid spent \$797 million on EpiPen after rebates.³³ Acting CMS

administrator Andy Slavitt noted, Mylan should have been paying 23.1% instead of 13%, but failed to do so because the company improperly classified EpiPen as a generic, despite being told its classification was incorrect.³⁴ This is a taxpayer issue because states and the federal government use the rebates from drug manufacturers to offset the cost of covered medicines. Although the entire amount of EpiPen sales does not go directly to Medicaid, Evercore ISI analyst, Umer Raffat, has estimated that about 20% of sales have.³⁵ In October 2016, Mylan agreed to a \$465 million settlement with the U.S. Department of Justice.³⁶ Although it was originally believed EpiPen would be relabeled as a brand-name drug by April 2017, recent reports state Mylan will be fighting this change.

The second example of misclassification involves a Delaware-based corporation, Dava Pharmaceuticals. Brought under the False Claims Act (“FCA”), Dava was charged with

³² James Matthews et al., *The EpiPen Controversy Signals Intensifying Scrutiny of Drug Classification Under Medicaid Rebate Program*, HEALTHCARE LAW TODAY, (Sept. 07, 2016), <https://www.healthcarelawtoday.com/2016/09/07/the-epipen-controversy-signals-intensifying-scrutiny-of-drug-classification-under-medicare-rebate-program/>.

³³ Ed Silverman, *Mylan overcharged Medicaid for EpiPen for years, despite warnings*, STAT, (Oct. 05, 2016), <https://www.statnews.com/pharmalot/2016/10/05/mylan-overcharged-medicare-epipen/>.

³⁴ *Id.*

³⁵ *Id.*

³⁶ Ed Silverman, *Mylan to pay \$465 million to settle claims of shortchanging Medicaid*, STAT, (Oct. 07, 2016), <https://www.statnews.com/pharmalot/2016/10/07/mylan-465-million-settlement-epipen-medicare/>.

underpaying their rebate obligations through the MDRP between October 2005 and September 2009.³⁷ The participating states and the federal government found that Dava had misclassified three of their drugs as non-innovator drugs for Medicaid rebate purposes.³⁸ Dava paid a total of \$11 million between state and federal damages to compensate Medicaid and various federal healthcare programs for its conduct.³⁹

The third example involves KV Pharmaceutical's failure to advise CMS that two of its' unapproved products did not qualify for coverage under federal and state health care programs.⁴⁰ According to the settlement, Ethex (subsidiary of KV) submitted false quarterly reports to the government relating to two of its' drugs.⁴¹ Although the FDA deemed the drugs "less than effective" and ineligible for reimbursement by the government under Medicaid, Ethex actively promoted them as effective for rebate purposes.⁴² KV was required to pay a total of \$17 million to Medicaid and various federal healthcare programs to compensate for its conduct.⁴³

The final example, occurring in 2009, involved four pharmaceutical companies, Mylan Pharmaceuticals, Inc., UDL Laboratories, Inc., AstraZeneca Pharmaceuticals LP, and Ortho McNeil Pharmaceutical, Inc. Each settled as part of a Medicaid underpaid rebate fraud case.⁴⁴

³⁷ *A.G. Schneiderman Announces \$28 Million in Settlements With Two Pharmaceutical Companies for Violating Medicaid Regulations*, ATTORNEY GENERAL ERIC T. SCHNEIDERMAN, (Mar. 01, 2012) <http://www.ag.ny.gov/press-release/ag-schneiderman-announces-28-million-settlements-two-pharmaceutical-companies>.

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.*

⁴³ *A.G. Schneiderman Announces \$28 Million in Settlements With Two Pharmaceutical Companies for Violating Medicaid Regulations*, ATTORNEY GENERAL ERIC T. SCHNEIDERMAN, (Mar. 01, 2012) <http://www.ag.ny.gov/press-release/ag-schneiderman-announces-28-million-settlements-two-pharmaceutical-companies>.

⁴⁴ *NC Wins \$3.5 Million From 4 Drug Makers, Says AG Cooper: Pharmaceutical companies underpaid rebates to Medicaid*, NORTH CAROLINA DEPARTMENT OF JUSTICE ATTORNEY GENERAL ROY COOPER, (Oct. 20, 2009) [http://www.ncdoj.gov/News-and-Alerts/News-Releases-and-Advisories/Press-Releases/NC-wins-\\$3-5-million-from-4-drug-makers,-says-AG-C.aspx](http://www.ncdoj.gov/News-and-Alerts/News-Releases-and-Advisories/Press-Releases/NC-wins-$3-5-million-from-4-drug-makers,-says-AG-C.aspx).

The four companies were required to pay a total of \$124 million nationally including \$3.5 million to North Carolina.⁴⁵

These examples serve as demonstrations that the EpiPen incident was not an outlier, and that this type of fraud needs to be properly addressed as it affects the government's budget and the U.S. taxpayers.

III. CMS's Final Rule and the Narrow Exception

On January 21, 2016, CMS released its Covered Outpatient Drugs final rule to help combat the misclassification issue.⁴⁶ The primary objective was to address key areas and changes of the MDRP under the Affordable Care Act. The rule assists states and the federal government in managing drug costs, establishes the long-term framework for implementation of the MDRP, and creates a fairer reimbursement system for Medicaid programs and pharmacies.⁴⁷ It attempts to manage drug costs by establishing a definition of AMP for inhalation, infusion, instilled, implanted, or injectable drugs, so states can collect rebates on more expensive infused and injected drugs, which are an increasing expense to the Medicaid program.⁴⁸ The deadline for compliance with this rule is March 31, 2017.⁴⁹ In efforts to expand the program, the scope of the word "state" will now incorporate U.S. territories by April 1, 2020.⁵⁰ Under 81 Fed. Reg. 5170, 5193, "[a]ll drugs marketed under an NDA, other than an ANDA, regardless of when they were

⁴⁵ *Id.*

⁴⁶ *Covered Outpatient Drugs Policy*, MEDICAID.GOV, <https://www.medicaid.gov/medicaid/prescription-drugs/covered-outpatient-drug-policy/index.html>, (last accessed Mar. 25, 2017).

⁴⁷ Ned Milenkovich, *CMS releases final rule for covered outpatient drug*, MODERNMEDICINE NETWORKS: DRUG TOPICS, (Apr. 10, 2016), <http://drugtopics.modernmedicine.com/drug-topics/news/cms-releases-final-rule-covered-outpatient-drugs?page=0,0>.

⁴⁸ *Id.*

⁴⁹ Chris Cobourn, *CMS Issues Guidance on Drug Category Narrow Exception*, HURON, <https://www.huronconsultinggroup.com/resources/life-sciences/drug-category-narrow-exception-guidance-from-cms>, (last accessed Mar. 13, 2017).

⁵⁰ *Covered Outpatient Drugs Policy*, MEDICAID.GOV: KEEPING AMERICA HEALTHY, <https://www.medicaid.gov/medicaid/prescription-drugs/covered-outpatient-drug-policy/index.html>, (last accessed Feb. 25, 2017).

approved, should be categorized as single source or innovator multiple source drugs, *unless* CMS determines that a narrow exception applies as discussed pursuant to this final rule.”⁵¹ Further stating “[t]here may be very limited circumstances where, for the purposes of the Medicaid Drug Rebate (MDR) program, certain drugs might be more appropriately treated as if they were approved under an ANDA and classified as a non-innovator multiple source drug.”⁵²

The narrow exception deals with certain drugs approved under a paper NDA prior to the enactment of the Hatch-Waxman Amendments of 1984 or under certain types of literature-based 505(b)(2) NDA approvals after the Hatch-Waxman Amendments of 1984.⁵³ The Hatch-Waxman Amendments provided some protection for drug innovators while facilitating and providing incentives for companies to file ANDAs.⁵⁴ This Act came to be following the drug regulations of the early 1960’s. After 1962, the FDA added the requirement that drugs must be approved for effectiveness and not just safety.⁵⁵ This additional requirement lead generic drug companies to stop competing as they did not want to allocate the additional financial resources to conduct clinical trials.⁵⁶ After the passing of the Hatch-Waxman Act, the regulations to get to market were lessened, while still ensuring their products were safe and effective.⁵⁷ The regulatory pathways to get ANDA approval around that time were uncertain. With this in mind, it would be

⁵¹ James Matthews et al., *The EpiPen Controversy Signals Intensifying Scrutiny of Drug Classification Under Medicaid Rebate Program*, HEALTHCARE LAW TODAY, (Sept. 07, 2016), <https://www.healthcarelawtoday.com/2016/09/07/the-epipen-controversy-signals-intensifying-scrutiny-of-drug-classification-under-medicaid-rebate-program/>.

⁵² *Id.*

⁵³ Chris Cobourn, *CMS Issues Guidance on Drug Category Narrow Exception*, HURON, <https://www.huronconsultinggroup.com/resources/life-sciences/drug-category-narrow-exception-guidance-from-cms>, (last accessed Mar. 13, 2017).

⁵⁴ Amanda Baltazar, *The Hatch-Waxman Act – How it Changed the Pharm Industry: Changing the Playing Field for Branded and Generic Drugs*, THE BALANCE, <https://www.thebalance.com/the-hatch-waxman-act-how-it-changed-the-pharma-industry-2663817>, (last updated May 15, 2016).

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ *Id.*

more appropriate to treat certain NDAs approved around that time as ANDAs and classify them as non-innovator drugs.

Manufacturers will have four quarters, after the April 1, 2017 effective date, to submit appropriate materials to CMS demonstrating why the narrow exception should apply.⁵⁸ Included in submission, a manufacturer may include information such as a copy of the FDA approval letter for an NDA or any indication that the drug never received patent protection/market exclusivity.⁵⁹ These few examples do not constitute an exhaustive list of materials a manufacturer may include. Following the application for a narrow exception, CMS will review these materials and make one of two decisions. They will either confirm in writing that this narrow exception does apply to the drug at issue and permit reclassification as a non-innovator multiple source drug; or state that the exception does not apply, and the manufacturer must continue to report the drug as either a single source or innovator multiple source drug.⁶⁰ Manufacturers may not rely on previous written communications from CMS to justify classification of a drug marketed under an NDA as a non-innovator drug.⁶¹

IV. Proposed Solution

With CMS's final rule set for implementation this calendar year, the issue of classifying certain DDCPs is still seeking a solution. The proposed legislation will be based on the foundation of CMS's final rule and will be first published six-months after the March 2017 deadline for narrow exception applications. After the final rule takes effect, any drug that is approved under a NDA will be considered an innovator drug and will be subject to the 23.1%

⁵⁸ Chris Cobourn, *CMS Issues Guidance on Drug Category Narrow Exception*, HURON, <https://www.huronconsultinggroup.com/resources/life-sciences/drug-category-narrow-exception-guidance-from-cms>, (last accessed Mar. 12, 2017).

⁵⁹ *Id.*

⁶⁰ *Id.*

⁶¹ *Id.*

rebate amount. Any application that is approved under an ANDA will be considered a non-innovator drug and held to the 13% rebate amount. If a classification does not seem appropriate, the manufacturer is capable of appealing for a narrow exception, but it must be submitted by the March 31, 2017 deadline.⁶² This proposed legislation will seek to answer what DDCPs who are still questioning their classification status should do after the March 2017 deadline. Much like Mylan's EpiPen, a legitimate argument will exist that while the administering device is patented and qualified under a NDA, the administered drug may still be a generic drug under an ANDA.

The proposed legislation will provide two options regarding the classification of these DDCPs: (1) the creation of a definitive bright line rule in regards to these products, or; (2) the creation of a new intermediate classification under the MDRP.

a. Option One: Bright Line Rule and Patent Exclusivity Waivers

The first option creates a bright line rule to help resolve issues with classification for manufacturers who have failed to fall under CMS's narrow exception. There will be new guidelines to follow if a manufacturer wants its' drug to possess the potential to be a non-innovator drug and pay the lesser rebate. The first guideline involves patent exclusivity waivers. When a drug is approved under a NDA it is granted New Drug Product Exclusivity under the Federal Food, Drug, and Cosmetic Act under section 505(c)(3)(E) and 505(j)(5)(f).⁶³ In 1984, Title 1 of the Hatch-Waxman Amendments was amended to provide for New Drug Product Exclusivity in an attempt to encourage research and development.⁶⁴ Exclusivity provides the applicant of an approved NDA certain protection against the competition in the market. This

⁶² *Id.*

⁶³ *Small Business Assistance: Frequently Asked Questions for New Drug Product Exclusivity*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES: U.S. FOOD & DRUG ADMINISTRATION, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm069962.htm>, (last accessed Feb. 18, 2017).

⁶⁴ *Id.*

protection precludes approval of certain 505(b)(2) applications or certain ANDAs for a period of time.⁶⁵ Once approved, the NDA is granted a five-year period of exclusivity if the product contained chemical entities never previously approved, either alone or in combination.⁶⁶ During this five-year period, no 505(b)(2) ANDA applications may be submitted unless an exclusion applies. Examples of these exclusions include: orphan drug exclusivity, pediatric exclusivity, and a four-year submission exclusion is allowed if the application contains a certification of patent invalidity or non-infringement.⁶⁷ When a product receives any length of exclusivity it is registered in the Orange Book & Supplements where other manufacturers can view what products are currently under patent.

The exclusivity waiver will not be retroactive in nature. Meaning any current exclusivity rights a manufacturer possesses will be honored. This legislation targets NDA applicants. They will be provided two options following a submission. The first option states, if the applicant plans to use their maximum exclusivity rights and become enrolled in the MDRP, they will be approved for innovator status and the corresponding 23.1% rebate amount as described in the current final rule.

The second option, assuming their patent will no longer be protected after the time limit, will allow the manufacturer to either partially or fully waive their exclusivity rights upon acceptance of their application and, if enrolled in the MDRP, be classified as a non-innovator. Waiving valuable years of patent protection may initially seem to be a detriment, as manufacturers will not possess the allotted time against competition. This time is crucial in an attempt to collect the funds they expended for research and development. The incentive of the

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ *Id.*

waiver will be that the federal government will reimburse the manufacturer a percentage of their research and development costs depending on how many years of patent protection they waive. For example, if a manufacturer is granted the full five-years of exclusivity after its NDA is approved, and it chooses to waive the entire five-years, the government will reimburse the entire amount of research and development that was spent creating the drug. The scale of reimbursement will be fixed on 20% per one year waived of exclusivity rights. To illustrate, if a manufacturer waives one year of exclusivity, the government will reimburse 20% of the total research and development costs. If they waive two years, 40% of reimbursement, three years, 60% of reimbursement, four years, 80% of reimbursement. This would provide the manufacturer with the decision of whether to take the risk and keep the full five-year protection and receive no guaranteed government reimbursement, or to take the guaranteed reimbursement, but fall victim to the invisible hand of the market and lose the protection against competition. This will require the manufacturer to conduct a risk-benefit analysis of any financial factors involved and to decide whether receiving the reimbursement along with the lower rebate percentage will fit their business plan.

Opponents of the waiver provision may be skeptical that without exclusivity rights, pharmaceutical companies may decide investing in new drugs is not a prudent business decision. The reimbursement payments should provide an adequate incentive for drug manufacturers to continue to strive for innovative new cures to ailments in the present and in the future. This will also help solidify whether a drug is an innovator or non-innovator to avoid potential fraudulent activity regarding rebates.

b. Option Two: Intermediate Classification

The second solution is to create an intermediate classification for DDCPs. By creating this new category, all parties involved will need to provide flexibility that in return will help eliminate any excess spending. This may be in the form of government funds saved, or the manufacturers avoiding potential lawsuits down the road. Instead of paying the innovator rebate price of 23.1% of AMP, or the non-innovator price of 13% of AMP, a product that has the capacity to fit under either will pay 18% in rebates. This intermediate classification would be sustained until the patent exclusivity of a NDA approval would expire, subsequently allowing the company to reclassify as a generic or reapply for another NDA.

An alternative way for a manufacturer to place their product in the intermediate category would be measuring the products effects in degrees of medical necessity. For the purpose of this paper, the federal standard for medical necessity will an adoption of California's definition of the term. This is because the current federal standard is not defined under the Medicaid Act. The standard's definition of medical necessity will be satisfied if a treatment is reasonable and necessary to prevent significant illness or disability, relieve severe pain, or save someone's life.⁶⁸ Following this definition, if a NDA approved product fails to fall under the narrow exception, a manufacturer will be able to file a separate appeal for the intermediate classification by showing that their product is not used in medically necessary treatments. The rationale behind this decision is that when a NDA is approved, there is market exclusivity on the product. By decreasing the amount of rebate percentage that the manufacturer owes, they may be less incentivized to raise the price of their products. By owing less in rebates to the government and states, replenishing their research and development funds will become more attainable without

⁶⁸ Elizabeth Dickey, *Getting Approval for Medicaid Services: Medical Necessity*, NOLO, <http://www.nolo.com/legal-encyclopedia/getting-approval-medicaid-services-medical-necessity.html>, (last visited Mar. 13, 2017).

raising the price of their drug. Gaining access to the intermediate classification will provide a definitive rebate percentage to help eliminate potential future fraud.

Implementation of this legislation will be handled similarly to other notices published by CMS. An initial notice will be published containing all of the provisions mentioned previously and a proposition to assist in the definition of certain DDCPs that have the potential for involvement in fraudulent classification. Upon the publication date, practitioners, consumers, and manufacturers will be allowed to provide comments on the proposed changes within a six-month period. These comments, along with any alternatives that are presented, will be taken into consideration. Following a three-month period of idea consolidation, a second final notice will be published. This notice will follow a more structured format and will include any ideas and alternative options provided from the comments from the first published notice that CMS has deemed to be both acceptable and practical. This second notice will be open to any further comments from the aforementioned parties for a span of six-months. Upon closure of the second notice, a finalized publication will be issued. There will be a one-year compliance grace period where manufacturers will then be on notice of the new changes to classifications of drug products that are enrolled in the MDRP. After the new rule is implemented, any new applications for NDAs will be facilitated following the new guidelines.

V. False Claims Act Liability

The False Claims Act, 31 U.S.C. § 3729(a) (“FCA”) provides a cause of action against “any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval, or . . . knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim.”⁶⁹ The Act’s scienter requirement

⁶⁹ 31 U.S.C. § 3729(a)(1)(A), (B) (1986).

defines “knowing” and “knowingly” to mean that a person has “actual knowledge of the information,” “acts in deliberate ignorance of the truth or falsity of the information,” or “acts in reckless disregard of the truth or falsity of the information.”⁷⁰ The Act defines “material” to mean “having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.”⁷¹ Persons who are in violation of the Act are liable for treble damages (three times the actual damages which the government sustains).⁷² Defendants found liable are further required pay a mandatory penalty (between \$5,00 and \$10,000) for each false claim.⁷³

Under the FCA, private individuals, known as relators, can bring qui tam suits against the pharmaceutical or health care company.⁷⁴ These actions were created to encourage private individuals to report wrongs against the government by providing a financial incentive.⁷⁵ Once the whistleblower has initiated the qui tam action, the government has two main options. First, the government may choose to intervene and take over the lawsuit.⁷⁶ This will result in the relator receiving 15-25% of the recovered funds. Second, if the government chooses not to

⁷⁰ *Universal Health Servs. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1996 (2016); citing (31 U.S.C. §3729(b)(1)(A)).

⁷¹ *Id.* (citing 31 U.S.C. § 3729(b)(4) (1986)).

⁷² 31 U.S.C. § 3729(a)(1) (1986).

⁷³ Kathleen McDermott et al., Morgan, Lewis & Bockius LLP, *Calculating Damages Under the False Claims Acts: Basic Considerations to Review*, https://www.morganlewis.com/pubs/bna_calculatingdamagesunderfalseclaimsact_may2013.pdf (last visited February 25, 2017); see 31 U.S.C. § 3729(a)(1) (1986).

⁷⁴ Berg & Anderson, *Overview of the FCA and its Qui Tam Provisions*, <https://www.bafirm.com/practice-areas/qui-tam-litigation/overview/overview-of-the-fca-and-its-qui-tam-provisions/> (last visited Feb. 25, 2017).

⁷⁵ *Id.*

⁷⁶ Kathleen McDermott et al., Morgan, Lewis & Bockius LLP, *Calculating Damages Under the False Claims Acts: Basic Considerations to Review*, https://www.morganlewis.com/pubs/bna_calculatingdamagesunderfalseclaimsact_may2013.pdf (last visited Feb. 25, 2017).

intervene, the relator can continue the lawsuit independently and collect between 25-30% of the recoveries.⁷⁷

Mylan Pharmaceutical relies on a 1997 letter from CMS when determining its' product was able to be classified as a non-innovator drug instead of an innovator.⁷⁸ Under the language of the FCA, manufacturers should be held liable for misclassifying their products under the MDRP, because in doing so, they are knowingly misrepresenting the amount of rebate they owe to the government. The 2016 Supreme Court case, *United Health Services v. United States ex. rel. Escobar*, 136 S. Ct. 1989 demonstrates how manufacturers with prior CMS approval to classify their products as non-innovator drugs may possess the ability to prove they lacked the scienter requirement to qualify for a FCA violation. The *Escobar* court held that a manufacturer can be held liable under the FCA for misrepresentations if it makes specific representations about the goods or services provided, but fails to disclose noncompliance with material statutory, regulatory, or contractual requirements.⁷⁹ This means that a manufacturer enrolled in the MDRP may be held liable under the FCA for failing to disclose their product's misclassification, even if they accurately represent their product under the program. In the case of Mylan, they possessed previous contact with CMS in the 1997 letter. This would make it difficult for CMS to show the misclassification was material, since they previously had the opportunity to declare EpiPen an innovator drug as chose not to. Therefore, while this may allow Mylan to avoid the scienter requirement under the FCA, other manufacturers may not possess the prior CMS acknowledgment to avoid FCA violations.

⁷⁷ *Id.*

⁷⁸ Silverman, *supra* note 31.

⁷⁹ *Escobar*, 136 S. Ct. at 2001.

Pursuing pharmaceutical manufacturers knowing misrepresentations under FCA liability, will provide the necessary deterrent effect to minimize misclassification fraud. The FCA provides for three main sources of deterrence to ensure manufacturer's of DDCPs do not misclassify their products, and instead present an inquiry to CMS before applying.

First, if an FCA violation is proven, companies will be charged between \$5,000-\$10,000 per false claim plus treble damages.⁸⁰ For large manufacturers providing interstate products, this can easily result in millions of dollars in damages. The magnitude of FCA damages in relation to large pharmaceutical manufacturers is best illustrated by examining the 2016 settlement involving Wyeth and Pfizer Inc. (Pfizer purchased Wyeth for \$68 billion in 2009).⁸¹ Wyeth and Pfizer settled with the Department of Justice in 2016 for \$784.6 million in regards to “Wyeth’s knowing false and fraudulent prices on two of its’ proton pump inhibitor (PPI) drugs, Protonix Oral and Protonix IV.”⁸² Principal Deputy Assistant Attorney General Benjamin C. Mizer discussing the settlement stated “[t]his settlement demonstrates our unwavering commitment to hold pharmaceutical companies responsible for pursuing pricing schemes that attempt to manipulate and overcharge federal health care programs – programs that protect the poor and disabled – for drugs sold to commercial customers at much lower prices.”⁸³

Second, under the FCA, private individuals can bring qui tam actions against corporations. These private individuals need specific knowledge about the violations.⁸⁴ This scienter requirement usually means the relators will be employees of the company. If any

⁸⁰ McDermott et al., *supra* note 73.

⁸¹ Andrew Ross Sorkin & Duff Wilson, *Pfizer Agrees to Pay \$68 Billion for Rival Drug Maker Wyeth*, THE NEW YORK TIMES, (Jan. 25, 2009), <http://www.nytimes.com/2009/01/26/business/26drug.html>.

⁸² Wyeth and Pfizer Agree to Pay \$784.6 Million to Resolve Lawsuit Alleging That Wyeth Underpaid Drug Rebates to Medicaid, 16 OFF. PUB. AFF. 498 (2016).

⁸³ *Id.*

⁸⁴ Kerry Parker & Daniel R. Levy, *Actual Knowledge of False Claims Required*, LORMAN, (Aug. 17, 2017), <http://www.lorman.com/resources/actual-knowledge-of-false-claim-required-15395>.

employee learns of the manufacturers knowing misclassification, either through word of mouth or billing practices, this will allow a qui tam action to ensue.

Third, enrolling in the MDRP allows pharmaceutical manufacturers to guarantee their products are better represented on the Medicaid ledgers, therefore, prescribed more often. This provides a substantial financial benefit even though it contains a rebate subscription. If a manufacturer is found in violation of the FCA, CMS has the ability to bar the company from participating in any federal government program going forward.⁸⁵ This can equate to a financial death penalty for companies that rely heavily on federal reimbursement to stay afloat. These three penalties for violating the FCA should serve as a substantial deterrent for pharmaceutical manufacturers to properly classify their drug when enrolling in the MDRP.

VI. Conclusion

Compliance with CMS's Covered Outpatient final rule still allows for a gap in the classifications that needs to be filled with a more precise placement of these products that have the potential to create Medicaid fraud. This potential fraud should be thrust to the forefront when taking into consideration the lasting ramifications it may have on taxpayers. Following the enactment of the ACA's Medicaid Expansion plan, the total amount of people currently receiving health care benefits through Medicaid or CHIP (Children's Health Insurance Program) is approximately 70 million.⁸⁶ This was following the Supreme Court's ruling that state Medicaid expansion must be voluntary.⁸⁷ For a vast majority of this population, Medicaid is the only way they can afford health care. Therefore, it is imperative that the taxpayer's and federal

⁸⁵ *False Claims Act Penalties: Civil and Criminal Penalties*, CHAPMAN LAW GROUP, <http://chapmanlawgroup.com/falseclaimsactpenalties/>, (July 27, 2015).

⁸⁶ Kimberly Leonard, *Medicaid Enrollment Surges Across the U.S.*, U.S. NEWS & WORLD REPORT, <http://www.usnews.com/news/articles/2015/02/24/medicaid-enrollment-surges-across-the-us>, (Feb. 24, 2015, 6:06 PM).

⁸⁷ *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566, 2667 (2012).

government's funds are treated with the utmost respect and fiscal responsibility. Creating this new classification system for DDCPs will help conserve money for the citizens and help to appropriately allocate money from the federal budget. At the time of this writing the new President Donald Trump's regime is attempting to implement a new federal health care policy to replace the Patient Protection and Affordable Care Act. With the health care sector preparing for a potential shift, this proposed legislation coupled with the deterrence of a False Claims Act violation, has the potential to create a framework for CMS to follow in the coming years.