

## Does our Current Regulatory System Incentivize Pharmaceutical Companies to Commit Fraud while Ignoring Research and Development Duties?

by Abel Roman

### Introduction

On November 4<sup>th</sup>, 2013, global health care giant Johnson & Johnson and its subsidiaries reached a settlement amount of \$2.2 billion dollars.<sup>1</sup> Considered one of the largest health care fraud settlements in United States history, Johnson & Johnson agreed to pay this amount to resolve the civil and criminal allegations of promotions not approved as safe and effective, kickbacks to physicians, and violations of statutes,<sup>2</sup> particularly violations of the False Claims Act.<sup>3</sup> This type of offense has been common with pharmaceutical companies in the past ten years in regards to false advertising, but the federal government still gives pharmaceutical companies tax breaks for advertising which represents billions of dollars in lost revenue for the federal government.<sup>4</sup> With these tax exemptions, pharmaceutical companies are given an incentive to commit fraud for corporate greed while neglecting to put funds towards research and development.

Johnson & Johnson is not the only pharmaceutical company that has been fined for illegally promoting, or misbranding a drug. Consider the following examples:

- Pfizer and Merck & Co., two of the largest pharmaceutical companies in the world, were fined for misbranding or

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<sup>1</sup> *Johnson & Johnson To Pay More Than \$2.2 Billion To Resolve Criminal And Civil Investigations*, The U.S. Department of Justice, <https://www.justice.gov/opa/pr/johnson-johnson-pay-more-22-billion-resolve-criminal-and-civil-investigations>, Nov. 4, 2013, (last visited March 12, 2017).

<sup>2</sup> *Id.*

<sup>3</sup> The False Claims Act, 31 U.S.C. §§ 3729–3733, imposes liability on persons and companies (typically federal contractors) who defraud governmental programs.

<sup>4</sup> *Sen. Franken Introduces Bill To End Tax Breaks For Drug Company Advertising*, U.S. Senate Al Franken, [https://www.franken.senate.gov/?p=press\\_release&id=3384](https://www.franken.senate.gov/?p=press_release&id=3384), Mar. 3, 2016, (last visited March 12, 2017).

promoting drugs illegally with the intent to defraud or mislead.

- Pfizer was fine \$2.3 billion dollars in 2009, one of the largest criminal fines ever imposed in the United States. Pfizer pled guilty to misbranding Bextra with the intent to defraud or mislead.<sup>5</sup> Bextra was a painkiller that the FDA had previously reviewed and had found that the specified dosage was dangerously high.<sup>6</sup>
- Merck & Co. settled for a fine of \$950 million dollars for illegally promoting the pain killer, Vioxx. Merck & Co made false or misleading statements about the drug's heart safety to increase sales and promoted Vioxx as a treatment for arthritis before it had been approved for that use.<sup>7</sup>

This type of behavior shows that a more affirmative control needs to be taken against these companies, particularly when they are being exempt from paying taxes for the promotion of their drugs.

Johnson & Johnson, Merck & Co., and Pfizer are three of the largest global pharmaceutical companies with millions of dollars in net earnings every year. Johnson & Johnson has recorded a revenue of \$212 billion dollars in the past 3 years while also spending \$64 million in marketing and \$24 billion in research and development.<sup>8</sup> Merck & Co. has recorded \$133 billion dollars in revenue the past 3 years while spending \$36 million in marketing and 22 billion in

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<sup>5</sup> *Justice Department Announces Largest Health Care Fraud Settlement In Its History*, U.S. Department of Justice, Sept. 2, 2009, <https://www.justice.gov/opa/pr/justice-department-announces-largest-health-care-fraud-settlement-its-history>, (last visited March 12, 2017).

<sup>6</sup> *Id.*

<sup>7</sup> *U.S. Pharmaceutical Company Merck Sharp & Dohme To Pay Nearly One Billion Dollars Over Promotion Of Vioxx®*, U.S. Department of Justice, Nov. 22, 2011, <https://www.justice.gov/opa/pr/us-pharmaceutical-company-merck-sharp-dohme-pay-nearly-one-billion-dollars-over-promotion>, (last visited March 12, 2017).

<sup>8</sup> Annual Report 2014 Johnson & Johnson, [http://files.shareholder.com/downloads/JNJ/3799648053x0x807837/30638d44-13ae-47e2-bd6d-fe40ddebcb15a/place\\_holder\\_annual.pdf](http://files.shareholder.com/downloads/JNJ/3799648053x0x807837/30638d44-13ae-47e2-bd6d-fe40ddebcb15a/place_holder_annual.pdf), (2014), (last visited March 12, 2017).

research and development.<sup>9</sup> Pfizer has recorded \$160 billion dollars in revenue the past 3 years while spending \$45 billion dollars on marketing and only 22 billion on research and development.<sup>10</sup> These fortune five hundred companies account for \$146 billion dollars in marketing and only \$70 billion in research and development. From 2012 to 2014, the Fortune 500 pharmaceutical companies mentioned above accumulated a total revenue of \$506 billion and net earnings of \$108 billion dollars. In the past three years alone, these Fortune 500 pharmaceutical companies have contributed 7.2% of their total revenue to Research & Development, but have expended 28.8% on marketing and administrative costs. The marketing expenses these companies accumulated surpass how much they have made in net revenue in the span of three years by \$37 billion dollars, yet net revenue has surpassed research & development expenses by \$38 billion dollars, which indicates their priorities in regards to funding the company's programs.

Pharmaceutical companies began to focus on marketing and reaching consumers directly during the early 1990s, in part due to the aging of baby boomers, and the increase in the number of patients who are seeking more medical information and are actively participating in decisions affecting their health.<sup>11</sup> In regards to the increase of Direct-to-Consumer advertising of prescription drugs, in August of 1997, the FDA issued Guidance entitled, "Guidance for Industry: Consumer-Directed Broadcast Advertisements." That publication clarified the Agency's interpretation of the existing regulations.<sup>12</sup> The clarification report released by the FDA opened a whole new marketing sector for pharmaceutical companies to reach their

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<sup>9</sup> Merck & Co., Inc. - Financials - Annual Reports & Proxy, <http://investors.merck.com/financials/annual-reports-and-proxy/default.aspx>, (last visited March 12, 2017).

<sup>10</sup> 2015 Pfizer Financial Report, [http://www.pfizer.com/investors/financial\\_reports/financial\\_reports](http://www.pfizer.com/investors/financial_reports/financial_reports), (last visited Feb. 18, 2017).

<sup>11</sup> S.M. Wolfe, *Direct-to-Consumer Advertising: Education or Emotion Promotion?* New England Journal of Medicine. 2002;346(7):524-26, <https://www.ncbi.nlm.nih.gov/pubmed/11844857>, (last visited March 12, 2017).

<sup>12</sup> O.O. Commissioner, *Testimony - Regulating Prescription Drug Promotion*, July 24, 2009, <https://www.fda.gov/NewsEvents/Testimony/ucm115080.htm>, (last visited March 12, 2017).

consumers directly instead of relying on doctors to pass on their information to their patients. The FDA clarification report's main objective was to clarify how pharmaceutical companies can advertise their products directly to consumers, while adequately providing ways in which they can label their product and refer consumers to a toll-free number, print ads, a website or to their pharmacists or physician from where they could obtain complete information about the product's risks and benefits.<sup>13</sup>

Due to the clarification report from the FDA, direct to consumer advertising of prescription drugs dramatically grew from an annual total spending of \$985 million dollars in 1996 to \$4 billion dollars in 2005. At the same time, professional promotion costs increased from \$3.7 billion dollars in 1995 to \$6.7 billion dollars in 2005. This led to promotional spending growth from \$11.4 billion dollars in 1996 to \$29.9 billion dollars in 2005.<sup>14</sup> After the FDA 1997 Clarification Report, the golden age of pharmaceutical companies began to diminish, not because of lack of innovative ideas but because of changes in pharmaceutical priorities.

The golden age of pharmaceutical companies was a time of innovation for pharmaceutical companies. From 1978 to 1989, 15.6 percent of approved drugs were judged as important therapeutic gains. Internationally, from 1974 to 1994, 11% were judged as important to therapeutic and pharmacologically innovative.<sup>15</sup> During the mid-1990's, the Prescription Drug User Fee Act (PDUFA) was enacted which allowed the federal government to negotiate a plan with the Pharmaceutical Companies in which they would pay the FDA

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<sup>13</sup> Julie Donohue, *A History Of Drug Advertising: The Evolving Roles Of Consumers And Consumer Protection*, The Milbank Quarterly, Dec. 2006, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2690298/>, (last visited March 12, 2017).

<sup>14</sup> Julie M. Donohue, Ph.D., Marisa Cevasco, B.A., and Meredith B. Rosenthal, Ph.D., *A Decade Of Direct-To-Consumer Advertising Of Prescription Drugs*, New England Journal of Medicine, 357:673-681, August 16, 2007, <http://www.nejm.org/doi/full/10.1056/NEJMsa070502>, (last visited March 12, 2017).

<sup>15</sup> D. W. Light and J. R. Lexchin. *Pharmaceutical Research And Development: What Do We Get For All That Money?* *BMJ* 345, Aug. 7, 2012, <http://www.bmj.com/bmj/section-pdf/187604?path=/bmj/345/7869/Analysis.full.pdf>, (last visited March 12, 2017).

for each drug review to help cover the operating costs at the FDA. By paying these fees, the FDA was required to approve or disallow new drug applications at a fixed period of time after each submission.<sup>16</sup>

This requirement has led the FDA to be too dependent on pharmaceutical companies to supply information such as company run clinical trials so that the FDA can meet the fixed period deadline. Since then, reports have concluded that between 85% to 90% of all new drugs have provided few to no clinical advantages for patients.<sup>17</sup> Many new safe drugs that the FDA has approved have been later categorized as too dangerous, which leads them to remove them from the market or require warnings.<sup>18</sup> With the FDA being tied and dependent upon analysis supplied by the drug companies they are supposed to regulate, the adverse drug reactions reported to the FDA has nearly tripled from 156,000 in 1995 to 460,000 in 2005, compared to 1985 when only 38,000 were submitted.<sup>19</sup> Most of the blame from the public goes to Pharmaceutical companies, with patients not realizing that they get prescribed these medications not from the pharmaceutical companies but from their trusted physicians.

Physicians are the gateway for the pharmaceutical companies to reach the patient. They determine what medication is best for the patient, while also receiving kickbacks and compensation from the pharmaceutical companies to prescribe their medication. In 2013, general payment to physicians from pharmaceutical companies was 756 million dollars. This included a total of 1,392 total companies who made payments averaging \$1.8 million each to

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<sup>16</sup> Julie M. Donohue, Ph.D., Marisa Cevasco, B.A., and Meredith B. Rosenthal, Ph.D., "A Decade Of Direct-To-Consumer Advertising Of Prescription Drugs," *New England Journal of Medicine*, 357:673-681, August 16, 2007, <http://www.nejm.org/doi/full/10.1056/NEJMsa070502>, (last visited March 12, 2017).

<sup>17</sup> D. W. Light and J. R. Lexchin, *Pharmaceutical Research And Development: What Do We Get For All That Money?*, *BMJ* 345, Aug. 7, 2012, <http://www.bmj.com/bmj/section-pdf/187604?path=/bmj/345/7869/Analysis.full.pdf>, (last visited March 12, 2017).

<sup>18</sup> *The Risks Of Prescription Drugs*, Edited By Donald Light, Columbia University Press, 2010, <https://cup.columbia.edu/book/the-risks-of-prescription-drugs/9780231146920>, (last visited March 12, 2017).

<sup>19</sup> *Id.*

general physicians.<sup>20</sup> In 2014, \$2.07 billion was given to physicians from a total of 1,580 companies, which averaged \$1.7 million dollars from each company. And finally, in 2015, \$2 billion was given to pharmaceutical companies from a total of 1,456 companies with an average of \$1.8 million per company.<sup>21</sup> The total amount given to physicians from 2013 to 2015 amounted to \$4.8 billion, yet the total amount pharmaceutical companies have given to teaching hospitals and research payments to hospitals from 2013 to 2015 was only \$3.3 billion dollars.<sup>22</sup> Pharmaceutical company payments to physicians can be broken down into 7 sectors which are entertainment fees, consulting fee, compensation for services, honoraria, food and beverage, gift, and travel & lodge.<sup>23</sup> These seven sectors represent how pharmaceutical companies categorized their payments to physicians. The amount varies according to how well any given physician pleases the pharmaceutical company.<sup>24</sup>

In the case of the *Unites States of America vs. Allergan Inc.*<sup>25</sup>, 2010, Allergan was charged with allegedly hosting numerous advisory boards designed to elicit feedback from doctors about their experience with Botox. Instead, over 200 top prescribing doctors attended the Allergan Institute, a two-day invitation marketing program held in a resort club in Newport Beach. Doctors were paid \$1,500 to listen to presentations filled with promises to reward hundreds of its top injectors with consulting fees and corporate attention.<sup>26</sup> Attending these sponsored events and accepting funding for travel or lodging for educational purposes has been directly associated with increased

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<sup>20</sup> *Open Payments Data – CMS*, OpenPaymentsData.CMS.gov., <https://openpaymentsdata.cms.gov/>, (last visited March 12, 2017).

<sup>21</sup> *Id.*

<sup>22</sup> *Id.*

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

<sup>24</sup> *Id.*

<sup>25</sup> Charles Ornstein, *Allergan Paid Doctors to Attend Advisory Boards*, ProPublica, Allergan Sentencing Memo, <http://www.documentcloud.org/documents/11064-allergan-sentencing-memo.html#annotation/a3>, (last visited March 12, 2017).

<sup>26</sup> *Id.*

prescription rates of the sponsor's medication.<sup>27</sup>

In a recent study, it was shown that conference travel influenced prescribing behavior by 42% to both residents and physicians. Gifts given by pharmaceutical companies to physicians were attributed for influencing prescribing behaviors in physicians by 13% with 45% of the study group saying they would have kept the contact with the pharmaceutical company even if no gifts were given. Consumers should be made aware that doctors are used by the pharmaceutical companies to reach the consumer. Doctors are the only people who can prescribe these medications, which is the reason why the pharmaceutical companies begin to advertise to them when they are still residents. Interactions with physician residency programs is said to influence residents from 29% to 49%, while it influences physician prescribing behavior from 58% to 70%.<sup>28</sup> According to the available data, it shows that physicians gain most of their knowledge about a prescription drug from drug representatives, which of course, influences their prescribing behavior. While at the same time, only 26% of doctors receive knowledge of new pharmaceutical drugs from medical journals.<sup>29</sup>

According to author, Amanda Cochran, "It's illegal to give kickbacks to a doctor to prescribe drugs, but it is legal to give money to doctors to help promote your drug".<sup>30</sup> The use of kickbacks is a serious criminal matter, any payment that appears to have been made, either directly or indirectly to a client, patient, or customer for influencing a third party to purchase from, use

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<sup>27</sup> A. Wazana, *Physicians and the Pharmaceutical Industry Is a Gift Ever Just a Gift?* JAMA. 2000;283(3):373-380, <http://www.cwbpi.com/AIDS/reports/JAMAGhostPharma.pdf>, Jan.19, 2000, (last visited March 12, 2017).

<sup>28</sup> Id.

<sup>29</sup> *Getting Doctors to Say Yes to Drugs*, The Blue Cross/Blue Shield Association, 2003, [http://www.thedcasite.com/Kickbacks/Getting\\_doctors\\_to\\_say\\_yes\\_to\\_drugs.pdf](http://www.thedcasite.com/Kickbacks/Getting_doctors_to_say_yes_to_drugs.pdf), (last visited March 12, 2017).

<sup>30</sup> Amanda Cochran, *Does Your Doctor Have Ties To Big Pharma? How You'll Be Able To Find Out*, CBS News, March 4, 2014, <http://www.cbsnews.com/news/does-your-doc-have-ties-to-big-pharma-how-youll-be-able-to-find-out/>, (last visited March 12, 2017).

the services of, or otherwise deal with the person who pays the kickback can be charged with a criminal offense.<sup>31</sup> The types of payments given to doctors to promote the drug have been proven to influence the decision of a doctor's prescription rate of that pharmaceutical company's top brand drug. One recent study has shown that physicians who accepted payments from drug companies were two to three times more likely to prescribe these top brand drug.<sup>32</sup> The potential problem with this practice lies with identifying whether the drugs are needed, are likely to meet the needs of the patient, or are the most cost-effective option. Doctors may prescribe the top brands (which may be the more costly option) rather than giving other alternatives such as generic drugs or alternative.

Payments to physicians from pharmaceutical companies to notice their brands happen in every city. In the city of Boca Raton alone, the total compensation doctors have received from pharmaceutical companies is \$2.9 million dollars for 2015,<sup>33</sup> including the following:

- \$1.3 million dollars for compensation for services other than consulting
- Thirty-one thousand dollars in gifts
- Seven hundred and twelve thousand dollars in travel & lodging
- One hundred and eighty-four dollars in honoraria
- Seven hundred and twelve thousand dollars in consulting fees
- Four hundred thousand dollars in food & beverage.<sup>34</sup>

Senator Al Franken from Minnesota recently introduced a new bill to congress called the Protecting Americans from Drug Marketing Act. The bill is

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<sup>31</sup> Publication 535 (2015), Business Expenses. IRS, <https://www.irs.gov/publications/p535/ch11>, (last visited October 9, 2016).

<sup>32</sup> Ryann Grochowskie Jones and Charles Ornstein. *Matching Industry Payments To Medicare Prescribing Patterns: An Analysis*, Pro Publica, March 2016, <https://static.propublica.org/projects/d4d/20160317-matching-industry-payments.pdf?22>, (last visited March 12, 2017).

<sup>33</sup> *Open Payments Data – CMS*, [OpenPaymentsData.CMS.gov.](https://openpaymentsdata.cms.gov/), <https://openpaymentsdata.cms.gov/>, (last visited March 12, 2017).

<sup>34</sup> *Id.*

designed to amend the Internal Revenue Code of 1986 to deny the deduction for advertising and promotional expenses for prescription drugs.<sup>35</sup> This bill first died in 2009 in the senate finance committee, but has been recently brought back and is awaiting review. The Protecting Americans from Drug Marketing Act states that in general, no deduction shall be allowed under this chapter for expenses relating to direct-to-consumer advertising of prescription drugs for any taxable year.<sup>36</sup> In order to get pharmaceutical companies back on track, we need Washington to stand up against these companies and have them pay their fair share. This is the type of change that is needed in order for pharmaceutical companies to stop taking advantage of the tax codes which costs the federal government up to \$3.5 billion dollars a year.<sup>37</sup>

On the other hand, if we do try to prevent pharmaceutical companies from directly promoting their products to physicians, it could potentially violate the *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.* case in which the US Supreme court found that, "A State may not suppress the dissemination of concededly truthful information about entirely lawful activity, fearful of the information's effect upon its disseminators and its recipients".<sup>38</sup> According to the result of the case, states cannot prevent pharmaceutical companies from advertising. It was referred to as a form of taxation, which is a form of money demanded by a government or burdensome charge that may prevent many smaller pharmaceutical companies from advertising their product because of the burden this new tax would place on them.

In the 1950's Democratic Senator Estes Kefauver, Chairman of the United

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<sup>35</sup> *Protecting Americans From Drug Marketing Act*, Senate Bill 2623, U.S. 114Th Congress (2015-2016), <https://www.congress.gov/bill/114th-congress/senate-bill/2623/text>, (last visited March 12, 2017).

<sup>36</sup> *Id.*

<sup>37</sup> *Sen. Franken Introduces Bill To End Tax Breaks For Drug Company Advertising*, U.S. Senate Al Franken, [https://www.franken.senate.gov/?p=press\\_release&id=3384](https://www.franken.senate.gov/?p=press_release&id=3384), Mar. 3, 2016, (last visited March 12, 2017).

<sup>38</sup> *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (May 24, 1976), <https://www.law.cornell.edu/supremecourt/text/425/748>, (last visited March 12, 2017).

States Senate's Anti-Trust and Monopoly Subcommittee investigated pharmaceutical companies and found that:

- Twenty four percent of their revenue went to promotion.
- Costs and prices were extravagantly increased by large expenditures in marketing
- Most of the industry's new products were no more effective than established drugs on the market.<sup>39</sup>

Sixty years later not much has changed. Today, pharmaceutical companies only contribute 7.2% of their total revenue to Research & Development while 28.8% went on marketing and administrative. Adverse drug reactions reported to the FDA has nearly tripled from 156,000 in 1995 to 460,000 in 2005. Since 1996 advertising of prescription drugs has jumped from 985 million dollars to \$4 billion dollars in 2005, Professional promotion costs increased from \$3.7 billion dollars in 1995 to \$6.7 billion dollars in 2005, and promotional spending growth jumped from \$11.4 billion dollars in 1996 to \$29.9 billion dollars in 2005. In the end, Johnson & Johnson, Merck & Co., and Pfizer have accounted for \$146 billion dollars in marketing while only contributing \$70 billion in research and development. These three companies are the largest global pharmaceutical companies with millions of dollars in net earnings every year, yet they continue to put profits and promotions over human health.

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39 Marc Gagnon and Joel Lexchin, *The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States*, (2008), PLoS Medicine 5(1): e1. doi:10.1371/journal.pmed.0050001, <http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0050001>, (last visited April 6, 2017).