**PAUL E. SIMMERLY**
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September 1, 2015

Honorable William H. Walls
Judge, United States District Court
Martin Luther King Building
& U.S. Courthouse
50 Walnut Street
Newark, NJ 07101

Re: United States of America vs. Robert Menendez;
U.S. District Court Cause No. 2:15-cr-00155-WHW-1

**Allegations of interference with Medicare Fraud prosecutions**

Dear Judge Walls:

I am writing to you regarding the above-entitled criminal prosecution of Senator Robert Menendez over which you are presiding. The Department of Justice is attempting to prosecute Senator Menendez for allegedly interfering with their Medicare Fraud investigation of Dr. Salomon Melgen. No one, including people representing Senator Menendez, has requested that I contact you.

The purpose of this correspondence is to inform you that I believe that Eric Holder, the previous Attorney General of the United States, is guilty of the same kind of conduct for which Senator Menendez is being criminally prosecuted. Further, it is my belief that the United States Department of Justice has full knowledge of this conduct, has approved it and has covered up this wrongdoing, as well as the criminal conduct committed by pharmaceutical giant Johnson & Johnson involving Medicare Fraud, which was extensively detailed in a secret arbitration proceeding conducted by Judicial Arbitration and Mediation Services (JAMS).

Epoetin Alfa is a drug marketed and sold as an anti-anemia (anti-fatigue) treatment. It is an erythropoietin stimulating agent (ESA) that increases the red blood cell count. It is the drug used by bike racer Lance Armstrong. Epoetin Alfa was invented and patented by Amgen, Inc. which sells the drug under the trade names Aranesp and Epogen (aka "EPO"). All Epoetin Alfa sold in the United States is manufactured by Amgen and has always been so manufactured. Amgen licenses Epoetin Alfa for sale by Johnson & Johnson under a Product License Agreement

for all uses except treatment of dialysis patients. Johnson & Johnson sells Epoetin Alfa through its wholly-owned subsidiary Ortho Biotech Products, LP, under the trade name Procrit. ***Aranesp, Epogen and Procrit are the same drug – just different trade nam***es.

Johnson & Johnson and Amgen have been in a legal war for approximately the last two decades over the Epoetin Alfa Product License Agreement and whether it was breached. This litigation is some of the largest in U.S. history. Johnson & Johnson Procrit salesman, Gig Harbor, Washington resident Mark E. Duxbury, was a key witness for Amgen in two aspects of this litigation, the latest being a secret JAMS (Judicial Arbitration and Mediation Service) Arbitration that went on for approximately six years, from about 1997 through 2002. Duxbury, one of Johnson & Johnson's top Procrit salespersons, was described as a "rogue" employee by Johnson & Johnson and was fired. This is a universal Big Pharma characterization applied to whistleblowers.

The secret JAMS arbitration was conducted in Chicago and was entitled ***Amgen, Inc. v. Ortho Pharmaceutical Corporation.*** Ortho Pharmaceutical Corporation is now known as Ortho Biotech Products, LP. The sole purpose behind the secrecy of the JAMS Arbitration was to keep the Medicare fraud of the two companies secret from prosecutors, shareholders, the media and the public. The formula for the drug is public knowledge. The only companies selling ESA's are Amgen and Johnson & Johnson, so there are no proprietary sales secrets.

I have described this JAMS proceeding as one of the biggest legal proceedings in history. This is my own characterization based upon the fact that it went on for at least six years, the final arbitration hearing lasted about six months, there were more than 250 depositions taken all over the country (Duxbury 4 times) and, if rescission had been granted, Johnson & Johnson would have lost its most profitable product (perhaps $30 billion of future sales). I was present for Duxbury's testimony and personally observed approximately ten million pages of documents in shelves spread out over the several floors of the office building rented solely for the purpose of conducting this secret arbitration.

The issue involved in this massive arbitration was which company had breached the Product License Agreement and, if there was a breach, what were the damages. ***In order to litigate this issue, every aspect of the promotion, marketing and sale of Aranesp, Epogen and Procrit was put into evidence, including evidence of the promotion, marketing and sale of Aranesp, Epogen and Procrit in violation of the Medicare laws.*** Over a hundred attorneys were in attendance at each day of the final arbitration hearing (a formal trial), listening to their clients' testimony describing ongoing criminal Medicare Fraud and allowing their clients to commit perjury and obstruct justice. All of the evidence was recorded and the testimony and depositions transcribed and everything was indexed. This proceeding provided everything that the Department of Justice needed to successfully prosecute this Medicare Fraud activity. Duxbury and three other witnesses testified truthfully at the Arbitration Hearing. They were all fired and retaliated against. JAMS did nothing to help them.

Both Amgen, Inc. and J&J/Ortho Biotech Products, LP promoted, marketed and sold Aranesp (by Amgen), Epogen (by Amgen) and Procrit (by Ortho Biotech) in the exact, same way. The Department of Justice prosecuted Amgen, Inc. and in December of 2012, Amgen agreed to settle for a fine of $762 million to resolve criminal and False Claims Act allegations. See the DOJ Press Release: http://www.justice.gov/opa/pr/amgen-inc-pleads-guilty-federal-charge-brooklyn-ny-pays-762-million-resolve-criminal

Attorney General Holder, however, directed his Department of Justice attorneys not to intervene in the case of ***U.S. ex rel. Duxbury and McClellan v. Ortho Biotech Products, LP***, District Court of Massachusetts Cause No. 03-CV-12189-RWZ, a Medicare Fraud False Claims Act ("Qui Tam") case involving J&J/Ortho Biotech's blockbuster drug, Procrit. This case involves what is possibly the largest Medicare Fraud in history, perhaps $10 billion in damages to the U.S. taxpayers depending upon how penalties are assessed. At one time, this drug was the most reimbursed Medicare drug and accounted for sales of around $4 billion for Johnson & Johnson. ***However, this drug may have killed over 500,000 people***. For a while it was promoted as a remedy for fatigue associated with cancer chemotherapy. The only problem was that it was found to stimulate cancer growth and received a "black box warning". The FDA had failed to make Johnson & Johnson perform all the required testing.

J&J's Procrit is an erythropoietin stimulating agent (ESA), just like Amgen's Aranesp and Epogen. All these drugs have received the **same, identical** warnings from the FDA. These drugs are medically interchangeable. If Amgen can be prosecuted for off-label promotion of Aranesp and Epogen, then J&J should be prosecuted as well for off-label promotion of Procrit. And Procrit may be the deadliest prescription drug in history.

The reason Mr. Holder and the Department of Justice directed his attorneys not to intervene in the Duxbury suit is because Defendants Johnson & Johnson and Ortho Biotech Products, LP, are clients of Mr. Holder's former law firm, Covington & Burling. I believe that his failure to intervene goes against the advice of his Justice Department attorneys working on the case. Mr. Holder does not want to intervene because it would hurt his former clients and former law firm and undoubtedly force Johnson & Johnson to settle. Covington & Burling represent Ortho Biotech Products, LP, in the Duxbury lawsuit.

While in private practice before being appointed U.S. Attorney General, Mr. Holder specialized in defending Big Pharma drug companies in Medicare Fraud cases just like ***Duxbury.*** He may have even worked on the ***Duxbury*** case while in private practice, an allegation that has never been denied. Mr. Duxbury filed his False Claims Action case in 2003, well before Mr. Holder became Attorney General in 2008. Obviously, a man with the legal intellect and experience to be appointed Attorney General of the United States, specializing in this kind of case and armed with unlimited resources is going to have worked at some point during these five years on Johnson & Johnson's defense of Mr. Duxbury's $10 billion case, a defense of probably

the firm's most important client. Why would Covington & Burling not utilize Mr. Holder's expertise?

Mr. Holder should have recused himself from any decision-making in the Duxbury case. He had a blatant conflict of interest and his refusal to recuse himself is a violation of the ethics laws.

The ***Duxbury*** case has been ongoing for ten years. Ten pages of Covington & Burling's website (www.cov.com) brag about how a client can benefit by its lawyers' government contacts.

A more comprehensive explanation of the ***Duxbury*** Medicare Fraud claims is contained in the attached letters, in particular the Hurley letter of March 28, 2014. The Department of Justice has failed to provide any explanation whatsoever for why it failed to intervene in the ***Duxbury*** matter.

In the 2009 DOJ prosecution of Big Pharma company Pfizer, Mr. Holder recused himself because his firm, Covington & Burling, had worked defending Pfizer in that prosecution. See http://www.cbsnews.com/news/pfizer-to-pay-record-23b-settlement. The same principles should have applied in the ***Duxbury*** case and Mr. Holder should have recused himself. He failed to do so.

On July 10, 2013, I filed the attached Ethics Complaint with the Office of Professional Responsibility over this matter. I received the attached frivolous response to that Ethics Complaint dated November 4, 2013 which contained a factually and legally inaccurate explanation. I sent three reply letters on February 17, 2014, March 28, 2014, and July 3, 2014 but received no response. On July 7, 2014 I filed the attached Ethics Complaint with the Office of Professional Responsibility against Justice Department attorneys involved in the ***Duxbury*** case. No response to that Complaint has ever been received. Requests for documents I made under the Freedom of Information Act have also been ignored. On May 13, 2015, I sent the attached Complaint to the Office of the Inspector General of the U.S. Department of Justice. In response, I received the same, unsigned form letters dated May 28, 2015 and dated July 13, 2015 which provided no response to my Complaint other than to state that no further action would be taken. It is readily apparent by not signing these letters that the people in the USDOJ Office of Inspector General do not want to take responsibility and accountability for their actions by approving this blatant wrongdoing and become the next Lois Lerner, the corrupt IRS official.

Several hundred Johnson & Johnson executives, Amgen executives and their attorneys should have been prosecuted for criminal Medicare Fraud, Obstruction of Justice, Contempt of Court (for violating numerous "Corporate Integrity Agreements") and Perjury. They have illegally promoted ESA's, knowingly withheld documents demanded by Justice Department subpoenas, perjured themselves, violated Corporate Integrity Agreements and engaged in organized criminal conspiracies in violation of the RICO laws. But, just like their banking,

mortgage and financial industry counterparts, they are given a pass by the Justice Department. Different rules of conduct apply to the corporate and legal elite. This should not be the case.

Johnson & Johnson has now settled at least *fifteen* Medicare Fraud lawsuits over the past two decades averaging more than $302 million each. Johnson & Johnson and Amgen have each been subpoenaed for their documents relating to their promotion and marketing of ESA's. Each of these companies has signed Corporate Integrity Agreements promising not to engage in this conduct in the future. Obviously, these Corporate Integrity Agreements (Federal Court Orders) have been ignored and I seriously doubt that full compliance with DOJ Subpoenas has occurred. Isn't this Obstruction of Justice and Contempt of Court?

The U.S. Constitution guarantees us the Equal Protection of the laws. There is no excuse for selectively prosecuting Senator Menendez for interference with Medicare Fraud prosecutions and not prosecuting former AG Eric Holder for the same thing. The same high standards that apply to the conduct of a United States Senator certainly should also apply to a United States Attorney General, the highest law enforcement officer in the land. For the U.S. Attorney General to prosecute a man for the same crime the Attorney General is guilty of is preposterous.

I have previously advised Mr. Harold Malkin, AUSA for the Western District of Washington, Emily Langlie, PR Spokesperson for the Western District, and J. Moss, in charge of the JAMS Chicago office, that I would be initiating this communication and publishing a series of articles about this matter. No one has voiced any objection.

All of what I have stated is true and has been forwarded to many people in the Department of Justice and in government. No portion of what I have said has ever been denied.

Please contact me if you have any questions or need further supporting material.

Thank you for your attention to this matter.

Very truly yours,

Paul E. Simmerly

PAUL E. SIMMERLY

Encl.

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July 10, 2013

Robin C. Ashton
Counsel
Office of Professional Responsibility
950 Pennsylvania Avenue, N.W., Suite 3266
Washington, DC 20530-0001

Dear Counsel Ashton:

I wish to make a complaint to the Office of Professional Responsibility against Attorney General Eric Holder over his refusal to have the Department of Justice intervene in the case of ***U.S. ex rel Duxbury and McClellan v. Ortho Biotech Products, LP, District Court of Massachusetts Cause No. 03-CV-12189-RWZ***, a Medicare Fraud False Claims Act ("Qui Tam") case involving Ortho Biotech's blockbuster drug, Procrit. Ortho Biotech Products, LP, is a subsidiary of Johnson & Johnson.

The reason Mr. Holder and the Department of Justice have failed to intervene is because Defendants Johnson & Johnson and Ortho Biotech Products, LP, are clients of Mr. Holder's former law firm, Covington & Burling. Mr. Holder does not want to intervene because it would hurt his former clients and undoubtedly force them to settle. Covington & Burling represent Ortho Biotech Products, LP, in the ***Duxbury*** lawsuit. While in private practice, Mr. Holder specialized in defending Big Pharma drug companies in Medicare Fraud cases. He may have even worked on the ***Duxbury*** case while in private practice. The ***Duxbury*** case has been ongoing for ten years. Ten pages of Covington & Burling's website (www.cov.com) brag about how a client can benefit by its lawyer's government contacts.

In the 2009 DOJ prosecution of Big Pharma company Pfizer, Mr. Holder recused himself because his firm, Covington & Burling, had worked defending Pfizer in that prosecution. The same principles should apply in the ***Duxbury*** case and Mr. Holder should recuse himself.

In another recent Medicare Fraud case, the DOJ aggressively prosecuted Big Pharma company Amgen over its marketing and sales practices for its drug Aranesp. Aranesp is an erythropoiesis-stimulating agent (ESA); an anit-anemia drug. This Amgen prosecution directly benefitted Mr. Holder's former client, Johnson & Johnson, d/b/a Ortho Biotech Products, LP, because Johnson & Johnson markets this same drug under the brand name Procrit. This drug is given to dialysis patients and AIDS patients, has been given to cancer patients (until it was determined that it promoted tumor growth) and has been given, illegally, to cyclists to help them win races.

From the attached DOJ Press Release announcing the $762 million settlement with Amgen:

> Amgen's internal sales and marketing materials made plain that Amgen's misbranding of Aranesp was the company's core business strategy to gain market share from its only ESA competitor, Procrit, sold by Johnson & Johnson.

The ***Duxbury*** case is by far the biggest Medicare Fraud case in history - $3 to $10 billion dollars in damages to the U.S. taxpayers. You would think that intervention in this case would be just the thing Mr. Holder and the Obama Administration would want right now. The ***Duxbury*** case has more proof than any previous Medicare Fraud case in the form of vast amounts of documentation collected by the whistleblowers. As detailed below, the marketing and sale of Procrit was the subject of one of the biggest lawsuits in U.S. history, a six year long secret arbitration between Amgen and Johnson & Johnson (Ortho Biotech) that culminated in a six month long final hearing. The Arbitration was conducted by an organization called JAMS (Judicial Arbitration and Mediation Service).

The DOJ has the unprecedented litigation benefit of having the entire record of this JAMS Arbitration, transcribed and indexed, available for use in a Medicare Fraud prosecution. Every aspect of the marketing and sale of this drug by both Johnson & Johnson and Amgen was litigated to almost unbelievable lengths. As an indication of the volume of the evidence which is available to the DOJ if it wanted it, consider that Ortho was awarded attorney fees of $150 million as the prevailing party in this secret JAMS arbitration. Presumably, Amgen attorneys had a similar bill. That means that the DOJ has the unprecedented benefit of at least $300 million in legal work by some of the finest attorneys in the nation into how this drug was marketed and sold by Johnson & Johnson. Of course, this secret arbitration also covered how Amgen marketed and sold the drug (same drug, just different brand names). However, as far as I know, the DOJ has never used, or even obtained, the evidence and testimony from this secret JAMS arbitration, even though it aggressively prosecuted Amgen. Why is this? I think it is because it would shed unwanted light on Johnson & Johnson's illegal conduct and people would ask, why prosecute Amgen and not also Johnson & Johnson?

The sale of this drug has been pervasive. Procrit was, at its height, Johnson & Johnson's most profitable drug, producing revenues of up to $4 billion per year. It was the number one most reimbursed drug by Medicare. This is the same drug used for "doping" by Lance Armstrong and other cyclists. Incredibly, despite Amgen's recent monumental legal problems, Amgen continues to sponsor the Tour de California bike race. 500,000 people may have died from using this drug.

Please let me know if you need additional information or documentation. Thank you.

Very truly yours,

S/

PAUL E. SIMMERLY

**U.S. Department of Justice**

Office of Professional Responsibility

*950 Pennsylvania Avenue, NW Room 3266*
*Washington, DC 20530*

NOV 0 4 2013

Paul E. Simmerly
14418 S.D. 24th Street
Bellevue, WA 98007

Dear Mr. Simmerly:

This is in response to your correspondence to the Office of Professional Responsibility (OPR), in which you complained that Attorney General Eric Holder failed to require Department of Justice (DOJ) attorneys to intervene in a lawsuit brought by a private party under the False Claims Act, *United States ex rel. Duxbury v. Ortho Biotech Products,* No. 03-CV-12189-RWZ (D. Mass.). You alleged that this failure was due to a conflict of interest on the Attorney General's part.

It appears from OPR's review of the docket entries in the case that you were counsel of record for the relator, Duxbury, when the case was initiated in the United States District Court in 2003. It further appears, as you should have been aware, that the United States filed a notice of election to decline to intervene in the *Duxbury* case in July 2005, several years before Mr. Holder became Attorney General. Thus, the allegation that Attorney General Holder had a conflict of interest with respect to the Department's decision not to formally intervene in the *Duxbury* case lacks merit. Accordingly, we concluded that no action by this Office is warranted.

We regret that we are unable to be of further assistance to you in this matter.

Sincerely,

Raymond C. Hurley

Raymond C. Hurley
Associate Counsel

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February 17, 2014

Mr. Raymond C. Hurley
Associate Counsel
Office of Professional Responsibility
950 Pennsylvania Avenue, N.W., Room 3266
Washington, DC 20530

Re: Complaint against Attorney General Eric Holder

Dear Mr. Hurley:

This is in reply to your November 4, 2013 response to my Complaint against Attorney General Eric Holder in which I complained that Mr. Holder failed to require Department of Justice attorneys to intervene in the False Claims Act ("Qui Tam") case of *United States ex rel. Duxbury v. Ortho Biotech Products,* Cause No. 03-CV-12189-RWZ (D. Mass.). I alleged that this failure was due to a conflict of interest on the part of Attorney General Holder.

First of all, my address is "14418 S.E. 24th Street" and not "14418 S.D. 24th Street" as stated in your letter.

In your letter to me of November 4, 2013, you stated that your office determined that there was no conflict of interest because "the United States filed a notice of election to decline to intervene in the Duxbury case in July 2005, several years before Mr. Holder became Attorney General." You therefore concluded that no action by your Office was warranted. You never addressed my conflict of interest allegations in any way.

Unfortunately, and with all due respect, it appears that the Office of Professional Responsibility is either not familiar with False Claims Act law or is deliberately disregarding its provisions. The False Claims Act ("Qui Tam" law or "Lincoln Law") clearly allows the Department of Justice to withdraw its election and to intervene in a case at any time. Further, the dismissal of the Duxbury case has absolutely no effect on the rights of the United States government to continue with these claims which the Department of Justice knows have substantial merit.

Tell me, if we had settled the Duxbury case after the notice of election to decline to intervene was filed in July of 2005, would the Department of Justice forfeit its share of the fraud recovery? I think not. Quite obviously, the government of the United States has a continuing interest in a False Claims Act case until it is over and that interest is not affected by declining to intervene. If you disagree, I will be happy to alert the Courts that the Department of Justice takes the position that the interest of the United States is terminated with prejudice once an election to not intervene is filed.

You state in your letter that your office has conducted a "review of the docket entries in the case...." It does not appear that such a review ever took place. Even a cursory review of the docket entries would show your office that the Department of Justice took an active role during the entire ten years that the Duxbury matter was in litigation between 2003 and 2012, ***including during the eight (8) years after the Department of Justice filed a notice of election to decline to intervene in July of 2005.***

The United States Department of Justice filed a Brief for the United States as Amicus Curiae in the Duxbury case with the United States Supreme Court in May of 2010. A copy is attached. As you know, filing such a Brief involves a substantial investment of time and resources. Why would Acting Solicitor General Neal Katyal, Assistant Attorney General Tony West, Deputy Solicitor General Malcolm Stewart, Assistant to the Solicitor General Jeffrey Wall, Justice Department Attorney Douglas Letter and Justice Department Attorney Charles Scarborough waste their time doing that if the Duxbury claims did not have substantial merit and were no longer of substantial interest to the Department of Justice and United States taxpayers in 2010, some five years after it declined to intervene?

The United States Department of Justice has also appeared as Amicus Curiae in the Duxbury appeals to the United States Court of Appeals for the First Circuit. Attached is the Cover Page and the Table of Contents from the Brief for the United States as Amicus Curiae in the first appeal filed in August of 2008. Why would Assistant Attorney General Gregory Katsas, United States Attorney Michael Sullivan and Appellate Staff Attorneys Douglas Letter and Charles Scarborough waste their time doing that if the Duxbury claims did not have substantial merit and were no longer of substantial interest to the Department of Justice and United States taxpayers in 2008?

The United States Department of Justice has also filed briefs with the U.S. District Court of Massachusetts in response to every motion filed in the Duxbury case during the ten years it was in litigation. In essence, each one of these briefs argued that the Duxbury case should not be dismissed but if it was dismissed, the Court should continue to recognize the claims of the United States which, of course, have nothing to do with whether Mr. Duxbury is qualified to act as a False Claims Act Relator. Why would Justice Department attorneys waste their time doing that if the Duxbury claims did not have substantial merit and were no longer of substantial interest to the Department of Justice and United States taxpayers after the Justice Department declined to intervene?

The consumer/taxpayer watchdog/advocacy group Taxpayers Against Fraud also filed an Amicus Curiae Brief in support of Mr. Duxbury's claims. The Cover Page and Table of Contents

from that Brief is attached. Why would their attorneys waste their time doing that if the Duxbury claims did not have substantial merit?

You, everyone in your office dealing with this matter and I all know the real reason for the failure of the Department of Justice to intervene in this matter and act on the Duxbury claims. Attorney General Holder has vetoed action against Johnson & Johnson. Johnson & Johnson is represented in the Duxbury matter by Covington & Burling, Mr. Holder's former law firm. Before Mr. Holder was appointed as Attorney General he specialized in defense of Big Pharma companies in Medicare Fraud cases just like this. Mr. Duxbury filed his False Claims Action case in 2003, well before Mr. Holder became Attorney General in 2008. Obviously, a man with the legal intellect to be appointed Attorney General of the United States, who specialized in this kind of case and who was armed with unlimited resources is going to have worked at some point during these five years on Johnson & Johnson's defense of Mr. Duxbury's $10 billion case, a defense of probably the firm's most important client. Why would Covington & Burling not utilize Mr. Holder's expertise? Ten pages of the Covington & Burling website trumpet how much influence they have with the federal government. Take a look, it's shameless and disgraceful. (www.cov.com) In the 2009 DOJ prosecution of Big Pharma company Pfizer, Mr. Holder recused himself because his firm, Covington & Burling, had worked defending Pfizer in that prosecution. The same principles should apply in the Duxbury case. Mr. Holder should have recused himself from any decision-making in the Duxbury case. He had a blatant conflict of interest and his refusal to recuse himself is a violation of the ethics laws.

Several hundred Johnson & Johnson executives, Amgen executives and their attorneys should have been prosecuted for criminal Medicare Fraud, Obstruction of Justice and Perjury. They have illegally promoted ESA's, knowingly withheld documents demanded by Justice Department subpoenas, perjured themselves, violated Corporate Integrity Agreements and engaged in organized criminal conspiracies in violation of the RICO laws. But, just like their banking, mortgage and financial industry counterparts, they are given a pass by the Justice Department. Different rules of conduct apply to the corporate and legal elite.

Since my Complaint was not answered in any meaningful way, I hereby renew it. Please determine whether Mr. Holder ever worked on the Duxbury case at any time while in private practice. I do not intend to let this matter drop and will continue to blow the whistle as long as it takes.

Very truly yours,

PAUL E. SIMMERLY

Attachments

# PAUL E. SIMMERLY

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March 28, 2014

Mr. Raymond C. Hurley
Associate Counsel
Office of Professional Responsibility
950 Pennsylvania Avenue, N.W., Room 3266
Washington, DC 20530

Re: Complaint against Attorney General Eric Holder

Dear Mr. Hurley:

This is in further reply to your November 4, 2013 response to my Complaint against Attorney General Eric Holder in which I complained that Mr. Holder failed to require Department of Justice attorneys to intervene in the False Claims Act ("Qui Tam") case of *United States ex rel. Duxbury v. Ortho Biotech Products,* Cause No. 03-CV-12189-RWZ (D. Mass.). I alleged that this failure was due to a conflict of interest on the part of Attorney General Holder.

I further allege that Attorney General Holder acted illegally and unethically by failing to prosecute his former client, Johnson & Johnson, and its executives, for Medicare Fraud, Obstruction of Justice, perjury, securities fraud, failure to comply with numerous federal and state subpoenas, failure to comply with multiple "Corporate Integrity Agreements" executed after each of the fifteen (15) previous Medicare Fraud settlements with Johnson & Johnson over the past two decades, and other crimes against the United States. These allegations involve the participation of Johnson & Johnson in a secret JAMS (Judicial Arbitration and Mediation Service) Arbitration that went on for approximately six years, from about 1997 through 2002, and the conduct that was involved in that legal proceeding.

Epoetin Alfa is a drug marketed and sold as an anti-anemia (anti-fatigue) treatment. It is an erythropoietin stimulating agent (ESA). It increases the red blood cell count. Epoetin Alfa was invented and patented by Amgen, which sells the drug under the trade name Epogen (aka "EPO"). I believe that all Epoetin Alfa sold in the United States is manufactured by Amgen and has always been so manufactured. Amgen licenses Epoetin Alfa for sale by Johnson & Johnson under a Product License Agreement for all uses except treatment of dialysis patients. Johnson & Johnson sells Epoetin Alfa through its wholly-owned subsidiary Ortho Biotech Products, LP, under the trade name Procrit. As stated in the attached Wikipedia article about the drug:

> **Epoetin alfa** (rINN) (pron.: /ɛˈpoʊ.itin/) is human erythropoietin produced in cell culture using recombinant DNA technology.[1] Authorised by the European

> Medicines Agency on 28th of August 2007, it stimulates erythropoiesis (increases red blood cell levels) and is used to treat anemia, commonly associated with chronic renal failure and cancer chemotherapy. Epoetin is marketed under the trade names **Procrit** and **Epogen**. Its annual cost to U.S. patients is $8,447 per patient per year.[2]
>
> For several years, Epogen was the single most expensive drug paid for by U.S. Medicare. Dosing is controversial, and higher doses, to raise hematocrit to normal levels, are associated with higher risks of hospitalization, strokes and death.[3]

This Wikipedia article is inaccurate when it states that Epoetin Alfa is used to treat anemia in chemotherapy patients. It ***formerly*** was used extensively to treat cancer patients. In 2007, the FDA slapped a black box warning on all erythropoietin stimulating agents (ESA's) – Johnson & Johnson's Procrit and Amgen's Epogen and Aranesp - because these drugs ***promote*** cancer. In 2011, the FDA changed this to warning doctors, hospitals and patients that using Procrit and the other ESA's can cause "death and other serious side effects." This does not do much for the patients prescribed Procrit over the previous two decades, a period of time when so much Procrit was sold that it was ***Medicare's most reimbursed drug.*** Since Procrit was Medicare's most-reimbursed drug and was sold over a two-decade period, it is reasonable to conclude that if it was promoted, marketed and sold in violation of the Medicare laws, the amount of the damages would be in the billions of dollars.

Amgen also manufactures, promotes, markets and sells the drug Aranesp. Procrit, Aranesp and Epogen are all erythropoietin stimulating agents (ESA's). Procrit and Epogen are the same, identical drug. Aranesp is a synthetic form of erythropoietin. Procrit, Epogen and Aranesp are the same class of drugs and are promoted, marketed, prescribed and sold for the same uses. They are all subject to the Product License Agreement between Amgen and Johnson & Johnson. They were and are all subject to the same FDA warnings, which are attached.

***It is believed that use of Epoetin Alfa may have killed up to half a million people.***

Epoetin Alfa is also used to treat tired bike racers. This was the drug used by Lance Armstrong and other bike racers for illegal doping. See the attached articles. Ironically, the use of this drug may have promoted Lance Armstrong's cancer. Incredibly, despite the tremendous bad publicity caused by Armstrong and blood doping in cycling, Amgen continues to promote the biggest bicycling road race in the United States, the "Amgen Tour of California."

Johnson & Johnson and Amgen have been in a legal war for approximately the last two decades over the Epoetin Alfa Product License Agreement and whether it was breached. This litigation is some of the largest in U.S. history. Johnson & Johnson Procrit salesman, Gig Harbor, Washington resident Mark E. Duxbury, was a key witness for Amgen in two aspects of this litigation, the latest being a secret JAMS (Judicial Arbitration and Mediation Service) Arbitration that went on for approximately six years, from about 1997 through 2002. Duxbury, one of Johnson & Johnson's top Procrit salespersons, was described as a "rogue" employee by Johnson

& Johnson and was fired. This is a universal Big Pharma characterization applied to whistleblowers.

The secret JAMS arbitration was conducted in Chicago and was entitled ***Amgen, Inc. v. Ortho Pharmaceutical Corporation.*** Ortho Pharmaceutical Corporation is now known as Ortho Biotech Products, LP. It is a wholly owned subsidiary of Johnson & Johnson. The sole purpose behind the secrecy of the JAMS Arbitration was to keep the Medicare fraud of the two companies secret from prosecutors, shareholders, the media and the public. The formula for the drug is public knowledge. The only companies selling ESA's are Amgen and Johnson & Johnson, so there are no proprietary sales secrets.

The secret JAMS arbitration proceeding was conducted by former federal Judge Frank J. McGarr. I have described this proceeding as one of the biggest legal proceedings in history. This is my own characterization based upon the fact that it went on for at least six years, the final arbitration hearing lasted about six months, there were 250+ depositions taken all over the country (Duxbury 4 times) and, if recission had been granted, Johnson & Johnson would have lost its most profitable product (perhaps $30 billion of future sales). I was present for Duxbury's testimony and personally observed approximately ten million pages of documents in shelves spread out over the several floors of the office building rented solely for the purpose of conducting this secret arbitration.

The issue involved in this massive arbitration was who had breached the Product License Agreement and, if there was a breach, what were the damages. ***In order to litigate this issue, every aspect of the marketing and sale of Epogen and Procrit was put into evidence, including evidence of the marketing and sale of Epogen and Procrit in violation of the Medicare laws.*** Over a hundred attorneys were in attendance at each day of the final arbitration hearing (a formal trial), listening to testimony describing ongoing criminal Medicare Fraud and allowing their clients to commit perjury and obstruct justice. These same attorneys would then go on to advise their clients in how to continue to commit Medicare Fraud in the future. All of the evidence was recorded and the testimony and depositions transcribed and I am sure it was indexed. Duxbury and three other witnesses testified truthfully at the Arbitration Hearing. They were all fired and retaliated against. JAMS did nothing to help them.

In a written brief, Johnson & Johnson's attorney made the statement that in order for the Arbitrator to rule in favor of Amgen, the Arbitrator would have to conclude that Duxbury and the other three ("disguntled, disaffected, former Procrit salespersons") were telling the truth and that every other witness for Johnson & Johnson was committing perjury:

> Amgen asks Your Honor to reject, virtually in whole, the testimony of Ortho executives as perjury. Executive after executive from Ortho testified about the reasons why the company implemented the programs that it did, its analysis of its marketing opportunities and its efforts to limit dialysis sales. If this testimony is true, then Amgen's case utterly fails. In that event, the documented handful of FSDC (free-standing dialysis center) sales reflects no more, and no less, than this reality: they were simply an incidental and unintended by-product of Ortho's efforts to obtain its legitimate market.

> **Thus, Amgen is forced to take an extraordinary litigation position. It must argue, as it has, that every senior member of Ortho's management has secretly conspired to breach the Product License Agreement and to lie about it when questioned under oath. This go-for-broke strategy collapses under the weight of its utter implausability.** (Emphasis added)

Arbitrator McGarr concluded exactly that. On October 18, 2002, Arbitrator McGarr ruled in favor of Amgen and ordered Ortho Biotech to pay Amgen $150 million, together with attorney fees and costs.

Duxbury knew so much about Big Pharma that he was hired by well-known Seattle mass torts attorney, Steve Berman, as his firm's "Pharmaceutical Paralegal" at a six-figure salary. Mr. Berman represented approximately thirteen states in the litigation against the tobacco industry. Duxbury showed Berman where all the Big Pharma skeletons were buried. It is fair to compare Mr. Duxbury with Jeffrey Wygand, the main whistleblower in the tobacco litigation brought by the states. Wygand was portrayed by actor Russell Crowe in the Al Pacino movie, "The Insider".

Duxbury and fellow award-winning Procrit salesperson Dean McClellan filed a False Claims Act (Qui Tam) case in 2003. A copy of their First Amended Complaint in **U.S. ex rel Duxbury and McClellan v. Ortho Biotech Products, LP, U.S. District Court Cause No. 03-CV-12189-RWZ** is attached. It contains comprehensive, highly-detailed allegations of Medicare Fraud by Johnson & Johnson in the promotion, marketing and sale of Procrit. Dean McClellan, another highly decorated Procrit salesperson, was dismissed as a Relator because he was not the first to file, a requirement for bringing a False Claims Act case. Mark Duxbury's premature death made it impossible to prevent the case from being dimissed. This dismissal, however, had nothing to do with the substantive merits of the Medicare Fraud claims.

The Department of Justice actively and vigorously participated in the Duxbury and McClellan case, sending representatives to every hearing, filing briefs and even having the U.S. Solicitor General file an Amicus Brief with the Supreme Court when Johnson & Johnson petitioned for a Writ of Certiorari.

Amgen was just hit with a $762 Medicare Fraud settlement involving its promotion, marketing and sale of Aranesp. Johnson & Johnson markets, promotes and sells Procrit in the same, identical way. A copy of the Department of Justice Press Release announcing the Amgen settlement is attached and states that:

> "The settlement represents the single largest criminal and civil False Claims Act settlement involving a biotechnology company in U.S. history."
>
> .
> .
> .
>
> "This sends a powerful message to pharma companies: you must not put profits ahead of patients' health and doctors' trust. Drugs should be prescribed because they make people better, not because they make companies money," **said**

**Western District of Washington U.S. Attorney Durkan.** "The coordination by our office, the U.S. Attorney's Offices in the Eastern District of New York and Massachusetts and Main Justice also shows that there is no corner of the country where these actors can hide."

The attached Department of Justice Press Release **confirms** that the Department of Justice has concluded that Amgen's Aranesp was in the same class of drugs as Procrit, was intended for the same, identical uses and was promoted, marketed and sold as part of Amgen's strategy to compete with Procrit and gain market share from Johnson & Johnson:

> **"Amgen's internal sales and marketing materials made plain that Amgen's misbranding of Aranesp was the company's core business strategy to gain market share from its only ESA competitor, Procrit, sold by Johnson & Johnson. At the time of Aranesp's 2002 launch, doctors typically prescribed Procrit to treat the anemic patient populations for which Aranesp was approved. To compete with Procrit, Amgen built the Aranesp commercial strategy around the unapproved, off-label approach of a less frequent dosing schedule, which Amgen sales representatives argued was more convenient for patients and more profitable for doctors. Amgen implemented this illegal commercial effort through its promotion of off-label doses from two to four times larger than those approved by the FDA, administered far less frequently than approved by the FDA."**
>
> **"When this unapproved, off-label dosing effort proved commercially successful, Amgen sales and marketing executives determined that capturing the population of anemic cancer patients who were not undergoing chemotherapy was "the next big thing" and would give Amgen a "51 percent [ESA] market share." Accordingly, the company set about capturing the off-label market of patients suffering from anemia caused by cancer itself, rather than anemia caused by chemotherapy, and its sales representatives began marketing the safety and efficacy of Aranesp in that population. Ultimately, in 2007, the FDA determined that Aranesp increased the risk of death in that very population."**

(emphasis added).

As you can see from this DOJ Press Release, this settlement resulted from the filing of ten False Claims Act (Qui Tam) cases. Apparently, the "first to file" requirement of the False Claims Act was waived, unlike the situation in the Duxbury/McClellan case. All ten of these cases were filed after the Duxbury and McClellan case against Johnson & Johnson and its subsidiary, Ortho Biotech Products LP. In other words, Duxbury and McClellan did not copy the allegations contained in any of these ten False Claims Act lawsuits against Amgen; the Duxbury and McClellan allegations were not "parasitic," to use the derogatory term invented by our Courts to denigrate the efforts of people trying to expose fraud on the U.S. taxpayers at great personal cost which include employment termination, defamation, blackballing within the pharmaceutical industry and, in Mark Duxbury's case, possible suicide.

As you can see, the same allegations and claims that were just settled in the Amgen case involving the promotion, marketing and sale of Aranesp were first brought by Duxbury and McClellan in their case involving Procrit. Johnson & Johnson's Procrit is the same drug (Epoetin Alfa) and same chemical formula manufactured and sold by Amgen as Epogen (EPO) - it was invented and owned by Amgen and only licensed to Johnson & Johnson (Ortho) for sale. The only differences are that different brand names are used and that in the Duxbury/McClellan case the Medicare Fraud damages to the U.S. taxpayers are greater (estimated at $3 to $10 billion depending on how penalties are assessed), there is more evidence and more people taking this poison have died (500,000), thus making Procrit the deadliest prescription drug ever and the subject of the largest Medicare Fraud in history.

The significance of this is that all of the "pre-requisites," if you will, have been met in order for the government to pursue fraud litigation against Amgen and Johnson & Johnson. The same testing that was used for Aranesp and Epogen was used for Procrit. The same trials that were used for Aranesp and Epogen are applicable to Procrit. The same studies that were done on the effects of taking Aranesp and Epogen are applicable to Procrit. The same FDA warnings were made on all three of these drugs. As shown by the attached DOJ Press Release announcing the Amgen settlement, decades of litigation between the two companies over their territories and the secret JAMS Arbitration, Procrit, Aranesp and Epogen competed for the same markets. The drugs were medically interchangeable.

Dean McClellan has literally thousands of Procrit documents and sales and promotional material. Some of that material is provided herewith. The Department of Justice should be interested in all of these documents in Mr. McClellan's possession. He will not be keeping them forever. Please advise immediately whether the DOJ wants these documents or does not want them. Mr. McClellan's resume' is attached.

Medicare will pay for a drug's off-label use if it is medically accepted. Acceptance can be determined by referring to what are called compendia, comprehensive drug summaries compiled by experts and consulted by the government. The Department of Justice has determined that this standard did not apply to Amgen's promotion, marketing and sale of Aranesp and therefore Medicare should not have had to pay for its off-label uses. Amgen's off-label promotion of uses for Aranesp were not medically acceptable. By settling, Amgen has admitted this. Amgen promoted illegal off-label uses of Aranesp. The same reasoning should apply to Johnson & Johnson's illegal off-label promotion of Procrit. The same "pre-requisites" – testing, trials, studies, medical "non-acceptability", FDA warnings – apply to both companies and all three of the ESA drugs –Aranesp, Epogen and Procrit. The Department of Justice ***has*** pursued litigation against Amgen; it has ***refused*** to do so against Johnson & Johnson. Why? What am I missing?

The attached *Public Citizen News* article lists ***303 Medicare Fraud settlements*** from 1991 through the end of 2012 involving $30 billion in fraud against the U.S. taxpayers and our health care system.

Johnson & Johnson just settled a Medicare Fraud case involving its drug Risperdal for $2.2 billion. The DOJ Press Release announcing the settlement is attached. This Risperdal

settlement has been described by the Department of Justice in its official Press Release as "one of the largest health care fraud settlements in U.S. history." ***The Risperdal case is at least the 15th time that Johnson & Johnson has settled Medicare Fraud cases like this over the past 23 years according to the attached article from Public Citizen News.*** Johnson & Johnson is now the second greatest Big Pharma offender. Including Risperdal, the ***average*** amount of these 15 settlements was more than $302 million. Each one probably had a "Corporate Integrity Agreement", similar to the one signed in the Risperdal matter, where Johnson & Johnson agreed not to do it again. Since each case takes at least five years to go from filing to settlement, there were several such cases pending at any one time during this 23 year period, including when each of the 15 "Corporate Integrity Agreements" were signed. This conduct was not accidental; it was deliberate and calculated. Could a person get away with 15 murders over the course of 23 years where he admitted his crime each time? How can this ***ongoing*** criminal fraud perpetrated by Johnson & Johnson on the U.S. taxpayers be allowed to go on?

Keep in mind that these are ***settlements***, where the Big Pharma wrongdoing is admitted and liability is not contested. Hundreds of other identical cases are pending. All of the Medicare and Medicaid Fraud cases involve the same identical conduct in the marketing, promotion and sale of prescription drugs. Only the names of the drugs and the Big Pharma companies involved are different. No executive or employee of a Big Pharma company has ever gone to jail. The Big Pharma companies take full advantage of lax FDA and DOJ enforcement and promote these drugs for unapproved uses and dosages. Doctors and hospitals receive cash payments and other gratuities for doing so. False Medicare and Medicaid claims are submitted so the U.S. taxpayers pick up the bill.

Both Amgen and Johnson & Johnson have been served with subpoenas at various times during the last decade by the Department of Justice and the States demanding production of sales and promotional materials relating to ESA's. Did these companies produce the documents and transcripts of more than 250 depositions and six months of testimony from the secret JAMS Arbitration between them in response to these subpoenas? If not, isn't this Obstruction of Justice?

A "Corporate Integrity Agreement" is usually signed when a settlement is reached which requires that the offending company agree to not violate the law in the same way again. As shown by the incredible numbers of repeat violations of the Medicare laws, these Agreements are not obeyed by Big Pharma and enforcement of these Agreements by the DOJ is obviously universally ignored. Why? Without enforcement, is it any wonder that there are repeat violations by the same company?

Everything needed for a successful, multi-billion dollar Medicare Fraud prosecution of Johnson & Johnson by the DOJ has been laid out. The DOJ has the unprecedented benefit of having had a six-month long trial conducted (the JAMS Arbitration) covering every aspect of the promotion, marketing and sale of Procrit. Ten million pages of documents were produced and then indexed and scanned. More than 250 depositions and six months of testimony were transcribed. Procrit salesperson Dean McClellan has thousands of pages of Procrit promotional and sales material. The DOJ can compare this evidence with what Johnson & Johnson and Amgen supplied in response to the subpoenas issued to them over the past decade and see if

there was compliance. The evidence will show that Corporate Integrity Agreements have been ignored. The Amgen - Aranesp settlement has shown how ESA's are marketed. The Johnson & Johnson – Risperdal settlement has given the DOJ insight into the workings of J &J.

This Procrit case was the subject of a Dutton book, ***Blood Feud*** (in hardback) and ***Blood Medicine*** (in paperback), and a movie script is being written. The Duxbury claims are the subject of four published court decisions – three federal and one state. Mark Duxbury's great uncle, Bruce Crandall, was honored by the NFL Seattle Seahawks and raised the 12th Man flag at a recent game. He won the Medal of Honor in Vietnam for flying ammo and water in to the first major battle of the Vietnam War and flying the wounded out. He was portrayed by Greg Kinnear in the Mel Gibson movie "We Were Soldiers."

Unfortunately, Mark Duxbury died before he could complete his case. It was his wish that this unbelievable healthcare, corporate and legal corruption be exposed, prosecuted and stopped from ever happening again.

Attorney General Holder has vetoed action against Johnson & Johnson. Johnson & Johnson is represented in the Duxbury matter by Covington & Burling, Mr. Holder's former law firm. Before Mr. Holder was appointed as Attorney General he specialized in defense of Big Pharma companies in Medicare Fraud cases just like this. Mr. Duxbury filed his False Claims Action case in 2003, well before Mr. Holder became Attorney General in 2008. Obviously, a man with the legal intellect to be appointed Attorney General of the United States, who specialized in this kind of case and who was armed with unlimited resources is going to have worked at some point during these five years on Johnson & Johnson's defense of Mr. Duxbury's $10 billion case, a defense of probably the firm's most important client. Why would Covington & Burling not utilize Mr. Holder's expertise? Ten pages of the Covington & Burling website trumpet how much influence they have with the federal government. Take a look, it's shameless and disgraceful. (www.cov.com)

In the 2009 DOJ prosecution of Big Pharma company Pfizer, Mr. Holder recused himself because his firm, Covington & Burling, had worked defending Pfizer in that prosecution. The same principles should apply in the Duxbury case. Mr. Holder should have recused himself from any decision-making in the Duxbury case and from any involvement in determining whether to prosecute Johnson & Johnson. He had a blatant conflict of interest and his refusal to recuse himself is a violation of the ethics laws.

Several hundred Johnson & Johnson executives and their attorneys should have been prosecuted for criminal Medicare Fraud, securities fraud, Obstruction of Justice and Perjury. They have illegally promoted ESA's, knowingly withheld documents demanded by Justice Department subpoenas, perjured themselves, violated Corporate Integrity Agreements and engaged in organized criminal conspiracies in violation of the RICO laws.

Very truly yours,

PAUL E. SIMMERLY

Paul E. Simmerly
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July 3, 2014

Robin C. Ashton
Counsel
Office of Professional Responsibility
950 Pennsylvania Avenue, N.W., Suite 3266
Washington, DC 20530-0001

Dear Counsel Ashton:

On July 10, 2013 (one year ago) I filed with your office a Formal Complaint against United States Attorney General Eric Holder alleging that he had a conflict of interest by failing to recuse himself from participation in the case of ***United States ex rel Duxbury v. Ortho Biotech Products, L.P.***, (a wholly owned subsidiary of Johnson & Johnson) and by interfering with the decisions of the Department of Justice on whether to intervene in that lawsuit and whether the Department of Justice should prosecute Johnson & Johnson for Medicare Fraud. A copy of that Complaint is enclosed.

Johnson & Johnson and its wholly owned subsidiary, Ortho Biotech Products,LP, are represented by Mr. Holder's law firm, Covington & Burling. Prior to being appointed Attorney General, Mr. Holder specialized at Covington & Burling in defending Big Pharma companies in these kinds of Medicare Fraud cases. I believe that Mr. Holder actually worked on the Duxbury case prior to his appointment as Attorney General.

On November 4, 2013, I received a frivolous response to my Complaint from Mr. Raymond C. Hurley of the Office of Professional Responsibility of the United States Department of Justice. That response is enclosed and states that the election by the DOJ to decline to intervene in the Duxbury case took place in July 2005, several years prior to Mr. Holder becoming Attorney General, and therefore no action by your Office is warranted.

On February 17, 2014, I sent Mr. Hurley a reply which points out that his response is completely erroneous because the United States and the Department of Justice can change its mind and decide to intervene at any time. That reply is enclosed.

Attached is the Amicus Curiae Brief of the United States to the U.S. Supreme Court in ***Ortho Biotech Products, LP, Petitioner, v. United States ex rel. Duxbury, Respondent,*** U.S. Supreme Court No. 09-654, filed by the Department of Justice in 2010, some five years after the

government declined to intervene and two years after Mr. Holder became Attorney General. I quote from Page 2:

> "If the government declines to intervene, the relator "shall have the right to conduct the action," but the district court "may nevertheless permit the Government to intervene at a later date upon a showing of good cause." 31 U.S.C. 3730 (c)(3)."

In my reply letter of February 17, 2014 to Mr. Hurley I renewed my conflict of interest complaint. I have received no response of any kind to date.

I respectfully request a response.

Please let me know if you need additional information or documentation. Thank you.

Very truly yours,

PAUL E. SIMMERLY

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email: psimmerly@hermanrecor.com

July 7, 2014

Robin C. Ashton
Counsel
Office of Professional Responsibility
950 Pennsylvania Avenue, N.W., Suite 3266
Washington, DC 20530-0001

RE: Ethics Complaints against Department of Justice attorneys Jamie Yavelberg, Patricia Connally and Raymond C. Hurley

Dear Counsel Ashton:

I wish to make formal Ethics Complaints against Department of Justice attorneys Jamie Yavelberg, Patricia M. Connally and Raymond C. Hurley.

On July 10, 2013 (one year ago) I filed with your office a Formal Complaint against United States Attorney General Eric Holder alleging that he had a conflict of interest by failing to recuse himself from participation in the case of ***United States ex rel Duxbury v. Ortho Biotech Products, L.P.***, (a wholly owned subsidiary of Johnson & Johnson) and by interfering with the decisions of the Department of Justice on whether to intervene in that lawsuit and whether the Department of Justice should prosecute Johnson & Johnson for Medicare Fraud. A copy of that Complaint is enclosed.

Johnson & Johnson and its wholly owned subsidiary, Ortho Biotech Products, LP, are represented by Mr. Holder's law firm, Covington & Burling. Prior to being appointed Attorney General, Mr. Holder specialized at Covington & Burling in defending Big Pharma companies in these kinds of Medicare Fraud cases. I believe that Mr. Holder actually worked on the Duxbury case prior to his appointment as Attorney General.

On November 4, 2013, I received a frivolous response to my Complaint from Mr. Raymond C. Hurley of your Office of Professional Responsibility of the United States Department of Justice. That response is enclosed and states that the election by the DOJ to decline to intervene in the Duxbury case took place in July 2005, several years prior to Mr. Holder becoming Attorney General, and therefore no action by your Office is warranted.

On February 17, 2014, I sent Mr. Hurley a reply which points out that his response is completely erroneous because the United States and the Department of Justice can change its mind and

decide to intervene at any time. That reply is enclosed. Presumably, since he does not handle Medicare Fraud and False Claims Act cases and is not familiar with the Duxbury case, Mr. Hurley talked to other Justice Department officials when preparing his answer to my Complaint against Mr. Holder. These other Justice Department officials undoubtedly included Jamie Yavelberg and Patricia M. Connolly, the Justice Department attorneys handling the Duxbury case. Mr. Hurley, and these other Justice Department officials, clearly knew that what was stated in the November 4, 2013 Justice Department letter signed by Mr. Hurley was an intentional misrepresentation and designed to cover-up unethical and illegal conduct on the part of Attorney General Holder.

Attached is the Amicus Curiae Brief of the United States to the U.S. Supreme Court in ***Ortho Biotech Products, LP, Petitioner, v. United States ex rel. Duxbury, Respondent,*** U.S. Supreme Court No. 09-654, filed by the Department of Justice in 2010, some five years after the government declined to intervene and two years after Mr. Holder became Attorney General. I quote from Page 2:

> "If the government declines to intervene, the relator "shall have the right to conduct the action," but the district court "may nevertheless permit the Government to intervene at a later date upon a showing of good cause." 31 U.S.C. 3730 (c)(3)."

This confirms - without question - that the United States may intervene at any time in a False Claims Act case. I very much resent the intentional misrepresentations to the contrary made by your office in your November 4, 2013 letter to me.

In my reply letter of February 17, 2014 to Mr. Hurley and your office, I renewed my complaint against Mr. Holder. I have received no response of any kind to date.

Jamie Yavelberg and Patricia M. Connolly were the Justice Department attorneys who represented the United States in the ***Duxbury*** False Claims Act case. My allegations against them are as follows:

- Ms. Yavelberg and Ms. Connolly failed to see that Attorney General Holder recused himself from participation in the ***Duxbury*** case;
- Ms. Yavelberg and Ms. Connolly allowed Attorney General Holder to participate in the ***Duxbury*** case despite the fact that his former law firm, Covington & Burling, represented Ortho Biotech/Johnson & Johnson and Mr. Holder personally performed legal work for Ortho Biotech/Johnson & Johnson on the ***Duxbury*** case during the approximately five years (2003–2008) the case was in litigation before Mr. Holder became Attorney General;
- Ms. Yavelberg and Ms. Connolly allowed Attorney General Holder to make the decisions for the United States to not intervene in the ***Duxbury*** case and to not prosecute Ortho Biotech/Johnson & Johnson for Medicare Fraud despite Mr. Holder's blatant conflict of interest. The decisions to not intervene and to not prosecute saved Mr. Holder's and his law firm's client, Ortho Biotech/Johnson &

Johnson, approximately $10 billion in Medicare Fraud damages that would have been assessed, as well as millions of dollars in attorney fees;

- Ms. Yavelberg and Ms. Connolly failed to inform the Courts and opposing counsel of Attorney General Holder's conflicts of interest;
- Ms. Yavelberg, Ms. Connolly, Raymond C. Hurley and other Justice Department officials have engaged in a cover-up of Attorney General Holder's conflicts of interest;
- Mr. Hurley and other Justice Department officials have made intentional misrepresentations to me in the letter from your office dated November 4, 2013.

I request that formal responses to these allegations be made by each of these individuals and that I be provided with copies of those responses. Please consider this a request under the Freedom of Information Act.

Let me know if you need additional information or documentation.

Very truly yours,

PAUL E. SIMMERLY

**PAUL E. SIMMERLY**
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VIA Facsimile (202) 616-9881and regular mail

May 13, 2015

U.S. Department of Justice
Office of Inspector General Hotline
Investigations Division
950 Pennsylvania Avenue, N.W.
Suite 4706
Washington, D.C. 20530

Re: Interference by Department of Justice personnel with Medicare Fraud prosecutions

Dear Sir or Madam:

I am writing to inform you that former U.S Attorney General Eric Holder and various other U.S. Justice Department attorneys have interfered with Medicare Fraud prosecutions. Further, Mr. Holder and these attorneys have covered up Mr. Holder's interference with those Medicare Fraud prosecutions.

Attorney General Holder refused to have the Department of Justice intervene in the case of ***U.S. ex rel Duxbury and McClellan v. Ortho Biotech Products, LP, District Court of Massachusetts Cause No. 03-CV-12189-RWZ***, a Medicare Fraud False Claims Act ("Qui Tam") case involving Ortho Biotech's blockbuster anemia drug, Procrit. Ortho Biotech Products, LP, is a subsidiary of Johnson & Johnson. This case involves what is possibly the largest Medicare Fraud in history, perhaps $10 billion in damages to the taxpayers depending upon how penalties are assessed.

The reason Mr. Holder and his Department of Justice failed to intervene is because Defendants Johnson & Johnson and Ortho Biotech Products, LP, are clients of Mr. Holder's former law firm, Covington & Burling. I believe that his failure to intervene goes against the advice of his Justice Department attorneys working on the case. Mr. Holder does not want to intervene because it would hurt his former clients and undoubtedly force them to settle. Covington & Burling represents Ortho Biotech Products, LP, in the ***Duxbury*** suit. While in private practice, Mr. Holder specialized in defending Big Pharma drug companies in Medicare Fraud cases. He may have even worked on the ***Duxbury*** case which in private practice, an allegation that has never been denied. The ***Duxbury*** case has been ongoing for ten years. Ten

pages of Covington & Burling's website (www.cov.com) brag about how a client can benefit by its lawyers' government contacts.

A more comprehensive explanation of the ***Duxbury*** Medicare Fraud claims is contained in the attached complaint letters, in particular the letter to Raymond C. Hurley of March 28, 2014. The Justice Department has failed to provide any explanation whatsoever for why it failed to intervene in the Duxbury matter.

In the 2009 DOJ prosecution of Big Pharma company Pfizer, Mr. Holder recused himself because his law firm, Covington & Burling, had worked defending Pfizer in that prosecution. The same principles should have applied in the ***Duxbury*** case and Mr. Holder should have recused himself in that case. He failed to do so.

On July 10, 2013, I filed the attached Ethics Complaint with the Office of Professional responsibility over this matter. I received the attached frivolous response to that Ethics Complaint dated November 4, 2013 which contained an explanation that was factually and legally inaccurate by all objective standards. I sent three reply letters on February 17, 2014, March 28, 2014, and July 3, 2014 (copies attached) which received no response. On July 7, 2014 I filed the attached Ethics Complaint with the Office of Professional Responsibility against Justice Department attorneys involved in this matter. No response to that Ethics Complaint has ever been received. My requests for documents under the Freedom of Information Act have also been ignored.

Please consider this a formal renewal of my Ethic Complaints. I respectfully request a written acknowledgment of this communication. Please also let me know if a formal Ethics Complaint form is needed and let me know the status of my Freedom of Information Act requests.

Please let me know if you need further information or documentation. Thank you very much.

Very truly yours,

PAUL E. SIMMERLY

Encl.

**U.S. Department of Justice**

Office of the Inspector General

*Investigations Division*

*1425 New York Avenue NW, Suite 7100*
*Washington, D.C. 20530*

May 28, 2015

Paul E. Simmerly
14418 S.E. 24th St
Bellevue, WA 98007

Dear Mr. Simmerly:

The purpose of this letter is to acknowledge receipt of your correspondence dated May 13, 2015. The Investigations Division of the Office of the Inspector General has thoroughly reviewed the material and concluded that the issues raised do not warrant an investigation by this office. Accordingly, this office will take no further action regarding your correspondence and considers the matter closed.

Thank you for giving us the opportunity to review your concerns.

Sincerely,

Office of the Inspector General
Investigations Division

**U.S. Department of Justice**

Office of the Inspector General

*Investigations Division*

*1425 New York Avenue NW, Suite 7100*
*Washington, D.C. 20530*

July 13, 2015

Paul E. Simmerly
14418 S.E. 24th St
Bellevue, WA 98007

Dear Mr. Simmerly:

The purpose of this letter is to acknowledge receipt of your correspondence dated May 13, 2015. The Investigations Division of the Office of the Inspector General has thoroughly reviewed the material and concluded that the issues raised do not warrant an investigation by this office. Accordingly, this office will take no further action regarding your correspondence and considers the matter closed.

Thank you for giving us the opportunity to review your concerns.

Sincerely,

Office of the Inspector General
Investigations Division