NO ACT

PE 12-27-10

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549-4561

DIVISION OF
CORPORATION FINANCE

11005756

February 22, 2011

Elizabeth A. Ising
Gibson, Dunn & Crutcher LLP
1050 Connecticut Avenue, N.W.
Washington, DC 20036-5306

Act: 1934
Section:
Rule: 14a-8
Public
Availability: 02-22-2011

Re: Johnson & Johnson
Incoming letter dated December 27, 2010

Dear Ms. Ising:

This is in response to your letter dated December 27, 2010 concerning the shareholder proposal submitted to Johnson & Johnson by Paul W. Cahan. We also received letters from the proponent on January 26, 2011 and February 16, 2011. Our response is attached to the enclosed photocopy of your correspondence. By doing this, we avoid having to recite or summarize the facts set forth in the correspondence. Copies of all of the correspondence also will be provided to the proponent.

In connection with this matter, your attention is directed to the enclosure, which sets forth a brief discussion of the Division's informal procedures regarding shareholder proposals.

Sincerely,

Gregory S. Belliston
Special Counsel

Enclosures

cc: Paul W. Cahan

*** FISMA & OMB Memorandum M-07-16 ***

February 22, 2011

Response of the Office of Chief Counsel
Division of Corporation Finance

Re: Johnson & Johnson
Incoming letter dated December 27, 2010

The proposal calls for the company to work with the FDA "to add warning on labels to all Levaquin tablets, and injection solutions informing all patients that Levaquin has a 'Black Box' Warning."

There appears to be some basis for your view that Johnson & Johnson may exclude the proposal under rule 14a-8(i)(7), as relating to Johnson & Johnson's ordinary business operations. In this regard, we note that the proposal relates to the manner in which the company labels particular products. Proposals concerning the manner in which a company sells particular products are generally excludable under rule 14a-8(i)(7). Accordingly, we will not recommend enforcement action to the Commission if Johnson & Johnson omits the proposal from its proxy materials in reliance on rule 14a-8(i)(7).

Sincerely,

Charles Kwon
Special Counsel

DIVISION OF CORPORATION FINANCE
INFORMAL PROCEDURES REGARDING SHAREHOLDER PROPOSALS

The Division of Corporation Finance believes that its responsibility with respect to matters arising under Rule 14a-8 [17 CFR 240.14a-8], as with other matters under the proxy rules, is to aid those who must comply with the rule by offering informal advice and suggestions and to determine, initially, whether or not it may be appropriate in a particular matter to recommend enforcement action to the Commission. In connection with a shareholder proposal under Rule 14a-8, the Division's staff considers the information furnished to it by the Company in support of its intention to exclude the proposals from the Company's proxy materials, as well as any information furnished by the proponent or the proponent's representative.

Although Rule 14a-8(k) does not require any communications from shareholders to the Commission's staff, the staff will always consider information concerning alleged violations of the statutes administered by the Commission, including argument as to whether or not activities proposed to be taken would be violative of the statute or rule involved. The receipt by the staff of such information, however, should not be construed as changing the staff's informal procedures and proxy review into a formal or adversary procedure.

It is important to note that the staff's and Commission's no-action responses to Rule 14a-8(j) submissions reflect only informal views. The determinations reached in these no-action letters do not and cannot adjudicate the merits of a company's position with respect to the proposal. Only a court such as a U.S. District Court can decide whether a company is obligated to include shareholder proposals in its proxy materials. Accordingly a discretionary determination not to recommend or take Commission enforcement action, does not preclude a proponent, or any shareholder of a company, from pursuing any rights he or she may have against the company in court, should the management omit the proposal from the company's proxy material.

From: PAUL *** FISMA & OMB Memorandum M-07-16 ***
Sent: Wednesday, February 16, 2011 1:20 PM
To: shareholderproposals
Cc: dchia@its.jnj.com
Subject: Fw: Johnson & Johnson Shareholder Proposal

Dear Ladies and Gentlemen:
Just forwarding to you (to keep in proper protocol) the latest communication between myself, shareholder of 51 shares of Johnson & Johnson and writer of a Proxy for their 4/2011 annual meeting, and the company.
Respectfully yours,
Paul W. Cahan

*** FISMA & OMB Memorandum M-07-16 ***

----- Forwarded Message ----
From: "Chia, Douglas [JJCUS]" <DChia@its.jnj.com>
To: PAUL *** FISMA & OMB Memorandum M-07-16 ***
Sent: Tue, February 15, 2011 4:31:46 PM
Subject: RE: Johnson & Johnson Shareholder Proposal

Paul:

I am not aware of any strict time limit. The rule says you should do this "promptly" to the extent you feel you need to raise any issues.

Doug

From: PAUL [mailto:*** FISMA & OMB Memorandum M-07-16 ***
Sent: Tuesday, February 15, 2011 9:50 AM
To: Chia, Douglas [JJCUS]
Subject: Re: Johnson & Johnson Shareholder Proposal

Dear Douglas:
Thank you for sending me this.
I believe I have five business days to respond to you, G & D and the SEC regarding my opinion with back-up research and evidence of any possible false and misleading statements that your firm has made in this attached statement... from the time I receive written word from the SEC.... if they approve my Proxy.
Is that time-frame correct?
Regards,
Paul Cahan

From: "Chia, Douglas [JJCUS]" <DChia@its.jnj.com>
To: *** FISMA & OMB Memorandum M-07-16 ***

Sent: Tue, February 15, 2011 12:43:30 AM
Subject: Johnson & Johnson Shareholder Proposal

Dear Paul:

As indicated in our prior correspondence, Johnson & Johnson has indicated to the Securities and Exchange Commission (SEC) that it intends to omit from its proxy statement and form of proxy for its 2011 Annual Meeting of Shareholders the shareholder proposal that you submitted. If the SEC concurs that the proposal in its original form need not be included in the Company's proxy materials, the Company will not include your proposal from its proxy materials. However, if the SEC does not concur, the Company intends to exercise its right to include a statement of its views regarding the proposal in its proxy materials. Therefore, pursuant to Rule 14a-8(m) of the Securities Exchange Act of 1934, as amended, we are providing to you this copy of the Company's Statement in Opposition.

We are providing you this Statement in Opposition solely as a precautionary measure. By providing you this statement, the Company does not waive its request that the SEC concur that the proposal may be excluded, and does not waive its right to revise the attached statement if the SEC requires you to make revisions to your proposal or supporting statement.

Please contact me if you have any questions regarding this matter.

Kind regards,

Doug

Douglas K. Chia
Assistant General Counsel & Corporate Secretary
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
Tel: (732) 524-3292
Fax: (732) 524-2185
E-mail: dchia@its.jnj.com

January 26, 2011 Paul W. Cahan

*** FISMA & OMB Memorandum M-07-16 ***

Via E-mail

Office of Chief Counsel
Division of Corporation Finance
Securities and Exchange Commission
100 F Street, NE
Washington, DC 20549

Ladies and Gentlemen:

This letter is in response to the No-Action Request letter sent by Gibson and Dunn on behalf of Johnson & Johnson regarding the shareholder proposal (hereafter referred to as "The Proposal") submitted by Mr. Paul W. Cahan (hereafter referred to as "The Proponent").

This letter was prepared at no cost to The Proponent by someone who has no legal background and who wishes to remain anonymous. This author would like to note that they were severely and permanently disabled and disfigured at a young age by Levaquin®, the Johnson & Johnson product being discussed in The Proposal, but stands to gain nothing personally if The Proposal is allowed to be voted upon or passed by the shareholders of Johnson & Johnson.

This author has hereby granted full use of this document to The Proponent. All attached exhibits were provided by The Proponent.

Arguments provided by Gibson and Dunn in their No-Action Request letter will be identified in this document by the use of half-inch margins, 11 pt. font, justified text and quotation marks. Rebuttals will follow these selected arguments and will contain no such alterations to standard formatting in order to clearly identify this author's responses.

Pursuant to Rule 14a-8(k), a copy of this letter has been concurrently sent to Douglas K. Chia, Assistant General Counsel & Corporate Secretary, Johnson & Johnson and Elizabeth A. Ising, Gibson and Dunn.

To begin, the opening argument from Gibson and Dunn's No-Action Request:

"BASIS FOR EXCLUSION

> We hereby respectfully request that the Staff concur in our view that the Proposal may be excluded from the 2011 Proxy Materials pursuant to Rule 14a-8(i)(7) because the Proposal relates to the Company's ordinary business operations (*i.e.*, regulatory matters concerning labeling, and sales of, a particular product)."

The text of Rule 14a-8(i)(7) states: "Management functions: If the proposal deals with a matter relating to the company's ordinary business operations." There is no clear provision relating to "Regulatory matters concerning labeling, and sales of, a particular product." While this interpretation could possibly be derived from specific precedents, it seems clear that the implication on the part of Gibson and Dunn that this wording is an official part of the SEC ruling itself is without merit.

> "The Company may exclude the Proposal pursuant to Rule 14a-8(i)(7) because it deals with matters relating to the Company's ordinary business operations. In Exchange Act Release No. 40018 (May 21, 1998) (the "1998 Release"), the Commission explained that the ordinary business exclusion rests on two central considerations. The first consideration relates to the subject matter of a proposal; the 1998 Release provides that "[c]ertain tasks are so fundamental to management's ability to run a company on a day-to-day basis that they could not, as a practical matter, be subject to direct shareholder oversight.""

In the Exchange Act Release No. 40018 that Gibson and Dunn cited above, the SEC seeks to clarify the stated consideration with the following sentence: "Examples include the management of the workforce, such as the hiring, promotion, and termination of employees, decisions on production quality and quantity, and the retention of suppliers."

The Proposal does not remotely touch on such issues, nor does it touch on issues that could be considered tangentially related.

The labeling of a single product does not – in any conceivable or logical fashion – infringe on the company's management's ability to run a company on a day-to-day basis. The author of this letter finds no substantial argument on Gibson and Dunn's part as to how it could and therefore submits that their statement is without basis.

> "The second consideration is the degree to which the proposal attempts to "micro-manage" a company by "probing too deeply into matters of a complex nature upon which shareholders as a group, would not be in a position to make an informed judgment." Id. (citing Exchange Act Release No. 12999 (Nov. 22, 1976))."

This author was unable to locate the text of cited Exchange Act Release No. 12999 on the SEC website, nor any other final ruling from the year 1976. Instead, this author chooses to again cite Exchange Act Release No. 40018, in which the SEC has perhaps since

clarified Gibson and Dunn's cited Exchange Act and includes the following sentence: "This consideration may come into play in a number of circumstances, such as where the proposal involves intricate detail, or seeks to impose specific time-frames or methods for implementing complex policies."

The Proposal neither "Involves intricate detail," nor does it "Seek to impose specific time-frames or methods for implementing complex policies."

While The Proposal does request additional labeling, it does not impose a specific time-frame, and does not even propose the exact wording that such labeling would contain. As discussed throughout this document below, it is also questionable as to whether The Proposal pertains to "Complex policies."

In regards to the notion that The Proposal would be "probing too deeply into matters of a complex nature upon which shareholders, as a group, would not be in a position to make an informed judgment," the recent addition of a "Black Box Warning" (which is the strongest warning label that the Food and Drug Administration can apply) to the product in question, along with the general public's basic knowledge of medication labeling, should serve as evidence that most, if not all, of the shareholders should have at least some knowledge of the issue at hand.

Also, in April of 2008, The Proponent gave a speech at Johnson & Johnson's shareholder meeting, in which he outlined his injuries and made a public plea that certain actions be taken by the company to prevent others from being injured in the same manner; as of this date, none of his proposals have been enacted. Therefore, many of the shareholders should not only have knowledge of the issue at hand, but some may even remember The Proponent himself. A transcript of his speech is attached. [Exhibit A]

> "A. The Proposal's Focus on the Company's Labeling of its Products Renders the Proposal Excludable Under Rule 14a-8(i)(7)
>
> We believe that the Proposal impermissibly relates to the Company's ordinary business operations because the Proposal's thrust and focus concerns the Company's labeling and sale of its products. "

Once again, this author can find no language in Rule 14a-8(i)(7) or Exchange Act Release No. 40018 that pertains to the labeling of a company's products.

> "As discussed below, the Staff consistently has concurred that the appropriate labeling of a company's products is a matter of ordinary business.
> The Staff has consistently taken the position that a company's decisions regarding the selection and labeling of products are ordinary business matters and thus that shareholder proposals concerning such decisions may be excluded under Rule 14a-8(i)(7)."

Claimed SEC consistency does not constitute a valid or binding argument. While precedents should naturally be taken into consideration when relevant, the mere existence of precedents does not rise to the level of official ruling.

> "For example, in Campbell Soup Co. (avail. Aug. 21, 2009), the Staff concurred in the exclusion of a shareholder proposal requesting the company to adopt specific labeling requirements for its products relating to sodium levels and launch an advertising campaign educating people on healthy diets."

In this cited precedent, the shareholder proposal was excluded based on considerations not related to labeling. The SEC specifically stated in that particular case that the issue of labeling was not even considered in its ruling.

> "See also The Coca Cola Co. (avail. Jan. 22, 2007) (concurring in exclusion of a proposal that requested the company to adopt specific requirements relating to labeling caffeinated beverages and that the company stop "caffeinating" its root beer and other beverages because the proposal dealt with a matter of ordinary business operations)"

This cited precedent concerned not merely the labeling of products, plural, but also related to specific ingredients in those products. The Proposal being discussed in this letter contains no such specificity, nor does it touch on the issue of production or ingredients.

> "H.J. Heinz Co. (avail. June 14, 1991) (concurring in exclusion pursuant to Rule 14a-8(c)(7) of a proposal that requested the company to refrain from labeling products with characters, signs or symbols of any specific race, religion, or culture because the proposal dealt with a matter of ordinary business operations). In H.J. Heinz Co., the Staff expressly noted the company's position that "management's decisions concerning the company's product names and labels relate to the conduct of ordinary business operations.""

While this precedent does actually specifically relate to the labeling of products, it was again concerned with labeling of products, plural, not merely one specific product. It is also fairly clear that the label changes being discussed in that case did not pertain to proven health risks or constitute a significant social policy issue.

> "In this regard, the Proposal would involve the Company with the work of pharmacists that ultimately place the labels on the bottles that patients receive.

> The labels placed on pharmacy vials are under the control of the pharmacist; they are not under the control of the manufacturer or marketer of the prescription medicines, such as the Company. Not only would such labeling require the Company to work with the FDA, but it would also involve business negotiations between the Company and the countless number of third parties actually filling patient prescriptions of a specific medicine." The Proposal acknowledges this in the supporting statement: "This will take working with FDA and companies that provide computerized LABELING services when a prescription is filled. Thus, the Proposal is excludable as relating to the Company's ordinary business operations, because it relates to the labeling of one of the Company's products and attempts to delve into the complex pharmaceutical product labeling process for end-users beyond the Company's immediate control."

While it is true that it is typically the job of a pharmacy worker to print and place the actual label on the bottle or packaging of a pharmaceutical product, this argument on the part of Gibson and Dunn is misleading. The Proposal does not ask Johnson & Johnson to micro-manage and oversee each and every prescription filled, but merely to facilitate the creation of labels regarding the existence of or referencing the contents of the aforementioned "Black Box Warning."

This is made clear in The Proposal itself, already quoted by Gibson and Dunn above, but repeated here: "This will take working with FDA and companies that provide computerized LABELING services when a prescription is filled." There is no wording in The Proposal that suggests that Johnson & Johnson work with any pharmacists or other retailers.

Current bottles and packages of Levaquin® often already come with warning labels on them, stating such things as "Do not take antacids, iron, or vitamin/mineral supplements within two hours of this medication," "You should avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medication," and "May cause dizziness. Do not drive or perform other potentially dangerous tasks until you know how this medicine will affect you." [Exhibit B]

These specific labels, while pertinent, do not represent the most significant risks associated with Levaquin®.

Labels placed on medication bottles and packaging are printed at the time a medication is dispensed. This is generally an automated process, accomplished by use of one of the various brands of software available to pharmacies and based on drug-specific information, interactions and warnings.

It is therefore not true that the creation of such labels would "Involve business negotiations between the Company and the countless number of third parties actually filling patient prescriptions of a specific medicine." It would merely involve the same process that prompted and created the warning labels already present on dispensed prescriptions of Levaquin®.

> "It should be noted that the Company has worked in the past, and continues to work, with the FDA on the "black box warning" that appears in the Medication Guide for LEVAQUIN®, as well as all labeling for LEVAQUIN®. All Company labeling is approved by the FDA."

As shown in Exhibit B, the patient receiving that prescription for Levaquin® did not receive any information regarding the "Black Box Warning," nor did they receive the FDA-Approved Medication Guide for Levaquin®, despite this prescription being filled on November 18th, 2009, well over a year after the Food and Drug Administration requested the addition of the "Black Box Warning" on all fluoroquinolone antibiotics.

This not only demonstrates the need for the directive outlined in The Proposal, but also serves as evidence of The Proposal's claim that "Current communication is failing."

> "The Staff has also consistently recognized that decisions regarding the safety of particular products sold by retailers are excludable as relating to a company's ordinary business operations."

As explained above, The Proposal does not concern the selling or distribution of the product by retailers. It is the position of this author that all such precedents cited to lend weight to Gibson and Dunn's above argument are therefore entirely irrelevant.

> "*B. The Proposal Involves Ordinary Business Matters Because It Dictates the Company's Involvement in Regulatory Activities Concerning a Specific Company Product*
>
> We believe that the Proposal impermissibly relates to the Company's ordinary business operations because the Proposal directs the Company to work with one of its regulators, the FDA, regarding the warnings to be placed on one of its products. As discussed below, the Staff consistently has concurred that shareholder proposals that – similar to the Proposal – attempt to micro-manage a company by attempting to dictate their involvement and participation with respect to specific legislative or regulatory initiatives are excludable under Rule 14a-8(i)(7)."

This author can find no text in Rule 14a-8(i)(7) which states the impermissibility of any and all proposals which involve a governmental agency, regulatory or otherwise. The Proposal simply directs that Johnson & Johnson work with the Food and Drug Administration with regards to making sure that patients who are prescribed Levaquin®

are properly warned of the potential and serious risks on the bottle or packaging itself, rather than solely in a separate document (which, as shown in Exhibit B, is not universally provided).

The wording of The Proposal was derived in part from correspondence between The Proponent and Norman Rosenthal, MD, Vice President, Medical Affairs at Ortho McNeil Janssen Pharmaceutical, Inc. (a subsidiary of Johnson & Johnson and manufacturer of Levaquin®), in which he states "We are currently in the process of discussing with the FDA how to best implement this labeling change as well as other communications concerning tendon rupture." [Exhibit C]

Further, according to the Food and Drug Administration (Federal Register 73 Fed. Reg. 2848 FDA 314.70), drug companies may unilaterally decide to alter labeling so long as it meets the following requirement:
(2)(i) To add or strengthen a contraindication, warning, precaution, or adverse reaction.

However, it seems more prudent for The Proposal to seek a bilateral approach with the company and the Food and Drug Administration with regards to any labeling additions. The Food and Drug Administration, as an oversight body with regulatory abilities over Johnson & Johnson and other major drug manufacturers, should be viewed as a complimentary component or entity to be involved in any such matters.

> "Labeling of medicines is a highly regulated and complex process, and there are additional requirements specifically regarding "black box warnings." Further, it is rare for particular warnings to be placed on product packaging that are unrelated to mode of administration of a drug or product preparation. Asking the Company's shareholders to determine whether it is prudent for the Company to embark on what would be a highly unorthodox course of action in connection with a regulatory process for one of its products would be asking the shareholders to probe too deeply into a highly complex matter, upon which they, as a group, would not be in a position to make an informed judgment. As a result, as further discussed below, the Proposal is excludable under Rule 14a-8(i)(7)."

As shown in Exhibit B, it not "Rare" by any means for "Particular warnings to be placed on product packaging that are unrelated to mode of administration of a drug or product preparation." In fact, it is exceedingly common and already in place for the product in question here, Levaquin®.

Countless medications come with various warnings on the bottle or packaging, many stating such things as "May cause drowsiness. Alcohol may intensify this effect. Please use care when operating a car or dangerous machines," and "May cause Headache."

It is also not uncommon for language pertaining to "Black Box Warnings" to be placed on product labels. Many antidepressants, such as Fluoxetine HCL (generic for Prozac®) often contain warnings stating things such as "Call doctor if you experience mood changes, sadness, depression or fear." [Exhibit D] Labels such as this were created as a result of the "Black Box Warning" being added to antidepressants, which warn of suicidal thoughts or actions and therefore serve as precedent for what The Proposal is seeking.

Given these facts, it is clearly not a "Highly unorthodox course of action" that the Proposal would be seeking the shareholders to vote upon and certainly not a request that they "probe too deeply into a highly complex matter, upon which they, as a group, would not be in a position to make an informed judgment."

> "While the Proposal relates to regulatory activities, it also suggests instituting a change in a highly regulated labeling process, and therefore, we believe that the precedent related to legislative matters and lobbying activities is on point."

As discussed above, The Proposal does not suggest instituting a *change* in a highly regulated labeling process. It is directed at getting Johnson & Johnson to work within the already-established guidelines for such labeling, to work with the regulatory agency involved in such guidelines and to work with labeling companies, all in an effort to properly inform patients of the serious risks associated with this particular product.

> "In this regard, the Staff has concurred that lobbying proposals are excludable under Rule 14a-8(i)(7) if they concern legislative or other political activities relevant to particular aspects of the company's business."

This author finds the notion that The Proposal is in any way related to "Lobbying" to be bordering on preposterous. At the risk of sounding pedantic, Merriam-Webster defines "Lobby" (intransitive verb) as: "To conduct activities aimed at influencing public officials and especially members of a legislative body on matters of legislation."

The Proposal does not seek any such actions, nor any that could be considered tangentially related. This attempt on the part of Gibson and Dunn to conflate the terms "Work with" and "Lobby" is nothing short of semantic garbling which only seeks to muddle the issue at hand.

Therefore, it is abundantly clear that any and all such precedents related to "Lobbying" are unrelated to The Proposal and are therefore entirely irrelevant.

"*C. The Proposal Does Not Implicate a Significant Policy Issue*

> We are aware that the Staff has not permitted the exclusion of certain shareholder proposals requesting that a company label its products with information related to general health or safety concerns. *See, e.g., Exxon Mobil Corp. (Lalanne)* (avail. Mar. 12, 2007) (shareholder proposal requesting that the company provide information at the pump regarding the carbon dioxide emissions generated by the fuel sold); *PepsiCo, Inc.* (avail. Mar. 2, 2007) (shareholder proposal requesting that the board adopt a policy to identify and label all food products manufactured or sold by the company under its brand names or private labels that may contain genetically engineered ingredients); *R.J. Reynolds Tobacco Holdings, Inc.* (avail. Mar. 7, 2002) (shareholder proposal requesting that the company include additional information in the packaging of tobacco products); *McDonald's Corp. (Harrington Investments, Inc., et al.)* (avail. Mar. 22, 2000) (shareholder proposal requesting that the board adopt a policy to remove genetically-engineered crops, organisms or products from its product line until long-term testing has shown they are not harmful to humans, animals or the environment)."

Much like the above-cited proposals, The Proposal in question seeks that pertinent information be made available in a manner that the vast majority of people consuming the product will see and be made aware of. Upon reading the provided summary above, The Proposal seems nearly identical to the cited precedent regarding R.J. Reynolds Tobacco Holdings, Inc, in that it seeks additional information be placed directly on product packaging.

> "Each of the above proposals, however, involved situations where there was an alleged public health or safety concern involving broad-based or widely recognized and debated human health or environmental risks (*i.e.*, food safety, cigarette smoking and greenhouse gas emissions) and addressed all of a company's products that might raise those concerns. In contrast, the Proposal relates solely to one of the Company's products – LEVAQUIN® – and solely to alleged reactions to that single medication."

The Food and Drug Administration, in a letter to Ms. Ilona Scott, Director of Regulatory Affairs at Ortho McNeil-Janssen Pharmaceutical, Inc. stated in part that "Levaquin poses a serious and significant public health concern..." and that "FDA has determined that Levaquin is a product that has serious risk(s) (relative to benefits) of which patients should be made aware because information concerning the risk(s) could affect the patients' decision to use, or continue to use Levaquin." [Exhibit E]

It seems prudent here to emphasize the Food and Drug Administration's own wording: **Levaquin poses a serious and significant public health concern...**

The addition of the "Black Box Warning" to all fluoroquinolone antibiotics such as Levaquin® was supported by a lawsuit filed by the advocacy group Public Citizen

(*Public Citizen v. FDA*, D.D.C. No. 08-cv-005). The Attorney General of Illinois also submitted a citizen's petition to the FDA seeking action on the same issue.

Further, there was a legal case won in Minnesota recently by John Schedin against Johnson & Johnson and Ortho-McNeil-Janssen Pharmaceuticals (US District Court District of Minnesota, File No. 08-md-1943). Mr. Schedin was awarded $700,000 in actual damages and $1.1 million dollars in punitive damages as a result of his disabling tendon ruptures resulting from his exposure to Levaquin®. Over 2,600 other such trials are currently pending against the company. The full transcript of Mr. Schedin's lawsuit can be found online at http://www.mnd.uscourts.gov/MDL-Levaquin/Transcripts/2010/092810.pdf.

On November 17, 2010, the U.S. Department of Health and Human Services (HHS), the Food and Drug Administration (FDA) and the Center for Drug Evaluation and Research (CDER) held a public workshop titled "Safe Use Initiative." During this workshop, Carl Krauss, MD, a former medical officer for the FDA and someone who oversaw Levaquin® for the FDA, stated in part: "... we recently conducted a survey on Medscape, 4,000 practitioners participated. And what I found out was that the number one drug interaction listed in the MedGuide, which is with nonsteroidals and the quinolones, 90 percent of practitioners were totally unaware of it, which was surprising to me." He went on to say, "And then also just asking folks in our clinic whether they are aware of the tendonopathy signal, most also were unaware of that..." The entire transcript of this workshop is available online at http://www.fda.gov/downloads/Drugs/NewsEvents/UCM235768.pdf.

If surveys of prescribing physicians reveal an overwhelming lack of knowledge about the serious risks and interactions associated with Levaquin®, the conclusion that patients themselves are even less informed is obvious and inescapable.

Since it has not yet been provided in full by any party with interest in The Proposal, what follows is the full text of the "Black Box Warning," as included in the full prescribing information:

> "WARNING:
> Fluoroquinolones, including LEVAQUIN®, are associated with an increased risk of tendinitis and tendon rupture in all ages. This risk is further increased in older patients usually over 60 years of age, in patients taking corticosteroid drugs, and in patients with kidney, heart or lung transplants."

Unfortunately, that warning leaves out key components of the nature of these risks, including the possibility of delayed-onset tendon injuries. Here is the full text of the warning included in the FDA-Approved Medication Guide for Levaquin®:

> **"What is the most important information I should know about LEVAQUIN®?**

LEVAQUIN® belongs to a class of antibiotics called fluoroquinolones. LEVAQUIN® can cause side effects that may be serious or even cause death. If you get any of the following serious side effects, get medical help right away. Talk with your healthcare provider about whether you should continue to take LEVAQUIN®.

• **Tendon rupture or swelling of the tendon (tendinitis).**
• Tendons are tough cords of tissue that connect muscles to bones.
• Pain, swelling, tears, and inflammation of tendons including the back of the ankle (Achilles), shoulder, hand, or other tendon sites can happen in people of all ages who take fluoroquinolone antibiotics, including LEVAQUIN®. The risk of getting tendon problems is higher if you:
• are over 60 years of age
• are taking steroids (corticosteroids)
• have had a kidney, heart or lung transplant.
• Swelling of the tendon (tendinitis) and tendon rupture (breakage) have also happened in patients who take fluoroquinolones who do not have the above risk factors.
• Other reasons for tendon ruptures can include:
• physical activity or exercise
• kidney failure
• tendon problems in the past, such as in people with rheumatoid arthritis (RA).
• Call your healthcare provider right away at the first sign of tendon pain, swelling or inflammation. Stop taking LEVAQUIN® until tendinitis or tendon rupture has been ruled out by your healthcare provider. Avoid exercise and using the affected area. The most common area of pain and swelling is the Achilles tendon at the back of your ankle. This can also happen with other tendons. Talk to your healthcare provider about the risk of tendon rupture with continued use of LEVAQUIN®. You may need a different antibiotic that is not a fluoroquinolone to treat your infection.
• Tendon rupture can happen while you are taking or after you have finished taking LEVAQUIN®. Tendon ruptures have happened up to several months after patients have finished taking their fluoroquinolone.
• Get medical help right away if you get any of the following signs or symptoms of a tendon rupture:
• hear or feel a snap or pop in a tendon area
• bruising right after an injury in a tendon area
• unable to move the affected area or bear weight"

Of notable import is the bullet point which reads: "Tendon rupture can happen while you are taking or after you have finished taking LEVAQUIN®. Tendon ruptures have happened up to several months after patients have finished taking their fluoroquinolone."

To this author's knowledge, fluoroquinolones such as Levaquin® are the only commonly-prescribed FDA-approved medication which can continue to cause new adverse reactions long after the drug has been discontinued by the patient.

[Some types of chemotherapy (*i.e.* platinum-based and taxane drugs) can cause delayed-onset adverse reactions, most specifically peripheral neuropathy (a type of debilitating, potentially-irreversible nerve damage which Levaquin® has also been shown to cause). The difference, however, is that prior to cancer patients being given chemotherapeutic agents, they are generally counseled at length by their doctors about this possibility and given copious amounts of information before choosing to embark on their treatment plan.]

The vast majority of people who take a medication (whether prescription or over-the-counter) naturally presume that any side-effects experienced while taking that medication will cease once the medication has been stopped. It is therefore inconceivable and unprecedented that any medication which defies this type of common-sense thinking would not come with ample warnings and counseling before treatment has begun.

A tendon rupture is a life-altering and catastrophic event, one which can result in lasting or permanent disability and severe pain. Such ruptures can result in complete loss of function in the affected limb(s), loss of employment, surgeries and/or casting, untold costs to the patient (personal, emotional and financial), significant financial loss to health insurance providers and exponentially greater costs to society at large should the patient be forced to file for disability.

The Proponent himself is now permanently disabled due to bilateral Achilles tendon ruptures and chronic tendonitis. [Exhibit F] As shown in that Exhibit, The Proponent was prescribed a ten day course of Floxin® on April 15th, 1998. He began experiencing pain approximately one week after he finished his prescription of the drug. By September 3rd of that same year, he was still experiencing pain, but had actually noted some improvement. However, by October 10th of 1998, these injuries had progressed to the point of bilateral Achilles tendon ruptures. The drug he was given, Floxin® (now discontinued, but also made by Johnson & Johnson), was, according to the FDA, so similar to Levaquin® that the two were considered interchangeable in Johnson & Johnson's NDA (New Drug Application) for Levaquin® (NDA 20634), which is available online at http://www.accessdata.fda.gov/drugsatfda_docs/nda/96/020634_levaquin_toc.cfm).

Without adequate prior warning, patients do not have the level of informed consent required to submit to taking such risks. Given the potential for delayed-onset spontaneous tendon rupture (that is, rupture with no prior warning signs) associated with fluoroquinolone antibiotics (*Casparian, J. M., Luchi, M., Moffat, R. E. & Hinthorn, D. (2000). Quinolones and tendon ruptures. Southern Medical Journal 93, 488–91.*), they also do not have the knowledge to connect a possibly-delayed tendon injury to an antibiotic that they had taken "Up to several months" prior. Very few people would experience a complete tendon tear six months after completing a course of antibiotics for an uncomplicated condition such as acute sinusitis and ever even consider the possibility that the medication and the injury were related in any way. The very notion that a person could take a medication, suffer a catastrophic injury months later, and then *not ever know*

that it was that medication which caused that injury, is wholly unacceptable and every conceivable effort should be taken to avoid any such scenarios.

The Proposal – which simply calls for small label additions to be added directly to the bottle or packaging of Levaquin® – is the very least that should be done regarding this situation.

As clearly shown above, and in direct contradiction to Gibson and Dunn's claim, The Proposal clearly involves situations where there are public health or safety concerns involving broad-based or widely recognized and debated human health risks. It also calls into question the language used by Gibson and Dunn, in which they use the phrase "...alleged reactions..." These reactions have been proven beyond a shadow of a doubt and the company that they represent, Johnson & Johnson, openly admits to this.

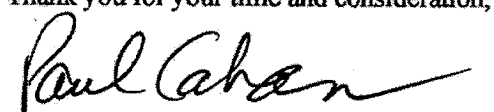
Conclusion

It is an unfortunate situation that The Proposal has been made necessary at all and it is more unfortunate that Johnson & Johnson, by hiring Gibson and Dunn to file a No-Action Request letter with the SEC, is attempting to block it from being voted upon by their shareholders. As shown above, Johnson & Johnson could have already taken the steps outlined in the proposal on its own and there are already warnings on the packaging and bottles of the product in question, proving that there are no impediments to the implementation of the directive outlined in The Proposal.

The Proposal, if allowed to be voted upon and passed by a majority of the stockholders at Johnson & Johnson, would benefit all involved parties. This includes the company and the stockholders themselves (by reducing the number of lawsuits, associated legal damages and fees and the negative publicity associated with same) and the general public at large (by helping to inform and thereby mitigate unnecessary, possibly permanent and disabling adverse drug reactions).

This document clearly demonstrates that The Proposal is not excludable under either of the two primary considerations that the SEC follows when determining excludability under Rule 14a-8(i)(7) and that The Proposal undoubtedly relates to a significant social policy issue.

Thank you for your time and consideration,



Paul W. Cahan

cc: Douglas K. Chia, Johnson & Johnson
Elizabeth A. Ising, Gibson and Dunn

Exhibit A

Transcript of Paul's speech at the April 2008 Johnson & Johnson shareholders meeting.

William C. Weldon – Chairman, Board of Directors, Chief Executive Officer and Chairman, Executive Committee: Umm, number 3?

Microphone Manager # 3: Mr. Chairman, Paul Cahan from Passaic Park has a question regarding differentiating bonus programs between pharmaceutical and consumer products.

Paul: Thank you. For the last ten years I've been struggling with a severe reaction to Floxin, your antibiotic that's very strong; it's similar to Levaquin. And I...I ask that you please consider three things:

One is to drop Floxin and Levaquin from any bonus programs for your employees so research and marketing and your sales people are gonna be more objective and they'll tell more of the truth in the labels that it can cause severe, delayed reactions. If it was on the label, I wouldn't be here today.

And two, to please consider advising doctors to...to use these as not first-line defenses in common...in common infections. All I had was a simple urinary tract infection that 12 million people in the U.S. get every year and there was no need for me to have been given that kind of a [Paul choking up here] strong drug that ruined my life.

And please add a warning label: Severe, delayed reactions are possible on these two drugs. And, I had two tendon ruptures, a tumor developed, I have nerve and muscle and tendon problems to this day (in both ankles and calves, both hands, and both elbows and shoulders) and I want you to be a hero and heroes act when they volunteer to do things, not when they're ordered by the FDA. Thousands of J&J employees are heroes every day. I know tens of thousands donate blood to hospital patients (each year, through my past work with New York Blood Center) and I ask you to treat the patients who take your drugs in the same way.

William C. Weldon: Thank you.

Paul [Interrupting]: Stick to your credo.

William C. Weldon: Thank you very much for your comments. We...we will continue to work to make sure we encourage and...and protect the safety of the patients that consume our products and use them. We really appreciate it.

Paul [Interrupting]: I hope you...I hope you...you further...further the label...put on the label warnings: severe, delayed reactions are possible. I would have stopped at the tiniest sign that I had, regardless of what doctors say.

William C. Weldon: Thank you very much. Appreciate your comments.

[Applause]

Page 21 redacted for the following reason:
- - - - - - - - - - - - - - - - - - -
*** FISMA & OMB Memorandum M-07-16 ***

GR

PRESCRIPTION INFO

*** FISMA & OMB Memorandum M-07-16 ***

Rx:
Filed: 11/18/2009
Drug: LEVAQUIN 500 MG TAB
NDC: 60459-0925-60
Qty: 7
Days: 7 Refills: 0
Prescriber: COSTANTINO, PETER DAVID

MEDICATION INFO

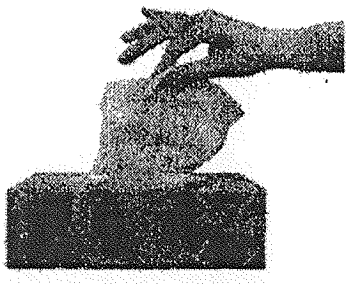
THIS MEDICINE IS A(N)
FILM-COATED PEACH
RECTANGULAR (ROUNDED
END)-SHAPED TABLET IMPRINTED
WITH LEVAQUIN ON ONE SIDE AND
500 ON THE OTHER SIDE.

DIRECTIONS

1-Drink plenty of fluids while on this medication
2-Finish all medication. Take on schedule.
3-Do not take with antacids /iron/vitamins
4-If dizziness occurs, drive with caution.
6-Avoid prolonged exposure to sun.Use sunscreen
6-Not recommended for patients under 18yrs old
7-Not recommended for use while breast-feeding
8-Promptly report tendon pain or swelling.

WARNINGS

TETRACYCLINES
PENICILLINS



Grab a tissue to help stop your sniffles.

Whether you need tissues for a cold or allergies, our tissues can help give your nose comfort and prevent germs from spreading.

We have a variety of tissues to choose from:

Lotion
Menthol
Unscented
Soft and Strong
Soft and Soothing

Tissue Tip:
Use a tissue to cover you nose and mouth when you sneeze or cough, and then throw it away and wash your hands. Try our travel pack tissues to place in your briefcase, purse, glove box or pocket.

Your pharmacist can help you choose the best medicine to help relieve your cold or allergy symptoms.

Folic Acid Is Important For All Women Capable Of Becoming Pregnant

Taking B vitamin or folic acid for women before conception and during early pregnancy has been shown to reduce neural tube defects.

The folic acid found in multivitamins works best for good health. The easiest way for women to know they're getting the right amount of folic acid is to take a multivitamin that has 400 mcg of folic acid every day. Correlate taking your daily multivitamin with another daily activity, like brushing your teeth. Good health habits lead to healthy living!

- Research suggests that folic acid may also help protect your baby from certain other birth defects related to the heart, limbs and face.
- Folic acid may also help in the protection of women and men from types of heart disease and certain cancers.
- Remember to read the contents written on the side of your cereal box to look for 100% of your daily recommended amount of folic acid.
- Folic acid is a B vitamin. Many foods are high in folate, the natural form of vitamin B. This includes such foods as beans, leafy green vegetables and orange juice.

Talk to your pharmacist and your doctor about which multivitamin or folic acid supplement is right for you.

*** FISMA & OMB Memorandum M-07-16 *** *** FISMA & OMB Memorandum M-07-16 ***

*** FISMA & OMB Memorandum M-07-16 ***

FILLED ON: 11/18/2009

GR

GR KA

Note: 100% original size print

1/31/11 PC

$25.00

TOTAL: $98.70
TP BAL DUE: $73.70

COPAY: $25.00

EMPIRE BCBS /EMP

*** FISMA & OMB Memorandum M-07-16 ***

$25.00

*** FISMA & OMB Memorandum M-07-16 ***

Date Filled: 11/18/2009

Rx#
LEVAQUIN 500 MG TAB MCNE
NDC: 50458-**0925**-50
Qty: 7
Days: 7
Prescriber: COSTANTINO, PETER D.

YOUR PRESCRIPTION INFORMATION

GENERIC NAME: LEVOFLOXACIN (lee-voe-FLOX-a-sin)

COMMON USES: This medicine is a quinolone antibiotic used for treating inf infections or viral infections (such as the common cold).

BEFORE USING THIS MEDICINE: WARNING: This medicine is associated witl greater in patients who are over 60 years old, patients who take corticosteroi affected. However, problems may also occur in other tendons (eg, in the arm, include pain, soreness, redness, or swelling of a tendon or joint; bruising right TELL YOUR DOCTOR RIGHT AWAY if you experience any of these symptoms INFORM YOUR DOCTOR OR PHARMACIST of all prescription and over-the-co procainamide, quinidine, sotalol). ADDITIONAL MONITORING OF YOUR DOSE macrolides (eg, erythromycin), methadone, paliperidone, phenothiazines (eg, ch medicines (eg, glyburide), corticosteroids (eg, prednisone), anticoagulants (eg, duloxetine). DO NOT START OR STOP any medicine without doctor or pharma (eg, myasthenia gravis), increased pressure in the brain, Alzheimer disease, brai to the sun; diabetes; low blood potassium levels; chest pain; angina; heart probl arthritis; liver problems; kidney problems or decreased kidney function; or heart, Tell your doctor if you participate in strenuous physical work or exercise. USE O potassium levels. Contact your doctor or pharmacist if you have any questions o

HOW TO USE THIS MEDICINE: Follow the directions for taking this medicine pr time you refill this medicine. Ask your doctor, nurse, or pharmacist any question this medicine is recommended. Check with your doctor for instructions. DO NOT Examples of these products include antacids, multivitamins, quinapril, and calciu certain food or product. IF YOU ALSO TAKE sucralfate or didanosine, do not take temperature, between 59 and 86 degrees F (15 and 30 degrees C). Store away f INFECTION COMPLETELY, take this medicine for the full course of treatment. Ke you remember. If it is almost time for your next dose, skip the missed dose and g

CAUTIONS: DO NOT USE THIS MEDICINE if you are allergic to any ingredient in counts, may be performed while you use this medicine. These tests may be used t TESTS. Be sure your doctor and lab personnel know you are taking this medicine. Use this medicine with caution. Do not drive or perform other possibly unsafe task (pseudomembranous colitis) may rarely occur. This may develop while you use the stools occur. Do not treat diarrhea without first checking with your doctor. TELL Y exercise until further instruction from your doctor. THIS MEDICINE MAY CAUSE Y sunscreen or wear protective clothing if you must be outside for more than a short decrease the effectiveness of the vaccine. BEFORE YOU BEGIN TAKING ANY NEW may be more sensitive to its effects (eg, tendon problems), especially if they take c used with extreme caution in CHILDREN younger than 18 years old; they may be m discuss the benefits and risks of using this medicine while you are pregnant. This m Check blood sugar levels closely. Ask your doctor before you change the dose of yo

POSSIBLE SIDE EFFECTS: SIDE EFFECTS that may occur while taking this medicine with your doctor. CONTACT YOUR DOCTOR IMMEDIATELY if you experience blood hallucinations; inability to move or bear weight on a joint or tendon area; moderate or sleeplessness); muscle pain or weakness; new or worsening nightmares; pain, sorene diarrhea; severe or persistent dizziness, lightheadedness, tiredness, or weakness; seve fainting; fast breathing; flushing; increased sweating; increased thirst, hunger, or urina nerve problems (eg, changes in perception of heat or cold; decreased sensation of tou discharge, irritation, or odor; vision changes; or wheezing. AN ALLERGIC REACTION difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue; side effects that may occur. If you have questions about side effects, contact your hea

OVERDOSE: If overdose is suspected, contact your local poison control center or emer

ADDITIONAL INFORMATION: DO NOT SHARE THIS MEDICINE with others for whom

The information in this monograph is not intended to cover all possible uses, directions,

11/18

ORTHO-McNEIL JANSSEN
SCIENTIFIC AFFAIRS, LLC

Exhibit C

1000 Route 202, PO Box 300, Raritan, NJ 08869-0602, Tel (908) 218 6000

September 2, 2008

Mr. Paul Cahan

*** FISMA & OMB Memorandum M-07-16 ***

Dear Mr. Cahan:

Please allow this letter to respond on behalf of the correspondence you recently sent to several members of the Johnson & Johnson Board of Directors. Your letters have been referred to me for reply since I serve as Vice President, Medical Affairs in support of Ortho-McNeil Janssen Pharmaceutical, Inc. (OMJPI), the Johnson & Johnson company that markets Levaquin. In this capacity, I am aware of the current status of the flouroquinolone labeling.

Initially, let me say that I do remember your statement made during the question and answer session at the Annual Shareholders' Meeting this past April and I am sorry to hear of your health problems and the impact that it has had on your life. In your letter, you reference the recent FDA communications concerning revisions to the labeling for quinolone products, including the Boxed Warning that addresses the risks of tendon rupture. This communication, which applied to all fluoroquinolones as class labeling, was based on new safety information, including a new analysis of available literature and post-marketing adverse event reports. In your letter, you ask that our company "not fight" the FDA's recommendation.

Let me assure you that OMJPI has always supported the FDA's commitment to increase awareness of important safety information regarding the use of quinolones. Our company's interactions with the FDA over the years in general and specifically with respect to the issue of tendon related events are consistent with and supportive of that commitment. We are currently in the process of discussing with the FDA how to best implement this labeling change as well as other communications concerning tendon rupture.

I trust this addresses the concerns raised in your letter and I thank you for contacting our company.

Very truly yours,

Norman Rosenthal

Norman Rosenthal, M.D.

NR/las

Page 25 redacted for the following reason:

*** FISMA & OMB Memorandum M-07-16 ***

Exhibit E

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 20-634/S-053
NDA 20-635/S-058
NDA 21-721/S-021

Ortho McNeil- Janssen Pharmaceutical, Inc.
c/o Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
Attention: Ms. Ilona Scott
Director, Regulatory Affairs
Route 202, P.O. Box 300
Raritan, NJ 08869-0602

Dear Ms. Scott:

We have received your supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

Drug Product Name	NDA Number	Supplement number	Date of supplement	Date of receipt
Levaquin® (levofloxacin) Tablets	20-634	S-053	October 31, 2008	October 31, 2008
Levaquin® (levofloxacin) Injection and Levaquin® (levofloxacin in 5% dextrose) Injection	20-635	S-058	October 31, 2008	October 31, 2008
Levaquin® (levofloxacin) Oral Solution	21-721	S-021	October 31, 2008	October 31, 2008

We acknowledge receipt of your submission dated April 10, 2009

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

Title IX, Subtitle A, Section 901 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amends the Federal Food, Drug, and Cosmetic Act (FDCA) to authorize FDA to require the submission of a Risk Evaluation and Mitigation Strategy (REMS) for an approved drug if FDA becomes aware of new safety information and makes a determination that such a strategy is necessary to ensure that the benefits of the drug outweigh the risks (section 505-1(a)). This provision took effect on March 25, 2008.

Since Levaquin® was approved on December 20, 1996, we have become aware of risk of tendon-related adverse events we have become aware of additional information about the risk of tendon-related adverse events as described in our July 7, 2008 letter. This information was not available

when Levaquin® was granted marketing authorization. Therefore, we consider this information to be "new safety information" as defined in FDAAA.

In accordance with section 505-1 of FDCA, as one element of a REMS, FDA notified you in our July 7, 2008, letter that the development of a Medication Guide was required as provided for under 21 CFR Part 208. In response, you converted your previously approved patient package insert to a Medication Guide and revised it to include the new safety information. Pursuant to 21 CFR Part 208, FDA has determined that Levaquin® poses a serious and significant public health concern requiring the distribution of a Medication Guide. The Medication Guide is necessary for patients' safe and effective use of Levaquin®. FDA has determined that Levaquin® is a product that has serious risk(s) (relative to benefits) of which patients should be made aware because information concerning the risk(s) could affect patients' decisions to use, or continue to use Levaquin®. Under 21 CFR 208, you are responsible for ensuring that the Medication Guide is available for distribution to patients who are dispensed Levaquin®.

Your proposed REMS, submitted on October 31, 2008 and appended to this letter, is approved. The REMS consists of the Medication Guide included with this letter and the timetable for submission of assessments of the REMS included in your April 10, 2009 submission.

Your assessment of the REMS should include an evaluation of:

a. Patients' understanding of the serious risks of Levaquin®
b. A report on periodic assessments of the distribution and dispending of the Medication Guide in accordance with 21 CFR 208.24
c. A report on failures to adhere to distribution and dispensing requirements, and corrective actions taken to address noncompliance

Prominently identify submissions containing REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission:

NDA 20-634, NDA 20-635, NDA 21-721 REMS ASSESSMENT

NEW SUPPLEMENT FOR NDA 21-634, NDA 20-635, NDA 21-721
PROPOSED REMS MODIFICATION
< other supplement identification > [if included]
<REMS ASSESSMENT> [if included]

If you do not submit electronically, please send 5 copies of submissions containing REMS assessments or proposed modifications of the REMS.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert, Medication Guide). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, **"SPL for approved NDA 20-634/S-053, NDA 20-635/S-058 and, NDA 21-721/S-021."**

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Hyun Son, Pharm.D., Acting Safety Regulatory Project Manager, at (301) 796-1600.

Sincerely,

{See appended electronic signature page}

Ozlem Belen, M.D., MPH
Deputy Director for Safety
Division of Special Pathogen and Transplant Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: REMS
Medication Guide

Page 30 redacted for the following reason:

*** FISMA & OMB Memorandum M-07-16 ***

535 East 70th Street, New York, NY 10021

THE HOSPITAL FOR SPECIAL SURGERY

Dr Jonathan T. Deland
Adult Foot and Ankle Surgery

212-606-1665
FAX 212-794-4291

Paul Cahen

*** FISMA & OMB Memorandum M-07-16 ***

*** FISMA & OMB Memorandum M-07-16 ***

September 3, 1998

INITIAL OFFICE VISIT 7/8/98

This patient complains of pain over both of his achilles tendons and radiation of the pain to the anterior ankle over the past few months. He took a ten day course of Floxin and noted pain one week after this. He is able to ambulate and has had some improvement.

PHYSICAL EXAMINATION shows there is tenderness over both achilles tendon and the Thompsons test is negative and he is able to heel rise bilaterally.

There is good dorsiflexion ankle strength as well as inversion/eversion.

He is to avoid pounding-type activities on his foot. I also recommend he avoid stairs and hills. His tendons are at risk for rupture and there is probably some degeneration possibly secondary to the antibiotic.

Jonathan Deland, MD
kn

NY License No. 147211
Provider # 97F011

Jonathan T. Deland, M.D.
The Hospital for Special Surgery
535 East 70th Street
New York, NY 10021
(212) 606-1665

Tax ID# 13-3623941
Region IV
WCB

Paul Cahan

*** FISMA & OMB Memorandum M-07-16 ***

Statement Date
05/07/99

Date(d)	CPT Code	Mod	Description	Charges	Credits & Adjustments
08/05/98	29405		Application of Short Leg Cas	160.00	
09/16/98	99213		Office Visit-Follow-UP Lev 3	150.00	

Your Insurance
Company Has Paid YOU
Its Share of Your Bill.
YOUR ACCOUNT IS NOW
DUE AND PAYABLE.

ICD-9	Description
1. 727.67	RUPTURE ACHILLES TENDON
2. 726.71	ACHILLES TENDONITIS

Current Balance
310.00

This bill is payable upon receipt.

This bill may be directly forwarded to your insurance company

For billing inquiries call PMI at 212-861-7040

Pg. 27

535 East 70th Street, New York, NY 10021

THE HOSPITAL FOR SPECIAL SURGERY

212-606-1665
FAX 212-794-4291

Dr Jonathan T. Deland
Adult Foot and Ankle Surgery

*** FISMA & OMB Memorandum M-07-16 ***

October 10, 1998

Paul Cahan

*** FISMA & OMB Memorandum M-07-16 ***

October 10, 1998

Sherronda Williams
Senior Human Resources Representative
New York Blood Center
150 Amsterdam Avenue 3rd Floor
New York, NY 10023

Deland

To Whom It May Concern:

Please be advised that Paul Cahan is a patient under my care for rupture achilles tendon and achilles tendonitis. Mr. Cahan is unable to return to work at this time. His next scheduled appointment is October 28, 1998 and he will be re evaluated at that time.

I hope this has been helpful. If you have any further questions please contact my office at 212/606-1665.

Sincerely,

Jonathan T. Deland, M.D.

Pg. 28

EXHIBIT G
Resource for Readers of Rebuttal Document
Submitted by Paul W. Cahan Jan 26, 2011

There are some large documents referenced in the rebuttal letter.
Please find below some suggestions to important sections within those documents.

Page 10
Website reference to Mr. Schedin's Levaquin Tendon Lawsuit
http://www.mnd.uscourts.gov/MDL-Levaquin/Transcripts/2010/092810.pdf
against Johnson & Johnson. This is an 83 page document.
You may want to focus on Pages 20 line 9, through page 25;
you will see why his case was won on the basis of Levaquin's
grossly inadequate warning labels.

Page 10:
http://www.mnd.uscourts.gov/MDL-Levaquin/Transcripts/2010/092810.pdf
FDA Center for Drug Evaluation and Research transcript.
This is a 176 page document.
Dr. Kraus's credentials and important comments on the need for label changes
to help both physicians and patients appear primarily on pages 167 - 170.

The discussion of Levaquin and Floxin equivalence, relevant to Exhibit F.
When you click on this site, it is a large, scientific
document. www.accessdata.fda.gov/drugsatfda_docs/nda/96/020634_levaquin_toc.cfm .
It lists four files. Click on File 4 when you go into the site on "Statistical Review
and Evaluation" Nov. 21, 1996 NDA #(s) 20-634 and 20-635. A quote from that
file is:

"Introduction
The sponsor is requesting approval for the use
of LEVAQUIN (levofloxacin) tablets for the above
seven indications. Levofloxacin is the levorotatory
isomer of the D,L-racemate of ofloxacin and a synthetic
fluorinated carboxyquinolone".

Continue...

The additional studies and articles, below, are supporting documents that speak to higher incidence levels of tendon adverse reactions with Levaquin, further supporting the dire need for stronger warnings and education, and the fact that global health is impacted.

Swiss Study (Swiss Medical Journal / Bulletin des médecins suisses / Bollettino \B. Schnyder, P. Caduff) (Multi-country data)

Swiss Medical Journal / Bulletin des médecins suisses / Bollettino

dei medici svizzeri • 2003, 84: No1 / 2 29

(see chart 7) Levaquin Incidence rates higher compared to others in the class (Switzerland ICS database and World (WHO database).

http://www.saez.ch/pdf/2003/2003-02/2003-02-694.PDF

World Health Organization Health Alert WHO)

http://www.who.int/medicines/publications/newsletter/en/news2002_1.pdf

Dear Doctor Letters issued for Levaquin 2000, 2001, in France and Italy due to postmarketing tendon disorder incidence; data collected and action taken over a brief period of time. These are referenced in the Schedin law suit document.

Public Citizen , August 29, 2006 Petition for Black Box Warning on Fluoroquinolone Antibiotics issued to FDA, Statistical data showing higher incidence Levaquin.

http://www.citizen.org/Page.aspx?pid=693

Former FDA Commissioner Dr. David Kessler is cited as concluding that only about one percent (1%) of serious reactions are ever reported to FDA (8th short Paragraph)
http://occupational-therapy.advanceweb.com/Article/Is-Med-Watch-Looking-for-You.aspx

one last item:

Exhibit B, third page:
The Levaquin package insert photograph has a hand-written note:
" Note: 100% original size print"
It would appear 100% print-size, if I sent a hard-copy.
In this format, it is smaller to some degree than what patient sees.

GIBSON DUNN

Gibson, Dunn & Crutcher LLP

1050 Connecticut Avenue, N.W.
Washington, DC 20036-5306
Tel 202.955.8500
www.gibsondunn.com

Elizabeth A. Ising
Direct: 202.955.8287
Fax: 202.530.9631
EIsing@gibsondunn.com

Client: C 45016-01913

December 27, 2010

VIA E-MAIL

Office of Chief Counsel
Division of Corporation Finance
Securities and Exchange Commission
100 F Street, NE
Washington, DC 20549

Re: *Johnson & Johnson*
Shareholder Proposal of Paul W. Cahan
Exchange Act of 1934—Rule 14a-8

Ladies and Gentlemen:

This letter is to inform you that our client, Johnson & Johnson (the "Company"), intends to omit from its proxy statement and form of proxy for its 2011 Annual Meeting of Shareholders (collectively, the "2011 Proxy Materials") a shareholder proposal (the "Proposal") and statements in support thereof received from Paul W. Cahan (the "Proponent").

Pursuant to Rule 14a-8(j), we have:

- filed this letter with the Securities and Exchange Commission (the "Commission") no later than eighty (80) calendar days before the Company intends to file its definitive 2011 Proxy Materials with the Commission; and

- concurrently sent copies of this correspondence to the Proponent.

Rule 14a-8(k) and Staff Legal Bulletin No. 14D (Nov. 7, 2008) ("SLB 14D") provide that shareholder proponents are required to send companies a copy of any correspondence that the proponents elect to submit to the Commission or the staff of the Division of Corporation Finance (the "Staff"). Accordingly, we are taking this opportunity to inform the Proponent that if the Proponent elects to submit additional correspondence to the Commission or the Staff with respect to this Proposal, a copy of that correspondence should be furnished concurrently to the undersigned on behalf of the Company pursuant to Rule 14a-8(k) and SLB 14D.

THE PROPOSAL

The Proposal states:

> Vote FOR working with FDA to add warning on labels to all Levaquin tablets, and injection solutions informing all patients that Levaquin has a "Black Box" Warning regarding severe and permanent delayed reactions that could cause **permanent pain and disability**.

(Emphasis in original)

The Proposal also includes a supporting statement that explains the Proponent's basis for submitting the Proposal. The supporting statement focuses on the need for the Company to work with the U.S. Food and Drug Administration (the "FDA") with respect to information concerning LEVAQUIN®, one of the Company's products. A copy of the Proposal, as well as related correspondence with the Proponent, is attached to this letter as Exhibit A.

BASIS FOR EXCLUSION

We hereby respectfully request that the Staff concur in our view that the Proposal may be excluded from the 2011 Proxy Materials pursuant to Rule 14a-8(i)(7) because the Proposal relates to the Company's ordinary business operations (*i.e.*, regulatory matters concerning labeling, and sales of, a particular product).

ANALYSIS

The Proposal May Be Excluded Under Rule 14a-8(i)(7) Because It Deals With Matters Related To The Company's Ordinary Business Operations.

The Company may exclude the Proposal pursuant to Rule 14a-8(i)(7) because it deals with matters relating to the Company's ordinary business operations. In Exchange Act Release No. 40018 (May 21, 1998) (the "1998 Release"), the Commission explained that the ordinary business exclusion rests on two central considerations. The first consideration relates to the subject matter of a proposal; the 1998 Release provides that "[c]ertain tasks are so fundamental to management's ability to run a company on a day-to-day basis that they could not, as a practical matter, be subject to direct shareholder oversight." *Id.* The second consideration is the degree to which the proposal attempts to "micro-manage" a company by "probing too deeply into matters of a complex nature upon which shareholders as a group, would not be in a position to make an informed judgment." *Id.* (citing Exchange Act Release No. 12999 (Nov. 22, 1976)).

A. *The Proposal's Focus on the Company's Labeling of its Products Renders the Proposal Excludable Under Rule 14a-8(i)(7)*

We believe that the Proposal impermissibly relates to the Company's ordinary business operations because the Proposal's thrust and focus concerns the Company's labeling and sale of its products. As discussed below, the Staff consistently has concurred that the appropriate labeling of a company's products is a matter of ordinary business.

The Staff has consistently taken the position that a company's decisions regarding the selection and labeling of products are ordinary business matters and thus that shareholder proposals concerning such decisions may be excluded under Rule 14a-8(i)(7). For example, in *Campbell Soup Co.* (avail. Aug. 21, 2009), the Staff concurred in the exclusion of a shareholder proposal requesting the company to adopt specific labeling requirements for its products relating to sodium levels and launch an advertising campaign educating people on healthy diets. *See also The Coca Cola Co.* (avail. Jan. 22, 2007) (concurring in exclusion of a proposal that requested the company to adopt specific requirements relating to labeling caffeinated beverages and that the company stop "caffeinating" its root beer and other beverages because the proposal dealt with a matter of ordinary business operations); *H.J. Heinz Co.* (avail. June 14, 1991) (concurring in exclusion pursuant to Rule 14a-8(c)(7) of a proposal that requested the company to refrain from labeling products with characters, signs or symbols of any specific race, religion, or culture because the proposal dealt with a matter of ordinary business operations). In *H.J. Heinz Co.*, the Staff expressly noted the company's position that "management's decisions concerning the company's product names and labels relate to the conduct of ordinary business operations."

Here, the Proposal specifically requests the Company to work with the FDA with respect to including a specific warning label on LEVAQUIN® tablets and injection solutions.[1] In this regard, the Proposal would involve the Company with the work of pharmacists that ultimately place the labels on the bottles that patients receive. The labels placed on pharmacy vials are under the control of the pharmacist; they are not under the control of the manufacturer or marketer of the prescription medicines, such as the Company. Not only would such labeling require the Company to work with the FDA, but it would also involve business negotiations between the Company and the countless number of third parties actually filling patient prescriptions of a specific medicine. The Proposal acknowledges this

---

[1] It should be noted that the Company has worked in the past, and continues to work, with the FDA on the "black box warning" that appears in the Medication Guide for LEVAQUIN®, as well as all labeling for LEVAQUIN®. All Company labeling is approved by the FDA.

in the supporting statement: "This will take working with FDA and companies that provide computerized LABELING services when a prescription is filled." Thus, the Proposal is excludable as relating to the Company's ordinary business operations, because it relates to the labeling of one of the Company's products and attempts to delve into the complex pharmaceutical product labeling process for end-users beyond the Company's immediate control.

The Staff has also consistently recognized that decisions regarding the safety of particular products sold by retailers are excludable as relating to a company's ordinary business operations. *See e.g., Lowes Companies Inc.* (avail. Mar. 18, 2010) (concurring in exclusion of a proposal requesting the company to label all glue traps sold in its stores with a warning stating that consumers may find animals stuck in the traps alive and struggling and that these traps pose danger to companion animals, wildlife and human health); *Home Depot Inc.* (avail. Mar. 12, 2010) (same); *Wal-Mart Stores, Inc.* (avail. Feb. 27, 2008) (concurring in exclusion of a proposal requesting a report on the company's policies on product safety); *The Home Depot, Inc.* (avail. Jan. 25, 2008) (same); *Family Dollar Stores, Inc.* (avail. Nov. 6, 2007) (concurring in exclusion of a proposal requesting that the board publish a report evaluating the company's policies and procedures for systematically minimizing customers' exposure to toxic substances and hazardous components in its marketed products). Here, the Proposal is directed at safety warning information to be provided BY RETAILERS with respect to one of the Company's products. Accordingly, consistent with Staff precedent, it is excludable as relating to the Company's ordinary business operations.

B. The Proposal Involves Ordinary Business Matters Because It Dictates the Company's Involvement in Regulatory Activities Concerning a Specific Company Product

We believe that the Proposal impermissibly relates to the Company's ordinary business operations because the Proposal directs the Company to work with one of its regulators, the FDA, regarding the warnings to be placed on one of its products. As discussed below, the Staff consistently has concurred that shareholder proposals that – similar to the Proposal – attempt to micro-manage a company by attempting to dictate their involvement and participation with respect to specific legislative or regulatory initiatives are excludable under Rule 14a-8(i)(7).

As a preliminary matter, the language of the Proposal clearly indicates that the Proposal's focus is on the Company's interaction with the FDA concerning LEVAQUIN®. In addition, the supporting statement refers exclusively to the need for the Company to work with the FDA regarding LEVAQUIN® labeling. In this regard, when assessing proposals under Rule 14a-8(i)(7), the Staff considers both the resolution and the supporting statement as a whole. *See, e.g.*, Staff Legal Bulletin No. 14C, part D.2. (June 28, 2005); *Corrections*

Corporation of America (avail. Mar. 15, 2006); *General Electric Co. (St. Joseph Health System and the Sisters of St. Francis of Philadelphia)* (avail. Jan. 10, 2005).

Labeling of medicines is a highly regulated and complex process, and there are additional requirements specifically regarding "black box warnings." Further, it is rare for particular warnings to be placed on product packaging that are unrelated to mode of administration of a drug or product preparation. Asking the Company's shareholders to determine whether it is prudent for the Company to embark on what would be a highly unorthodox course of action in connection with a regulatory process for one of its products would be asking the shareholders to probe too deeply into a highly complex matter, upon which they, as a group, would not be in a position to make an informed judgment. As a result, as further discussed below, the Proposal is excludable under Rule 14a-8(i)(7).

While the Proposal relates to regulatory activities, it also suggests instituting a change in a highly regulated labeling process, and therefore, we believe that the precedent related to legislative matters and lobbying activities is on point. In this regard, the Staff has concurred that lobbying proposals are excludable under Rule 14a-8(i)(7) if they concern legislative or other political activities relevant to particular aspects of the company's business. *See, e.g., General Electric Co. (Flowers)* (avail. Jan. 29, 1997) (concurring in exclusion of a proposal seeking to prohibit the company's board from using company funds for citizen ballot initiatives, including initiatives related to the company's products, noting that "the proposal is directed at matters relating to the conduct of the [c]ompany's ordinary business operations (*i.e.*, lobbying activities which relate to the [c]ompany's products)"); *Pacific Enterprises (Henson)* (avail. Feb. 12, 1996) (concurring in exclusion of a proposal submitted to a California utility asking that it dedicate the resources of its regulatory, legislative and legal departments to ending California utility deregulation was excludable because it was "directed at involving the [c]ompany in the political or legislative process that relates to aspects of the [c]ompany's operations"); *General Motors Corp. (Barnet)* (avail. Mar. 17, 1993) (concurring in exclusion of a proposal to require an automobile manufacturer to cease lobbying to influence legislation dealing with automobile fuel economy standards, noting that "the proposal appears to be directed toward the [c]ompany's lobbying activities concerning its products.").

The Staff further stated its view regarding political activities in *General Electric Co.* (avail. Feb. 22, 2000) where a proposal requested a report "outlining [the company's] policies and use of shareholder funds for political purposes." According to the Staff, this proposal was not excludable because it focused on the company's "general political activities *rather than [the company's] products, services or operations*" (emphasis added). In contrast, the Staff has concurred that a proposal is excludable where, as here, it is directed at a company's involvement in the legislative or regulatory process on a specific issue relating to the Company's business. For example, in *International Business Machines Corp.* (avail.

Jan. 21, 2002) the Staff concurred that a proposal requiring the company to "[j]oin with other corporations in support of the establishment of a properly financed national health insurance system" was excludable because it "appears directed at involving IBM in the political or legislative process relating to an aspect of IBM's operations." *See also Bristol Myers Squibb Co. (AFL-CIO Reserve Fund)* (avail. Feb. 17, 2009) (concurring in the exclusion of a proposal requesting a report on the company's lobbying activities and expenses relating to the Medicare Part D Prescription Drug Program and on lobbying activities and expenses of any entity supported by the company during the 110th Congress); *Microsoft Corp.* (avail. Sept. 29, 2006) (concurring in the exclusion of a proposal calling for an evaluation of the impact on the company of expanded government regulation of the Internet); *International Business Machines Corp.* (avail. Mar. 2, 2000) (concurring in the omission of a proposal requesting that the company prepare a report discussing issues under review by federal regulators and legislative proposals relating to cash balance plan conversions, where the Staff stated, "[w]e note that the proposal appears directed at involving IBM in the political or legislative process relating to an aspect of IBM's operations"); *Pepsico, Inc. (United Brotherhood of Carpenters)* (avail. Mar. 7, 1991) (concurring in exclusion of a shareholder proposal calling for an evaluation of the impact on the company of various health care reform proposals being considered by federal policy makers).

The Staff's view regarding the excludability of narrowly focused proposals under Rule 14a-8(i)(7) is also reflected in the precedent addressing shareholder proposals on corporate charitable giving. In this context, the Staff has recognized a distinction under Rule 14a-8(i)(7) between proposals that are not excludable because they address generally a company's charitable giving policies and excludable proposals that focus on charitable contributions to specific types of organizations. For example, in *Johnson & Johnson* (avail. Feb. 12, 2007), a proposal requesting that the Board of Directors implement a policy listing all charitable contributions on the company's websites was excludable notwithstanding its facially neutral language. The Staff concurred that the proposal could be excluded under Rule 14a-8(i)(7), because the supporting statement and two of the seven "Whereas" clauses preceding the resolution centered around contributions to Planned Parenthood and organizations that support abortion and same-sex marriage. *See also Bank of America Corp.* (avail. Jan. 24, 2003) (permitting exclusion of a proposal to cease making charitable contributions because the preamble and supporting statement frequently referenced abortion and religious beliefs); *American Home Products Corp.* (avail. Mar. 4, 2002) (concurring in exclusion of a facially neutral proposal requesting that the board form a committee to study the impact charitable contributions have on the business of the company and its share value, because five of the six "whereas" clauses preceding the resolution referenced abortion and organizations that support or perform abortions); *Schering-Plough Corp.* (avail. Mar. 4, 2002) (concurring in exclusion of a proposal requesting that the company form a committee to study the impact charitable contributions have on the business of the company

and its share value, where each of the five statements in the proposal's preamble referenced abortion and the supporting statement centered around a discussion of Planned Parenthood).[2]

In each of the no-action letters discussed above, shareholder proposals were found to be directed toward specific kinds of organizations and therefore were excludable under Rule 14a-8(i)(7) as relating to the company's ordinary business operations. Similarly, the Proposal and the supporting statement here do not refer generally to the Company's regulatory or political activities, but rather focus exclusively on the interaction of the Company with one of its regulators, the FDA, with respect to one of its products, LEVAQUIN®. The Proposal therefore clearly attempts to "micro-manage" the Company and relates to matters that cannot, as a practical matter, "be subject to direct shareholder oversight." Thus, the Proposal may be excluded under Rule 14a-8(i)(7) as relating to the Company's ordinary business matters.

C. The Proposal Does Not Implicate a Significant Policy Issue

We are aware that the Staff has not permitted the exclusion of certain shareholder proposals requesting that a company label its products with information related to general health or safety concerns. *See, e.g., Exxon Mobil Corp. (Lalanne)* (avail. Mar. 12, 2007) (shareholder proposal requesting that the company provide information at the pump regarding the carbon dioxide emissions generated by the fuel sold); *PepsiCo, Inc.* (avail. Mar. 2, 2007) (shareholder proposal requesting that the board adopt a policy to identify and label all food products manufactured or sold by the company under its brand names or private labels that may contain genetically engineered ingredients); *R.J. Reynolds Tobacco Holdings, Inc.* (avail. Mar. 7, 2002) (shareholder proposal requesting that the company include additional information in the packaging of tobacco products); *McDonald's Corp. (Harrington Investments, Inc., et al.)* (avail. Mar. 22, 2000) (shareholder proposal requesting that the board adopt a policy to remove genetically-engineered crops, organisms or products from its product line until long-term testing has shown they are not harmful to humans, animals or the environment).

---

[2] The foregoing precedents, as with the Proposal, are distinguishable from proposals that either employed neutral language throughout the preamble and supporting statement, or where the supporting statement contained only a brief or isolated reference to specific organizations or types of organizations as examples of organizations that might interest shareholders or be controversial. *See, e.g., PepsiCo, Inc.* (avail. Mar. 2, 2009); *Ford Motor Co.* (avail. Feb. 25, 2008); *General Electric Co.* (avail. Jan. 11, 2008).

Each of the above proposals, however, involved situations where there was an alleged public health or safety concern involving broad-based or widely recognized and debated human health or environmental risks (*i.e.*, food safety, cigarette smoking and greenhouse gas emissions) and addressed all of a company's products that might raise those concerns. In contrast, the Proposal relates solely to one of the Company's products – LEVAQUIN® – and solely to alleged reactions to that single medication.

The Proposal is more similar to proposals that relate to product ingredients where the Staff has found that they do not implicate a significant policy issue. For example, in *Walgreen Co.* (avail. Oct. 13, 2006), the Staff concurred in the exclusion of a shareholder proposal requesting a report concerning suspected carcinogens, mutagens, reproductive toxicants and certain other chemicals in the company's private label cosmetics and personal care products. The Staff agreed with the company that the proposal did not involve a significant policy issue and noted that the proposal was related to the company's ordinary business operations. Significantly, the proposal in *Walgreen Co.* mentioned that specific types of FDA approvals were required with respect to the cosmetic products and that the ingredients and materials the company uses in manufacturing its products are regulated by the FDA. *See also Wal-Mart Stores, Inc.* (avail. Mar. 11, 2008) (cited above); *The Coca Cola Co.* (avail. Jan. 22, 2007) (cited above); *Wal-Mart Stores, Inc. (Green Century Capital Management, Inc., et al.)* (avail. Mar. 24, 2006) (concurring in exclusion of a shareholder proposal requesting that the company publish a report evaluating its policies and procedures for minimizing customers' exposure to toxic substances in products); *H.J. Heinz Co.* (avail. June 2, 1999) (concurring in exclusion of a shareholder proposal requesting that the company stop adding a certain food coloring to its pickles).

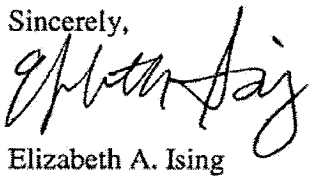
Accordingly, consistent with Staff precedent, the Proposal is excludable under Rule 14a-8(i)(7) as relating to the Company's ordinary business operations.

CONCLUSION

Based upon the foregoing analysis, we respectfully request that the Staff concur that it will take no action if the Company excludes the Proposal from its 2011 Proxy Materials. We would be happy to provide you with any additional information and answer any questions that you may have regarding this subject.

If we can be of any further assistance in this matter, please do not hesitate to call me at (202) 955-8287 or Douglas K. Chia, the Company's Assistant General Counsel and Corporate Secretary, at (732) 524-3292.

Sincerely,



Elizabeth A. Ising
Enclosure(s)

cc: Douglas K. Chia, Johnson & Johnson
Paul W. Cahan

100989236_9

Exhibit A

Untitled

Oct. 18, 2010

FISMA & OMB Memorandum M-07-16

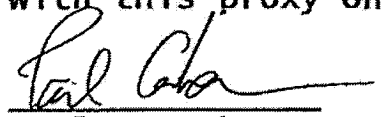
Steven M. Rosenberg
Secretary
Associate General Counsel
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick NJ 08933-0026

Dear Mr. Rosenberg:

Enclosed is my Shareholder Proxy for the April 2011 Annual meeting. It is 495 words, which is less than the 500 maximum.

Your records will show that I held at least $2,000.00 worth of J&J stock for the time period required for the 2011 Shareholder Meeting. I do intend on holding all my shares through this meeting in April 2011 and beyond.

As the SEC regulations state, either I or a representative will attend the April 2011 meeting with this proxy on the ballot.



Paul W. Cahan

cc: B. Crouse
J. Mullen

Vote FOR working with FDA to put a warning on Levaquin tablet bottles, oral solution packages, and injection packages informing "out-patient" and hospitalized patients and families that Levaquin has a "Black Box" Warning regarding severe delayed reactions. Example:

Urgent Warning: Read all Inserts Carefully
STOP if smallest skin, tendon, muscle reaction,
otherwise severe delayed reaction and permanent pain and disability is possible.

There is no information on the bottle informing patients that this is a "black box" medication, and no indication that small adverse reactions can build-up in the body and later erupt in a serious irreversible cascade of inflammatory and destructive cellular events that is extremely painful and irreversible. If one has a MINOR reaction, sometimes it does NOT slowly worsen while one completes the prescribed dose. It can stabilize or decrease giving the patient a false sense of security while completing the prescription. This is what happened to me in 1998 after 10 days of Floxin and I am permanently disabled. If patients read the fine print and inserts they may know this, if they do not, many are in grave danger. Current communication is failing. There have been over 50,000 adverse reactions reported to the FDA on Levaquin, and over 12,000 individual safety reports. Complaints are "the tip of the iceberg." The tendon and neuropathic delayed reaction mechanism of Levaquin is different than many other medicines with black box warnings. Special attention needs to educate all patients of this.
Every patient needs to see something on the bottle and "front line" pharmacy printing when they receive the medicine to ensure they fully understand what any initial reaction means. Pharmacists cannot offer advise on medical issues. They only say: "Do you have any questions about this medicine?" Every patient and physician needs to know "up-front" the unique delayed reaction mechanism that causes permanent pain. This will take working with FDA and companies that provide computerized labeling services when a prescription is filled. Any decrease in sales will be offset by fewer lawsuits and be consistent with the corporate credo.

Information on a **bottle of Levaquin 500 mg. Tablet** filled Sept. 2009:
"Medication should be taken with plenty of water.
Take this medication at least 2 hours before or 2 hours after magnesium or aluminum containing antacids, or other products containing calcium, iron, or zinc.
Avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medication.
May cause dizziness.
This medicine is dispensed as a(n) PEACH, OBLONG-SHAPED, FILM COATED TABLET with LEVAQUIN imprinted on one side and 500 imprinted on the other side. "

No mention of the dangers on the bottle, often the only piece of information read by patients.
There is no cure for permanent reactions that damage tendons, cartilage, nerves, etc. (Levaquin is deemed Floxin's "mirror" drug; Floxin was discontinued in 2009.) Help preserve the health and happiness of shareholders, the public, and decrease government expenses supporting the permanently injured and disabled.

Sincerely,
Paul W. Cahan

Johnson & Johnson

DOUGLAS K. CHIA
ASSISTANT GENERAL COUNSEL
CORPORATE SECRETARY

ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-0026
(732) 524-3292
FAX: (732) 524-2185
DCHIA@ITS.JNJ.COM

November 1, 2010

VIA FEDEX

Paul W. Cahan

FISMA & OMB Memorandum M-07-16

Dear Mr. Cahan:

This letter acknowledges receipt by Johnson & Johnson (the "Company") on October 19, 2010 of the shareholder proposal submitted by you under Rule 14a-8 under the Securities Exchange Act of 1934, as amended (the "Rule"), regarding the labeling of LEVAQUIN, for consideration at the Company's 2011 Annual Meeting of Shareholders (the "Proposal").

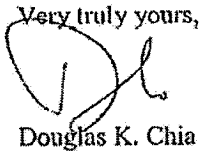
Please be advised that you must comply with all aspects of the Rule with respect to your shareholder proposal. The Proposal contains certain procedural deficiencies, which Securities and Exchange Commission ("SEC") regulations require us to bring to your attention. Please furnish to us, within 14 days of your receipt of this letter, proof that you, Paul W. Cahan, have continuously held at least $2,000 in market value, or 1%, of Johnson & Johnson securities entitled to be voted on the Proposal at the 2011 Annual Meeting for at least one year by the date you submitted the Proposal, as required by paragraph (b)(1) of the Rule. The Company's stock records do not indicate that you are the record owner of Company shares. To remedy this defect, you must provide sufficient proof of your ownership of the requisite number of Company shares as of the date you submitted the Proposal. As explained in Rule 14a-8(b), sufficient proof may be in the form of:

- a written statement from the "record" holder of your shares (usually a broker or a bank) verifying that, as of the date the Proposal was submitted, you continuously held the requisite number of Company shares for at least one year; or
- if you have filed with the SEC a Schedule 13D, Schedule 13G, Form 3, Form 4 or Form 5, or amendments to those documents or updated forms, reflecting your ownership of the requisite number of shares as of or before the date on which the one-year eligibility period begins, a copy of the schedule and/or form, and any subsequent amendments reporting a change in your ownership level.

The SEC's rules require that any response to this letter be postmarked or transmitted electronically no later than 14 calendar days from the date you receive this letter. Please address any response to me at Johnson & Johnson, One Johnson & Johnson Plaza, New Brunswick, NJ 08933, Attention: Corporate Secretary. Alternatively, you may send your response to me via facsimile at (732) 524-2185 or via e-mail at *dchia@its.jnj.com*. For your convenience, a copy of the Rule is enclosed.

In the interim, you should feel free to contact either my colleague, Lacey Elberg, Assistant Corporate Secretary, at (732) 524-6082 or me at (732) 524-3092 if you wish to discuss the Proposal or have any questions or concerns that we can help to address.

Very truly yours,



Douglas K. Chia

cc: L. P. Elberg, Esq.

Enclosure

Shareholder Proposals – Rule 14a-8

§240.14a-8.

This section addresses when a company must include a shareholder's proposal in its proxy statement and identify the proposal in its form of proxy when the company holds an annual or special meeting of shareholders. In summary, in order to have your shareholder proposal included on a company's proxy card, and included along with any supporting statement in its proxy statement, you must be eligible and follow certain procedures. Under a few specific circumstances, the company is permitted to exclude your proposal, but only after submitting its reasons to the Commission. We structured this section in a question-and-answer format so that it is easier to understand. The references to "you" are to a shareholder seeking to submit the proposal.

(a) **Question 1: What is a proposal?**
A shareholder proposal is your recommendation or requirement that the company and/or its board of directors take action, which you intend to present at a meeting of the company's shareholders. Your proposal should state as clearly as possible the course of action that you believe the company should follow. If your proposal is placed on the company's proxy card, the company must also provide in the form of proxy means for shareholders to specify by boxes a choice between approval or disapproval, or abstention. Unless otherwise indicated, the word "proposal" as used in this section refers both to your proposal, and to your corresponding statement in support of your proposal (if any).

(b) **Question 2: Who is eligible to submit a proposal, and how do I demonstrate to the company that I am eligible?**

(1) In order to be eligible to submit a proposal, you must have continuously held at least $2,000 in market value, or 1%, of the company's securities entitled to be voted on the proposal at the meeting for at least one year by the date you submit the proposal. You must continue to hold those securities through the date of the meeting.

(2) If you are the registered holder of your securities, which means that your name appears in the company's records as a shareholder, the company can verify your eligibility on its own, although you will still have to provide the company with a written statement that you intend to continue to hold the securities through the date of the meeting of shareholders. However, if like many shareholders you are not a registered holder, the company likely does not know that you are a shareholder, or how many shares you own. In this case, at the time you submit your proposal, you must prove your eligibility to the company in one of two ways:

(i) The first way is to submit to the company a written statement from the "record" holder of your securities (usually a broker or bank) verifying that, at the time you submitted your proposal, you continuously held the securities for at least one year. You must also include your own written statement that you intend to continue to hold the securities through the date of the meeting of shareholders; or

(ii) The second way to prove ownership applies only if you have filed a Schedule 13D (§240.13d-101), Schedule 13G (§240.13d-102), Form 3 (§249.103 of this chapter), Form 4 (§249.104 of this chapter) and/or Form 5 (§249.105 of this chapter), or amendments to those documents or updated forms, reflecting your ownership of the shares as of or before the date on which the one-year eligibility period begins. If you have filed one of these documents with the SEC, you may demonstrate your eligibility by submitting to the company:

(A) A copy of the schedule and/or form, and any subsequent amendments reporting a change in your ownership level;

(B) Your written statement that you continuously held the required number of shares for the one-year period as of the date of the statement; and

(C) Your written statement that you intend to continue ownership of the shares through the date of the company's annual or special meeting.

(c) **Question 3: How many proposals may I submit?**
Each shareholder may submit no more than one proposal to a company for a particular shareholders' meeting.

(d) **Question 4: How long can my proposal be?**
The proposal, including any accompanying supporting statement, may not exceed 500 words.

(e) **Question 5: What is the deadline for submitting a proposal?**

(1) If you are submitting your proposal for the company's annual meeting, you can in most cases find the deadline in last year's proxy statement. However, if the company did not hold an annual meeting last year, or has changed the date of its meeting for this year more than 30 days from last year's meeting, you can usually find the deadline in one of the company's quarterly reports on Form 10-Q (§249.308a of this chapter) or 10-QSB (§249.308b of this chapter), or in shareholder reports of investment companies under §270.30d-1 of this chapter of the Investment Company Act of 1940. In order to avoid controversy, shareholders should submit their proposals by means, including electronic means, that permit them to prove the date of delivery.

(2) The deadline is calculated in the following manner if the proposal is submitted for a regularly scheduled annual meeting. The proposal must be received at the company's principal executive offices not less than 120 calendar days before the date of the company's proxy statement released to shareholders in connection with the previous year's annual meeting. However, if the company did not hold an annual meeting the previous year, or if the date of this year's annual meeting has been changed by more than 30 days from the date of the previous year's meeting, then the deadline is a reasonable time before the company begins to print and mail its proxy materials.

(3) If you are submitting your proposal for a meeting of shareholders other than a regularly scheduled annual meeting, the deadline is a reasonable time before the company begins to print and mail its proxy materials.

(f) **Question 6: What if I fail to follow one of the eligibility or procedural requirements explained in answers to Questions 1 through 4 of this section?**

(1) The company may exclude your proposal, but only after it has notified you of the problem, and you have failed adequately to correct it. Within 14 calendar days of receiving your proposal, the company must notify you in writing of any procedural or eligibility deficiencies, as well as of the time frame for your response. Your response must be postmarked , or transmitted electronically, no later than 14 days from the date you received the company's notification. A company need not provide you such notice of a deficiency if the deficiency cannot be remedied, such as if you fail to submit a proposal by the company's properly determined deadline. If the company intends to exclude the proposal, it will later have to make a submission under §240.14a-8 and provide you with a copy under Question 10 below, §240.14a-8(j).

(2) If you fail in your promise to hold the required number of securities through the date of the meeting of shareholders, then the company will be permitted to exclude all of your proposals from its proxy materials for any meeting held in the following two calendar years.

(g) **Question 7: Who has the burden of persuading the Commission or its staff that my proposal can be excluded?** Except as otherwise noted, the burden is on the company to demonstrate that it is entitled to exclude a proposal.

(h) **Question 8: Must I appear personally at the shareholders' meeting to present the proposal?**

(1) Either you, or your representative who is qualified under state law to present the proposal on your behalf, must attend the meeting to present the proposal. Whether you attend the meeting yourself or send a qualified representative to the meeting in your place, you should make sure that you, or your representative, follow the proper state law procedures for attending the meeting and/or presenting your proposal.

(2) If the company holds its shareholder meeting in whole or in part via electronic media, and the company permits you or your representative to present your proposal via such media, then you may appear through electronic media rather than traveling to the meeting to appear in person.

(3) If you or your qualified representative fail to appear and present the proposal, without good cause, the company will be permitted to exclude all of your proposals from its proxy materials for any meetings held in the following two calendar years.

(i) **Question 9: If I have complied with the procedural requirements, on what other bases may a company rely to exclude my proposal?**

(1) *Improper under state law:* If the proposal is not a proper subject for action by shareholders under the laws of the jurisdiction of the company's organization;
Note to paragraph (i)(1): Depending on the subject matter, some proposals are not considered proper under state law if they would be binding on the company if approved by shareholders. In our experience, most proposals that are cast as recommendations or requests that the board of directors take specified action are proper under state law. Accordingly, we will assume that a proposal drafted as a recommendation or suggestion is proper unless the company demonstrates otherwise.

(2) *Violation of law:* If the proposal would, if implemented, cause the company to violate any state, federal, or foreign law to which it is subject;
Note to paragraph (i)(2): We will not apply this basis for exclusion to permit exclusion of a proposal on grounds that it would violate foreign law if compliance with the foreign law would result in a violation of any state or federal law.

(3) *Violation of proxy rules:* If the proposal or supporting statement is contrary to any of the Commission's proxy rules, including §240.14a-9, which prohibits materially false or misleading statements in proxy soliciting materials;

(4) *Personal grievance; special interest:* If the proposal relates to the redress of a personal claim or grievance against the company or any other person, or if it is designed to result in a benefit to you, or to further a personal interest, which is not shared by the other shareholders at large;

(5) *Relevance*: If the proposal relates to operations which account for less than 5 percent of the company's total assets at the end of its most recent fiscal year, and for less than 5 percent of its net earnings and gross sales for its most recent fiscal year, and is not otherwise significantly related to the company's business;

(6) *Absence of power/authority*: If the company would lack the power or authority to implement the proposal;

(7) *Management functions*: If the proposal deals with a matter relating to the company's ordinary business operations;

(8) *Relates to election: If the proposal relates to an election for membership on the company's board of directors or analogous governing body;*

(9) *Conflicts with company's proposal*: If the proposal directly conflicts with one of the company's own proposals to be submitted to shareholders at the same meeting;
Note to paragraph (i)(9): A company's submission to the Commission under this section should specify the points of conflict with the company's proposal.

(10) *Substantially implemented*: If the company has already substantially implemented the proposal;

(11) *Duplication*: If the proposal substantially duplicates another proposal previously submitted to the company by another proponent that will be included in the company's proxy materials for the same meeting;

(12) *Resubmissions*: If the proposal deals with substantially the same subject matter as another proposal or proposals that has or have been previously included in the company's proxy materials within the preceding 5 calendar years, a company may exclude it from its proxy materials for any meeting held within 3 calendar years of the last time it was included if the proposal received:

(i) Less than 3% of the vote if proposed once within the preceding 5 calendar years;

(ii) Less than 6% of the vote on its last submission to shareholders if proposed twice previously within the preceding 5 calendar years; or

(iii) Less than 10% of the vote on its last submission to shareholders if proposed three times or more previously within the preceding 5 calendar years; and

(13) *Specific amount of dividends*: If the proposal relates to specific amounts of cash or stock dividends.

(j) **Question 10: What procedures must the company follow if it intends to exclude my proposal?**

(1) If the company intends to exclude a proposal from its proxy materials, it must file its reasons with the Commission no later than 80 calendar days before it files its definitive proxy statement and form of proxy with the Commission. The company must simultaneously provide you with a copy of its submission. The Commission staff may permit the company to make its submission later than 80 days before the company files its definitive proxy statement and form of proxy, if the company demonstrates good cause for missing the deadline.

(2) The company must file six paper copies of the following:

(i) The proposal;

(ii) An explanation of why the company believes that it may exclude the proposal, which should, if possible, refer to the most recent applicable authority, such as prior Division letters issued under the rule; and

(iii) A supporting opinion of counsel when such reasons are based on matters of state or foreign law.

(k) **Question 11: May I submit my own statement to the Commission responding to the company's arguments?**
Yes, you may submit a response, but it is not required. You should try to submit any response to us, with a copy to the company, as soon as possible after the company makes its submission. This way, the Commission staff will have time to consider fully your submission before it issues its response. You should submit six paper copies of your response.

(l) **Question 12: If the company includes my shareholder proposal in its proxy materials, what information about me must it include along with the proposal itself?**

(1) The company's proxy statement must include your name and address, as well as the number of the company's voting securities that you hold. However, instead of providing that information, the company may instead include a statement that it will provide the information to shareholders promptly upon receiving an oral or written request.

(2) The company is not responsible for the contents of your proposal or supporting statement.

(m) **Question 13: What can I do if the company includes in its proxy statement reasons why it believes shareholders should not vote in favor of my proposal, and I disagree with some of its statements?**

(1) The company may elect to include in its proxy statement reasons why it believes shareholders should vote

against your proposal. The company is allowed to make arguments reflecting its own point of view, just as you may express your own point of view in your proposal's supporting statement.

(2) However, if you believe that the company's opposition to your proposal contains materially false or misleading statements that may violate our anti-fraud rule, §240.14a-9, you should promptly send to the Commission staff and the company a letter explaining the reasons for your view, along with a copy of the company's statements opposing your proposal. To the extent possible, your letter should include specific factual information demonstrating the inaccuracy of the company's claims. Time permitting, you may wish to try to work out your differences with the company by yourself before contacting the Commission staff.

(3) We require the company to send you a copy of its statements opposing your proposal before it mails its proxy materials, so that you may bring to our attention any materially false or misleading statements, under the following timeframes:

(i) If our no-action response requires that you make revisions to your proposal or supporting statement as a condition to requiring the company to include it in its proxy materials, then the company must provide you with a copy of its opposition statements no later than 5 calendar days after the company receives a copy of your revised proposal; or

(ii) In all other cases, the company must provide you with a copy of its opposition statements no later than 30 calendar days before its files definitive copies of its proxy statement and form of proxy under §240.14a-6.

From: PAUL***FISMA & OMB Memorandum M-07-16***
To: Chia, Douglas [JJCUS]
Sent: Sat Dec 18 12:19:31 2010
Subject: Copy Letter to Board

Dec. 18, 2010

FISMA & OMB Memorandum M-07-16

TO: Johnson and Johnson Board of Directors

FROM: Paul W. Cahan

Shareholder

You may remember me as the person who wrote you in the past asking for your help to strengthen the labels on Levaquin antibiotic to help prevent future injuries. I spoke at the April 2008 Shareholder meeting. It's been a few years now, and the company has done nothing.

I have written a shareholder proxy on this issue for April 2011 vote, attached, which I am writing you about.

The trials have begun against J&J by victims of Levaquin, and the company lost the first case of course, since they are obviously negligent in telling the truth to consumers about the serious consequences that Levaquin can cause, and the permanent, non-resolving damage that is done to tendons, and ALL the connective tissues and cells to the tendons, that being cartilege, nerves, muscles etc (I'm no doctor, just a patient with 24/7 pain despite pain killers)

I have submitted the attached shareholder proxy for April 2011 as a way

to stop this immoral, unethical corporate practice of hiding the

ugly truth about this medicine. It should be used only as a last resort medicine

where other antibiotics fail.

The lawyers at the company have told me that they MAY ask the SEC within the next two weeks, to allow them NOT to put this proxy to vote. They may argue that it "interferes and

is about normal operating conditions/decisions of the company."

Is hurting people permanently your companies' normal operating function?

I think it's pretty obvious, since J&J lost the first case of many on this

very issue that it would make the company look pretty stupid to the public

if they tried to block this proxy. Public Citizen sued the FDA on this very same issue

a few years ago, numerous attempts by many have been made to safeguard patients

who receive Levaquin, and inform the doctors about the true extent of it's dangers,

and the company does not care to do so. Now, the trials have begun. All this damage

and legal expense could have been avoided if they had run the company in an ethical manner.

Now is the time to begin changing a broken system.

Since I believe most Americans are in favor of truth in advertising, especially when it comes to their health, they would vote FOR my proxy. Since the FDA and J&J have NOT

enforced the truth be told on the labels of this dangerous compound, I have faith that the shareholders will see that voting FOR this proxy is the right thing to do,

and add pressure to the firm to 'bite the bullet" and do this. It would risk lower sales in the long run, but

as a comparison, what were the consequences when BP took shortcuts and the bosses didn't tell the workers the risks of their drilling practices? It led to the deaths of many workers, and the

near demise of the company and the southeast coastline. The damage Levaquin has caused

is much worse, has ruined many more lives, and have led to hundreds of deaths from organ failure and in some cases suicide. The tendon rupture issue is just one of many permanent damages

that are caused.... and even the tendon problems are not 'normal' tendon problems like a sports injury where one point of damage is done.... this damage is biologically caused and when there are

numerous small tears of the tissue, nothing can cure it; the pain is nothing you can imagine unless it happens to you.

I request that you consider calling Mr. Weldon, or Mr. S. Rosenberg, or Douglas Chia in their legal department at 732-524-3292 and let them know your feelings on this subject. I trust that you will follow-through with your responsibility as a member of the Board of Directors of a Health CARE Company.

Sincerely yours,

Paul W. Cahan

cc: D. Chia

J. Mullen

B. Crouse

S. Rosenberg

Senator Bill Pascrell

Two attachments

1) Levaquin lawsuit news

2) Shareholder Proxy

Document5

Dec. 18, 2010

FISMA & OMB Memorandum M-07-16

TO: Johnson and Johnson Board of Directors

FROM: Paul W. Cahan
Shareholder

You may remember me as the person who wrote you in the past asking for your help to strengthen the labels on Levaquin antibiotic to help prevent future injuries. I spoke at the April 2008 Shareholder meeting.

It's been a few years now, and the company has done nothing. I have written a shareholder proxy on this issue for April 2011 vote, attached, which I am writing you about.

The trials have begun against J&J by victims of Levaquin, and the company lost the first case of course, since they are obviously negligent in telling the truth to consumers about the serious consequences that Levaquin can cause, and the permanent, non-resolving damage that is done to tendons, and ALL the connective tissues and cells to the tendons, that being cartilege, nerves, muscles etc (I'm no doctor, just a patient with 24/7 pain despite pain killers)

I have submitted the attached shareholder proxy for April 2011 as a way to stop this immoral, unethical corporate practice of hiding the ugly truth about this medicine. It should be used only as a last resort medicine where other antibiotics fail.

The lawyers at the company have told me that they MAY ask the SEC within the next two weeks, to allow them NOT to put this proxy to vote. They may argue that it "interferes and is about normal operating conditions/decisions of the company."

Is hurting people permanently your companies' normal operating function?

I think it's pretty obvious, since J&J lost the first case of many on this very issue that it would make the company look pretty stupid to the public if they tried to block this proxy. Public Citizen sued the FDA on this very same issue a few years ago, numerous attempts by many have been made to safeguard patients who receive Levaquin, and inform the doctors about the true extent of it's dangers, and the company does not care to do so. Now, the trials have begun. All this damage and legal expense could have been avoided if they had run the company in an ethical manner. Now is the time to begin changing a broken system.

Since I believe most Americans are in favor of truth in advertising, especially when it comes to their health, they would vote FOR my proxy. Since the FDA and J&J have NOT enforced the truth be told on the labels of this dangerous compound, I have faith that the shareholders will see that voting FOR this proxy is the right thing to do, and add pressure to the firm to 'bite the bullet" and do this. It would risk lower sales in the long run, but as a comparison, what were the consequences when BP took shortcuts and the bosses didn't tell the workers the risks of their drilling practices? It led to the deaths of many workers, and the near demise of the company and the southeast coastline. The damage Levaquin has caused is much worse, has ruined many more lives, and have led to hundreds of deaths from organ failure and in some cases suicide. The tendon rupture issue is just one of many permanent damages that are caused.... and even the tendon problems are not 'normal' tendon problems like a sports injury where one point of damage is done.... this damage is biologically caused and when there are numerous small tears of the tissue, nothing can cure it; the pain is nothing you can imagine unless it happens to you.

I request that you consider calling Mr. Weldon, or Mr. S. Rosenberg, or Douglas Chia in their legal department at 732-524-3292 and let them know your feelings on this subject. I trust that you will follow-through with your responsibility as a member of the Board of Directors of a Health CARE Company.

Sincerely yours,

Paul W. Cahan

cc: D. Chia
J. Mullen
B. Crouse
S. Rosenberg
Senator Bill Pascrell

Two attachments
1) Levaquin lawsuit news
2) Shareholder Proxy

[redacted]

From: PAUL FISMA & OMB Memorandum M-07-16***
Sent: Friday, December 17, 2010 12:18 AM
To: Chia, Douglas [JJCUS]
Subject: Re: Shareholder Proposal

thank u

From: "Chia, Douglas [JJCUS]" <DChia@its.jnj.com>
To: PAUL FISMA & OMB Memorandum M-07-16***
Sent: Fri, December 17, 2010 12:08:16 AM
Subject: RE: Shareholder Proposal

Per your request, please see attached.

Douglas K. Chia
Assistant General Counsel & Corporate Secretary
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
Tel: (732) 524-3292
Fax: (732) 524-2185
E-mail: dchia@its.jnj.com

From: PAUL FISMA & OMB Memorandum M-07-16***
Sent: Friday, December 17, 2010 12:05 AM
To: Chia, Douglas [JJCUS]
Subject: Re: Shareholder Proposal

would you mind sending me another copy of the SEC regulations.
i misplaced it... in pain and on pain meds, you know that my organization skills are not what they used to be.
thank you.

From: "Chia, Douglas [JJCUS]" <DChia@its.jnj.com>
To: PAUL FISMA & OMB Memorandum M-07-16***
Sent: Thu, December 16, 2010 11:16:45 PM
Subject: RE: Shareholder Proposal

Mr. Cahan:

Thank you for your note.

We may go to the SEC to see whether they would object if we exclude your proposal from our 2011 Proxy Statement on the grounds that what your proposal is asking may not be a proper subject for a shareholder proposal to be included in a proxy statement under Rule 14a-8. This would be because this proposal deals with a matter relating to the company's ordinary business operation. If we do so, it will be by no later than December 27, 2010. You will receive a copy of anything that we send to the SEC, and you may submit your own response to the SEC. The SEC would then get back to all of us prior to the time our 2011 Proxy Statement

is mailed. Please refer to the copy of Rule 14a-8 that we sent you with our original response to your proposal as it outlines this process.

Regards,

Douglas K. Chia
Assistant General Counsel & Corporate Secretary
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
Tel: (732) 524-3292
Fax: (732) 524-2185
E-mail: dchia@its.jnj.com

From: PAUL FISMA & OMB Memorandum M-07-16***
Sent: Thursday, December 16, 2010 12:09 PM
To: Chia, Douglas [JJCUS]
Subject: Fw: Shareholder Proposal

Mr. Chia:
Can I interpret the statement of your's , below, to mean that J&J will print my shareholder proxy in early 2011 and let the shareholders VOTE to decide whether or not to agree with the concept and action towards changing the label of Levaquin, and making it more honest in warning patients that Levaquin has a black box warning, and that it can lead to delayed reactions that could cause permanent pain and disabilty ?
I would think that the recent verdict in Minn. would certainly be in my favor of having shareholders know about this problem, and be able to DO something about it since it affects both the health of the general population and your companies' value in terms of litigation costs.
Please respond as soon as possible, preferably by tomorrow, Friday Dec. 17. If you are still in the process of "review" please let me know the deadline date when I will know of your intentions to have my proxy put to shareholder vote or not in April 2011.
thank you.
Paul Cahan

From: "Chia, Douglas [JJCUS]" <DChia@its.jnj.com>
To: PAUL FISMA & OMB Memorandum M-07-16***
Sent: Mon, November 15, 2010 1:54:37 PM
Subject: RE: Shareholder Proposal

Mr. Cahan:

Yes, we will work with the revised version of the proposal, which we received by mail today.

Douglas K. Chia
Assistant General Counsel & Corporate Secretary
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
Tel: (732) 524-3292
Fax: (732) 524-2185
E-mail: dchia@its.jnj.com

From: PAUL FISMA & OMB Memorandum M-07-16***
Sent: Friday, November 12, 2010 2:31 PM
To: Chia, Douglas [JJCUS]
Subject: Re: Shareholder Proposal

Thanks.
Is the revised proxy proposal within acceptable
time frame?
Paul Cahan

From: "Chia, Douglas [JJCUS]" <DChia@its.jnj.com>
To: PAUL FISMA & OMB Memorandum M-07-16***
Sent: Fri, November 12, 2010 11:03:29 AM
Subject: RE: Shareholder Proposal

Mr. Cahan:

We received your fax of the E-Trade letter. Thank you.

Douglas K. Chia
Assistant General Counsel & Corporate Secretary
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
Tel: (732) 524-3292
Fax: (732) 524-2185
E-mail: dchia@its.jnj.com

From: PAUL FISMA & OMB Memorandum M-07-16***
Sent: Thursday, November 11, 2010 11:18 PM
To: Chia, Douglas [JJCUS]
Subject: Re: Shareholder Proposal

Mr. Chia:
Thank you for informing me of this.
Today I was told E-Trade cannot send this to third party (J&J)

I faxed you the required letter at 5 pm Thursday 11/11/10.
Please confirm that you received it.
Also, one detail on the proxy.
Attached is final version. I forgot to mention that the FDA approved "Patient Guide" that was approved in Oct. 2008 is NOT reaching patients in the pharmacy. I have numerous anecdotal reports of this, any randomly selected pharmacist or patient can testify about this. Please not the mention of this point which I put in capital letters to emphasize. Also, I simplified and clarified the proxy's opening remarks.
Thanks.

Paul W. Cahan
Attachment: revised proxy

Vote FOR working with FDA to add warning on labels to all Levaquin tablets, and injection solutions informing all patients that Levaquin has a "Black Box" Warning regarding severe and permanent delayed

reactions that could cause **permanent pain and disability.**

There is no information on the bottle informing patients that this is a "black box" medication,

and no indication that small adverse reactions can build-up in the body and later erupt in an irreversible cascade of inflammatory and destructive cellular events that is extremely painful and irreversible. If one has a MINOR reaction, sometimes it does NOT slowly worsen while one completes

the prescribed dose. It can stabilize or decrease giving the patient a false sense of security while completing the prescription. This is what happened to me in 1998 after 10 days of Floxin and I am permanently disabled. If patients read the fine print and inserts they may know this, if they do not, many are in grave danger. Current communication is failing. There have been over 50,000 adverse reactions reported to the FDA on Levaquin, and over 12,000 individual safety reports. Complaints are "the tip of the iceberg." The tendon and neuropathic delayed reaction mechanism of Levaquin is different than many other medicines with black box warnings. Special attention needs to educate all patients of this.

Every patient needs to see something on the bottle and "front line" pharmacy printing when they receive the medicine to ensure they fully understand the consequences of any minor initial reaction. Pharmacists cannot offer advise on medical issues. They only say: "Do you have any questions about this medicine?" Every patient and physician needs to know "up-front" the unique delayed reaction mechanism that causes permanent pain. THE 2008 MEDICATION GUIDES ARE NOT REACHING PATIENTS. This will take working with FDA and companies that provide computerized LABELING services when a prescription is filled. Any decrease in sales will be offset by fewer lawsuits and be consistent with the corporate credo.

Information on the **bottle of Levaquin 500 mg. Tablets:**

"Medication should be taken with plenty of water.

Take this medication at least 2 hours before or 2 hours after magnesium or aluminum containing antacids, or other products containing calcium, iron, or zinc.

Avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medication. May cause dizziness.

This medicine is dispensed as a(n) PEACH, OBLONG-SHAPED, FILM COATED TABLET

with LEVAQUIN imprinted on one side and 500 imprinted on the other side. "

No mention of the dangers on the bottle, often the only piece of information read by patients.

There is no cure for permanent reactions that damage tendons, cartilage, nerves, etc. (Levaquin is deemed Floxin's "mirror" drug; Floxin was discontinued in 2009.) Help preserve the health and happiness of shareholders, the public, and decrease government expenses supporting the permanently injured and disabled.

Sincerely,

Paul W. Cahan

FISMA & OMB Memorandum M-07-16

Holding 51 Shares

From: "Chia, Douglas [JJCUS]" <DChia@its.jnj.com>
FISMA & OMB Memorandum M-07-16
Sent: Thu, November 11, 2010 2:34:43 PM
Subject: Shareholder Proposal

Dear Mr. Cahan:

Thank you for your e-mail correspondence of November 4, 2010.

We await sufficient proof of your ownership of the requisite number of Company shares as of the date you submitted the Proposal, which we requested in our letter of November 1, 2010.

Regarding the questions you have asked in your latest correspondence, we will not comment on the factual accuracy of anything stated in the Proposal or your supporting statement.

Kind regards,

Douglas K. Chia
Assistant General Counsel & Corporate Secretary
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

Tel: (732) 524-3292
Fax: (732) 524-2185
E-mail: dchia@its.jnj.com

Vote FOR working with FDA to add warning on labels to all Levaquin tablets, and injection solutions informing all patients that Levaquin has a "Black Box" Warning regarding severe and permanent delayed reactions that could cause **permanent pain and disability.**

There is no information on the bottle informing patients that this is a "black box" medication, and no indication that small adverse reactions can build-up in the body and later erupt in an irreversible cascade of inflammatory and destructive cellular events that is extremely painful and irreversible. If one has a MINOR reaction, sometimes it does NOT slowly worsen while one completes the prescribed dose. It can stabilize or decrease giving the patient a false sense of security while completing the prescription. This is what happened to me in 1998 after 10 days of Floxin and I am permanently disabled. If patients read the fine print and inserts they may know this, if they do not, many are in grave danger. Current communication is failing. There have been over 50,000 adverse reactions reported to the FDA on Levaquin, and over 12,000 individual safety reports. Complaints are "the tip of the iceberg." The tendon and neuropathic delayed reaction mechanism of Levaquin is different than many other medicines with black box warnings. Special attention needs to educate all patients of this. Every patient needs to see something on the bottle and "front line" pharmacy printing when they receive the medicine to ensure they fully understand the consequences of any minor initial reaction. Pharmacists cannot offer advise on medical issues. They only say: "Do you have any questions about this medicine?" Every patient and physician needs to know "up-front" the unique delayed reaction mechanism that causes permanent pain. THE 2008 MEDICATION GUIDES ARE NOT REACHING PATIENTS. This will take working with FDA and companies that provide computerized LABELING services when a prescription is filled. Any decrease in sales will be offset by fewer lawsuits and be consistent with the corporate credo.

Information on the **bottle of Levaquin 500 mg. Tablets**:
"Medication should be taken with plenty of water.
Take this medication at least 2 hours before or 2 hours after magnesium or aluminum containing antacids, or other products containing calcium, iron, or zinc.
Avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medication. May cause dizziness.
This medicine is dispensed as a(n) PEACH, OBLONG-SHAPED, FILM COATED TABLET with LEVAQUIN imprinted on one side and 500 imprinted on the other side."

No mention of the dangers on the bottle, often the only piece of information read by patients. There is no cure for permanent reactions that damage tendons, cartilage, nerves, etc. (Levaquin is deemed Floxin's "mirror" drug; Floxin was discontinued in 2009.) Help preserve the health and happiness of shareholders, the public, and decrease government expenses supporting the permanently injured and disabled.

Sincerely,
Paul W. Cahan

Holding 51 Shares

E*TRADE FINANCIAL

E*TRADE Securities LLC
P.O. Box 1542
Merrifield, VA 22116-1542

tel 1-800-ETRADE-1
www.etrade.com
Member FINRA/SIPC

November 9, 2010

Paul W. Cahan

FISMA & OMB Memorandum M-07-16

Re: E*TRADE Securities Account FBO Paul W. Cahan

Dear Mr. Cahan,

This letter is in response to your request received on November 4, 2010, for written confirmation of your ownership of Johnson & Johnson (JNJ) shares in the above referenced E*TRADE Securities Account.

Please allow this letter to serve as confirmation that Paul W. Cahan is the beneficial owner of shares of Johnson & Johnson (JNJ) with a market value of over $2,000.00 as of market close on October 19, 2010. We can also confirm that Mr. Cahan has owned shares of Johnson & Johnson (JNJ) continuously for at least one year prior to October 19, 2010

E*TRADE Securities is committed to providing quality customer service. Should you have any further questions, please contact a Financial Service Associate at 1.800.387.2331. Representatives are available seven days a week, 24 hours a day.

Sincerely,

Jason Summers
Correspondence Specialist
E*TRADE Securities LLC

[redacted]

From: PAUSMA & OMB Memorandum M-07-16***
Sent: Thursday, November 04, 2010 12:21 PM
To: Chia, Douglas [JJCUS]
Subject: My Shareholder Proxy
Attachments: proxyOne.wpd

Follow Up Flag: Follow up
Flag Status: Completed

Mr. Chia: November 4, 2010

Just to let you know I received your letter. The brokerage house I use, E-Trade, is taking care of this. You will receive the letter within the time-frame specified.

I do have a few questions.

I did not put in the proxy the number of shares I hold. If you want that in, attached is modified version, bringing wordcount to 498.

I will also send this to you in the mail.

Most important, are the facts in the proxy consistent with J&J info?

If not, there is time to revise, I would think. I don't want to be surprised later.

1) The number of reactions is from the FDA reports. Do you agree with it?

It's probably much higher actually. If you have the number, please let me know.

I said "50,000 adverse reactions reported to the FDA on Levaquin, and over 12,000 individual safety reports."

2) is the quote I have on what is now written on the bottle of Levaquin tablets correct? was it updated since I got this?

3) Is it OK for me to have said anything about my own situation... that I had 10 days of Floxin in 1998 etc...? can a proxy be personalized like that?

I would think so.

4) Is the company info that Levaquin is Floxin's "mirror" drug correct?

I got that info. from various sources. I also heard that when J&J petitioned the FDA for Levaquin approval, Floxin data was used.

4) Lastly: my computer showed a word-count of 498. If you find that this is in error and I've exceeded the maximum allowed words, let me know before the deadline and I'll gladly revise.

Thank you for responding in a timely manner to these questions, since there are time constraints in this matter.

Sincerely,
Paul W. Cahan

Vote FOR working with FDA to put a warning on Levaquin tablet bottles, oral solution packages, and injection packages informing "out-patient" and hospitalized patients

and families that Levaquin has a "Black Box" Warning regarding severe delayed

reactions. Example:

Urgent Warning: Read all Inserts Carefully

STOP if smallest skin, tendon, muscle reaction,

otherwise severe delayed reaction and permanent pain and disability is possible.

There is no information on the bottle informing patients that this is a "black box" medication,

and no indication that small adverse reactions can build-up in the body and later erupt in a serious irreversible cascade of inflammatory and destructive cellular events that is extremely painful and irreversible. If one has a MINOR reaction, sometimes it does NOT slowly worsen while one completes

the prescribed dose. It can stabilize or decrease giving the patient a false sense of security while completing the prescription. This is what happened to me in 1998 after 10 days of Floxin and I am permanently disabled. If patients read the fine print and inserts they may know this, if they do not, many are in grave danger. Current communication is failing. There have been over 50,000 adverse reactions reported to the FDA on Levaquin, and over 12,000 individual safety reports. Complaints are "the tip of the iceberg." The tendon and neuropathic delayed reaction mechanism of Levaquin is different than many other medicines with black box warnings. Special attention needs to educate all patients of this.

Every patient needs to see something on the bottle and "front line" pharmacy printing when they receive the medicine to ensure they fully understand what any initial reaction means. Pharmacists cannot offer advise on medical issues. They only say: "Do you have any questions about this medicine?" Every patient and physician needs to know "up-front" the unique delayed reaction mechanism that causes permanent pain. This will take working with FDA and companies that provide computerized labeling services when a prescription is filled. Any decrease in sales will be offset by fewer lawsuits and be consistent with the corporate credo.

Information on the **bottle of Levaquin 500 mg. Tablets**:

"Medication should be taken with plenty of water.

Take this medication at least 2 hours before or 2 hours after magnesium or aluminum containing antacids, or other products containing calcium, iron, or zinc.

Avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medication. May cause dizziness.

This medicine is dispensed as a(n) PEACH, OBLONG-SHAPED, FILM COATED TABLET

with LEVAQUIN imprinted on one side and 500 imprinted on the other side. "

No mention of the dangers on the bottle, often the only piece of information read by patients.

There is no cure for permanent reactions that damage tendons, cartilage, nerves, etc. (Levaquin is deemed Floxin's "mirror" drug; Floxin was discontinued in 2009.) Help preserve the health and happiness of shareholders, the public, and decrease government expenses supporting the permanently injured and disabled.

Sincerely,

Paul W. Cahan

FISMA & OMB Memorandum M-07-16

Holding 51 Shares

Vote FOR working with FDA to put a warning on Levaquin tablet bottles, oral solution packages, and injection packages informing "out-patient" and hospitalized patients
and families that Levaquin has a "Black Box" Warning regarding severe delayed
reactions. Example:

Urgent Warning: Read all Inserts Carefully
STOP if smallest skin, tendon, muscle reaction,
otherwise severe delayed reaction and permanent pain and disability is possible.

There is no information on the bottle informing patients that this is a "black box" medication, and no indication that small adverse reactions can build-up in the body and later erupt in a serious irreversible cascade of inflammatory and destructive cellular events that is extremely painful and irreversible. If one has a MINOR reaction, sometimes it does NOT slowly worsen while one completes the prescribed dose. It can stabilize or decrease giving the patient a false sense of security while completing the prescription. This is what happened to me in 1998 after 10 days of Floxin and I am permanently disabled. If patients read the fine print and inserts they may know this, if they do not, many are in grave danger. Current communication is failing. There have been over 50,000 adverse reactions reported to the FDA on Levaquin, and over 12,000 individual safety reports. Complaints are "the tip of the iceberg." The tendon and neuropathic delayed reaction mechanism of Levaquin is different than many other medicines with black box warnings. Special attention needs to educate all patients of this. Every patient needs to see something on the bottle and "front line" pharmacy printing when they receive the medicine to ensure they fully understand what any initial reaction means. Pharmacists cannot offer advise on medical issues. They only say: "Do you have any questions about this medicine?" Every patient and physician needs to know "up-front" the unique delayed reaction mechanism that causes permanent pain. This will take working with FDA and companies that provide computerized labeling services when a prescription is filled. Any decrease in sales will be offset by fewer lawsuits and be consistent with the corporate credo.

Information on the **bottle of Levaquin 500 mg. Tablets**:
"Medication should be taken with plenty of water.
Take this medication at least 2 hours before or 2 hours after magnesium or aluminum containing antacids, or other products containing calcium, iron, or zinc.
Avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medication. May cause dizziness.
This medicine is dispensed as a(n) PEACH, OBLONG-SHAPED, FILM COATED TABLET with LEVAQUIN imprinted on one side and 500 imprinted on the other side. "

No mention of the dangers on the bottle, often the only piece of information read by patients. There is no cure for permanent reactions that damage tendons, cartilage, nerves, etc. (Levaquin is deemed Floxin's "mirror" drug; Floxin was discontinued in 2009.) Help preserve the health and happiness of shareholders, the public, and decrease government expenses supporting the permanently injured and disabled.

Sincerely,
Paul W. Cahan

FISMA & OMB Memorandum M-07-16

Holding 51 Shares