Appendix B: Sample Request for Medical Records

ABC Hospital
80 East Street
Somewhere, ZA 00000
ATTN: Medical Records

RE: Name, social security number, date of patient

Dear Sir or Madam:

Pursuant to [cite statute for your state, found in Appendix A], I am hereby requesting copies of all of my medical records pertaining to inpatient services from [insert dates of inpatient care]. I understand that you have the statutory right to charge me up to $0.45 per page [or whatever your State law allows], and that you have thirty (30) days [or whatever your State law allows] to respond to this request.

Thank you.

Sincerely,

Patient

NOTE: This letter can be used for individual doctors as well as hospitals. If you are requesting your doctor's file, though, you probably don't want to limit your request to a period of days or months, which you do want to do with a request to a hospital. *See* Appendix A for your State's law. There may be "buzz words" or, in some States, exact language that should be included in your letter requesting records. If you are requesting mental health or HIV/AIDS records, you must state that expressly.

Appendix C: Sample Health Insurance Appeal Letters

A. Health Insurance – Formulary 1

RE: Patient Name, Patient ID number, Claim number if possible

Dear Sir or Madam:

I am writing to appeal the letter I received from you indicating that you would be charging me out-of-formulary co-pays for Nexium because you have functional equivalents on the formulary. Because you are erroneous regarding the existence of functional equivalents on the formulary in my case, I am asking you to reconsider your position.

I have Crohn's disease and a history of duodenal ulcer. As your pharmacy records no doubt show, I was on Prilosec for years. Prilosec is the drug on your formulary that you believe is equivalent to Nexium. For as long as Prilosec was addressing my symptoms, I was perfectly content to use that drug.

However, you will note from the enclosed pathology report that my situation changed over the past few months. In about March 2003, I began having upper GI burning and discomfort, along with nausea. In addition, I began to vomit, which is not one of my usual Crohn's symptoms. My gastroenterologist, Dr. L, performed an endoscopy and colonoscopy on June xx, 200x. As you can see, the pathology report indicates that the duodenal biopsy showed "patchy increase eosinophiloc and plasmacellular inflammation, no neutrophils, villous blunting or granulomas," and the gastric biopsy showed "oxyntoantral junction mucosa showing patchy active gastritis; no granulomas . . . ." In the comment, the pathologist indicates that he believes these upper GI biopsies indicate upper GI involvement of Crohn's.

Whether or not these biopsies indicate the spread of Crohn's to my upper GI tract, there is no question that they objectively confirm the subjective symptoms of nausea, burning, and vomiting that I have been experiencing. As a result of the receipt of these biopsy results, Dr. L decided that I should switch from Prilosec to Nexium since the Prilosec clearly did not have my upper GI symptoms under control. I also take Carafate and Zofran for nausea. Since switching to Nexium, I have had a significant improvement in the upper GI burning, and I have not vomited, although I remain nauseated on and off.

As I am sure you are aware, Crohn's disease is a very difficult illness, especially when it is spreading aggressively, and leads to dehydration and malnutrition, which themselves create secondary consequences of the Crohn's. At the moment, I am barely working, spending most of my time in bed. Last week, I was informed by an expert endocrinologist that my inability to absorb and metabolize Vitamin D properly can and, left untreated, would have led to my eventual death. My body is starved for protein and calcium. My feet are the size of footballs and my fingers are like sausages. In the 27

years since I was diagnosed, this is by far the worst attack I have had, and all of my doctors concur that aggressive treatment is warranted.

Although Nexium is only one small part of that, it is crucial that I not lose the ability to get and keep meds and food down. If that happens, and my physicians have to find another way to deliver nutrition and medication to me, ABC Insurance will be paying for far more than Nexium.

For now, though, the only point that really matters is that I tried your formulary medication and it did not work. You certainly have my assurance that, as soon as things are improved and I no longer need a stronger drug than Prilosec, I will go back to it gladly. For now, though, there is no question that I need to do everything I can to keep an already terrible situation from getting worse.

Of course, you have my permission to obtain any additional information you would like from my physicians. However, I believe that the enclosed pathology report, along with your own records, which will corroborate that I was on Prilosec for years, should be enough for you to acknowledge that you do not have a medically equivalent drug to Nexium on your formulary for me at this time.

Please let me know if you would like any additional information. Thank you.

Sincerely,

Patient

B. Health Insurance – Formulary 2

Dear Sir or Madam:

I am writing to appeal the quota you have placed on my use of Zofran for nausea. Apparently, you will only allow me to have 24 pills at a time, and that is supposed to last 30 days. I need a larger quantity.

As you know from my records, I have had Crohn's disease for 27 years. Your records will show that I have had the worst flare of my life over the past 2.5 years, while I watched myself get sicker and sicker to the point that I could barely work. By the time I began seeing out-of-network physicians at great expense to me, I was, according to them, on the verge of kidney failure and death.

Since I began seeing new doctors, we have made great strides in regaining my health. Nutritionally, I am much improved, and the Crohn's appears to be under control with Remicade. The last step was surgery on November 6, performed by Dr. M, one of the leading colo-rectal surgeons in the country. Dr. M found that my small intestine was

literally tied up in knots by adhesions. During a 5-hour surgery, he made his way inch by inch down the small intestine to free it all up of adhesions, without making a single cut into the intestine. In addition, Dr. S performed a complete hysterectomy to address the large fibroids I have had in my uterus (thereby eliminating ABC Insurance Co.'s expense for high dose birth control pills to control the bleeding from the fibroids).

I have been home from the hospital for about a week. I am just over 2 weeks post-op. And I am very, very nauseated. Our best guess is that it is from the pain meds, which I have decreased as far as I can in light of the post-op pain I am in. As you know, I have been taking Zofran since last spring when the nausea got bad, and I never complained about the quantity you allowed because, at that time, I did not need it every day, and I don't recall ever needing it more than once in a single a day. However, since the surgery, the nausea has been worse. The doctors' belief is that, once I heal from the surgery and wean off the pain meds, the nausea will subside. But for now, because I cannot eat much but I have to take post-op pain meds, nausea is part of my daily life.

As you know from my records, I have tried compazine and phenergen, and the only thing that has worked is Zofran. As best I can tell, there is nothing less expensive on your formulary that would have the same result. At the moment, I am taking as many as 3 pills in a 24-hour period when the nausea is its worst.

I am set to see Dr. M for my first post-op appointment tomorrow. At the top of my list of things to talk with him about is the nausea. I have every reason to believe that this is a short-term post-op issue, and not something ABC Insurance Co. will have to be paying for endlessly. Indeed, once I have completed my recuperation, ABC Insurance Co.'s costs for prescriptions, doctor visits, outpatient procedures, etc. should decrease tremendously. The healthier I get, the less I am required to burden ABC Insurance Co. I am in the home stretch here. Please just help me through this last hurdle. Indeed, if you would just change this rule for 90 days and then revisit it – I promise you that I am more anxious to get well and stop taking these meds than you are.

Thank you for your consideration.

Sincerely,

Patient

C. Health Insurance Appeal – Coverage

NOTE: This is a sample that is fairly long and complex involving an inpatient admission and surgery. It is included here as an example of the level of detail that is necessary. Take from it whatever you find is helpful to you. Note how critical it is to know the nature of your policy's coverage.

ABC Insurance Company
Anywhere, USA

RE: Patient's name, Insurance ID number, and claim numbers if possible

Dear Sir or Madam:

I am writing to appeal your handling of all of the above-referenced claims, and any additional outstanding claims, relating to surgery that occurred on [date]. Not one of the claims I have submitted has been handled correctly. I would appreciate your attention to this matter.

[Describe the procedures you had done, whether inpatient or outpatient, including dates, physicians' names] Enclosed are two operative reports [or whatever you have] verifying that there were two surgeries performed at the same time, one colo-rectal and one gynecological.

By Explanations of Benefits ("EOBs") dated [fill in date] you paid claim number [fill in], which included Dr. M's bill in the amount of $xxxx, with a patient balance of $xxx. You also paid a claim for "Dr. S Hosp. Med. Care." You paid $xxx with a patient balance of $xxx.

On [date], I called your customer relations line about claims numbered [fill in]. I spoke with a Mrs. Martin who agreed that both claims had been processed incorrectly. The inpatient hospital bill was paid as if it were an in-network hospital, which it is not. Instead, the hospital should be paid either 70% or 100% of the reasonable and customary charges for a hospital in New York, or so I have been told by countless ABC Insurance Co. customer relations people with whom I have been speaking for months, since I began receiving out-of- network services.

Similarly, according to Ms. Martin, the rejection of the anesthesiologist's bill also was incorrect since ABC Insurance's claims department already had a copy of the operative report and knew that Dr. A was the anesthesiologist. Ms. Martin and I also discussed Dr. S's bill, since by this time, it had become clear to both myself and Ms. Martin that there was some confusion about claims for two surgeries on the same date. She assured me that, if I faxed her the operative report, she would make sure that it would be forwarded to the people handling both the anesthesiologist's claim as well as Dr. S's claim. I am enclosing a copy of my note to Ms. Martin pointing to the relevant portions of the operative report that referred to the anesthesiologist by name, and that referred to both Dr. M and Dr. Ss, setting forth their distinct roles.

The next EOB I received related again to Dr. T – Hosp. Med. Care. Please note that this claim was paid by ABC Insurance on the [date] EOB. However, now, in claim number [fill in], that payment was reversed. The reason given was that "Medical care within the aftercare period is included in the surgical allowance. The surgery was submitted on a separate claim. **Participating providers** should not bill separately for

these services."[86] (emphasis added). I called and spoke to customer relations on December 16, 2003. She reviewed the claim, told me that Insurance Co. was fully aware that Dr. T is **not** a participating provider, and that she would send this claim, too, back to claims processing. She also told me that the remaining claims – the hospital inpatient bill, Dr. S's bill, and the anesthesiologist's bill all were still being reviewed.

That was 3 days ago. I now have received an EOB rejecting Dr. T's bill in its entirety because "this procedure is a duplicate to one already processed." Once again, the claims processor did not understand that there were two distinct surgeries being performed using one incision on the same date.

Since I faxed the first operative report to Ms. Martin, I did receive Dr. S's operative report, which I enclose here, along with copies of the EOBs to which I am referring in this letter.

The bottom line is that my policy pays 70% of usual and customary in the location where the out-of-network service is provided until I have paid $2,000 out of pocket, at which point ABC Insurance Co. pays 100% of usual and customary. This has been confirmed for me over and over each time I have to call customer service. I have paid well more than $2,000 out of pocket, especially if you consider pre-op consultations, labs, etc. Thus, first of all, the inpatient hospital and "Dr. T Hosp. Med. Care" claims should be revised to reflect the correct payment for out-of-network claims.

Second, ABC Insurance Co.'s claims personnel should, by now, understand that I had two surgeries on one day, and the claims for Dr. S and the anesthesiologist should be paid, as well, since they both held unique roles in the surgery, independent of Dr. M's bill, which is the only claim that has been paid. Clearly, the fact that I had two surgeries on one day is to Insurance Co.'s long-range benefit since two inpatient hospital stays associated with the same two surgeries if done on different days would cost ABC Insurance Co. thousands of dollars. The need for both surgeries is well-documented; my gynecologist, Dr. N, has been trying to treat me for pain and bleeding from fibroids for years. After unsuccessfully attempting an ablation, Dr. N told me that hysterectomy was the only treatment remaining.

There are a number of reasons why I had these surgeries performed out of state. First, even a cursory review of ABC Insurance Co's payment history for me for the past 2.5 years will show that I have gotten sicker and sicker, while doctors in my geographic area had no idea what to do for me. In fact, my in-network primary care physician, Dr. J, argued strenuously in favor of having the surgery done out of state. I spoke with the in-network surgeon who had performed my prior colo-rectal surgeries, Dr. C, and he was very comfortable with me going out of state for the surgery.

In any event, as you know, I am permitted to go out-of-network even if it's simply out of choice rather than medical necessity, as my treating physicians agreed it was. I had two surgeries at once because it meant one incision, one hospitalization, one

[86] Please note that neither surgeon, Dr. M nor Dr. S, has billed for any after-care.

administration of general anesthesia accompanied by the usual risks. Similarly, it is to ABC Insurance Co's benefit as well. Although there are two surgeons who have every right to be paid the usual and customary amounts, there is only one anesthesiologist, one inpatient hospital stay, etc.

I hope that this information explains the situation. Every provider was out-of-network, so the inpatient hospital bill has to be re-processed accordingly. The anesthesiologist is entitled to be paid, as well. The adjusted claim related to Dr. T, which is based on the misunderstanding that he was an in-network provider, should be reversed. And Dr. S, the gynecological surgeon, also should be paid the usual and customary fee for the surgery he performed in the geographic area in which the surgery was performed.

Because these providers are out-of-network, I have had to pay a number of them up front. There are other claims pending related to the same hospitalization that involve over $3,000 out-of-pocket that I paid, and I have had to make payments to both surgeons in cash while we all wait for ABC Insurance Co. to get a proper understanding of each of these claims. As you can imagine, the delay caused by the fact that almost every claim involves some error creates a tremendous financial burden on me, at a time when I am supposed to be recovering from surgery.

I trust that the information provided herein is sufficient to allow you to straighten out these claims. Of course, if you would like additional information, please let me know.

Thank you.

Sincerely,

Patient

D. Health Insurance Appeal – Coverage – ERISA "full and fair review" – "Experimental, investigational, unproven"

ABC Insurance Company
Anywhere, USA

RE: Patient X
ID no.12345678

Dear Sir or Madam:

I have been retained to represent Patient X in her appeal from ABC Insurance Company's ("ABC") noncoverage decision dated January 31, 2005, in which ABC

indicated that it would not cover implantation of a gastric neurostimulator. [87] A copy of my medical release and authorization is enclosed.

The procedure employed by ABC in reviewing this matter to date has deprived Patient X of the "full and fair review" required by the Employee Retirement Income Security Act ("ERISA"). As such, this alone would be a reason for a court to overturn ABCs decision.

In addition, since we know that ABC has granted coverage for this same device in other patients, and since the only reason ABC has given to support the noncoverage decision is that the device is experimental, if there is a reason that has not been shared, then ABC has further violated ERISA's requirement of a "full and fair review."

Finally, on the merits, the efficacy of this device is well-documented, and medically necessary in Patient X's case.

For these reasons, we ask that ABC reverse its decision and cover the cost of implantation and maintenance of this device.

I. Full and Fair Review

Here, ABC has not provided full and fair review in two respects. First, ABC shirked its obligation to provide copies of the documents it relied upon in making its noncoverage decision; second, ABC has failed to state the reasons for the noncoverage decision. Each of these is a reason to reverse the noncoverage decision.

A. ERISA Requires that Claims Review Be Full and Fair

ERISA requires "full and fair review" by ERISA plan administrators. 29 U.S.C. § 1133. The statute sets out the following duties for plan administrators:

> (1) provide adequate notice in writing to any participant or beneficiary whose claim for benefits under the plan has been denied, setting forth the specific reasons for such denial, written in a manner calculated to be understood by the participant, and
>
> (2) afford a reasonable opportunity to any participant whose claim for benefits has been denied for a ***full and fair review*** by the appropriate named fiduciary of the decision denying the claim.

29 U.S.C. § 1133 (emphasis added).

In addition, the Department of Labor has promulgated regulations that further clarify the nature and scope of full and fair review, as follows:

> (1) The specific reason or reasons for the denial;
> (2) Specific reference to pertinent plan provisions on which the denial is based;

[87] References to the gastric pacemaker, gastric electrical stimulation, and Enterra therapy are intended to be used synonymously throughout this letter.

(3) A description of any additional material or information necessary for the claimant to perfect the claim and an explanation of why such material or information is necessary; and
(4) Appropriate information as to the steps to be taken if the participant or beneficiary wishes to submit his or her claim for review.

29 C.F.R. § 2560.503-1(f). *See also Cannon v. UNUM Life Ins. Co. of America*, 219 F.R.D. 211, 215 (D. Maine 2004) ("The insurer is obligated to conduct 'full and fair' reviews of administrative appeals. 29 C.F.R. § 2560.503-1(h). Removal of 'contrary evidence' from the record does not comport with full and fair claims review and it should go without saying that it is never reasonable for a fiduciary to discard 'contrary evidence.'").

In short, "an administrator abuses its discretion when it fails to afford a claimant a 'full and fair review' of its decision to deny her claim." *Soron v. Liberty Life Assurance Co. of Boston*, 318 F.Supp.2d 19 (N.D.N.Y. 2004) (citing *Crocco v. Xerox Corp.,* 137 F.3d 105, 108 (2d Cir.1998)).

Here, ABC failed in two ways to provide full and fair review.

First, although it contains the following passage in its noncoverage decision, ABC fails to keep this promise; in fact, nobody at ABC with whom I have spoken even knows that this is a requirement or how it should be met. The ABC language is as follows:

> You may receive, upon request and free of charge, reasonable access to and copies of all documents, records and other information relevant to this request and an explanation of the scientific basis or clinical judgment that we relied upon in making our determination. This includes a copy of the internal rule, guideline, or protocol, if any, that we relied on in making the non-coverage decision for this request.

There is nothing wrong with this language; the problem is that ABC does not comply with requests pursuant to this language, as shown below.

Second, ABC states that coverage is denied because the device is experimental. However, ABC has not provided any information that would allow the claimant to understand why this case is different from others in which ABC has covered this same device.

B. ABC's Failure to Timely Respond to a Request for the Record Violates ERISA

As set forth above, ABC failed to respond to claimant's request for copies of the file upon which ABC relied.

"The core requirements of a full and fair review include 'knowing what evidence the decision-maker relied upon, having an opportunity to address the accuracy and reliability of that evidence, and having the decision-maker consider the evidence presented by both parties prior to reaching and rendering his decision.'" *White v. Airline Pilots Assoc Int'l*, No. 04 C 3307, 2005 WL 827001, *11-12 (N.D. Ill. Apr. 8, 2005) (citing *Brown v. Retirement Comm. of Briggs & Stratton Retirement Plan,* 797 F.2d 521, 534 (7th Cir.1986)). "'These requirements ensure that when a

claimant appeals a denial to the plan administrator, he will be able to address the determinative issues and have a fair chance to present his case." *Id.*

> To afford a plan participant whose claim has been denied a reasonable opportunity for full and fair review, the plan's fiduciary must consider any and all pertinent information reasonably available to him. The decision must be supported by substantial evidence. The fiduciary must notify the participant promptly, in writing and in language likely to be understood by laymen, that the claim has been denied with the specific reasons therefor. The fiduciary must also inform the participant of ***what evidence he relied upon*** and provide him with an opportunity to examine that evidence and to submit written comments or rebuttal documentary evidence. If the fiduciary allows third parties to appear personally, the same privilege must be extended to the participant.

Grossmuller v. Int'l Union, United Automobile Aerospace and Agricultural Implement Workers of America, 715 F.2d 853, 857-58 (3d Cir. 1983) (emphasis added). *See also Soron v. Liberty Life Assurance Co. of Boston*, 318 F.Supp.2d 19 (N.D.N.Y. 2004) (full and fair review requires that the fiduciary inform the claimant of the evidence the fiduciary relied on and an opportunity to submit comments and/or rebuttal).

Here (and in other ABC cases I am currently working on), ABC includes the above-quoted language in its noncoverage decision, but it does not respond to requests based on that language. ABC seems not even to be aware that this law exists. I wrote requesting a copy of Patient X's file on March 9. I called on April 19 and was told that the customer service representative would make sure my request was forwarded to the right person. I called again on May 2. First, I was told that something was mailed to me on March 31 (which I never received). Then, after asking to speak to a supervisor (Sally), I was told that a letter was sent to the patient on March 17 and then again on March 25. I informed Sally that neither I nor the insured every received any such correspondence, and she said that she would re-send it, which she did.

The March 25 letter from ABC said that ABC was in possession of my "grievance," and that corrective steps are needed. It then said that it would provide a certificate of coverage and quoted one sentence from the noncoverage letter. The certificate of coverage was not enclosed, and no other documents were provided. Laughably, I was referred to the Massachusetts Department of Public Health.

Upon receipt of this letter, I then called again on May 9, indicating that the correspondence did not include copies of documents ABC relied on. I spoke with someone named Alice, who said that a researcher would decide "what we can let out," and she would forwarded my letter to a researcher for response. I tried to explain to Alice that this is not what the law requires, but she was adamant.

I then received a telephone call from Joan Doe of the Massachusetts Department of Public Health, and she and I both tried to understand why ABC referred me to Massachusetts since nobody involved in this matter lives in Massachusetts. However, Ms. Doe was very helpful in that she provided me with the name of her ABC contact in regulatory affairs, John. I called John and he told me that he would get me the file. Next, he called and asked if I would like the file to be

faxed to me. I asked how large the file was since, typically, the file on one of these matters is roughly one-inch worth of paper. He ended up faxing me what he had, which was ABC's internal policy on the gastric pacemaker. I then called John and told him that I was entitled to copies of everything upon which ABC relied. He said he was sure they relied on everything that was submitted by or on behalf of Patient X. I explained again that they are required to send me EVERYTHING in their file.

On May 16, 2005, I finally got the documents I asked for on March 9. I have been told by the medical providers involved with this patient that what I received is *not* everything that was sent to ABC. Needless to say, in addition, this response was extraordinarily untimely.

As a matter of law, the claimant is entitled to know what records the insurer was relying on and what was excluded. Thus, when the insurer said that it had relied on all available records, the insured had every reason to believe that certain records related to his Social Security benefits were part of the record. *Harden v. American Express Financial Corp.*, 384 F.3d 498, 500 (8th Cir. 2004). The insurer's failure to either inform the insured that it was not relying on certain documents or to even obtain those records constituted a "serious procedural irregularity." *Id.* Thus, "although the insurer's decision would normally be subject to abuse-of-discretion review . . . we conclude that the district court should have applied a less deferential sliding-scale standard of review." *Id.* (citing *Shelton,* 285 F.3d at 642 (court may apply less deferential standard of review if plaintiff presents evidence demonstrating palpable conflict of interest or serious procedural irregularity that caused breach of plan administrator's fiduciary duty to plaintiff); *Woo v. Deluxe Corp.,* 144 F.3d 1157, 1161-62 (1998) (adopting sliding-scale standard of review where less deferential standard is appropriate)). *See also Cannon*, 219 F.R.D. at 214 ("Finding out just what information [the fiduciary] had and why it acted as it did depends upon the medical notes provided to it, the exchange of correspondence, and the recollections of oral conversations.") (citing *Doe v. Travelers,* 167 F.3d 53, 58 (1st Cir.1999)).

To this day, I am uncertain whether I am in possession of this entire file. If I have not received the entire file, then ABC has violated ERISA.

C. ABC's Noncoverage Decision Violates ERISA By Failing to State Reasons

"'ERISA and the Secretary of Labor's regulations under the Act require a 'full and fair' assessment of claims and clear communication to the claimant of the 'specific reasons' for benefit denial.'" *White v. Airline Pilots Assoc Int'l*, No. 04 C 3307, 2005 WL 827001, *10 (N.D. Ill. Apr. 8, 2005) (quoting *The Black & Decker Disability Plan v. Nord*, 538 U.S. 822, 830 (2003)).

> In general, ERISA and the Secretary of Labor's regulations under the Act requires that 'specific reasons for denial be communicated to the claimant and that the claimant be afforded an opportunity for 'full and fair review' by the administrator.' *Nord,* 538 U.S. at 825; *Halpin v. W.W. Grainger, Inc.,* 962 F.2d 685, 688 (7th Cir.1992); *see also Hawkins v. First Union Corp. Long-Term Disability Plan,* 326 F.3d 914, 919 (7th Cir.2003) (finding for the claimant despite the deference of the 'arbitrary and capricious' standard because there were mere "scraps" of evidence offsetting the conclusion that claimant was disabled); *Crespo v. Unum Life Ins. Co. of Am.,* 294 F.Supp.2d 980,

> 994 (N.D.Ill.2003) (finding that the insurance company's denial of claimant's claim was arbitrary and capricious because the review was neither full nor fair).

Id. at *11. "Thus, 'full and fair review' must be construed not only to allow a plan's trustees to operate claims procedures without the formality or limitations of adversarial proceedings but also to protect a plan participant from arbitrary or unprincipled decision-making." *Grossmuller v. Int'l Union, United Automobile Aerospace and Agricultural Implement Workers of America*, 715 F.2d 853, 857 (3d Cir. 1983).

> In the case of an adverse decision, a plan administrator
>
> has certain fiduciary duties to disclose to claimants materials [such as those described in the following parenthetical]. *See* 29 C.F.R. § 2560.503-1(g)(1)(A) (requiring claims administrators to include in a notification of an adverse benefit determination any 'internal rule, guideline, protocol, or other similar criterion [that] was relied upon in making the adverse determination, ... or a statement that such a rule, guideline, protocol, or other similar criterion was relied upon in making the adverse determination and that a copy of such rule, guideline, protocol, or other criterion will be provided free of charge to the claimant upon request').

Cannon v. UNUM Life Ins. Co. of America, 219 F.R.D. 211, 214 (D. Maine 2004).

For example, In *Nerys v. Building Service 32BB-J Health Fund*,[88] the plaintiff was denied disability benefits due to an injury to his knee. Plaintiff submitted numerous reports from physicians, and the defendant had him examined by a number of independent medical examiners.[89] The court found that the arbitrary and capricious standard of review applied because of discretion given to the Trustees.[90] In reviewing the medical evidence, the court rejected most of plaintiff's arguments, finding that acceptance of the opinion of some doctors and not others did not render the decision arbitrary and capricious.[91]

However, the court agreed with the plaintiff's claim that he was denied full and fair review. The court first stated the rule that "[a]n administrator's decision to deny a plan participant's claim for disability benefits is arbitrary and capricious if it is made in the absence of a 'full and fair review' . . . ." [92] The court found that the first letter denying benefits was insufficient in a number of respects. First, it did not explain the reason for the adverse determination, stating only that plaintiff did not qualify under the definition of "disability."[93] Second, the subsequent denial letter did not either describe the material or information needed to perfect plaintiff's claim or an explanation of why that information was needed.[94] Third, the Trustees did not

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[88] *Id.*
[89] *Id.* at *3.
[90] *Id.* at *5.
[91] *Id.* at *6.
[92] *Id.* at *8.
[93] *Id.*
[94] *Id.*

indicate what evidence they considered or how the evidence was assessed.[95] Because of these defects, the court concluded that the Trustees had not undertaken a "full and fair review" of the claim and, thus, their determination was arbitrary and capricious.

Here, it appears that ABC did not ask for any detailed medical records – unless, of course, ABC still hasn't provided me with its entire file. However, the denial letter states only one reason:

> For a service to be covered under the plan, it must be recognized as safe and effective for the diagnosis or treatment of a specified condition according to clinical evidence published in peer reviewed medical literature. Our clinical staff reviewed the submitted information. We determined that the Gastric Pacemaker is not considered a covered health service due to inadequate clinical evidence of safety and/or effectiveness in published, peer-reviewed literature for the treatment of the documented diagnosis. As a result, the proposed Gastric Pacemaker is considered unproven and is not eligible for benefits under the plan.

This could be said to any patient whose doctor wishes to insert a gastric pacemaker. It does not tell us what literature and/or medical records were reviewed. In fact, we know for a fact that ABC covers the cost of gastric pacemakers in some cases. I represent a patient in another matter who has a gastric pacemaker that was paid for by ABC. There is nothing in the denial letter that tells us why this case is different from any other case in which this device is covered – no reference to the medical condition that might make a gastric pacemaker more risky or more unfounded by the medical literature. In short, we have no idea at all what we need to address in order to succeed in this appeal. Thus, in this case, the purpose of requiring a statement of reasons is not met and the denial is lacking because it is not a "full and fair review."

II. THE NEED FOR ENTERRA THERAPY IS DIRE

Ms. Patient will die without this treatment. Ms. Patient suffers from severe bouts of nausea and vomiting secondary to gastroparesis – so severe that his physician has seen him on house calls because he was too ill to leave his home. Ms. Patient is diabetic, so this vomiting makes it impossible for him to control his diabetes – a problem that is life-threatening.

Health America's records of claims and payments would verify the frequency of Ms. Patient's hospitalizations and emergency room visits, which are becoming increasingly frequent. For example, Ms. Patient was hospitalized from February 21 to 27, 2007, and has made several trips to the emergency room between that date and today. In fact, he was in the emergency room the day before we filed our last appeal, April 25. He was admitted to the hospital three times in the last two months of 2006 for nausea, vomiting and dehydration. He has been to the emergency room several times since we last filed an appeal, as well.

We are not updating the medical records here because Ms. Patient is so sick; his father called me in tears to tell me that Patient will not live the 45 days we had to

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[95] *Id.* at *9.

file this appeal, so we are filing it immediately. However, Health America has all records of all hospitalizations in the form of claims and can verify that he is treated in the emergency room with great frequency.

Ms. Patient has endured "dozens" of hospital emergency visits and admissions (see enclosed chart), has been evaluated by several gastroenterologists, has undergone a full work-up, and the only abnormality is a "prominently delayed" gastric emptying, as shown by a November 15, 2006 gastric emptying study that showed that only .9% of the material had cleared his stomach after 60 minutes. Ms. Patient lost 30 pounds from November 2005 to March 2007.

Ms. Patient has tried Phenergan, Protonix, Reglan, Zelnorm, Nexium, and Zofran without relief. He also has tried Botox injections into the pylorus. He vomits roughly 7 times per day.

Ms. Patient's life depends on finding a treatment for his nausea and vomiting. Documents enclosed show glucose levels of 248 in February 2007; 172 in December 2006; and 305 in November 2006. The only treatment calculated to provide relief in a diabetic patient who is drug refractory is Enterra Therapy.

Finally, Ms. Patient's primary care physician, Dr. Dunn, has noted in the chart that he has told Health America that it "may be responsible if he ends his life because of this." (4/19/07 notes). Ms. Patient's desperation is palpable. He cannot continue to live with the kind of pain he has chronically, along with his nausea and vomiting.

Thus, Health America should reconsider and cover this life-saving treatment. Failure to do so is a death sentence for Patient.

III. ENTERRA THERAPY IS NOT EXPERIMENTAL, INVESTIGATIONAL OR UNPROVEN

It is important to be very clear about what this treatment is supposed to do. It is not a cure for gastroparesis, so to say that it is investigational for treating gastroparesis misses the point. Gastric electrical stimulation is designed to treat the nausea and vomiting secondary to gastroparesis, not the gastroparesis itself.

Gastric electrical stimulation (GES) is a medically accepted method of treatment for nausea and vomiting secondary to idiopathic or diabetic gastroparesis. On March 31, 2000, the Center for Devices and Radiologic Health (CDRH) of the FDA granted a Humanitarian Device Exception ("HDE") for Enterra Therapy. Letter from FDA to Medtronic granting HDE (March 31, 2000).[96] The FDA states that "[t]his device is indicated for the treatment of chronic, intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology." This – not treatment or cure of gastroparesis – is the intended use of Enterra Therapy. The CDRH does not grant a HDE without a finding that the benefits of the therapy exceed the risk, and the medical rationale for the use of the device is sound. 21 U.S.C. § 360j. The medical literature supports the FDA's finding.

Since that time, there have been **24 studies of 825 patients** who have received this device. H.C. Gonzalez, V. Velanovich, "Enterra Therapy: gastric

[96] All documents referred to herein are enclosed.

neurostimulator for gastroparesis," *Expert Rev Med Devices* 7(3), (2010). Not only have these studies documented improvement in nausea and vomiting, but they also show that GES reduces the need for prokinetics and anti-emetics. 76% of patients were able to discontinue enteral or parenteral feedings. In sum, "available publications suggest that high-frequency GES improves nausea, vomiting, quality of life, glycemic control, nutritional support and gastric emptying." Thus, the scientific literature fully supports the use of Enterra therapy when all other treatments have been exhausted, as in this case.

The seminal randomized controlled double-blind crossover study involving 33 patients demonstrated a statistically significant reduction in frequency of vomiting and improved quality of life in patients with intractable gastroparesis, and then additional results confirming these outcomes. Abell, et al., "Gastric Electrical Stimulation for Medically Refractory Gastroparesis," 125 *Gastroenterology* 421 (Aug. 2003). Long-term follow-up data confirmed improvement by short term, intermediate, and long-term measures with follow up to five years. Abell, et al., "Gastric Electrical Stimulation for Gastroparesis Improves Nutritional Parameters at Short, Intermediate, and Long-Term Follow-up," 27 *Journal of Parenteral and Enteral Nutrition* 277 (2003).

Researchers at several centers have been conducting trials for a decade to test the effects of Enterra Therapy, and several articles have been published in peer-reviewed medical journals. A recent randomized study demonstrated that patients receiving Enterra Therapy experienced a significant decrease in vomiting after twelve months of treatment. McCallum, et al., "Gastric Electrical Stimulation with Enterra Improves Symptoms from Diabetic Gastroparesis in a Prospective Study." *Clinical Gastroenterology and Hepatology*, 2009; doi: 10.1016/j.cgh.2010.05.020. The results of the study also showed that patients also experienced significant improvements in total symptom score, gastric emptying, quality of life, and median days in the hospital.

A similar 2008 study showed reduction in the severity of gastroparetic symptoms in all patients who received GES Therapy. Brody, et al., "Gastric Electrical Stimulation for Gastroparesis," 207(4) *J. Am. Coll. Surg.* 533-38 (Oct. 2008). In this study, fifty gastroparetic patients had the Enterra device implanted and six-month results showed improvement in symptoms that was sustained at twelve months. *Ibid.*

In one of the early studies, researchers found that the severity and frequency of nausea and vomiting was significantly improved at three months and sustained at twelve months. Forster, et al., "Gastric Pacing is a New Surgical Treatment for Gastroparesis," 182 *American Journal of Surgery* 676 (Dec. 2001). Subsequently, a multi-center clinical trial demonstrated an 80% diminution in nausea and vomiting for 97% of the subjects. Additionally, these results were corroborated by an average weight gain of 5.5% at one year. Abell, et al., "Gastric Electrical Stimulation in Intractable Symptomatic Gastroparesis," 66 *Digestion* 204 (Aug. 2002). Long-term follow-up data confirmed improvement by short term, intermediate, and long-term measures with follow up to five years. Abell, et al., "Gastric Electrical Stimulation for Gastroparesis Improves Nutritional Parameters at Short, Intermediate, and Long-Term Follow-up," 27 *Journal of Parenteral and Enteral Nutrition* 277 (2003).

In April 2006, the leading experts in the treatment of gastroparesis published a review of all of the literature relating to that treatment. This document contains

"areas developed by consensus agreement where clinical research trials remain lacking . . . ." Abell, et al., "Treatment of gastroparesis: a multidisciplinary clinical review," 18 *Neurogastroenterol Motil* 263-283 (2006). This review was performed by gastroenterologists, nutritionists, diabetologists, surgeons, pain management and psychology experts all of whom care for gastroparetics. These "consensus opinions were formulated by the authors to facilitate management" of gastroparesis. The consensus opinion regarding gastric electrical stimulation concluded that studies show that roughly three-quarters of patients implanted with Enterra Therapy had reductions in nausea and vomiting and did not need further surgery or other invasive treatment of their gastroparesis. In the only sham-stimulation study, a statistically significant number of patients had less vomiting, and patients preferred the ON status to the OFF status by a "threefold margin." In the open phase of this study, patients reported a 76% reduction in vomiting at 12 months. The consensus found that in several other studies, Enterra Therapy "has been reported to improve nutritional status, limit the need for prokinetic and antiemetic medications, reduce the need for supplemental nutrition, decrease health-related costs" and improve the condition of diabetic gastroparetic patients. One study shows 26% reduction in nausea and 44% reduction in vomiting persisting for up to 10 years after implantation. The consensus found the research to be "encouraging."

In addition, there have been several reviews of the medical literature. Recently, Expert Reviews evaluated the effectiveness of Enterra Therapy, based on a review of all studies testing its effectiveness, stating that "[c]ertainly, in the patient with persistent quality-of-life-limiting symptoms, the clinician should consider Enterra Therapy." Gonzalez and Velanovich, "Enterra Therapy: gastric neurostimulator for gastroparesis," *Expert Rev. Med Devices* 2010; 7(3): 319-32, 329. The authors explained how debilitating gastroparesis can be and noted that dietary instruction, behavioral modification, and medication often do not end suffering. Then they asserted, "[t]he fact that Enterra Therapy provides a modicum of relief to this group of patients who are at the 'end of the rope' speaks volumes for its effectiveness." *Ibid.* When medication does not improve the limiting symptoms of gastroparesis, GES has been shown to improve quality of life and gastroparetic symptoms for over five years. Reddymasu, et al., "Severe Gastroparesis: Medical Therapy or Gastric Electrical Stimulation." *Clinical Gastroenterology and Hepatology* 2010 February; 8(2): 117-24. For clinical use, Enterra is the only system currently available to improve gastroparetic symptoms. *Ibid.* In the last ten years, more than 4,000 patients in the United States have had the device placed. *Ibid.*

In 2009, a review of diagnostic and treatment tools for gastroparesis summarized the medical literature, stating that "[m]ultiple uncontrolled studies in diabetic, idiopathic and post-surgical gastroparesis have shown efficacy of GES." Waseem, et al., "Gastroparesis: Current diagnostic challenges and management considerations," *World J Gastroenterol* 2009 January 7; 15(1): 25-37. This article reports the results of several studies that demonstrate "long-term symptom benefits, which may persist for at least 10 years with improvements in body mass index, serum albumin, and glycemic control."

In 2007, two more surveys of the pertinent studies were published, each concluding that GES is effective in reducing the severity of gastroparetic symptoms. Abrahamsson, "Severe gastroparesis: new treatment alternatives," 21(4) *Best Pract. Res. Clin. Gastroenterol.* 645-55 (2007); Maranki and Parkman, "Gastric Electric Stimulation for the Treatment of Gastroparesis," 9(4) *Curr. Gastroenterol Rep.* 286-94 (Aug. 2007). Both of these surveys concluded that the studies demonstrated an

improvement in patients' nutritional status, need for prokinetic and antiemetic medications, and HbA1c values in diabetic patients. Maranki, *supra*, at 289. Further, the need for tube feeding and gastric surgery decreased. Abrahamsson, *supra*, at 650.

A 2006 study showed that GES greatly decreased symptoms and hospitalizations for as long as three years. Lin, et al., "Symptom responses, long-term outcomes and adverse events beyond 3 years of high-frequency gastric electrical stimulation for gastroparesis," 18 *Neurogastroenterol Motil* 18-27 (2006). Yet another study conducted at USC Los Angeles showed that Enterra Therapy returned patients to normal oral nutritional intake, increased body mass index, and improved gastric emptying rates. Mason, et al., "Gastric Electrical Stimulation: An Alternative Surgical Therapy for Patients with Gastroparesis," 140 *Arch Surg* 841 (Sept. 2005).

In 2005, a group of German researchers reported the results of a prospective single center study in which improved metabolic control in subjects with diabetic gastroparesis was demonstrated by reduced HbA1c levels in patients being managed with GES. van der Voort, et al., "Gastric Electrical Stimulation Results in Improved Metabolic Control in Diabetic Patients Suffering from Gastroparesis," *113 Exp Clinc Endocrinol Diabetes* 38 (2005). Around the same time, a retrospective series demonstrated the long-term improvement of upper GI symptoms, nutritional status, glucose control, and reduced number of hospitalizations. Lin, et al., "Treatment of Diabetic Gastroparesis by High-Frequency Gastric Electrical Stimulation," 27 *Diabetes Care* 1071 (May 2004). The same investigators then went on in a retrospective study to demonstrate a statistically significant reduction in the use of prokinetic/antiemetic medications. Cutts, et al., Is gastric electrical stimulation superior to standard pharmacologic therapy in improving GI symptoms, healthcare resources, and long-term healthcare benefits?" 17 *Neurogastroenterol Motil* 35 (2005). The conclusions of these studies were affirmed by a 2008 retrospective series that included studies completed between 2005 and 2008. McKenna, et al., "Gastric Electrical Stimulation is an effective and safe treatment for medically refractory gastroparesis," 144(4) *Surgery* 566-574 (Oct. 2008). That study concluded that "GES is the procedure of choice for patients with medically refractory gastroparesis symptoms." *Ibid*. at 571.

Finally, a study comparing GES to traditional pharmacological therapy showed that GES results in both improved GI symptoms and decreased costs. Cutts, et al., Is gastric electrical stimulation superior to standard pharmacologic therapy in improving GI symptoms, healthcare resources, and long-term healthcare benefits?" 17 *Neurogastroenterol Motil* 35 (2005). Similarly, GES has proven to enhance quality of life and lessen adverse symptoms. Velanovich, "Quality of Life and Symptomatic Response to Gastric Neurostimulation for Gastroparesis," *J. Gastroinest.Surg*. (2008).

In short, the medical literature strongly supports the use of Enterra Therapy to treat nausea and vomiting secondary to gastroparesis.

In addition, Enterra Therapy is becoming the standard of care for nausea and vomiting secondary to gastroparesis. We enclose medical policies from several large insurers that recognize that Enterra Therapy is medically necessary in cases in which nausea and vomiting secondary to gastroparesis is refractory to drug therapies and is resulting in serious nutritional deficiencies, as is the case here. Furthermore, we

enclose a Medicare bulletin listing all of the many insurance companies that have covered Enterra Therapy, along with decisions from both internal and external reviewers that show that Enterra is being approved on a nearly routine basis. United Healthcare's Technology Assessment dated December 18, 2008 reflects a finding that Enterra Therapy now is "proven," after years in which it previously considered the device to be investigational. Note that the number of external appeals approving this device grows almost weekly; independent reviewers are stating over and over that Enterra no longer can be treated as experimental or investigational, and that coverage must be granted. (*See, e.g.*, MCMC external reviews under General Motors benefit plan; U.S. Office of Personnel Management overruling of Mail Handlers Benefit Plan). The Blue Cross corporate policy is the only large-insurer medical policy that has not caught up with the times – and even many Blue Cross's around the country are making exceptions in cases in which it is very clear that GES not only is medically necessary, but – as here – is the only medical treatment that has alleviated the patient's symptoms.

Thus, all of the materials submitted herewith, including much of the medical literature, weighs in favor of finding that Enterra Therapy is a medically accepted treatment for the nausea and vomiting secondary to gastroparesis.

IV. Conclusion

I have attempted to provide a thorough and accurate review of this file, and have included medical information that, it appears, you were not provided earlier in the process. Of course, if you would like any additional information, or would like to discuss this matter, I am at your disposal.

Thank you.

Sincerely,

Jennifer C. Jaff

E. Off-Label Use – Medicare

January 10, 2007

OMHA Mid-West Field Office
BP Tower
Suite 1300
200 Public Square
Cleveland, OH 44114-2316

RE: Patient X
Treatment: Actiq
Appeal no.
Part D Plan: Humana

Dear Sir or Madam:

I am writing on behalf of Medicare enrollee Patient X. My Appointment of Representative and HIPAA release and authorization are enclosed. We ask that the undersigned be permitted to represent the enrollee in this hearing, and that the hearing be held by telephone so that the undersigned may participate from her office in Connecticut rather than from the enrollee's home in Louisiana.

Ms. X wishes to appeal the denial of coverage of Actiq on the ground that a government program is not permitted to refuse to cover a medication simply because it is approved by the FDA for some other use, but not the use for which it has been prescribed. Both the Medicare drug benefit provider (Humana) and Maximus Federal Services have stated that federal law precludes Medicare coverage of drugs that are not FDA approved for the intended use. This is a misreading of the law.[97]

Before commencing the legal analysis, though, it is important to note that Ms. X's Actiq was covered by her health insurance plan before she was compelled to participate in Medicare Part D. This is an instance in which a patient is far worse off with Medicare than with commercially available health insurance. In this case in particular, Ms. X has been using Actiq to control her pain for an extended period of time, and because it is addictive, she cannot stop using it "cold turkey" without, at the very least, some period of time in which to withdraw from Actiq. Medicare's flat denial of coverage creates a serious risk to Ms. X's health because it fails to recognize the harmful effects of drug withdrawal, especially when there is no other medication available under Medicare with which to replace Actiq.[98]

In addition, it is important to note at the outset that Ms. X suffers from Crohn's disease, which precludes the use of many of the more routine pain medications, which aggravate the digestive track. Thus, her pain management resources are limited. Further, her doctor, Dr. Zakem, has submitted a letter that is in Medicare's file that states that Actiq is the only pain medication that Ms. X can take that does not cause her to sleep all the time if taken in a sufficient dose to control her pain. Actiq comes in the form of a lollipop, which can be used by the patient as much or as little as needed, and which provides fast relief.

Now, to the law.

In *Weaver v. Reagen*, 886 F.2d 194, 197 (8th Cir. 1989), the court explained that, if prescription drugs are covered by a government entitlement program, the government cannot irrationally limit the scope of that coverage. The court found

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[97] Please note that Ms. X also sought an exception from Humana and Maximus, in addition to appealing the noncoverage decision. She sought the exception in recognition of the fact that Actiq is not on Humana's formulary. It does not appear that either Humana or Maximus responded to this request for exception; Maximus merely noted that Actiq is not on Humana's formulary.

[98] Ms. X has continued to use Actiq pending a final decision on her appeal. She has been paying for it personally. She is unable to continue to do so ad infinitum due to the cost. In the absence of an alternative treatment of her pain from fibromyalgia and Crohn's disease, and in light of the addictive nature of Actiq, which precludes stopping the drug "cold turkey," Medicare has left Ms. X with no option other than paying for the drug herself in the hope that her appeal ultimately will succeed.

that "FDA approved indications were not intended to limit or interfere with the practice of medicine nor to preclude physicians from using their best judgment in the interest of the patient." *Id.* at 198. The court quoted the text of an FDA bulletin as follows:

> The appropriateness or the legality of prescribing approved drugs for uses not included in their official labeling is sometimes a cause of concern and confusion among practitioners. Under the Federal Food, Drug, and Cosmetic (FD&C) Act, a drug approved for marketing may be labeled, promoted, and advertised by the manufacturer only for those uses for which the drug's safety and effectiveness have been established and which the FDA has approved. These are commonly referred to as the "approved uses." This means that adequate and well-controlled clinical trials have documented these uses, and the results of the trials have been reviewed and approved by the FDA.
>
> The FD&C Act does not, however, limit the manner in which a physician may use an approved drug. Once a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling. Such "unapproved" or, more precisely, "unlabeled" uses may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature.
>
> The term "unapproved uses" is, to some extent, misleading. It includes a variety of situations ranging from unstudied to thoroughly investigated drug uses. Valid new uses for drugs already on the market are often first discovered through serendipitous observations and therapeutic innovations, subsequently confirmed by well-planned and executed clinical investigations. Before such advances can be added to the approved labeling, however, data substantiating the effectiveness of a new use or regimen must be submitted by the manufacture to the FDA for evaluation. This may take time and, without the initiative of the drug manufacturer whose product is involved, may never occur. For that reason, accepted medical practice often includes drug use that is not reflected in approved drug labeling.
>
> With respect to its role in medical practice, the package insert is informational only. FDA tries to assure that prescription drug information in the package insert accurately and fully reflects the data on safety and effectiveness on which drug approval is based.

FDA Drug Bulletin: Information of Importance To Physicians and Other Health Professionals, April 1982, Volume 12 Number 1, Pages 4-5.

Based on this policy guidance, the court found "the fact that FDA has not approved labeling of a drug for a particular use does not necessarily bear on those uses of the drug that are established within the medical and scientific community as medically appropriate." 886 F.2d at 198. Thus, the court concluded that Medicaid could not limit the use of a drug to FDA approved indications.

Contrary to Medicare's analysis, there is nothing in the statutes and regulations governing the Medicare Part D benefit that precludes coverage for "unapproved" or "off-label" uses or otherwise distinguishes Medicare from the logical reach of *Weaver*. Medicare covers FDA approved drugs or drugs that are identical to such drugs and for which there is a compelling justification for its medical need. 42 U.S.C. § 1396r-8(k)(2)(A). Identical, related or similar drugs are defined as drugs of other "forms . . . of the same drug moiety. . . ." 21 C.F.R. § 310.6(b)(1). Here, there is no question that the active ingredient in Actiq – Fentanyl – is FDA approved for general use in controlling pain in the forms of a patch, an intravenously induced drug, and now in the oral form under the name Actiq. (See below).

In fact, the governing Medicare statute says nothing about *uses* of FDA approved drugs. The statute literally requires that the drug be one "which is approved for safety and effectiveness of a prescription drug . . . ." 42 U.S.C. § 1396r-8(k)(2)(A)(i). Here, there is no question that Actiq is FDA approved. The issue is whether Medicare must cover it as such, regardless of the use for which it is being prescribed. There is nothing in the law to preclude this reading of the statute.

In fact, under the FDA's policy guidance, set forth in full above, there is no question that Actiq may be prescribed for off-label uses – and that such prescribing is occurring. There is substantial medical literature holding that Actiq is effective and being used to treat many kinds of pain. In Webster, et al., "Oral Transmucosal Fentanyl Citrate Use in Chronic Noncancer Pain: A Retrospective Survey," several pain management experts reviewed the noncancer uses of Actiq, including back pain, figromyalgia, multiple sclerosis, sickle cell, pelvic and renal pain, and headaches. The authors of this study find that oral transmucosal fentanyl citrate – Actiq – was useful in the management of chronic noncancer pain disorders. This study covered 100 patients. The references listed in this paper are published in peer-reviewed journals. The authors list several published articles that discuss the use of Actiq in treating postoperative pain, burn wound care, migraine headaches, rheumatoid arthritis, and generalized chronic pain.

Also submitted to Medicare are copies of published articles that address the use of Actiq in treating migraine headaches, Landy, et al., "Oral transmucosal fentanyl citrate for the treatment of migraine headache pain in outpatients: a case series," *Headache*, 2004 Sep; 44(8): 762-6; and sickle cell pain. Shaiova, et al., "Outpatient management of sickle cell pain with chronic opioid pharmacotherapy," *J. Nat'l Med Assoc*. 2004 Jul; 96(7): 984-6. See also Stein, "Oral Transmucosal Fentayl Citrate Helps Migraineurs Avoid Emergency Room: Presented at AAPM," *DG Dispatch* (Feb. 21, 2003). The use of Actiq to control noncancer pain is so widely recognized that even various websites state that "Actiq may be used for purposes other than those listed in this medicine guide." http://www.drugs.com/actiq.html (last accessed 9/29/2006). See also Lichtor, et al., "The Relative Potency of Oral Transmucosal Fentanyl Citrate Compared with Intravenous Morphine in the Treatment of Moderate to Severe Postoperative Pain," *Anesth Analg* 1999; 89: 732-8; Sharar, et al., "A Comparison of Oral Tranasmucosal Fentanyl Citrate and Oral Hydromorphone for Inpatient Pediatric Burn Wound Care Analgesia," *J Burn Care Rehabil* 1998: 19; 516-21.

This should not be surprising because the use of Fentanyl and Fentanyl citrate to treat all types of chronic pain is widely accepted, and Actiq is simply an oral, transmucosal version of these active ingredients. Fentanyl citrate – exactly the same drug as Actiq – is used in injectable form "for analgesic action of short duration

during anesthetic periods, premedication, induction and maintenance, and in the immediate postoperative period (recovery room) as the need arises." (Fentanyl citrate labeling). Of course, Fentanyl is widely used in opioid-tolerant patients for both anesthesia and analgesia. The Duragesic patch is the most common form of Fentanyl, and is used to treat all manner of chronic pain. Actiq is an oral, transmucosal version of Fentanyl and, as such, its use beyond treatment of cancer patients should be unsurprising.

It is generally accepted that "Actiq . . . is also useful for breakthrough pain for those suffering bone injuries, severe back pain, neuropathy, arthritis, and some other examples of chronic nonmalignant pain." http://en.wikipedia.org/wiki/Fentanyl (last accessed on 9/29/2006). Thus, regardless of the FDA labeling, there is nothing preventing or precluding the responsible and safe use of Actiq to treat noncancer pain.

Thus, according to the FDA's own guidance about how to interpret FDA approval, the fact that Actiq is FDA approved only to treat noncancer pain should not preclude its prescription and use because "[i]n the face of widespread recognition by the medical community and the scientific and medical literature" that Actiq is effective in controlling noncancer pain, Humana may not "rely on the FDA approval process in a manner expressly rejected by the FDA." *Weaver v. Reagen*, 886 F.2d at 200. As a matter of law, Medicare cannot refuse to cover a medication based on its FDA labeling when the FDA itself says that FDA labeling should not be used in this manner.

The records submitted to Medicare, as acknowledge in the Maximus decision, contained a letter from Ms. X's treating physician indicating that he has tried Ms. X on other pain medications, which have not been suitable or effective. In fact, Ms. X has tried a Fentanyl patch, but it puts her to sleep when used in a dosage sufficient to treat her pain. Because Actiq allows the patient to titrate dosage quite easily, by using the lollipops only when needed, only for as long as needed, it provides advantages that are not found with other pain medications.

Thus, this appeal should be granted in this case because Ms. X's Crohn's disease precludes the use of anti-inflammatory pain medication, and other narcotics have not been sufficient to maintain Ms. X in a functioning capacity, out of bed. In the alternative, the FDA itself has said that its labeling should not be used to limit prescription or use of drugs. Under either analysis, Medicare should cover the cost of Actiq.

Of course, if you would like any additional information, please let me know.

Sincerely,

Jennifer C. Jaff

F. Off-Label Use - Insurance

June 6, 2011

New York State Insurance Department
PO Box 7209
Albany, NY 12224-0209

RE: Patient Patient
ABC Insurance Life Ins. Co.
ID no. W18586341702
Service: Rifaximin (Xifaxan)
Date of service: To be determined (prior authorization)

Dear Sir/Madam:

I am writing on behalf of Patient Patient to initiate an external appeal from ABC Insurance's noncoverage decision of rifaximin (Xifaxan). Enclosed is the New York State External Appeal Application, a check for $50 made out to ABC Insurance, and a copy of the final adverse decision.

ABC Insurance blindly followed the FDA labeling for Xifaxan in denying coverage rather than considering the standard of care in an evidence-based manner. As is set forth herein, Xifaxan is quite commonly used to treat Crohn's disease, again, when other antibiotics, including Flagyl, are ineffective. If ABC Insurance reviewed the medical literature beyond the FDA labeling, it would agree – as most insurers do – to cover Xifaxan in a case like this, in which it is medically necessary.

Indeed, before ABC Insurance was her insurer, Ms. Patient was on Xifaxan and it was covered by her previous insurance. It should be covered by ABC Insurance, as well. With Xifaxan, Ms. Patient has one or two formed stools per day. Without it, she has eight or more loose stools each day, sometimes with blood, and requires a complex and far more expensive medication regimen. Thus, not only is coverage in Ms. Patient's interest, but it also is in ABC Insurance's. The noncoverage decision should be reversed.

I. Ms. Patient Has Crohn's Disease That Is Not Responsive To Other Antibiotics

Ms. Patient has had Crohn's disease for 17 years. (1/24/2011 Dr. Smithline letter to Dr. Inamdar). A January 24, 2011 colonoscopy showed moderate ileitis at the terminal ileum and a stricture at 10-12 cm, "elephant ears" in the perianal area, and a partial fistula perianally, as well. *Ibid*. Thus, there is no question about her diagnoses.

Before she began taking Xifaxan, Ms. Patient was taking 12 Asacol per day, Proctofoam, "local steroids." (6/3/2009 Dr. Smithline office note). Previously, she had also taken "Remicade, 6MP, Steroid, ASA drugs and even courses of antibiotics for her symptoms." *Ibid*. Ms. Patient wished to withhold escalating to more aggressive treatment at the time because she was pregnant, although her C-reactive protein was 31 and her SED rate (ESR) was 54, which was evidence of inflammation. (6/3/2009 Lab Report).

However, she became more symptomatic. She reported that she had been on Flagyl beginning on May 21, 2009 for 10 days, after which she was better, but then her symptoms returned. She then went on Vancomycin, Flagyl, and Florastor (probiotic). However, her symptoms returned. At that time, she again went on Flagyl and Florastor, with some alleviation of symptoms, but aggravation of her Crohn's disease. (8/7/2009 Dr. Street office note).

Ms. Patient saw Dr. Street again on September 24, 2009, she was having bloody stools due to her Crohn's disease. Dr. Street discussed treatment options with Dr. Smithline, and they agreed to restart Vancomycin 125 mg and start Xifaxan at 200 mg tid "maybe indefinite [sic]." (Dr. Street 9/24/2009 office note).

By February 4, 2010, Ms. Patient had tapered to a low dose of Vancomycin in the previous week, and had been on Xifaxan consistently since the previous September. As a result, she was only moving her bowels once or twice per day. Her stools were formed. Although a stool sample showed that she was then negative for c-diff, Dr. Street continued Xifaxan "indefinitely." (2/4/2010 Dr. Street office note).

However, as stated above, on January 24, 2011, Ms. Patient again had an escalation of her symptoms. Dr. Street increased her dosage of Xifaxan to 550 mg bid. (2/1/2011 Dr. Street phone note; 2/11/2011 Dr. Street office note). Once again, it has controlled her symptoms.

Thus, Ms. Patient tried both Flagyl and Vancomycin before starting Xifaxan. She also tried Remicade, 5-ASA's, and steroids to treat her Crohn's disease. "Xifaxan is the only drug that has decreased the frequency of her Crohn's symptoms. It is vital that she continue to receive Xifaxan indefinitely . . . ." (5/20/2011 Dr. Street letter to ABC Insurance).

It is unusual for a patient with a long history of symptomatic Crohn's disease to have only one to two formed stools per day for extended periods while on only one medication. Indeed, Ms. Patient's Crohn's has been symptomatic on and off for many years. A June 2, 2003 colonoscopy showed disease from the terminal ileum with patchy disease all the way to the rectum, with deep linear ulcerations in the terminal ileum. (6/2/2003 Colonoscopy report). Going back to 2003, Ms. Patient was severely anemic. (10/13/2003, 8/20/2003, 5/28/2003, 5/16/2003, 5/15/2003, 4/4/2003, 3/30/2003, 3/28/2003, 3/15/2003, 2/20/2003 labs). She previously had been on 6MP, Flagyl, amoxicillin, Pentasa, all of which were of no benefit. (3/25/2004 Dr. Wolke office note). She began Remicade in April 2003 and was on it every seven or eight weeks through 2004. *Ibid.* (See also infusion chart notes). However, she still was having 6 to 8 bowel movements per day. (8/23/2004 Dr. Wolke office note).

By October 18, 2004, she was having four loose stools per day without bleeding on Remicade. (10/18/2004 Dr. Scudera office note). She wanted to stop treatment so that she could get pregnant. Thus, she had one more infusion in November 2004 and then stopped. (1/14/2005 Dr. Scudera office note). Because Dr. Scudera was concerned about her stopping all treatment, he prescribed Asacol 400 mg tid. (12/1/2004 Dr. Scudera office note). In January 2005, she was in clinical remission. (1/14/2005 Dr. Scudera office note).

However, several months later, she developed anal pain, and Dr. Scudera diagnosed an anal fissure and directed Ms. Patient to increase her Asacol.

(10/21/2005 Dr. Scudera office note). She remained in clinical remission after she became pregnant, although she continued on Asacol. (1/19/2006 Dr. Scudera office note).

Unfortunately, in the 32nd week of her pregnancy, she developed rectal pain and bleeding and swelling of her perianal tags. (5/30/2006 Dr. Scudera office note). Finding only perianal disease, Dr. Scudera prescribed Flagyl and Xylocaine, and again increased her Asacol. *Ibid.* She was stable thereafter, but a January 5, 2007 colonoscopy showed evidence of Crohn's colitis, with shallow ulcerations at the terminal ileum. (1/5/2007 Dr. Scudera Colonoscopy Report).

Thus, as is the case with most Crohn's patients, the flares have waxed and waned over the years. Were it for not the fact that Xifaxan has controlled the Crohn's, Ms. Patient would have started Humira by now, and it may not have been as effective as Xifaxan.

In sum, Xifaxan has had a remarkable effect on her Crohn's. Although she did well on Remicade for the Crohn's in the past, neither it nor Asacol would control both the Crohn's. There simply cannot be any question that Xifaxan has had the most beneficial effects on Ms. Patient's conditions. It is, therefore, medically necessary.

II. Xifaxan Is the Standard of Care for Treating Antibiotic Resistant Crohn's Disease

The medical literature shows that rifaximin has been shown to not only induce clinical remission in Crohn's disease patients, such as Ms. Patient, but also to maintain clinical remission. The medical literature supports what Ms. Patient's experience already has demonstrated – that rifaximin is an effective treatment for Crohn's disease.

Although rifaximin (Xifaxan) currently is FDA-approved only for traveler's diarrhea and hepatic encephalopathy, it has been "establishing an indication in the management of CD [Crohn's Disease]," for many years now. Day and Gearry, "Rifaximin and Crohn's Disease: A New Solution to an Old Problem?" *Dig. Dis. Sci.* 2010;55(4):877-9 (editorial). For example, a randomized, double-blinded, placebo-controlled trial of 79 patients with mild-to-moderate Crohn's disease found that rifaximin, at a dose of 800 mg twice per day, was superior to placebo in inducing clinical remission in active Crohn's disease. Prantera, et al., "Antibiotic treatment of Crohn's disease: results of a multicenter, double blind, randomized, placebo-controlled trial with rifaximin," *Aliment. Pharmacol. Ther.* 2006;23:1117-1125. In this study, patients received either 800 mg of rifaxmin twice per day, once per day, or placebo for twelve weeks. *Ibid.* Clinical remission, which was defined by a Crohn's Disease Activity Index[99] of less than or equal to 150, was achieved by fifty-two percent of the patients who received rifaximin twice per day, in comparison to thirty-two percent and thirty-three percent in the patients who received rifaximin once a day or the placebo, respectively. *Ibid.* Moreover, the number of treatment failures in the placebo group was significantly higher than those in the rifaximin 800

[99] The Crohn's Disease Activity Index (CDAI) is the tool used to quantify Crohn's disease patients' symptoms. Generally, a CDAI score between 200 and 400 is an indication of active Crohn's disease.

mg twice per day group. *Ibid.* Notably, the patients who responded the best to rifaximin twice per day were those with elevated C reactive protein[100] values. *Ibid.* In this group of forty-six patients – those with elevated CRP values – sixty-three percent of the patients were in remission by the end of the twelve week treatment period in comparison with only twenty-one percent on placebo. *Ibid.*

This study confirmed the results of earlier studies that found rifaximin to be safe and effective in the treatment of Crohn's disease patients. For example, an open-label study of twenty-three patients with active Crohn's disease found that after sixteen weeks of rifaximin treatment at a dose of 200 mg three times per day, the patients' mean CDAI score was reduced from an average of 280 to 161 – a forty-three percent reduction. Shafran and Johnson, "An open-label evaluation of rifaximin in the treatment of active Crohn's disease," *Curr. Med. Res. Opin.* 2005;21:1165-9. *See also*, Shafran and Johnson, "Efficacy and Tolerability of Rifaximin: A Nonabsorbed Oral Antibiotic In the Treatment of Active Crohn's Disease: Results of An Open-Label Study," *Am. J. Gastroenterol.* 2003;98(9 suppl):S250. After just four weeks of rifaximin treatment, fifty-seven percent of the patients exhibited more than seventy point improvement in their CDAI scores. *Ibid.* And, by the end of the sixteen week treatment period, eight-one percent of the patients showed more than a seventy point improvement in their CDAI scores. *Ibid.* Moreover, clinical remission, defined by a CDAI score of less than 150, was achieved at the end of treatment weeks 4, 8, 12, and 16 by 33 percent, 52 percent, 52 percent, and 62 percent of the patients, respectively. *Ibid.*

An even earlier study found the short-term administration of rifaximin to be effective in treating bacterial overgrowth in patients with inactive Crohn's disease. Biancone, et al., "Effect of Rifaximin on Intestinal Bacterial Overgrowth in Crohn's Disease as Assessed by the H2-Glucose Breath Test," *Curr. Med. Res. Opin.* 2000;16(1):14-20. In this prospective, longitudinal study, fourteen patients with inactive Crohn's disease of the ileum were given either rifaximin at a dose of 1200 mg per day or placebo for one week. *Ibid.* Before treatment with rifaximin, all fourteen patients tested positive for bacterial overgrowth, as assessed by the hydrogen breath test. *Ibid.* After fourteen days, one week after treatment stopped, the hydrogen breath test was negative in all seven of the treated patients, while the hydrogen breath test was only negative for two out of the seven patients in the placebo group. *Ibid.* As such, the results indicated that, "one week's administration of a non-absorbable antibiotic [rifaximin] is more effective than placebo in the treatment of intestinal bacterial overgrowth in patients with inactive Crohn's disease." *Ibid.*

More recent studies support the use of rifaximin in the treatment of Crohn's disease as well. For instance, an analysis of sixty-eight Crohn's disease patients' charts found that rifaximin therapy was associated with clinical improvement in Crohn's patients and, "may be a useful treatment option to consider for inducing and maintaining remission." Shafran and Burgunder, "Adjunctive Antibiotic Therapy with Rifaximin May Help Reduce Crohn's Disease Activity," *Dig. Dis. Sci.* 2010;55:1079-

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[100] C reactive protein (CRP) is one of the most important acute phase proteins and CRP elevation can be a sign of inflammation, infection, tissue necrosis or neoplasia. In Crohn's disease patients, CRP elevation is likely the result of inflammation, necrosis, or bacterial dysbiosis. Prantera, et al., "Antibiotic treatment of Crohn's disease: results of a multicenter, double blind, randomized, placebo-controlled trial with rifaximin," *Aliment. Pharmacol. Ther.* 2006;23:1117-1125.

1084. The median duration of rifaximin treatment was 16.6 weeks and the majority of the patients, ninety-four percent, received rifaximin at a dose of 600 mg per day. *Ibid*. Eighteen of the patients received only rifaximin, thirty-one patients received steroids concomitantly, and the remaining nineteen received other treatments that were not steroids throughout the treatment period. *Ibid*. The median baseline CDAI score before rifaximin was initiated was 265, but after treatment with rifaximin, Crohn's disease remission occurred in sixty-five percent of the patients. *Ibid*. Fifty-eight percent of the patients who received steroids concomitantly achieved remission, while seventy percent of the patients who did not receive steroids achieved remission with rifaximin. *Ibid*. Sixty-seven percent (twelve out of eighteen) of the patients who received rifaximin alone achieved remission, "suggesting that rifaximin therapy alone is capable of inducing remission of CD." *Ibid*. Moreover, these clinical improvements continued for four months after rifaximin initiation, also "suggesting that rifaximin may be beneficial in maintaining remission of CD." *Ibid*. Thus, rifaximin is capable of not only inducing remission in Crohn's disease patients, but also maintaining that remission.

Rifaximin also has been found to be an effective treatment in newly diagnosed Crohn's disease patients. Shafran and Burgunder, "Rifaximin for the treatment of newly diagnosed Crohn's disease: a case series," *Am. J. Gastroenterol.* 2008;103(8):2158-60. Indeed, it proved to be an effective first-line therapy in three different newly diagnosed Crohn's patients. *Ibid*. One patient, whose CDAI score was 260 before treatment, found that her gastrointestinal symptoms completely resolved after a five week treatment of rifaximin at 800 mg per day. *Ibid*. Her CDAI score dropped all the way down to 18. *Ibid*. Moreover, a small bowel capsule endoscopy revealed a substantial – greater than seventy-five percent – healing of the small intestinal mucosa. The patient remained asymptomatic for thirty-one weeks and counting with only rifaximin and no additional Crohn's disease medications. *Ibid*. Another twenty-five year old patient with newly diagnosed Crohn's disease experienced dramatic improvement with rifaximin after only four weeks of treatment. *Ibid*. After treatment with rifaximin, this patient's C-reactive protein (CRP) levels decreased and a small bowel capsule endoscopy revealed lesion healing, with an improvement in the number, size, depth, and extent of mucosal lesions compared to baseline. *Ibid*. Three months after initiating treatment with rifaximin, this patient also was able to discontinue iron supplementation because her anemia had stabilized and she remained symptom free. *Ibid*. Similarly, a forty-one year old male with newly diagnosed Crohn's disease found that his CDAI score dropped from 175 before treatment, to 91 after seven weeks of treatment with rifaximin. *Ibid*. A small bowel capsule endoscopy also revealed substantial mucosal healing after treatment with rifaximin. *Ibid*. Like the other two patients, this patient also maintained improvement with continued rifaximin treatment. *Ibid*. The dramatic relief that these patients found with rifaximin led the researchers to conclude that, ". . . these dramatic and encouraging mucosal improvements suggest that rifaximin may provide an effective first-line treatment in patients with CD involving the small intestine." *Ibid*.

Researchers are not exactly sure *why* rifaximin works so well for Crohn's disease – and other inflammatory bowel diseases[101] – but there is no doubt that it

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[101] Rifaximin (Xifaxan) is an effective treatment for ulcerative colitis, as well. *See* Guslandi, et al., "Rifaximin for Active Ulcerative Colitis," *Inflamm. Bowel Dis.* 2006;12(4):335 (letter to editor); Gionchetti, et al., "Management of Inflammatory Bowel Disease: Does Rifaximin Offer Any Promise?" *Chemother.* 2005;51(Supp 1):96-102; Baker, "Rifaximin: A Nonabsorbed Oral

works. Researchers hypothesize that the reason antibiotics, such as rifaximin, are so effective in treating Crohn's disease is because, "the partial suppression of the luminal flora could reduce the intensity of some symptoms, such as pain and diarrhea, consequently decreasing CDAI value." Prantera, et al., "Antibiotic treatment of Crohn's disease: results of a multicenter, double blind, randomized, placebo-controlled trial with rifaximin," *Aliment. Pharmacol. Ther.* 2006;23:1117-1125. Or, "[a]nother potential mechanism is that the suppression of bacterial flora might lead to down-regulation of the immune system in genetically susceptible individuals with a lack of tolerance to commensal bacteria." *Ibid.* In order to better understand the effect that rifaximin has on Crohn's disease, a recent study evaluated the effect of rifaximin treatment on the fecal microbiota of four patients affected by colonic active Crohn's disease. Maccaferri, et al., "Rifaximin modulates the colonic microbiota of patients with Crohn's disease: an *in vitro* approach using a continuous culture colonic model system," *J. Antimicrob. Chemother.* 2010;65(12):2556-2565. At a dose of 1800 mg per day, rifaximin demonstrated that it does not disrupt the overall biostructure of the human microbiota, nor does it exert any cytotoxic or genotoxic activities. *Ibid.* Instead, it provokes changes in bacterial metabolism and bifidobacterial numbers, "that support a functional advantage to the host." *Ibid.* Thus, it is clear that rifaximin has a positive role to play in the treatment of Crohn's patients, even if the exact mechanisms by which it does is not yet fully understood.

To add further support for the use of rifaximin in patients who suffer from Crohn's disease, a recent review of the medical literature found that, "[r]ifamycin derivatives either alone or in combination with other antibiotics appear[ed] to have a significant effect at inducing remission in active CD." Khan, et al., "Antibiotic Therapy in Inflammatory Bowel Disesae: A Systematic Review and Meta-Analysis," *Am. J. Gastroenterol.* 2011;106(4):661-673. Rifaximin is a rifamycin derivative. This conclusion was the result of a review of ten randomized controlled trials involving 1,160 patients with active Crohn's disease. *Ibid.* The support for the use of rifaximin to treat Crohn's disease is indisputable.

Thus, rifaximin is becoming the standard of care in Vancoymcin and Flagyl-resistant c-diff. It also has been shown to be effective in treating Crohn's disease. And in this case, we know that Ms. Patient's c-diff and Crohn's both respond very favorably to rifaximin. Thus, it should be considered medically necessary in her case.

III. Conclusion

The voluminous medical literature demonstrates that Xifaxan is entirely appropriate treatment for Crohn's and c-diff, especially when other antibiotics, including Flagyl, have proven ineffective. In Ms. Patient's case, she tried Flagyl and Vancomycin, and they did not control her c-diff or her Crohn's. She also has tried several other medications for Crohn's disease. Although Remicade was of some benefit, it would not also control her c-diff. Xifaxan has proven to be entirely efficacious in treating both the Crohn's and the c-diff. Therefore, it is medically necessary and should be approved.

Antibiotic," *Rev. Gastroenterol. Disord.* 2005;5(1):19-30; Thukral, et al., "The Role of Antibiotics in Inflammatory Bowel Disease," *Curr. Treat. Options Gastroenterol.* 2005;8(3):223-228; Gionchetti, et al., "Rifaximin in Patients with Moderate or Severe Ulcerative Colitis Refractory to Steroid-Treatment: A Double-Blind, Placebo-Controlled Trial," *Dig. Dis. and Sciences* 1999;44(6):1220-1221 (letter to editor).

Sincerely,

Jennifer C. Jaff*

* Admitted to practice law in Connecticut, New York and the District of Columbia. Advocacy for Patients is a 501(c)(3) tax-exempt organization and does not charge patients for its services. Advocacy for Patients is funded by, among other sources, grants from foundations and companies that engage in health care-related advocacy, manufacturing, delivery and financing. A list of grantors will be furnished upon request.

Appendix D: Sample Disability Letters

A. Disability Insurance Appeal

Note: This is a disability insurance appeal I prepared for a client who suffers from a number of disabilities. There are a number of things to be learned from this sample. First, I am including it here, with my client's permission, to show the detail that is required. Second, in this instance, the insurer obtained Independent Medical Exams ("IME"). This is so the insurer will have a defense to a charge that the payments were terminated wrongfully. It is critical to get copies of any IMEs, and critique them using the treating physician's records and, hopefully, correspondence responding to the IME. Finally, it is critical to know the standard that must be met under your policy. As you can see, in this case, my client's policy said that a patient is disabled if she can no longer perform the occupation she was in at the time of the disability. The insurance company's expert, and even the insurance company itself, was holding the patient to a higher standard, implying that she had to prove that she could no longer function in *any* job. This standard made all the difference.

This letter has been edited to eliminate some of the over 10 pages of analysis, but you should be able to get the idea. This client had saved every piece of paper relating to her disability from day one. It was invaluable to have that documentation.

Dear Sir or Madam:

I am writing on behalf of Patient L to appeal the decision set forth in a December 12, 2001 letter from Customer Care Specialist at ABC Insurance Company terminating disability insurance benefits. Because the analysis resulting in the termination entirely and utterly failed to consider the disability to Patient L's hands, wrists, and forearms that has been documented over the entire period of her disability, and because it misunderstands the nature of Patient A's policy and coverage, the termination must be reversed and benefits reinstated immediately.

Patient L is covered under the Premier Disability policy, which provides coverage when the insured is unable to perform his or her "regular job," meaning "the occupation in which you are engaged when a Disability starts [ ], even if you are working at another job." In other words, Patient L need not prove that she is unable to work at any profession; she need only prove that she is unable to perform the "substantial and material duties" of her occupation as insurance salesperson.

The termination decision fails to honor the terms of the policy, or to recognize the history of this claim, in a number of respects.