December 12, 2002

Blue Cross Blue Shield

Ron Romano, Ombudsman

Consumer Affairs

Fraud and Abuse Unit

25 Newport Avenue Ext.

North Quincy, MA. 02171

Dear Blue Cross Blue Shield:

As a year-long insured federal employee member of Blue Cross Blue Shield, two recent news developments (prescription restrictions placed on antipsychotic drugs for children by Blue Cross of California, and the advent of "predictive modeling" technology programs to determine which patients may have future health problems) have prompted me to write your Consumer Affairs and Fraud and Abuse Unit.

To sum up the substance of this letter, what would Blue Cross Blue Shield do if it determined that by authorizing and paying for a specific treatment, the following two situations would result:

1 . the patient/insured would develop acute and chronic adverse events and illnesses, there would be development of diseases, a need for cyclic appointments with primary and specialty physicians, requirements of expensive laboratory and radiological testing, multiple surgeries, numerous hospitalizations, with the accompanying plethora of prescription medicines - while the patient/insured paying their 'relatively' small portion of the bills; and,

2. Blue Cross Blue Shield would be paying the bulk of all these medical (primary, cardiology, rheumatology, gastroenterology, endocrinology, neurology, neuro-endocrinology, immunology, dermatology, orthopedics, etc.), dental, surgical, laboratory, radiology, hospital, and prescription bills.

A commonly prescribed drug, Lupron (leuprolide acetate, manufactured by TAP [Takeda- Abbott Pharmaceuticals]) has been wreaking havoc on the health and lives of thousands of women (as well as men and children) - and, based upon published medical, scientific, pharmaceutical, Food and Drug

Administration (FDA), and anecdotal evidence, it is quite reasonable to assume that lupron is responsible for the incursion of untold millions in post-lupron healthcare dollar expenses.

Recently, the federal government prosecuted TAP's conspiracy scheme of bribing physicians to prescribe lupron and fraudulently bill Medicare (for prostate cancer, although federal documents identify that associated purchase deals also involved gynecological indications) - and TAP is now recognized as "a criminal enterprise" and has paid the highest criminal fine in history (total fine: $875 million). And while the FDA, in its review of lupron MedWatch forms, has identified that men and women share similar (high rates) of adverse events to lupron, no attention was devoted to the health of these prostate patients post-lupron nor to any safety issues of lupron - prosecution was based solely on billing fraud and marketing issues. Curiously, the existence of thousands of lupron victims predates this 'billing' prosecution by nearly a decade (i.e., <www.lupronvictims.com>, and/or search AOL or Delphi message boards for "lupron"). There has been no substantive attention directed towards the safety problems of lupron, presumably because it is private insurers (and not Medicare) that bear the majority of the healthcare costs of these women (and children and younger men).

A simple, collaborative, computerized search of any and all insurer's database(s) would identify the healthcare costs that these patients/insurees had prior to lupron, and then comparison could be made to the healthcare costs that these patients/insurees have had subsequent to taking lupron. As a formerly healthy and full-time career R.N., my own medical bills and health history post-lupron illustrate this matter precisely. Prior to lupron, I carried the diagnoses of endometriosis, infertility, and a knee injury - and did not even have a primary physician. Since taking lupron, I have experienced an A-Z litany of medical maladies including, but not limited to: adenoma, ascites, adrenal insufficiency work-up is in process, arthritis, bradycardia, breast cysts, cardiac arrhythmias, dizziness, edema, fatigue, gastritis, gastro-esophageal reflux disease, hyperlipidemia, immune system abnormalities, joint pain, lesions (in nerves, on skin, and duodenal ulcer), lymphadenopathy (surgical consult pending), myalgia, memory loss, neuralgia, osteopenia and now osteoporosis (severe), polyclonal gamopathy, scoliosis, spasms, and ticks, to name a few.

Over the years, I've experienced periods of inability to work, which resulted in necessitating free care application - adding to the overall cost of healthcare. Since taking lupron, my life has consisted of a revolving door of physicians and specialists and laboratories and hospitals, an unending avalanche of medical, surgical, and prescription bills totaling thousands upon thousands upon thousands of dollars. To elaborate on merely one health issue, for example the status of my bones, my treating physicians have advised that my future likely consists of spontaneous fractures, compression fractures, and wheelchair - and my dentist says my "jaw is dissolving". My 72 year old, petite mother, who smokes, and has all her teeth (we've both seen the same dentist each for over 30 years) has no "dissolving jaw" (and I've lost one tooth and all my teeth have now become loosened) and her skeleton is in better shape than mine. After contact with a frightening number of other women (or their tearful, terrified husbands) nationwide over the last decade, with similar endocrine, orthopedic, arthritic, immunological, gastric, cardiac, etc. health problems post-lupron - I consider myself to be one of the 'luckier', 'healthier' victims.

As I perpetually have for some time, I could go on and on about the multitude of serious issues pertaining to lupron - such as:

-the NIH and OSHA classify lupron as a “hazardous drug”, the FDA classifies lupron as a pregnancy Category X drug, and lupron is an acknowledged reproductive and developmental teratogen … yet, Lupron is being prescribed on and off-label as standard treatment with no mention of its “hazardous” status, or;

- the reports of birth defects following inadvertent and advertent exposure to lupron, or;

- the 1999 FDA Review of lupron, in which the FDA reviewed over 6,000 MedWatch reports and "concluded that there were high prevalence rates for serious side effects", or;

- the fraudulent research (lead lupron investigator "falsifying and fabricating 80% of data" in 4 lupron studies ["Findings of Scientific Misconduct" - Federal Register, 5/1/96, Vol. 61(85): 19295-6-]), or;

- the contests held, according to published reports, by doctors and nurses for the money-bonus-prize for "[luring] the most lupron patients", or;

- the fact that in clinical trials of lupron's pain effectiveness for endometriosis, pain was made a primary end-point in the trials - yet concomitant opiod pain management (including Dilaudid) was prescribed and used during these trials, or;

- the rampant conflicts of interest involved with lurpon, or;

- the shocking information exposed within lupron NDA's (New Drug Applications to the FDA), i.e., pituitary adenomas developed in all rats at all doses and "there is no obvious reason to suggest that the same process could not occur in humans", or;

- the fact that original prostate clinical trials evidenced a reported 2 or 4 or 8% incidence of impotence as an adverse event, yet current medical journals document nearly 100% of patients experience impotence on lupron, - and, in fact, lupron is now utilized as "chemical castration" for sex offenders, or;

- the alarming number of words, sentences, paragraphs and pages purged from within the lupron NDA's (19 consecutive pages purged in just one instance alone), or:

- the numerous product liability lawsuits TAP has settled with secrecy agreements, or

- the lack of informed consent and inherent human experimentation involved when hazardous, teratogenic agents are injected without informed consent, or;

- the increasing number of states with mandated infertility coverage, prompted by heavy state-by-state lobbying from RESOLVE, Inc. (the nationwide organization "dedicated to educating, advocating, and supporting the infertile"), and the thousands upon thousands upon thousands of dollars RESOLVE, Inc. has received (according to available financial disclosure reports) from TAP over the years – including

thousands and thousands of dollars received from TAP at least as early as 1989, prior to any female indication approved by the FDA, or;

- the disturbing implications of a survey analysis published in 2002 in the journal Human Reproduction, proclaiming that there are "[h]igh rates of autoimmune and endocrine disorders, fibromyalgia, chronic fatigue syndrome and atopic diseases among women with endometriosis", yet this survey analysis is devoid of any information whatsoever about the respondent's past or present medical treatment for endometriosis. This survey was conducted by the Endometriosis Association (EA), and in the EA newsletter's 1998 publication of this survey's results, graphs indicate that approximately 30% of patients reported that the treatment of lupron did not help them. Since lupron is widely used for endometriosis, and since lupron has been associated with autoimmune and endocrine disorders, fibromyalgia, fatigue, etc., to attempt to claim these other diseases as 'co-morbid' to endometriosis without exploring/identifying that these 'co-morbid' diseases have been linked to causality to lupron is misleading and suspect. Of note, this peer reviewed publication did not identify that one author, the founder of the EA, has received hundreds of thousands of dollars, monies, grants, etc., from TAP (and other manufacturers of GnRHa [the class of drugs to which lupron belongs], or;

- the continued lack of FDA approval for the use of lupron in fertility treatment and in vitro fertilization (IW), despite the company conducting clinical trials studying lupron's "efficacy" (but not safety) in infertility and IW from 1987 through 1992 ~ these studies were subsequently "discontinued", and no one can ascertain whether their discontinuation and lupron's lack of FDA approval for fertility treatment or IVF was due to efficacy reasons, safety reasons, both reasons, or other reasons; or;

- the looming lupron class-action litigation visible on the horizon (related to adverse health effects vs. 'overbilling'), or;

- the ramifications upon healthcare workers administering lupron to patients, in light of NIH and OSHA's recommendation that two pair of chemotherapy gloves and a chemotherapy gown (among other protective gear) be worn when administering the hazardous drug lupron ... yet, no women receiving lupron injections report administration by a gowned or double-gloved healthcare provider; and in a survey I conducted in 1999 to random institutions nationwide (inquiring of their policy and procedure for their healthcare worker's administration of lupron), 100% of respondents identified that they had "no policy or procedure for the administration of Lupron", or;

- the inexplicable dichotomy in purporting lupron's safety and efficacy to fertility patients (who inject lupron daily for roughly one month [and note that young, healthy women undergoing fertility treatment (many for male factor) using lupron 1 mg per day wind up receiving 30 mgs in one month, while older men dying of prostate cancer receive a total of 7.5 mg of lupron in one month] and these fertility patients continue their daily lupron injections to within hours of ovulation and to within days of implantation of any fertilized ova)... yet, the American Hospital Formulary Service Technical Assistance Bulletin on Handling of Cytotoxic and Hazardous Drugs, in conjunction with OSHA, recommend that any healthcare worker who is considering conceiving or fathering a child should avoid handling hazardous agents (lupron) at least 3 months prior to conceiving/fathering any child, or;

- the suppression of known, documented risks of lupron to patients/insurees as well as their spouses (and in the case of fertility treatment, it is the spouse who frequently injects the woman with lupron - unaware of NIH and OSHA recommendations on protective gear to wear when handling a hazardous drug), or;

- the powerful influence of the media, as well as the powers influencing their stories, which promote the positive and ignore the negative, i.e. embryonic stem cell and therapeutic cloning research has been touted loudly as potential cures for diabetes, Alzheimers, Parkinson's disease, immune problems, arthritis, etc., and the push is on for the collection of more eggs to tinker with... yet, women who are superovulated to produce these eggs frequently use lupron, and women who have taken lupron have developed diabetes, memory loss, parkinsonian-like disorders, immune problems, arthritis, etc., etc., or;

- the tortuous journey of the last dozen years of my life in trying to get somebody (anybody!) interested in any and all of this, or; etc., etc., etc.

All these entangled facts, all these terrible post-lupron horror stories (including sudden death), all the false and questionable data - all needs a lot of attention by a lot of people.

But I've been going on and on about the above and nuchmuch more for a longlong time -and the bottom line is that the bottom line weighs heavy on top and it is, in the end, the bottom line that matters. So, with that said, I've just been hospitalized (again), requiring two hospitalizations since 9/8/02, and Blue Cross Blue Shield (thankfully) will pay my bills. Blue Cross Blue Shield, regrettably, has paid, is paying, and will continue paying for other lupron victims bills as well.

Blue Cross Blue Shield and other insurers will continue paying for serious, life-altering and life-threatening, adverse health sequelae following lupron 'treatment', and the patient/insured will continue to encounter serious, life-altering and life-threatening, adverse health sequelae following lupron 'treatment'... until and unless somebody acts, investigates, crunches the numbers, and exposes this very costly issue as the catastrophic problem that the lupron victims know it to be.

As a nurse, I've spent a life-time educating patients, helping them deal with their illnesses, allaying fears, answering questions, calming anxieties, resolving crises ... but I can't help these women, or their husbands, when they call, crying, pleading with me to help them do something. Their list and litany of serious health problems post-lupron, and their collective voice saying 'my doctor badgered me into taking lupron -I didn't want it and s/he made me take it - and now I’m sick all the time, and s/he doesn't want to deal with me now, and all the other doctors I'm having to see now have been telling me all these new medical problems are in my head, until of course my [fill in the A-Z symptom/disease] was finally diagnosed by [fill in A-Z diagnostic test/surgery], and now I've got another [fill in the A-Z symptom/disease] going on and still don't know why the other [fill in A-Z symptom/disease] isn't responding to [fill in A-Z medical/surgical/prescription treatment] — and all I'm told is no one can tell me what's happened to my body, but they all tell me emphatically and often angrily that these problems have absolutely nothing to do with lupron, and they won't discuss the matter ... I've had nothing but bizarre encounters with physicians whenever I bring the subject of lupron up - like it’s a conspiracy of silence'.

What do I say to these people? Having spent the majority of my career on an acute admitting psychiatric unit, it was expected to hear the above from a deluded, hypochondriacal, patient who was psychotic but physically fine - but what these women and men relate health-wise and experientially is as real as exactly what I've experienced. For just one inexplicable example of 'strange encounters', years ago one 'treating' physician (who vehemently resisted discussion of my post-lupron symptoms/diseases), after hearing my (self-triaged) complaints of gastric pain, edema in lower extremities, muscle spasms, and cardiac arrhythmias, replied angrily and dismissively (verbatim): "Those are bullshit symptoms."

Personal and collective experiences such as these drove me to advocate fiercely for attention to this matter, but despite my own herculean efforts (as well as the efforts of other lupron victims), as the quote from newspaper reports on the TAP-lupron-fraud-doctor-bribery-scheme-conspiracy case illustrates: "the safety of the drug is not in question". Perhaps the venue of government prosecution for lupron Medicare billing fraud is an inappropriate forum to address lupron's safety issues - but clearly any insurer's authorizing role and related financial expenditures are intimately linked to safety issues of any authorized drug.

And so, it is my hope that Blue Cross Blue Shield will share my concerns, and take the lead in a responsible investigation of this matter. Undoubtedly, this investigation would lead Blue Cross Blue Shield to identify a significant healthcare cost burden post-lupron. And hopefully, financial analysis will ultimately result in insurers' refusal of payment for lupron — prompting the savings of significant healthcare costs, preventing further lupron victims, and, hopefully, also result in provoking substantive study of the serious medical sequelae that present lupron victims face.

Thank you for your time, and for any consideration you might give to investigating this issue. Should you have any questions or require further information, please do not hesitate to contact me.

Sincerely,

Lynne Millican