Jeffrey Fudin, PharmD, DAIPM, FCCP, FASHP, FFSMB
357 Delaware Avenue #214
Delmar, NY 12054

[redacted]
F: 518-734-0288
Jeffrey.fudin@remitigate.com

Dr. Jeffrey Fudin
Remitigate Therapeutics
357 Delaware Ave, #214
Delmar, NY 12054

[redacted] BS, RN, OCN
Executive Director, [redacted] Albany
[redacted]
Albany, NY [redacted]

December 23, 2021

Ms. [redacted];

My name is Jeffrey Fudin and I am a patient receiving care at the Albany [redacted] outpatient clinic. The reason for this letter is fourfold. First to introduce myself, second to share some of my personal milestones and praise for the clinic and its providers, third to share some of the shortcomings by the clinic which for the most part have been adequately addressed after voicing my concerns, and fourth to seek your advocacy on a concerning personal and professional outstanding issue.

I'd like to start by acknowledging your impressive 20-year health care experience. I am particularly intrigued regarding Dr. [redacted]'s [redacted] comment which states, '[redacted] is a pioneer, who brings an impressive track record of strategic development and improving patient experience in cancer care." That, in addition to your credentials, direct patient care and advocacy is what motivated me to write this letter. Moreover, your experience as an IV Therapy educator dovetails nicely with the ultimate objective. After reading this letter, I'm sure you'll agree that the whole goal of my treatment is to foster normal living for as long as possible and hopefully, you will advocate for me to do just that in the spirit of fulfilling that goal together.

By way of background, I am a doctor of pharmacy (PharmD) with 40 years of experience in direct patient care as a clinical pharmacy specialist within the VA Healthcare system. The first 20-30% of my career was spent initially developing, and eventually practicing in a heme-onc clinic following a post-graduate fellowship in heme-onc at Upstate Medical Center in Syracuse NY. I also helped establish the first hospice in this geographical area at the Stratton VA. Subsequently I owned a high tech homecare infusion business at the height of the A.I.D.S. epidemic – in that capacity I would visit patients in their homes (with our nurses), so I am quite familiar with all the various central lines, their supply and maintenance requirements, aseptic technique, and advanced IV homecare issues related to total parenteral nutrition, patient controlled analgesia, various chemotherapies, and the technologies required to deliver such medications in the home setting. The balance of my career was spent developing and running (for many years) an outpatient pain clinic and answering acute pain consults within the hospital. Fast forward to present… I retired officially from the VA in 2016 but remained there for three years as a volunteer to participate in direct patient care, teaching, and as Residency Program Director (RPD) to keep our PGY2 Pain and Palliative Care program running. The RPD position was finally filled, but I remain today as a volunteer. Also, I spent many years teaching pharmacology in the Nurse Practitioner Program as the SAGE Colleges and continue as an

Adjunct Associate Professor at Albany College of Pharmacy and Health Sciences and also at Western New England University College of Pharmacy. Aside from that, I continue to spend most of my time professionally as an expert witness with most focus on pain-related pharmacotherapeutics, I frequently lecture regionally, nationally, and internationally, and continue with editorial commitments to several peer reviewed journals, and I continue to write for many medical, pharmacy, and nursing journals with over 350 publications worldwide, all while receiving treatment by [redacted] If you want to know more about me or follow my oncology blog journal, I encourage you to visit http://paindr.com.

My diagnosis of colorectal cancer began to unravel the last week of April 2021. Entering surgery on June 8th, 2-weeks following a one-week course of neoadjuvant radiation, with a presumption of Stage-3 disease, I was awakened postoperatively to learn that I was "loaded with tumors in the peritoneum and the only course of treatment is chemotherapy". The next day I met with [redacted] oncologist Dr. [redacted] and we discussed chemotherapy options. Within a short time, I began FOLFOX treatment at [redacted] I requested early on that I be an integral part of any medication decisions and to collaborate with Dr. [redacted] and advanced practice providers due to my background. All of the providers, especially Dr. [redacted] have been very gracious about that. There were some significant bumps in the road along the way, but together we sorted those things out. In late July for example, I requested dexamethasone because of significant belly bloating, discomfort, and inability to eat – it was unclear if this was due to radiation, chemotherapy, the cancer itself, neoplastic cell kill, or some combination thereof. What was clear is that I had a planned one-week trip to NJ to visit with family including all four of my children, their spouses, my four grandchildren, and my father who was to turn 90 that week, and whom I hadn't seen in close to two years due to the looming COVID pandemic. Obviously, my family was worried about me. My request to Dr. [redacted] was for dexamethasone. She was understandably hesitant due to the toxicities, but I felt the risks, at least in this case, did not outweigh the benefits. I'm happy to report that I did make that trip – I ate, participated in several physical activities with my family (with special attention to the grandchildren), and upon return, we had a large "celebration of life" party at my home in Delmar NY at which all attendees were fully vaccinated. The next hurdle was a transition off dexamethasone onto an acceptable analgesic, preferably not an opioid, since the bulk of the belly related issues seemed to be inflammatory pain. Various risks of NSAIDs with a platelet count in the 500 thousands included risk for bleeding or clotting, considering that presumably many of those platelets were non-functional. But opioids, which I presumed would be less effective, had the risk of constipation shortly after stent placement to the sigmoid-rectal junction. After careful consideration, I thought a relatively COX-2 selective NSAID at higher dosing (to minimize clot risk) with a proton pump inhibitor (selection based on drug interactions with ongoing antiemetics) for protection against GI bleed would be my best option. Dr. [redacted] and I agreed on a plan, and all is well. Appetite and eating remained great. The next hurdle was PO versus IV iron followed by my preference to discontinue oxaliplatin (due to risk for neuropathy) and switch to bevacizumab based on studies that showed equivalent efficacy for 6 versus 12 treatments with 50% reduction in iatrogenic neurotoxicity.[1] Dr. [redacted] was a bit reluctant, but in agreement, was familiar with the study I cited, and submitted the prior authorization. I have completed several courses since that time and feel great. The bottom line here is that I'm doing very well, I am quite functional, enjoyed a Thanksgiving feast with family, I'm working, traveling (business and leisure) playing, enjoying the grandchildren, and am anticipating the arrival of two more grandchildren in February. These improvements and milestones could not have been accomplished without the support of Dr. [redacted] and [redacted]

Now for the shortcomings, most of which I'm happy to report have been resolved, at least for me personally. Telephone communications have been a nightmare. There were a few instances where I tired to reach Dr. [redacted] The first hurdle is getting someone to answer versus a litany of automated prompts. Either way, if I was fortunate enough to speak to someone, it was generally an MA who then communicated with an RN, then to Dr. [redacted] then back to the RN, and a call back to me. I haven't called that often, but if/when I do, it's generally a complex issue that requires attention by my oncologist. There was one time I called with four issues which were clearly delineated. By the time the RN got back to me, she had the answer to two of the questions and somehow the other two were lost in numerous back and forth communications among staff. This issue has not been resolved

and I don't call anymore. The [redacted] portal was an issue previously. I had sent a few messages over the course of several weeks to Dr. [redacted] In some cases, I couldn't believe the flippant attitude in some of the responses from who I presumed was Dr. [redacted] It turns out that these responses were coming from an MA or RN and I had no idea. I brought this to the attention of administration and suggested from a practical, clinical, and liability perspective, all communications from your staff should include the name of the person responding, their credentials, and for whom on behalf of, they are responding. This was corrected rapidly after I had a discussion with administrative personnel.

The next item which I suspect is near and dear to your heart, was abysmal aseptic technique by close to 50% of nurses that either administered my chemotherapy, accessed my port, or did a pump disconnect on day-3. This was taken very seriously and was also addressed quickly - I've seen a vast improvement over the last 3 weeks. I could get into specifics, but I'll spare you the details.

I am grateful for the quick attention to those matters and for the cordial communications with administrative staff who listened to and quickly addressed these concerns.

And now, for the final enduring unresolved issue that I am hopeful we can sort out. As you can tell from my background, I am not new to this field and I am quite competent in the infusion environment and manipulating syringes / admixing medications, etc. Because I remain very active, because I travel for legal work and lectures, because of unpredictable flights and cancellation of flights in this current pandemic environment, because sometimes court hearings or depositions go on for longer than predicted, because occasionally I'd like the extra 2-days for leisure travel to my condo in Florida, I asked Dr. [redacted] if occasionally it would be okay for me to flush my port with 10cc normal saline and 5cc heparin lock flush, and remove the Huber needle. She was not aware of any patients that ever requested that, but she was not opposed if there were a way to work it out after she checked on policies and with appropriate administrative staff. She followed up as promised. When I returned to clinic, I was met by an administrative person who basically told me that after checking this out with the administration, the answer was a flat "no". I asked why, and she said it was because of liability issues. **My response was that I'd be willing to sign any paperwork relieving [redacted] of liability, and that I'd be happy to be observed by an RN who could sign off on me.** At the time, I wasn't even asking to do this routinely, as it is not problematic for me to make the 12-minute drive to clinic for a disconnect. In fact, I enjoy seeing the friendly staff. She agreed to bring my concerns back to administration. Several similar short meetings ensued with varying personnel and a few phone calls, all communications of which were quite cordial and attentive, even supportive of my request. I continued to receive an unwavering "no" first because of having "no policy" and then because of "liability". I did point out that their culpability is probably lessened since my documented complaint or poor aseptic technique (which by the way was a coincidence), because if my line did get infected, they could blame it on me in a court of law instead of their staff. Moreover, since infection is always an unfortunate risk of a central line, there probably is minimal culpability anyway. With ongoing resistance, I suggested to Dr. [redacted] that perhaps she could refer me to a high tech homecare company that could qualify me for a self-disconnect on day-3 of chemo. She placed that consult. Agency 1 declined my case because they weren't providing the drug (no doubt a profitability issue). I then requested a consult to another agency who were willing to do exactly what I asked – 2-3 visits, observation, and sign off on my competency. Once this was approved, [redacted] put up another barrier – this time it was, "we don't allow a disconnect by someone else if we connect the disposable ambulatory infuser". I fail to see how one has to do with the other, and it has not been explained to me why this is an issue. Now I'm thinking, I originally was told there was no policy, but I'm seeing that policies seem to emerge as they fit the narrative that [redacted] is unwilling to budge on this. At my latest communication I was told that if the homecare agency comes to my house on day-1 (after receiving treatment at [redacted] provides the 5-FU in an ambulatory pump for days 2 through 3, then that is acceptable. The homecare agency is willing to do that, but it adds another layer of care, someone coming into my house after seeing other patients (think pandemic), and elevated costs to me due to insurance issues.

There is considerable precedence for patients to be treated at home which has become even more prevalent during the current pandemic.[2,3] And as of today, although I never intended to do the disconnect myself each two weeks, COVID infections are increasing rapidly in the Capital District. As such, I feel that avoiding a visit to clinic reduces my potential exposure to COVID and other respiratory illnesses, especially since I'm immunocompromised. If [redacted] really had the patient's best interest at heart, there is no question that they would make this work for me. While I recognize that we live in a for profit healthcare environment, each patient's needs, skills and outcomes vary by circumstance and should be seriously recognized and appropriately addressed with consideration to individualized care, not by assembly line medicine.

In closing, I am asking for a reasonable relook at my request so that I can continue with all my chemotherapy at [redacted] including leaving the clinic on day-1 of chemo with a connected 5-FU ambulatory infuser, and that I simply be allowed to flush my line and pull out the needle. I don't think that's an unreasonable ask and I believe it would support the premise that [redacted] is in fact a premier provider. According to their website[4], "[redacted] has always been at the forefront of cancer care. …as a private, physician-owned practice, [redacted] prides itself on working closely with each patient and family, creating a personalized treatment plan. Our team of physicians, nurses and cancer care specialists are with you every step of the way—providing information and support, so you can focus on treatment and healing. I'm hoping that together we can resolve this issue and that [redacted] lives up to the claims on their website and so that I may continue to live life to the fullest with this unfortunate illness.

Respectfully,

**Jeffrey Fudin, PharmD, FCCP, FASHP, FFSMB**
**President, Remitigate Therapeutics**

Owner & Managing Editor, PainDr.com & Pain Blog
Adjunct Associate Professor, Western New England University College of Pharmacy
Adjunct Associate Professor of Pharmacy Practice & Pain Management, Albany College of Pharmacy & Health Sciences
Section Co-Editor, Pain Medicine (Opioids, Substance Abuse and Addictions Section)
Co-Editor-At-Large, Practical Pain Management

Office: 1-518-772-4100
Fax: 1-518-734-0288

Websites: http://www.paindr.com | http://www.remitigate.com
Facebook: https://www.facebook.com/PainDrJeffreyFudin
Twitter: https://twitter.com/jeffreyfudin https://twitter.com/noverdoseapp

**References:**

1. Tournigand C, Cervantes A, Figer A, Lledo G, Flesch M, Buyse M, Mineur L, Carola E, Etienne PL, Rivera F, Chirivella I. OPTIMOX1: a randomized study of FOLFOX4 or FOLFOX7 with oxaliplatin in a stop-and-go fashion in advanced colorectal cancer—a GERCOR study. Journal of clinical oncology. 2006 Jan 20;24(3):394-400.
2. Laughlin AI, Begley M, Delaney T, Zinck L, Schuchter LM, Doyle J, Mehta S, Bekelman JE, Scott CA. Accelerating the delivery of cancer care at home during the Covid-19 pandemic. NEJM Catalyst Innovations in Care Delivery. 2020 Jul 7;1(4).
3. As COVID-19 pandemic surges, cancer patients like Dean opt for at-home chemotherapy. The ASCO Post. 12/11/2020. Available at https://mhealthfairview.org/blog/as-covid-19-surges-cancer-patients-opt-for-at-home-chemotherapy
4. [redacted] Homepage/About Us. https://[redacted]com/about-us/