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President
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March 29, 2010

Stanley B. Cohen, M.D.
President
American College of Rheumatology
2000 Lake Boulevard, NE
Atlanta, GA 30319

Sent Via: Federal Express

Dear Dr. Cohen:

I have received your letter of March 24, 2010, and would like to address your concerns and clarify a few points.

I regret that my correspondence to you has been interpreted as being threatening. I assure you that was not my intent. I apologize for any unintended disrespect or negative feelings that my letters may have caused.

My letters to you were driven in part over my concern that we were receiving conflicting and confusing responses from the ACR leadership with regard to Colcrys® and illegal, unapproved colchicine. We first asked for a face-to-face meeting with you to hear your concerns and offer our perspective, but you opted to decline that request. Then, without offering us the opportunity to communicate directly with you, you sent an "advocacy letter" to FDA about Colcrys® and did not even copy us on it. I was informed about your letter to FDA by a news reporter, while I was being interviewed, and we subsequently obtained the letter from the ACR website about two weeks later.

That is when I sent my letter to ACR to communicate the medical, scientific, legal, and regulatory facts around this issue with the hope that the ACR would correct the factual inaccuracies in its letter to FDA. We then had a phone call with you, where you informed us that the ACR Board would consider this issue the following week and send us an official response thereafter. We waited for the week of the ACR Board meeting and then until Thursday of the next week. When we received no such response, Dr. Matthew Davis, our Chief Medical Officer, contacted you for an update, and you told him that ACR was not planning on sending us an official response and would instead publish an article on its position in an ACR journal more than a month later. At that point, I communicated directly with rheumatologists with my letter detailing the scientific, medical, regulatory, and legal distinctions between Colcrys® and unapproved colchicine. When my letter received no response, I instructed our General Counsel to send a communication asking those who had publicly distributed incorrect information to read my letter and correct the public record. Dr. Cohen, if you check your records of written correspondences and emails, then you will see that everything that I have just recounted is fully documented.

I hope you can appreciate my concern over what I believe to be extensive efforts on our part over the past few months to engage you and the rheumatology community in an ongoing dialogue, and my feeling that we have been shut out while we have been maligned through the citation of incorrect information.

Now we have been accused of threatening ACR members in an attempt to get them to advocate for our product. Such a conclusion is a perversion of the truth. I have acted as a friend of rheumatologists to alert them to the liability risks associated with prescribing illegal, unapproved colchicine. Based on how my actions have been misinterpreted by some of my fellow physicians, it's clear that my attempt to communicate subtly was not sufficient so I will now communicate explicitly.

The actions of ACR and certain rheumatologists have exposed some members of the rheumatology community to a "perfect storm" for medical malpractice liability. These individuals have advocated for the availability of an illegal, unapproved medication, when the safer FDA-approved product is fully available. But here is the key. They have done so in a patient population that is older, often suffering from multiple ailments and on polypharmacy, and thus more likely to have a significant negative medical event. Regardless of whether or not unapproved colchicine was responsible for the negative medical event, we all know the litigious environment in which we live. Also, I suspect that some medical malpractice insurance policies will not cover a doctor if the doctor advocated, unnecessarily, for patients to have access to an illegal product for which the physician now has to defend against a claim of injury. If you review my written correspondences to ACR and physicians, you will find that I have asserted, on behalf of physicians, that they had no choice but to use unapproved colchicine when no FDA-approved colchicine was available. I thought that ACR, as an official organization dedicated to protecting rheumatologists, and all individual doctors reading our letters, would understand this. We only asked those who have publicly supported incorrect information to correct their facts for the protection of the physician and for fairness to us.

Unfortunately, I was incorrect and my attempts to protect physicians have been twisted into a completely unsupported accusation that we are trying to intimidate physicians into advocating for our product. If you review the written record, you will see clearly that our position is correct and the accusation against us is a self-defeating distortion. At no point was it ever our intent to threaten anyone, and I regret that some have misinterpreted our actions. For those who had not communicated inaccurate information about unapproved colchicine and Colcrys®, there was nothing that they were asked to do. We were asking those who had publicly communicated inaccuracies about the status of unapproved colchicine and mischaracterized our substantial efforts to bring a better and safer colchicine to the market to read my letter, consider the facts, and correct the record if my letter gave them a new or better understanding of the issues.

In Mr. Magrab's letter to a group of physicians, he stated, "Now that doctors have been fully informed of the potential risks and liability associated with unapproved colchicine, if they are on record as having promoted the use or continued availability of this illegal product, then we are asking them to clarify the record...". Never did we threaten the physicians. In this era of rampant medical malpractice suits, it never occurred to us that any physicians would interpret this as our threatening them. We believed instead that those physicians who continue to advocate for the availability of unapproved colchicine would finally "wake up" to their own exposure. I suspect that those who have interpreted our actions, as you have characterized them in your letter to

me, as "...hostile, if not threatening ...", misinterpreted the message that we were sending. Never did we state, or insinuate, that we were contemplating any legal action against any physician. Quite frankly, I thought that physicians who received this letter would realize that they were walking into a potential medical malpractice liability situation and would be grateful that I had alerted them so they could get ahead of this issue and correct the record before any of their patients are injured by unapproved colchicine.

There is growing public interest in, and public scrutiny of, the issue of unapproved drugs. The *New York Times* published a front-page article about unapproved drugs in the Business Section this last weekend. Senator Grassley has introduced legislation to stop government payments for prescriptions of unapproved drugs. Dr. Woodcock has written FDA's position paper on unapproved colchicine. FDA has produced a 90-minute video on unapproved drugs that is now on the Agency's website.

Our letters to ACR as an organization, and to some individual members, were designed to inform them and request that those who have publicly advocated for unapproved colchicine, based upon factually incorrect information, correct their positions. I believed that this would have been welcomed by rheumatologists and seen as a service, not a hostile act. I can tell you that if I was unknowingly doing something that was wrong then I would welcome someone informing me what the correct path is and how to take corrective action.

Do we have our own motive for wanting physicians to support FDA's initiative to remove unapproved drugs from the market? Of course. But this is a case where the best interests of physicians, patients, and industry are all aligned in the same direction. That is why the reaction of ACR as an organization, and a small group of antagonistic rheumatologists, has been so puzzling to us.

At this point, I want to address a key issue, which is whether or not unapproved colchicine products are indeed illegal. This is a point which, based on my interpretation of the second paragraph in your letter, you appear to take issue with when you preface my reference to illegal, unapproved colchicine by writing, "as you phrase it."

I've attached a link to an FDA Warning Letter sent to Sunrise Pharmaceutical (I had sent a link in a previous correspondence, but I later learned that the link may have been incorrect). In the letter, the FDA makes clear that the sale of unapproved colchicine violates several federal statutes:

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm197966.htm>

For your ease of reference I have also reproduced below the relevant section from the Warning Letter:

New drug and misbranding violations for prescription drug products

In addition to the CGMP violations, you manufacture and market unapproved new drugs in violation of the Act at your facility at your facility at 665 E. Lincoln Avenue in Rahway, New Jersey. Based on the information collected during the inspection, you manufacture the following prescription drugs, including but not limited to:

- *Colchicine Tablets, 0.6 mg*
- *Hyoscyamine Sulfate Tablets, USP, 0.125 mg*

- *Hyoscyamine Sulfate Orally Disintegrating Tablets, 0.125 mg*
- *Hyoscyamine Sulfate Sublingual Tablets, 0.125 mg*

The above products are drugs within the meaning of Section 201 (g) of the Act, [21 U.S.C. 321 (g)] because as demonstrated by their labeling, they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases. Further, they are "new drugs" within the meaning of Section 201 (p) of the Act [21 U.S.C. 321 (p)] because they are not generally recognized as safe and effective for their labeled uses. Under Sections 301 (d) and 505(a) of the Act [21 U.S.C. 331 (a), (d) and 355(a)] a new drug may not be introduced into or delivered for introduction into interstate commerce unless an application approved by FDA under either section 505(b) or (j) of the Act [21 U.S.C. 355(b) or (j)] is in effect for the drug. Based on our information, there are no FDA-approved applications on file for these drug products.

Additionally, the above products are misbranded because, as prescription drugs, adequate directions cannot be written for them so that a layman can use these products safely for their intended uses. Consequently, their labeling fails to bear adequate directions for use as required under Sections 502(f)(1) of the Act [21 U.S.C. 352(f)(1)] and because the products lack required approved applications, they are not exempt from this requirement under 21 CFR 201.115. The introduction or delivery for introduction into interstate commerce of these products without approved new drug applications violates Section 301 (a) and (d) of the Act [21 U.S.C. 331 (a) and (d)].

It is clear that unapproved colchicine is in violation of several Federal Statutes.

There is another glaring inaccuracy in your most recent letter to me. You wrote, "I seriously doubt, as your letter of February 16, 2010 states, that members of the American College of Rheumatology have been attempting to prevent the Food and Drug Administration from removing as you phrase it, "illegal unapproved colchicine products from the market due to concerns for price-based patient access." In fact, it is incredulous to suggest that individual rheumatologists would have that level of influence over a federal agency. In any event, ACR is not aware of any of its members attempting to undertake such actions. Nor have I, or the ACR staff, encouraged any ACR members to attempt to influence the FDA in that manner."

However, there are at least three publicly available examples, two from your own ACR website and one from a published editorial from an ACR member, demonstrating that your statement is not true and you have advocated for keeping illegal, unapproved colchicine on the market.:

- In a report to ACR members about your meeting with the FDA, titled, "Summary of January 21 Teleconference with FDA Regarding Colchicine," available on the ACR website, ACR states, "The ACR suggested that the FDA prolong the usual "grace" period of one year before forcing other manufacturers to cease production of colchicine."
- On the ACR website page titled "ACR Federal Advocacy Hot Issues," a section highlighting ACR's meeting with the FDA states, "The College strongly encourages the Food and Drug Administration to grandfather unapproved colchicine and grant market approval to unapproved colchicine so that patients can continue to access this vital inexpensive treatment."
- In an editorial published in *Rheumatology News* in January, Dr. Edward Fudman writes that the price of colchicine will increase "unless rheumatologists and patients can convince the Food and Drug Administration to allow the colchicine made by generic manufacturers to stay on the market." Since the only colchicine that is "made by generic manufacturers" and is on the market is the illegal, unapproved colchicine, it is clear what Dr. Fudman means.

These three statements contradict the assertion in your letter that neither ACR nor ACR members have ever attempted to influence the FDA to keep unapproved colchicine on the market. This again raises my concern over incorrect or conflicting information around ACR's position on illegal, unapproved colchicine.

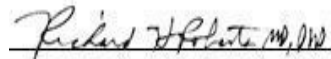
Having expressed my concerns over these issues, I must also express my gratitude to you and ACR for your positive response to our expanded Patient Assistance Program. Our goal is to ensure that patients who may benefit from Colcrys® are able to obtain it with no financial barriers to access. Our new program significantly expands the number of eligible patients. Under the program, uninsured and Medicare Part D patients with household incomes of up to four times the federal poverty level (up to \$88,000 per year for a family of four) can receive Colcrys® for \$5 a month. Uninsured and Medicare Part D patients with household incomes between four to six times the federal poverty level (up to \$132,000 per year for a family of four) can receive Colcrys® for \$25 a month.

I regret that my correspondence to you, which I had hoped would convey important information and call attention to previously unknown safety hazards associated with unapproved colchicine, was misconstrued as a threat. Again, let me assure you that was not my intent. Let me also assure you that we respect, support and advocate for the right of every physician to practice medicine in a manner that always puts the best interests of their patients before all else. I believe that any rational person, who reads what I have written above, will come to understand that I have attempted to protect physicians. Those who claim the opposite are twisting the facts and mischaracterizing my intent.

We also firmly believe that our work to develop a better and safer colchicine will make a positive and meaningful difference in the lives of patients with gout and Familial Mediterranean Fever (FMF).

Please feel free to contact me if you have any questions or concerns.

Sincerely,



Richard H. Roberts, M.D., Ph.D.
President & Chief Executive Officer
RHR/ph