Congress of the United States

Washington, DC 20515

May 23, 2011

Richard H. Roberts, MD, PhD
President, CEO and Chairman
URL Pharma, Inc.
1100 Orthodox Street
Philadelphia, PA 19124

Dear Dr. Roberts:

As Members of Congress with leadership positions on Committees of jurisdiction over health care issues, we take very seriously our responsibility to protect the interests of our nation's health care consumers and the health care system on which they rely.

As such, we have recently become increasingly concerned with the price of drugs in this country, and read with great interest the reports that your company is charging unreasonable prices for Colcrys, a medication used to treat gout flares and Familial Mediterranean Fever (FMF). Although colchicine, the active ingredient in Colcrys, has been widely available for years, it had never received FDA approval. In July 2009, URL Pharma obtained FDA approval for Colcrys and as a result was awarded three years of exclusive marketing for the treatment of gout flares. URL Pharma also received a term of seven years of Orphan Drug exclusivity for the use of Colcrys in the treatment of Familial Mediterranean Fever (FMF). Upon receiving this marketing exclusivity, it was reported that URL Pharma began charging prices that were fifty times higher than the price for colchicine—the price rose from $0.09 per pill to $4.85 per pill.

Colchicine plays an important role in preventing pain for elderly American gout patients. Charging prices for newly-patented drugs fifty times higher than for the price of the same drugs that have been used for decades greatly increases costs for our nation's health care system.

Doctors and patients were understandably upset at the news that a vital drug, once available for pennies per pill, was now going to be almost $5.00 per pill. High prices lead to tough choices for patients. Further, the higher price of this treatment will be borne by private health plans and the federal government, and will contribute to the continued overall growth in health spending. We were pleased to hear that the company is establishing an extensive patient access program. Still, questions remain over how the original price was calculated.

Therefore, we request that URL Pharma submit written documentation in response to the following questions and requests for information. The Attachment of this letter will specify in full detail what materials are to be included in response to this request.

1. What was the total cost of the clinical trials that led to the approval of Colcrys? Please detail all expenditures. What is the estimated cost of the post-market studies to which the company has committed?
2. Please provide copies of all correspondence with FDA related to Colcrys, including emails and formal letters.
3. How was the initial list price of Colcrys established? Please provide all internal documentation relating to the determination of the price, including but not limited to emails, correspondence with shareholders, and internal memos.
4. How much has URL Pharma spent on marketing Colcrys since its approval? How much does URL Pharma plan to spend on marketing this drug in the next year? What percentage of the marketing budget will be directed to Colcrys over the next year?
5. What is the total cost, and estimated unit costs, to manufacture Colcrys, and the components of such costs? What are the expected revenues and profits from sales of Colcrys? What are the anticipated revenues and profits from sales of Colcrys to Medicare, Medicaid, and other federal or state health care programs?
6. Is Colcrys available outside the United States? If so, what is the list price and profit margin in all other countries?
7. How many people have joined your newly-established patient access program for Colcrys? What percentage of those enrollees are gout patients, and what percentage are patients with Familial Mediterranean Fever?
8. How much is URL Pharma projecting in sales for fiscal year 2011?

Please furnish this documentation by electronic mail, fax, or hand delivery, no later than close of business on June 10, 2011. Any questions concerning this request may be directed to Jack Mitchell or Sarah Molinoff of the Senate Special Committee on Aging staff at (202) 224-5364. Thank you.

Sincerely,

Senator Herb Kohl

Congressman Henry Waxman

Congressman Frank Pallone

Congresswoman Diana DeGette

ATTACHMENT

GENERAL INSTRUCTIONS

1. The terms "URL Pharma" and "your institute" mean its corporation, or one or more of its divisions, subsidiaries or affiliates, or related entities, including any other companies or corporations with which "URL Pharma" entered into a partnership, joint venture or any other business agreement or arrangement.

2. In complying with this document request, produce all responsive documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, and representatives acting on your behalf. In addition, produce documents that you have a legal right to obtain, documents that you have a right to copy or have access to, and documents that you have placed in the temporary possession, custody, or control of any third party.

3. No documents, records, data or information requested by the Committee shall be destroyed, modified, removed or otherwise made inaccessible to the Committee.

4. If the document request cannot be complied with in full, it shall be complied with to the extent possible, which shall include an explanation of why full compliance is not possible.

5. In complying with this document request, respond to each enumerated request by repeating the enumerated request and identifying the responsive document(s).

6. Each document produced shall be produced in a form that renders the document susceptible of copying.

7. It shall not be a basis for refusal to produce documents that any other person or entity also possesses non-identical or identical copies of the same document.

8. If any document responsive to this request was, but no longer is, in your possession, custody, or control, identify the document (stating its date, author, subject and recipients) and explain the circumstances by which the document ceased to be in your possession, or control.

9. This request is continuing in nature. Any document, record, compilation of data or information, not produced because it has not been located or discovered by the return date, shall be produced immediately upon location or discovery subsequent thereto.

GENERAL DEFINITIONS

1. The term "document" means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to the following: memoranda, reports, statistical or analytical reports, books, manuals, instructions, financial reports, working papers, records notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, interoffice and intra office communications, electronic mail (E-mail), contracts, cables, notations of any type of conversation, telephone call, meeting or other communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motion pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, discs, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disc, or videotape. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.

2. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.

3. The terms "relate," "related," "relating," or "regarding" as to any given subject means anything that discusses, concerns, reflects, constitutes, contains, embodies, identifies, deals with, or is any manner whatsoever pertinent to that subject, including but not limited to documents concerning the preparation of other documents.

4. The terms "and" and "or" shall be construed broadly and either conjunctively or disjunctively to bring within the scope of this document request any information which might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa to bring within the scope of this document request any information which might otherwise be construed to be outside its scope. The masculine includes the feminine and neuter genders to bring within the scope of this document request any information that might otherwise be construed to be outside its scope.

5. The term "communication" means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, written, electronic, by document or otherwise, and whether face to face, in a meeting, by telephone, mail, telexes, discussions, releases, personal delivery, or otherwise. Documents that typically reflect a "communication" include handwritten notes, telephone memoranda slips, daily appointment books and diaries, bills, checks, correspondence and memoranda, and includes all drafts of such documents.