*La Muerte**

An Investigative Report on Vioxx and Corporate Marketing
in Puerto Rico.

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Consejo de Latinos Unidos
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*Spanish for Death.

Executive Summary

Key Findings

- As aggressive as Merck was in marketing Vioxx, Merck appears not to have adequately informed the public or medical community in Puerto Rico about the cardiovascular dangers of Vioxx, even after the FDA called on them to do so in late 2001.

- Merck appears to have failed to circulate information of the cardiovascular dangers in Spanish to the public or medical community in Puerto Rico between 2002 and 2004, time period after they had modified Vioxx warning labels (known as patient package inserts) and before the drug was pulled.

- Puerto Rico residents who used Vioxx and suffered cardiovascular problems feel they were used as "guinea pigs" and that the company should have informed them and their doctors of the associated risks. In one case, a victim knew about the dangers of using Vioxx with her kidney problems, but was never informed of the cardiovascular dangers.

Recommendations

- Merck and other leading pharmaceutical companies should institute a campaign in Spanish to educate the Puerto Rican community about the risks associated with their pharmaceutical products that is equal to the campaigns to promote their product.

- Merck and other leading pharmaceutical companies should publish all warning labels (patient package inserts) in Spanish and heavily distribute them with their representatives in Hispanic areas of the United States and in Puerto Rico.

- Merck should resolve these legal challenges by injured Vioxx patients fairly and equitably.

Introduction and Background

The Consejo de Latinos Unidos is a national non-profit organization that educates and assists Hispanics and others about health care, police protection, education and immigration. We are a consumer advocacy group. We were interested in doing an investigative study on Vioxx and the effects on Hispanic consumers. We decided to launch an investigative study in Puerto Rico, a perfect market to see how Hispanic consumers were impacted by Merck's corporate behavior.

Withdrawal

On September 30, 2004, Merck withdrew its painkiller Vioxx from the market. Vioxx had been introduced in 1999 as a pain reliever that would not upset the stomach or cause bleeding ulcers. Merck had made $2.5 billion from the sales of Vioxx in 2003. Now the company released the following statement:

> "Merck & Co., Inc. today announced a voluntary worldwide withdrawal of Vioxx (rofecoxib), its arthritis and acute pain medication. The company's decision, which is effective immediately, is based on new, three-year data from a prospective, randomized, placebo-controlled clinical trial, the APPROVe (Adenomatous Polyp Prevention on Vioxx) trial. The trial, which is being stopped, was designed to evaluate the efficacy of Vioxx 25 mg in preventing recurrence of colorectal polyps in patients with a history of colorectal adenomas. In this study, there was an increased relative risk for confirmed cardiovascular events, such as heart attack and stroke, beginning after 18 months of treatment in the patients taking Vioxx compared to those taking placebo. 'We are taking this action because we believe it best serves the interests of patients,' said Raymond V. Gilmartin, chairman, president and chief executive officer of Merck." [1]

Merck appeared to say the decision was based on "new" data that showed a link between Vioxx and heart attacks and strokes. As Dr. Wayne Ray told *The New York Times*, "A heart attack in exchange for an ulcer is a poor treatment."

Merck also appeared to say the company was serving the "interests" of their patients. But soon the ball of string unraveled.

A Four-Year-Old Problem

The truth about a four-year known problem came out soon after Merck pulled Vioxx. As reported in *The New York Times*:

> "In May 2000, executives at Merck, the pharmaceutical giant under siege for its handling of the multibillion-dollar drug Vioxx, made a fateful decision. The company's top research and marketing executives met that month to consider whether to develop a study to directly test a disturbing possibility: that Vioxx, a painkiller, might pose a heart risk. Two months earlier, results from a clinical trial conducted for other reasons had suggested such concerns. But the executives rejected pursuing a study focused on

[1] Merck Press Release, Whitehouse Station, NJ, September 30, 2004.

> Vioxx's cardiovascular risks. According to company documents, the scientists wondered if such a study, which might require as many as 50,000 patients, was even possible. Merck's marketers, meanwhile, apparently feared it could send the wrong signal about the company's confidence in Vioxx, which already faced fierce competition from a rival drug, Celebrex. 'At present, there is no compelling marketing need for such a study,' said a slide prepared for the meeting. 'Data would not be available during the critical period. The implied message is not favorable.' Merck decided not to conduct a study solely to determine whether Vioxx might cause heart attacks and strokes - the type of study that outside scientists would repeatedly call for as clinical evidence continued to show cardiovascular risks from the drug. Instead, Merck officials decided to monitor clinical trials, already under way or planned, that were to test Vioxx for other uses, to see if any additional signs of cardiovascular problems emerged. It was a recurring theme for the company over the next few years - that Vioxx was safe unless proved otherwise. As recently as Friday, in newspaper advertisements, Merck has argued that it took 'prompt and decisive action' as soon as it knew that Vioxx was dangerous. But a detailed reconstruction of Merck's handling of Vioxx, based on interviews and internal company documents, suggests that actions the company took - and did not take - soon after the drug's safety was questioned may have affected the health of potentially thousands of patients, as well as the company's financial health and reputation."[2]

Soon after Merck's announcement, international scientists and researchers released studies showing that the cardiovascular problems with Vioxx were known:

> "U.S. drugs giant Merck & Co Inc. should have pulled its Vioxx painkiller from the market four years ago because data showing it raised the risk of heart attacks has existed since 2000, Swiss scientists said on Friday. In a report for British medical journal *The Lancet*, researchers at the University of Berne said there was substantial evidence of the dangerous side effects of the drug by the end of 2000…. 'Our findings indicate that rofecoxib (Vioxx) should have been withdrawn several years earlier,' the scientists said. 'The company could and should have made the statement several years back, when the data we analyzed were readily available,' Matthias Egger, a professor at the university's department for Social and Preventative Medicine…."[3]

A Food and Drug Administration researcher, who had written about the known cardiovascular problems of Vioxx, had his report released earlier this year in Europe after it was withheld.

> "A [London] medical journal published a study Tuesday of coronary disease related to the anti-inflammatory drug Vioxx after withholding the report because the researcher said he had been threatened by superiors at the U.S. Food and Drug Administration. *The Lancet*, which originally planned to publish the paper on November 17, released the study online. Dr. David Graham, who works in the FDA's office of drug safety, has said he was firmly discouraged from publishing his data questioning the safety of Vioxx, which was withdrawn from the market in September. 'I was sent an e-mail by one of my

[2] Berenson, Alex, et al, "Despite Warnings, Drug Giant Took Long Path to Vioxx Recall," *The New York Times*, November 14, 2004.
[3] Armitage, Tom, *Reuters News Service*, November 4, 2004.

> supervisors threatening me with severe consequences' if the paper was published, Graham said in a telephone interview Monday. Believing he was threatened with dismissal, he said he asked *The Lancet* to withdraw the paper from publication in November [of 2004]."[4]

The FDA, humiliated by their lack of oversight, had earlier released an internal memorandum that showed that almost 28,000 heart attacks and deaths could possibly be linked to Vioxx.

> "Providing details from a report it had described broadly in August [2004], the Food and Drug Administration published a memorandum…that indicated Merck's Vioxx painkiller might have contributed to 27,785 heart attacks and deaths from 1999 through 2003. The memo, based on a sample of patient records, concluded that people taking Vioxx were more likely to have heart attacks or die from sudden cardiac arrest than people taking a competing painkiller, Celebrex from Pfizer."[5]

Acting Responsibly?

Even though the company was critically attacked for not alerting the public or withdrawing Vioxx earlier, "Merck executives said …that the company acted responsibly, voluntarily withdrawing Vioxx as soon as it had clear evidence the drug was harmful. And they said that even if they had conducted the type of study they discussed internally and rejected in 2000, the company might not have detected Vioxx's risks any sooner. 'Merck wasn't dragging its feet,' said Kenneth C. Frazier, the company's general counsel. 'It's pretty hard for me to imagine that you could have done this more quickly than we did.'" [6]

But "acting responsibly" was not the impression one would get from a scathing letter from the FDA that was sent to Merck in September of 2001. In the letter, a division of the FDA tells Merck that it "has reviewed [Merck's] promotional activities and materials [for Vioxx] and has concluded that they are false, lacking in fair balance, or otherwise misleading in violation of the Federal Food, Drug, and Cosmetic Act….You have engaged in a promotional campaign for Vioxx that minimizes the potentially serious cardiovascular findings that were observed in the Vioxx Gastrointestinal Outcomes Research (VIGOR) study, and thus, misrepresents the safety profile for Vioxx. Specifically, your promotional campaign discounts the fact that in the VIGOR study, patients on Vioxx were observed to have a four to five fold increase in myocardial infarctions (MIs) compared to patients on the comparator non-steroidal anti-inflammatory drug (NSAID), Naprosyn (naproxen)."[7]

Public Relations to the Rescue or to Cover Up

After withdrawing Vioxx and feeling the heat from plaintiff lawyers (who were filing hundreds of lawsuits), international scientists, and an FDA researcher, Merck put a public relations

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[4] *Associated Press*, London, England, January 25, 2005.
[5] Bloomberg News, "FDA Releases Memo on Vioxx," November 3, 2004.
[6] Berenson, Alex, et al, "Despite Warnings, Drug Giant Took Long Path to Vioxx Recall," *The New York Times,* November 14, 2004.
[7] Letter from the Food and Drug Administration to Merck & Company, dated September 17, 2001.

campaign into full swing. Merck's public relations "campaign to defend itself in the wake of the recall of the pain reliever Vioxx intensified as it placed a package of three full-page ads in seven prominent newspapers…. That follows several television appearances as well as testimony before Congress by the company's chief executive. But public relations experts are calling the campaign predictable… .Merck's strategy of asserting it withdrew Vioxx immediately upon learning there was a link between the drug and a higher risk of heart attack and strokes could backfire if plaintiffs' lawyers prove the company understood the side effects much earlier and stifled the news. That's because if lawyers prove Merck muzzled Vioxx's risks, the company may be forced to pay punitive as well as compensatory damages. The public relations campaign could be viewed as part of that cover up, said Benjamin Zipursky, a professor at Fordham University School of Law." [8]

FDA Panel Re-Approves Vioxx!

But last month the most "impressive" public relations stunt or cash-in on political chips came with the re-approval of Vioxx by an FDA panel. On February 18, 2005, an FDA "health advisory panel…confirmed cardiovascular risks from certain anti-inflammatory drugs, but agreed to the return of Vioxx, withdrawn last year, and continued sale of two similar medications whose safety was questioned. The 17-15 ruling on Vioxx paves the way for Merck to bring the controversial painkiller back to pharmacies. But some analysts said the decision was important mainly to help Merck fight a flood of litigation from Vioxx users."[9]

How could this be?

"Ten members of the Food and Drug Administration advisory panel who voted that a group of powerful pain killers, including the controversial drug Vioxx, should continue to be sold had ties to the drug makers, a new analysis shows. After three days of hearings on the drugs, … the panel voted …17-15 that Merck's Vioxx should be allowed back on sale. However, a copy [of the vote] obtained by The Associated Press indicated that the 10 panel members in question voted … 9-1 in favor of allowing Vioxx to be brought back onto the market. Without those ballots the vote would have been…14-8 to keep Vioxx off sale."[10]

[8] Agovino, Theresa, *Associated Press*, November 22, 2004.
[9] AFP, "FDA Narrowly Approves Vioxx," February 18, 2005.
[10] "10 on FDA Panel had Ties to Companies," *Associated Press*, February 25, 2005.

Tragedy in Puerto Rico

The tragedy in Puerto Rico is that many patients took the product without knowing the risks of heart attack or stroke. As one victim told us, "The only thing I can say is that I was told that [Vioxx] would damage my kidneys. This is why I did not take them daily."[11] She ended up having two heart attacks.

But why did patients fail to be informed?

As we investigated the problems in Puerto Rico, we were astounded to find that literature and documents from Merck were distributed to physicians and patients in English.

English is not spoken by all Puerto Ricans. Using English-only materials was a disservice and could have been responsible for many of the deaths and injuries suffered by the individuals and families that contacted the Consejo.

New Warning and Instruction Documents in 2002

After Merck received the scathing letter from the FDA in September of 2001 for downplaying the cardiovascular problems associated with Vioxx, Merck changed Vioxx's warning label (patient package insert) and prescribing information for physicians by April of 2002.

That April, Merck sent out a "Dear Doctor" cover letter along with the revised Patient Information and Prescribing Information documents.

The new warning label titled "Patient Information" simply declared as the second of Vioxx's "serious but rare side effects" the following: "Heart attacks and similar serious events have been reported in patients taking Vioxx." This was new information added in April of 2002.

However, a bigger and bolder change came in the Prescribing Information in a section titled "Information for Patients," which stated the following new information:

> "Physicians should instruct their patients to read the patient package insert before starting therapy with Vioxx and to reread it each time the prescription is renewed in case any information has changed."

Startling!

Yet that unique and specific instruction <u>was not even mentioned</u> in the "Dear Doctor" cover letter sent by Merck's Vice President of Medical and Scientific Affairs.

As a leading physician in Puerto Rico told us:

[11] Case 2210.

> "Even assuming that the 'Dear Doctor' letter reached physicians in any significant number, I can't remember any outreach or educational program by Merck locally or nationally specifically devoted to communicating these results. The patient package information was distributed in ridiculously low numbers versus the actual samples and **none of this was available in Spanish**. The information for patients contains an inadequate bullet point." (emphasis added)

Strongest Evidence: Patient Testimonials

The strongest evidence we collected about the problems facing Puerto Rican residents who used Vioxx is their testimonials. The Consejo received over 250 calls in less than a week when we launched our initial investigation. Here are a few of the stories we were told.

Merck Only "Interested in their Earnings"

"[Vioxx] was given to me by my doctor for muscle pain. I had a heart attack. I am not sure what amount I took because I took a lot because I have back pain, arthritis, and I have had knee surgery," says Israel L. "If something is not good for the public, [Merck] should not use us as guinea pigs. If people are aware that this is harmful then that is different. I would say that it was lack of ethics. If they knew that this was harmful and they were only interested in their earnings. I do not think that this is legal."[12]

Wife Recalls Husband's Sudden Death: "He was Gone in Less than Five Minutes"

Sulina M., gives us this heart-wrenching story: "My husband had a knee problem. He went to the emergency hospital in November [of 2004]. His knee was very swollen. The doctor told him he had a lot of liquid in his knee. He told him that he could not give him a shot because there were a lot of germs. He told him to take Vioxx. He took Vioxx for about a week or so. My husband was fine. But he had taken it before. He took it before. But I cannot find the prescription. They gave him about five little sample boxes of Vioxx. You know the sample boxes. He was fine, he went back to the doctor and he had some tests done. He went to his doctor and the doctor told him that his sugar was a little high. His physical results were fine. That was on Monday and on Tuesday we went shopping and then at night at about ten o'clock he went to bed and then he started shaking and shaking and I asked him what was wrong. He had a heart attack. He had a heart attack and a stroke. I called my neighbor who is a doctor and he told me he was gone. And I called a friend of mine who is also a doctor. They told me he was gone. He was gone in less than five minutes. Well, you know he was not taking anything else but Vioxx. Once in a while he took an aspirin. I do not think aspirin will kill you. I would tell them that they should have done more tests. It is hard for me to explain because I feel so…[crying] …I loved my husband for thirty-five years; it is not easy…[crying] I am losing my house [crying] I am losing everything. I am losing everything. I am so sorry for crying. It is very hard. The only proof I have are the sample boxes [of Vioxx]. I still have them here."[13]

[12] Case 2206.
[13] Case 2202.

Why Sell Vioxx if it is Harmful?

Elisa O. took Vioxx "for back pain. My therapist prescribed it. I took it on September 3rd and 4th. On October 17th I was on the phone with my niece and my mouth … I got tongue tied and my mouth turned, my vision blurred, my legs weakened and my hand weakened. I began moving my hand. I asked my son to take me to the hospital. I was in the hospital for five days. I had an MRI …. The doctor told me that the MRI showed that I had had a small stroke. I feel a lot of fatigue. [Merck does not appear to have] good manufacturers, engineers, and chemist. Why are they selling this medication if they know that it is harmful?"[14]

Vioxx "Complicated Our Health"

Victor H. says, "About four or five years ago I began getting chronic arthritis pain. To help with the pain I began taking Vioxx. While I was taking Vioxx I noticed that my blood pressure would rise. It rose so much that I now have to take high blood pressure medication….I almost had two strokes because my blood pressure was so high. [Merck] defrauded us. They were selling us something that was supposed to help us and instead it complicated our health. It has affected me that I feel very depressed and it has affected me psychologically. I was fooled, and so was my wife. They were selling me a product that was supposed to help my arthritis and not complicate it."[15]

Vioxx Helped With Pain, But Damage Done

"I fell off a chair and I went to hospital for my injuries [back and knee injury]," says Jorge C. "I was given Vioxx for the pain. I was waiting for my surgery appointment. I was supposed to have my back surgery on December 28th and I had a heart attack on December 23rd and I was hospitalized for five days. The medication really helped with my pain…[but] the damage [had] already been done."[16]

Merck "Hurt a Lot of Innocent People. We Just Wanted to Get Better"

"I noticed that I had chest pain," Milagros E. tells us. "I had an EKG and something came out abnormal. I now have abnormal heart palpitations and have had to go to emergency frequently for chest pain. I am now taking medication for high-blood pressure. The cardiologist gave me Vioxx in March [of 2004]. It made my blood pressure go up. If [Merck] knew that there was a problem with the medication they should have not had it in the market. This damaged a lot of us. I have three children. I am only 46- years old and my health has been declining. I am too young to be going through this. Why did they put their medication on the market if they knew there would be secondary affects? They have hurt a lot of innocent people. We just wanted to get better."[17]

[14] Case 2217.
[15] Case 2203.
[16] Case 2208.
[17] Case 2209.

A Vioxx-A-Day Leads to Near Stroke

I was taking one Vioxx pill daily," Enrique A. tells us. "I almost had a stroke. While taking Vioxx my face turned and my eyes turned also. [Vioxx is] a danger to people. A lot of elderly people have died while taking Vioxx."[18]

Merck "Never Informed Us" of Risks

"I was using Vioxx because I have a herniated disc. I had a heart attack. I had never connected my heart attack with the use of Vioxx," says Hector L. "When I heard the news that this medication was removed from the market because it was causing cardiac problems…perhaps this medication contributed to my heart attack. I am not sure if this is connected. I have had secondary affects. I am disabled for life now. After having my heart attack and now that I have asthma I cannot work. [Vioxx] was supposed to help with pain. They never informed us that this would affect our heart, or any other related heart ailments."[19]

One or Two Vioxx Pills Later, Mother has Stroke

"My mother [Olga Q.] took Vioxx for only one day," says daughter Isabel M. "She went to the doctor because she said that she had hand pain. The doctor prescribed Vioxx. She took one or two Vioxx [pills]. She took one when we got home and one right before going to bed. I really do not remember. The next morning when she woke up she was not able to move her right hand and the right side of her body. I took her to emergency. Her blood pressure was above 200. At the hospital she lost total movement of her right side of her body. From her neck, waist, right arm and right leg she has about 40% movement. She walks with a cane. She cannot move her right hand. She was hospitalized for six days. My mother has always thought that this medication caused her illness. She was always a healthy woman."[20]

Three Years of Taking Vioxx, Mother has Two Strokes

"[My mother] has arthritis. In 2000, she was given Vioxx. Last year in February 2003 she had a stroke and in June 2003 she had another. She was hospitalized both times. She has lost a lot of weight…and she has also lost her self-esteem," testifies Daniel R.[21]

Heart Injured

"I was taking Vioxx because I have so many different things: osteoporosis, herniated discs, injured arms. I get very bad kidney pain. I would take Vioxx whenever I had bad pain," says Alicia G. "I took it for two years. The doctor would give me the samples that were sent to her. There were times I purchased them. I would take the medicine and I would go without pain for about four to five days. One day I was getting ready to go out with a friend when I felt chest

[18] Case 2211.
[19] Case 2204.
[20] Case 2205.
[21] Case 2207.

pain. I had a heart attack. The paramedics could not diagnose my ailment. When I arrived at the hospital I was told that I had had a heart attack and that I was having another.…When my heart tests were done I was able to see that my heart was injured. The only thing I can say is that I was told that [Vioxx] would damage my kidneys. This is why I did not take them daily."[22]

Irresponsible

Rosa S, an unemployed and disabled patient, told us, "I was sick and I got worried when I read about Vioxx. I had had a small brain stroke. I am worried because I am now taking medication for a heart condition and to prevent blood clots. I got worried because even dermatologists were warning that this medication was bad for you. I do not know why they were giving this medication if I had two medical problems. I believe that they were promoting this medication a lot. I think that this medication really helped me a lot with my pain. The pain went away but then my face would paralyze. I am not sure of this has to do with the medication. I do not want to harm the doctor. [Merck] had representatives that were promoting this medicine to the doctors also. The doctors did not know a lot about what was happening. Recently I had to have other tests done. The cardiologist had to perform an EKG and other analysis—to verify that nothing is wrong. I have had to pay for all these tests. I do not want to harm the doctor. He seems to be a very nice person. I do not think it was his fault. He was not informed correctly. [Merck was] very irresponsible. They made sure that they promoted this product very well. They should have alerted the doctors about this problem. Doctors would have known that there were patients that would have not been able to take this medication. I was hospitalized and I was able to speak, and I have problems with blood clots. Doctors should have been notified. I have another question. I was recently given Celebrex. Should I take it?"[23]

The Consequences

"I had a brain stroke. I was sent to a neurologist. They did an MRI and they deduced that I had had a stroke and a heart attack," says Sara C. "I think that [Merck] often ignored a lot [of the problems associated with prescription drugs], and perhaps that is why doctors were prescribing [Vioxx]. The medication really takes the pain away and these are the consequences. [Merck] should do more research. There have been a lot of deaths because of this."[24]

"We Were an Experiment"

"I started taking Vioxx soon after it was on the market here in Puerto Rico. I took Vioxx almost every day. On June 21, 2004 I was having breakfast I started feeling as if my left side …my hand ... I started with my hand. I didn't pay much attention to it. I thought that it was just another ailment. I finished eating," Iris S. says. "When I stood to walk I did not have coordination. I got desperate; I made it to the kitchen and fell over the kitchen sink. I asked, "What is happening?" I took a deep breath and that did not help. I still could not see clearly. I was able to make it to a chair. I sat and started praying. My eldest son came to me I started speaking to him and I realized that I was not speaking clearly. My husband called [and] he

[22] Case 2210.
[23] Case 2201.
[24] Case 2213.

noticed that I was not speaking normally. I told him what had happened. He said I think you have had a heart attack. He told me to call the doctor. I called the doctor and described what had happened to me and he also said that he believed I had had a heart attack. He sent me to have an MRI; the MRI showed that I had had a heart attack. I continued taking Vioxx because I did not know that this was the problem. In September when they took Vioxx off the market I thought that maybe my heart attack was related to me taking Vioxx. They are treating us as if we were an experiment. The pill took the pain away, but I honestly think that this pill caused my heart attack."[25]

Love for Humanity

"My mother was a heart patient; we would take her to a cardiologist. She was taking Vioxx. She was sent to have a heart exam because she had chest pain," says daughter Aida O. about her mother Justa T. "She had by-pass surgery and after the surgery she continued having chest pain. I think that if they had knowledge that this medication was causing harm and they did not notify the patients, then I think they did wrong. I would tell them that they have to be more conscientious of the all the harm they have caused to the person. We are humans and we have feelings and we want to have a better quality of life. They should have a little more love for humanity and not love for money."[26]

Merck Knew that Vioxx was Harmful But Still Had it on the Market

"I had problems; I had a small heart attack. I had to start taking medication for heart palpitations. I did not know that Vioxx was affecting me this way," says Herman B."I think [Merck] knew what was happening…. This was a form of abuse. They knew that this was harmful and they still had it on the market."[27]

People Taken Advantage Of

Evelyn P. had taken Vioxx. She suffered two serious ailments that she believes was caused by Vioxx. "On one occasion I had lower abdominal pain and I had to go to emergency and another occasion I had facial paralysis [small stroke] and I was off of work for about five months. When I heard what Vioxx had been doing, I associated my situation with Vioxx. If they knew that this medication had secondary affects then they have taken advantage [of the people]."[28]

Help Us Merck!

Jose S. started taking Vioxx in November of 2002. "On January 12, 2003 I had a heart attack and I had two pulmonary embolisms. I was in the hospital for …one month in intensive care and another month in regular care. I was very bad. It affected my respiration and I have hypertension. I am taking blood pressure medication and I am also taking blood-thinning medication. I had never taken this medication in the past. When this occurred to me I felt very

[25] Case 2214.
[26] Case 2216.
[27] Case 2218.
[28] Case 2215.

bad. I did not know that my situation was related to Vioxx. After hearing that Vioxx was harmful now I believe that they did take advantage [of me. Merck needs] to be sincere and to give us the reasons for taking it off the market. [Merck needs] to help us or fix what they have caused."[29]

Governing Authorities Blamed

"[My daughter] did not have any heart problems. While she was taking that [Vioxx] medication she had a brain stroke," says Milagros D., mother of Arlene R. "The doctor says that she also has abnormal heart palpitations. Her blood pressure is also very high; it is over 200. She easily faints. 911 has had to take her to the hospital. They have to normalize her at the hospital. She cannot get upset or over worked because she gets sick. She has had to miss work and I have also had to miss work. This has been very difficult. [I]n the month of June she had a stroke. She has been very sick. If [Merck] knew that this medicine had secondary affects,….the governing authorities should have never authorized them to put this drug on the market."[30]

[29] Case 2219.
[30] Case 2212.

Conclusion

The residents of Puerto Rico who contacted us and the evidence we have reviewed against Merck demonstrates that Vioxx appears to be a health danger to some patients and, more importantly, Merck appears to have failed to inform the patients and physicians of Puerto Rico adequately.

We believe that in 2002 Merck should have aggressively informed physicians and patients in Puerto Rico about the risks associated with Vioxx with Spanish-language materials.

This oversight, this possible negligence, may have also impacted other Hispanic strongholds in the United States.

When corporations are more interested in increasing their sales than verifying safety or informing the public about their products, people are injured.

No matter how many public relation companies Merck hires or how many "advisory panels" bless the "limited-use" Vioxx, the residents in Puerto Rico deserve more from Merck.

We recommend the following:

- Merck and other leading pharmaceutical companies should institute a campaign in Spanish to educate the Puerto Rican community about the risks associated with their pharmaceutical products that is equal to the campaigns to promote their product.

- Merck and other leading pharmaceutical companies should publish all warning labels (patient package inserts) in Spanish and heavily distribute them with their representatives in Hispanic areas of the United States and in Puerto Rico.

- Merck should resolve these legal challenges by injured Vioxx patients in Puerto Rico fairly and equitably.

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About the Author

K.B. Forbes is the Executive Director of the Consejo de Latinos Unidos. Forbes is the author of six other Consejo investigative reports: *Cinco*, a report on hospital price gouging in Southern California (2001); *Ahora*, a report on allegations of police brutality in Southern California (2002); *Infierno*, a report on hospital price gouging in Chicago, Denver, Oklahoma City, and Orlando (2003); *Unconscionable*, a report on hospital price gouging and unfair trade practices in Fort Myers, Florida (2003); *Esperanza*, a report on aggressive court activity and hospital price gouging in Miami, Florida (2004); and *Engañar*, a report on HCA's Discount for the Uninsured program and deceptive corporate conduct (2004). A former journalist and English as a Second Language teacher near Watts, Los Angeles, he is the son of a Latino immigrant.

About the Consejo

The Consejo de Latinos Unidos, a national nonprofit organization which educates and assists Latinos and others in the areas of health care, immigration, education, and police protection, is supported almost exclusively by non-profit organizations. Consejo has offices in Los Angeles and Miami. Consejo receives no funding from insurance companies, political parties, or labor unions. In 2003, Consejo was credited by *The Wall Street Journal* with "a big win" after forcing the nation's second largest hospital chain, Tenet Healthcare, to change its aggressive billing practices against the uninsured by charging the uninsured the same prices insurance companies pay for the exact same care.