#1362

PARLODEL

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Joan Claybrook, President

April 12, 1995

Dr. U. Barlocher
Chairman of the Board
and Chief Executive Officer
Sandoz Pharma Ltd
CH-4002 Basel
Switzerland

Dear Dr. Barlocher,

Use of Bromocriptine (Parlodel) in Postpartum Lactation

We have learned from a Sandoz official that drug regulatory authorities in eight countries -- Argentina, Cyprus, Israel, Malaysia, Nigeria, Oman, South Korea, and UAE "have requested Sandoz to withdraw the indication of postpartum lactation suppression for bromocriptine (Parlodel)," and that "Sandoz has accepted the request of the authorities in these countries and is making appropriate labeling changes." However, in the rest of the world including the attached list of 45 countries, -- to the detriment of millions of women in these countries -- Sandoz continues to sell bromocriptine for lactation suppression. This is only a partial list of all countries in which the drug is labelled for lactation suppression. We demand that you immediately withdraw this indication in all countries where this has not been already done because, according to the United States Food and Drug Administration (FDA), **"therapeutic use of bromocriptine for the prevention of physiological lactation may lead to serious adverse experiences, including death and paralysis, in a small but significant number of patients....."** (See below)

As you know, the Public Citizen Health Research Group (HRG) led the campaign in the U.S. to have the postpartum lactation suppression indication removed for bromocriptine. In November 1988, HRG first petitioned the FDA in collaboration with the National Women's Health Network to ban <u>all</u> lactation suppressants including bromocriptine because these products were of doubtful value and posed serious risks to mothers. In June 1989, FDA's Fertility and Maternal Health Drugs Advisory Committee unanimously concluded that "the possibility that these drug products may cause serious adverse experiences in some patients outweighs the limited benefit of their use in a self-resolving condition that can be managed by more conservative treatment."

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Ralph Nader, Founder

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According to the FDA, lactation suppression can be effectively managed by conservative treatments like ice packs, and compression bandages with or without mild analgesics for the minority of women who experience pain.

Subsequently all manufacturers of other lactation suppressants except Sandoz agreed to FDA's request to voluntarily withdraw their products for this indication.

Meanwhile, FDA's spontaneous reporting system continued to receive reports of serious adverse experiences associated with bromocriptine use, including cases of stroke, seizure, hypertension, heart attack, and deaths in otherwise healthy women who were prescribed bromocriptine. As of June 1994, FDA had received 531 adverse reaction reports in women aged 15 through 45 who have used bromocriptine, including 32 deaths involving 14 women with strokes, 5 with heart attacks, and 8 with hypertension. In addition, there were -- as of June 1994, 36 additional reports of women with strokes, 14 with heart attacks, 73 with hypertension and 98 with seizures.

On August 16 1994, we sued the FDA because the agency failed to start the process of withdrawing the lactation suppression indication for bromocriptine. The very next day, the FDA posted a notice for the *U.S. Federal Register* announcing its intention to withdraw the approval of the lactation suppression indication for bromocriptine. **"FDA now has new information suggesting that therapeutic use of bromocriptine for the prevention of physiological lactation may lead to serious adverse experiences, including death and paralysis, in a small but significant number of patients. Patients at high risk of experiencing these serious adverse experiences cannot be adequately predetermined. In light of the limited benefit of using bromocriptine for the prevention of lactation, and the effectiveness and lack of serious adverse effects of conservative treatments such as breast binding with or without mild analgesics, the risk that bromocriptine may cause a serious adverse effect in a postpartum woman is unacceptable** (*Federal Register* Vol. 59 No. 162, August 23, 1994 p. 43347-43352)." And, as you know, on August 18, Sandoz voluntarily withdrew the drug for this indication in the US, and the next day in Canada.

We are surprised and very concerned that Sandoz has refused to withdraw the postpartum lactation suppression indication for bromocriptine worldwide. We demand that you urgently withdraw the lactation suppression indication in all the 45 or more countries where bromocriptine is marketed for this use and thereby prevent needless deaths and injuries in healthy young women who are continually being exposed to this dangerous drug. Otherwise, you are treating millions of women in the countries where you allow the marketing of bromocriptine for lactation suppression as second class citizens.

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We look forward to your prompt response.

Sincerely,

Syed Rizwanuddin Ahmad, MD, MPH
Researcher

Sidney M. Wolfe, MD
Director

Public Citizen Health Research Group

Encl:

cc: Dr. David Kessler, Commissioner, Food and Drug Administration. USA.

Partial List Of Countries Where Bromocriptine Is Available For Post Partum Lactation Suppression

Australia[1]	Mexico[3]
Belgium[1]	Netherlands[1]
Brazil	New Zealand[2]
Bulgaria[2]	Nicaragua[4]
Burkina Faso[3]	Norway[1]
Costa Rica[3]	Pakistan[3]
Croatia[3]	Panama[4]
Denmark[1]	Poland[3]
Dominican Republic[4]	Romania[2]
Ecuador[3]	Saudi Arabia[3]
El Salvador[4]	South Africa[1]
France[1]	Spain[1]
Germany[1]	Sweden[1]
Guatemala[1]	Switzerland[1]
Honduras[4]	Tanzania[3]
Hungary[2]	Thailand[3]
Ireland[2]	Turkey[2]
Italy[1]	Uganda[3]
Japan[1]	United Kingdom[1]
Latvia[3]	Uruguay[5]
Lithuania	
Luxembourg[3]	Yugoslavia[2*]
Mauritius[3]	Zimbabwe[3]

Sources:

1 = Martindale: The Extra Pharmacopoeia, 29th edition
2 = World Health Organization
3 = Health Action International
4 = Management Sciences for Health
5 = Pan American Health Organization
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