Setting the record straight

In many countries, government officials and doctors rely almost exclusively on pharmaceutical companies or their "detail men" for information on a drug's safety. The 1983 internal memo of Upjohn's reproduced here is an unusual glimpse into corporate strategy in getting across desired information. In Upjohn's cover memo, reference is made to Stephen Minkin, former nutrition director with the United Nations in Bangladesh, who has written several articles exposing problems with Depo-Provera and deficiencies in safety testing of the drug.

Note our rebuttals to Upjohn's "Key Response Statements."

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Form Response Letter

A number of our subsidiaries have asked for a basic form letter to use in responding to negative stories. This sample letter, prepared by R. K. Berger, can be translated and adapted to a variety of situations by incorporating selected key response statements discussed below.

Key Response Statements

These 12 statements provide replies to some of the most frequent charges against Depo-Provera. They can be inserted into the Form Response Letter as necessary.

Review of Response Procedures

To assist you in responding quickly to media attacks on Depo-Provera, I have attached a step-by-step guide. These procedures merely formalize what is established practice with our subsidiaries affected by negative Depo-Provera publicity.

In the coming months, we can expect increased media activity as the results from the U.S. and U.K. hearings are announced. We will keep you informed as events progress, and will supply supportive materials whenever possible. Please contact us if you have any questions.

Sincerely,

Leigh M. Bailey
Public Relations Associate
International Human Health

MULTINATIONAL MONITOR  February/March 1985  13
Dear Editor:

On [date] you published/ aired a story entitled, (title). This story concerned our product, Depo-Provera; unfortunately, it contained a number of false and inaccurate statements and I want to correct these inaccuracies for you and your readers/viewers. I think you will agree that health care products are of vital concern to consumers. We believe that the inaccuracies reporting to consumers of information about health care products is just as important.

First, Depo-Provera is an injectable product containing the drug medroxyprogesterone acetate. The product is injected intramuscularly and its contraceptive effect comes from suppression of pituitary hormones that cause release of a mature egg. The drug is also approved for use in many countries for treatment of endometriosis, breast and kidney cancer.

Second. In mony countries, drug "registration" implies registering the drug with customs. Even "approval" by a foreign health minister is often based only on information supplied by the drug company itself. The Swedish government, recognizing Depo-Provera's dangers unless it is administered with close monitoring, prohibits its international development agency from promoting the drug abroad.

Third. The FDA Board of Inquiry found that there is no proof that Depo-Provera does not cause cancer. Cancer did result in required tests of the drug conducted on beagle dogs and monkeys; Depo-Provera was the only contraceptive that caused cancer in both of these mammal tests.

Fourth. There have been no studies conducted of these children through puberty, when reproductive abnormalities would most likely become evident. One study of infants exposed to Depo-Provera through breast milk showed that Depo-exposed infants were more vulnerable to common infections than other children. A number of studies showing no difference in Depo-exposed and other children were reviewed by the FDA Board of Inquiry and found to be inadequate.

Sincerely yours,

[Subsidiary Gen.
or Medical Dir.]
6. The FDA Board of Inquiry criticized the scientific studies of Depo-Provera as being “haphazard” and “uncoordinated.”

7. Judith Weisz, chair of the FDA Board of Inquiry, has said of the OB-GYN advisory committee’s recommendation of approval of Depo-Provera, “Thiers was a free-wheeling discussion, not serious analysis. It’s a shame that it wasn’t, since they now get cited as the authorities.” One of the advisory committee’s own members commented that the more you know about physiology, the less you want to take this drug.

8. As the FDA Board of Inquiry stated, “The lack of adequate long-term follow-up of subjects cannot be obscured or excused by pooling of data from women who have used the drug for different periods of time and presenting these data in forms of ‘women years’ or months of use... While it takes nine months to produce a baby, nine women, each one contributing one month, cannot produce a baby.”

9. This is an especially important area where there hasn’t been adequate study with long term follow up.

10. It’s been a major concern of women’s groups and experts like the Medical Committee in England that the targetted population for this drug, often undereducated or underprivileged women, have the least ability to give informed consent. Griff Ross, the member of the FDA Board of Inquiry recommended to the panel by Upjohn, recommended that the drug be approved for use in the U.S. by drug abusers and the mentally retarded, two of the very groups unlikely to be able to give such consent. One of the major criticisms in the 1978 FDA audit of the Grady study in Atlanta was that neither staff nor patients seemed to be aware of the drug’s experimental status.