ATTENTION !!!

Changement d'adresse
Change of adress

A partir du 5 janvier 1987
On and after january 5, 1987

Ancienne adresse
Former address :

Institut de pharmacologie de
l'Université
Bugnon 21
CH-1005 Lausanne-Switzerland

Nouvelle adresse
New address :

Institut de pharmacologie de
l'Université
Bugnon 27
CH-1005 Lausanne-Switzerland

rcvd. 29.12.86.

Georges PETERS

DEPUTE AU GRAND CONSEIL VAUDOIS
PROFESSEUR A LA FACULTE DE MEDECINE
DE L'UNIVERSITE DE LAUSANNE

Téléphone privé : 021 / 32 79 26

INSTITUT DE PHARMACOLOGIE
DE L'UNIVERSITE DE LAUSANNE

Téléphone : 021 / 22 15 63 ou 021 / 22 12 09
Rue du Bugnon 21
1011 LAUSANNE - CHUV

1010 LAUSANNE, le December 18, 1986
Av. de Valmont 16

SAHELI Collective
SAHELI Women's Resource
Centre
Unit above Shop 105 to 108
Shopping Centre
Defence Colony Bridge
(South Side)
NEW DELHI 110 024
India

Dear Friends,

Thank you very much for sending me your very complete and well-written information on Norethisterone Enanthate in mass Family Planning Programmes.

I relayed the contents of the information to a number of people to whom I spoke. I shall also use it in the future and give your address to people who are interested in the topic.

I should be grateful if you could occasionally inform me on the fate of your petition to the Supreme Court of India.

With my best wishes for your activities and for the New Year I am

Yours very sincerely,

G Pe

Georges PETERS, M.D.
Professor and Chairman

Saheli

Women's Resource Centre

Date.....

Dear Friends,

We are writing to you in connection with the campaign we are undertaking against the introduction of Net-EN (Norethisterone Evanthate) an injectable contraceptive.

Earlier this month, we together with 8 other petitioners filed a writ petition in the Sup reme Court, seeking a stay order on the Government's plans to introduce this contraceptive in our mass Family Planning programme. (Further details about the petition can be found in the attached press release).

Through this petition, we also hope to create a national and in ternational debate on

a) the ethics of human experimentation, specially of women who are the focus of contraceptive research.

b) population con trol policies, the determinants which affect the choice of contraceptive research and marketing of contraceptives manufactured by multinational companies.

The Indian Government is currently doing more and more research on long-acting hormonal contraceptives, in the form of sub-dermal implants, vaginal rings etc. Injectables are only the first step towards what we perceive as greater state control over women's reproduction.

We appeal to you to join this camp aign by:-

1. Sending us letters of support to the petition.
2. Getting information on the testing and use of Net-EN in your country (see attached list of countries)
3. Pr oduct information sheets given by Schering, the manufacturer of Net-EN (Brand names are
4. Details of your Government's policy with regard to Net-EN.
5. Statements by medical practitioners for and against use of Net-EN.
6. Testimony of women who have used or been exposed to the drug.
7. Any other information which could helpour case.

A copy of the petition is being sent to :-

* Irene Dubal.
C/o Women & Development Programme,
Institute of Social Studies,
251, BADHUISWEG,
2597 JR, The Hague,
Netherlan ds.

* Judy Norsigian,
Boston Women's Health Book Collective,
465, Mt. Auburn Str eet, Watertown M A 02172, USA.

Unit above Shop 105 to 108. Shopping Centre, Defence Colony Bridge (South side), New Delhi-110 024
PHONE : 616485

* Marilee Karl,
ISIS,
via S. Maria dell 'Anima, 30.
00186 Roma, Italy.

† International Contraception, Abortion
& Sterilization Campaign (ICASC),
374, Grays Inn Road,
London, WC 1, England.

We consider this an urgent and very important issue and would appreciate a quick resp onse. The next hearing of this case is due to take place mid July 1986.

We will keep you informed of the latest developments.

Please address all correspondence to SAHELI, at the above mentioned address.

Yours sincerely.

SAHELI Collective.

Aktionsgemeinschaft Solidarische Welt e.V.
ASW

Action for World Solidarity Action Monde en Solidarité Accion Mundo Solidario ASW 1 Berlin 61, Friedrichstr. 236	Telefon: (030) 251 02 65 Germany – Allemagne	Bank für Gemeinwirtschaft–Berlin–Kto. Nr. 1600 220800, Blz. 100 101 11	Postscheck-Konto Berlin West 40 06-104

SAHELI
Women's Resource Center
Unit above Shop 105 to 108
Shopping Center
Defence Colony Bridge (south side)
NEW DEHLI 110 024

INDIA

Bezug/
Ref. No.: hs

26.11.1986

Dear Abba Bhaya and all the other women of Saheli,
many greatings to you!
I hope this letter will find you all in good health and mood.
Just recently I found in "Women In Action", Suppl. 5, of ISIS the information that you and others managed to obtain a court order halting trials of Net EN.
Congratulations to your success.

As we are here living in the same town where Schering has its headquarters we have some experiences of our own with the testing of new drugs (f.e. progesterone injections to induce abortion or IUD's) which was conducted in Berlin hospitals.

I started to collect information concerning Net En, and I hope in January I will have enough to send it to You. As some women here are thinking of a campaign concerning Net En and its testing and use in other countries like India, it would be of great help if you could give us informations about your activities in India - and your hopefully final success.

HopefullY this letter will reach you in time to support your activities.

Dear Abba, perhaps we'll meet again one day again.

I wish you all the best, much energy and courrage,
warm greetings

Helga Satzinger

Helga Satzinger
Action for World Solidarity.

p.s.: just now I got the article in EPW of Oct. 86 on Net En...very informative.

Warm greetings from Ruth as well.

Nalini

rcvd 1st Apr '87.

Aktionsgemeinschaft Solidarische Welt e. V. **ASW**

Action for World Solidarity · Accion Mundo Solidario · Action Monde en Solidarité · Ação Mundo Solidario

ASW, Friedrichstr. 236, D-1000 Berlin 61

SAHELI
Women's Resource Center
Unit above shop 105 to 108
shopping center
Defenso Colony Bridge (south side)
New Delhi 110 024
INDIA

27.3.87

Dear women of SAHELI,

as we would like to support your campaign against the introduction of the injectable contraceptive Net-En in the mass family planning programme I write to you this letter.

We got the copy of the petition via ISIS [redacted] but we don't know the actual state of the case. Did you finally succeed or is the case still pending?

As we would like to inform the public in West Germany about the proceedings of your activities we would be very glad to get some information about that from you.

As one of the producers of Net En is Schering it would be of some importance to have the latest news from you.

Once we get our activities started, we will inform you about them.

Many warm greetings to Abba Bhaya and all of you

Helga Satzinger

Helga Satzinger
action for world solidarity

Konten: BfG-Berlin 1600 22 08 00 (BLZ 100 101 11) u. PGA-Berlin 40 06-104 (BLZ 100 100 10) · Telefon:030-251 02 65

BOSTON
WOMEN'S
HEALTH
BOOK
COLLECTIVE

465 Mt. Auburn St.
Watertown, MA 02172 USA
617-924-0271

TO : WOMEN'S AND HEALTH GROUPS IN INDIA
FROM:N.SWENSON,BWHBC
RE: NET-EN, IN INDIA & IN THE U.S.
DATE; JULY, 1986

Part I: Publicity for Indian Groups

During Sathyamala's visit to our Collective's offices in late June and early July, 1986, on behalf of Saheli, the women's health group in Delhi, I consulted with a number of U.S.journalists, television commentators and government officials. Our mission was to get some publicity for the efforts of groups in India to stop NET-EN's mass introduction. Christopher Lyden, an excellent news commentator of Boston's Channel 2(Educational TV) immediately pointed out that, without a specific U.S. connection --- that is, without a U.S. manufacturer or the U.S. government being involved in some way--- there was not a "story" in the news sense, meaning, there was no specific action that a U.S. citizen could urge the government to take, for example. He did agree that it was of" human rights" interest, but in that sense like hundreds of other stories which are not, in the strictest sense, U.S.news.

In the next few days I talked with reporters at The Boston Globe, The New York Times, The Washington Post, and The Christian Science Monitor , as well as assorted wire services. The message was nearly unanimous from all of them: this is a story which must come out of India in order to arrive as "news" for U.S. consumption. During the last few calls, the most interesting information came from Morton Mintz, a very experienced journalist and writer whose most recent book is on the scandal of the Dalkon Shield, called "At Any Cost"(gave Sathya a copy; he previously wrote on the scandal of The Pill). While Mintz was despairing of the general U.S. climate for expose books(his is not selling), he did feel that the U.S. history of NET-EN would make the story highly effective coming from India(see Part II, below). He, and the other reporters, gave me names and locations for reaching suitable people in India who would likely tackle the story. Often, the same names came up from different sources. While most of the people I talked with said they would contact their representatives in India directly, it would be important for groups in India to make direct contact with those covering Indian news in India for all these papers.(Sathya has)

Part II: NET-EN in the U.S.

Prompted by an entry in Saheli's report that the U.S. Food and Drug Administration had given approval as early as November of 1983 for U.S. trials of NET-EN on women, I called several offices in the FDA and NIH(National Institutes of Health for Contraceptive Development). At the FDA I was told that, because of the protection of manufacturers'"proprietary" information, the FDA was never allowed to give out even the information that a drug was or was not going into trials, let alone when, where, or to what outcome. However, the FDA man I talked with either did not know or did not choose to tell me that whenever the NIH decides to sponsor the trial of a drug, that information then becomes public, and the various decisions in the process are available through the Freedom of Information Act (which ultimately must be how Saheli came to possess this information.)

The following is what NIH told me:
By the time NET-EN was approved for trials on women in November, the special FDA Board of Inquiry on Depo-Provera had already been convened(January '83), and the deliberations were underway. Since NET-EN resembles Depo in many ways, they said, and has been manipulated chemically so that its effects in the body persist even longer than Depo's, it was assumed that unless Depo were approved, NET-EN probably would not be, either. The representative I spoke with actually sits on the WHO Committee as well, and said, "If you don't like Depo, you definitely won't like NET-EN;it's not as good."(Because of its persistence in the body, presumably)

N.B. Just for the record, because we hear so many false reports, the FDA Board of Inquiry recommended against approval of Depo, but the final decision rests with the FDA Commissioner. We have had several Commissioners since, but none has made a decision about the use of Depo in the U.S. Meanwhile, however, the new drug export bill has passed. We don't know yet whether this may make it more possible for Upjohn Co. to open up foreign Depo markets previously closed because drugs not approved in the U.S. could not be exported. However, they would still have to apply for approval.

Notes for Sathya only(confidential verification) from Norma:

Part I: Globe: Judy Foreman, then to Kurt Sharfenberg, Editor. CSMonitor: Armen Sussna(gone to Delhi?) Washington Post: Lena Sun, Asia desk, would contact rep. in India, Richard Weintraub;Morton Mintz(see above); NYTimes: Steve Weisman(in India), has wife, former Post reporter Elisabeth Bumiller, who writes "investigative features" on India, women's issues there, should be contacted.

Part II:
I was given the name of Dr.Temple, the head of New Drug Evaluation at the FDA, by Dr. Forrest Greenslade of the Population Council. It was a representative of Dr. Temple's office (did not get his name,sorry, but I think it was Dick Treseli) who gave me the info re: the FDA's protection of drug co's proprietary information.

It was Dr. Henry Gablenick in NIHCD who gave me the information about NIH's role in releasing information and, I believe, is the one who said he sat on the WHO Committee evaluating NET-EN, and uttered the quote above.

It is also useful to recall that even when WHO came in with a late report of its Depo trials,(which was given to the FDA Board in secret at first,) the FDA Board of Inquiry members issued special letters stating explicitly that nothing in the evidence presented by WHO offered them any evidence to change their minds on the negative recommendation. You will also recall that a trial was conducted in the U.S. on a primarily poor black population at Emory(University) Grady Hospital in Atlanta, Georgia, which failed to follow protocols and produced many extreme symptoms among the experimental subjects.(Video,"The Ultimate Test Animal", by Karen Brannon of Minneapolis,MN, documents this)

and earlier acceptors (Table 4). In Khon Kaen, a local newspaper ran a story about the implants, and this also aided in recruitment.

Because the method was new, the overwhelming majority of the women consulted with other people prior to accepting. In each group according to source of information, the majority of women consulted with their husbands before accepting; overall, 62 percent consulted with their husbands. Sixteen percent spoke to health personnel, 9 percent consulted friends, and 5 percent spoke to women who had accepted implants at an earlier date. Eight percent of the acceptors said that they had consulted with no one during their decision process.

The Decision to Accept

A variety of motivations contributed to the decision to accept NORPLANT implants (Table 5). Women were attracted to the method because they had been told about the long protection provided by a single insertion (31 percent). A concomitant but much less important attraction was the fact that the method did not require frequent clinic visits. Four percent mentioned that the implants had worked well with other women.

Given that the acceptors were experienced contraceptors for the most part, it is perhaps not surprising that almost half were impelled by problems or dissatisfaction with the contraceptive that they had been using. More than a fourth of the acceptors said that they disliked the side effects, a sixth were "bored" with their method and were eager to try a new one, and a few women were afraid of using their old method for too long.

We asked the acceptors what worries, anxieties, or fears they had had about the method before they accepted the implants. The great majority of women at the time of the interview could recall no fear or anxiety (Table 6), but about 28 percent said that they had experienced some or considerable anxiety. The concerns mentioned most often were the fear of pain from the incision, anxiety caused by uncertainty about the long-term effects of the implants, and fear of cancer.

About 14 percent of the women said that they had sought encouragement from health personnel before accepting, and almost all of them said that the staff had clarified matters and had given them sufficient confidence to accept the implants. Only a few said that they had found the staff's explanation frightening and felt that it discouraged acceptance.

Discomfort

All interviewed acceptors were asked to recall whether they experienced any discomfort at all while the capsules were being inserted. Only 3 percent of the women reported that they had felt moderate or severe

TABLE 4 Sources of information about the availability of NORPLANT implants

Source	Percentage
Health personnel	48
Implant acceptors	33
Relatives or friends	10
Mass media	8
Ministry mobile units or other	1
Total	100
Number	704

TABLE 5 Principal reasons reported for accepting NORPLANT implants

Reasons	Percentage	
Positive motivations		38
Single insertion is long acting	31	
Only infrequent clinic visits required	2	
Has worked well for other women	4	
Recommendation		16
Health personnel said it was better than other methods	16	
Problems with other methods		46
Disliked side effects of other methods	26	
Afraid of using previous method for too long a time	4	
Bored with old method, eager to try new one	16	
No answer		<1
Total		100

TABLE 6 Degree and type of anxiety about NORPLANT implants

Category	Percent
Degree of anxiety	
No anxiety	
Some anxiety	
A good deal of anxiety	
Total	
Type of anxiety (total)	
Afraid of pain from incision	15
Anxiety about long-term effects	5
Fear of cancer	2
Fear caused by seeing women who had accepted	1
Fear that rumors about implants might come true	<1
Fear one would be unable to work after placement	<1
Fear of anesthesia	<1
Fear of changes in libido	<1
Other	1
No answer	2
Number	

Christian Conference of Asia

Urban Rural Mission

Secretary : Rev. Kwon Ho Kyung

Committee For Asian Women
57 Peking Road 4/F
Kowloon, Hong Kong.
Telephone : 3-7226150
Telex : 37618 URM HX
Cable : CHRISCONAS HONGKONG

Committee For Asian Women
Our Ref. ww-86166

18th August, 1986.

Campaign Against the Introduction of

Net-en in India

Dear Concerned Friends,

Enclosed is a letter we received from Saheli friends, appealing for support to their campaign against the injectable contraceptive NET-EN.

They have filed a writ petition in the supreme court against the introduction of this contraceptive in their mass Family Planning Programme. Any they call for international concern over the experimentation, state introduction and marketing of the hazardous contraceptive. We see this as an important and urgent issue, and therefore urge you to join in the campaign and give the necessary action and support to their campaign.

Please kindly also forward your response to CAW for our information.

Thank you.

In Solidarity,

(Ms Christine Chau)
Programme Coordinator
Committee For Asian Women

Saheli

Women's Resource Centre

Date..July..11..1986...

Dear Friends,

We are writing to you in connection with the campaign we are undertaking against the introduction of NET-EN (Norethisterone Enanthate), an injectable contraceptive.

In May 1986, we together with 8 other petitioners filed a writ petition in the Supreme Court, seeking a stay order on government's plans to introduce this contraceptive in our mass Family Planning programme. (Further details about the petition can be found in the attached press release).

Through this petition, we also hope to create a national and international debate on:

a) the ethics of humah experimentation, specially on women who are the targets of contraceptive research.

b) population control policies, the determinants which affect the choice of contraceptive research, and marketing of contraceptives manufactured by multinational companies.

The Indian govern ment is currently doing more and more research on long-acting hormonal contraceptives, in the form of sub-dermal implants, vaginal rings etc. Injectables are only th e first step towards what we perceive as greater State control over women's reproduction.

We appeal to you to join this campaigh by:

1. Sending us letters of support to the petition.
2. Getting information on the testing and use of NET-EN in your country (see attached list of countries).
3. Product information sheets given by Schering, the manufacturer of NET-EN. Brand names are Norigest, Nöristerat.
4. Details of your Government's policy with regard ~~to~~ to NET-EN.
5. Testimony of women who have used or been exposed to the drug.

Unit above Shop 105 to 108. Shopping Centre, Defence Colony Bridge (South side), New Delhi-110 024
PHONE : 616485

6. Statements by medical practitioners for and against use of NET-EN.

7. Any other information which could help our case.

We consider this an urgent and very important issue and would appreciate a quick response from you. The next hearing of this case is due to take place towards the end of this month.

We will keep you informed of the latest developments.

Please address all correspondence to Saheli, at the above mentioned address.

Looking forward to hearing from you.

Yours Sincerely,

Nalini Bhanot

NALINI BHANOT
(forSSaheli Collective)

COUNTRIES WHERE NET EN IS AVAILABLE

In 1983, Scher ing prov ided a list of 34 countries where Noristerat (Net-En) was available.

AUSTRALIA	BAHAMAS	BARBADOS
BELIZE	BERMUDA	CENTRAL AMERICA
CENTRAL AFRICAN REPUBLIC		CARACAO
DENMARK	DOMINICANREPUBLIC	FRANCE
GERMANY (FED. REP.)	GAUTEMALA	HIAT I
INDONESIA	KENYA	LIBERIA
PAKISTAN	PERU	PHILLIPINES
PORTUGAL	SIERRA LEONE	SINGAPORE
SOUTH AFRICA	SURINAM	THAILAND
TRINIDAD	ZAIRE	ZAMBIA

It is also be ing used in field studies in

BANGLADESH	CUBA	EGYPT
PEOPLE'S REP.OF CHINA		INDIA
IRELAND	SWITZERLAND	SWEDEN TUNISIA

THIS LIST MAY NOT BE EXHAUSTIVE

From
SAHELI,
WOMEN'S RESOURCE CENTRE,
UNIT ABOVE SHOP 105 to 108
SHOPPING CENTRE,
DEFENCE COLONY BRIDGE (SOUTH SIDE)
NEW DELHI 110 024.

DATE: MAY 1, 1986.

PRESS RELEASE

For the first time in India, the attempts of the Health Ministry and the ICMR to push a hazardous contraceptive for women has been challenged through a writ petition filed in the Supreme Court on the 7th of April 1986.

The Court to-day (Ist May 1986) issued notice to the respondents to show cause as to why the petition should not be admitted and stay order granted on further trials of the contraceptive. In addition to the Health Ministry, the ICMR, and the State of Andhra Pradesh, the Drug Controller of India was also impleaded as a respondent. The notice is returnable on July 15, 1986.

The contraceptive in question is Norethisterone- Oenanthate (Net-Oen), an injectable form of the female hormone, progesterone, similar to the controversial drug Depo-Provera. Produced by Sehering, a West German firm it was first marketed in Peru in 1967. In 1971, it was withdrawn as rats tested with this drug developed pituitary and breast nodules. Thereafter, it was put back on the market and is now being propagated as the ideal contraceptive for third world women.

The ICMR is currently engaged in the last stage of trials and the government plans to introduce it into the mass Family Planning Programme in a big way. Far from sharing the optimism of the government and the ICMR. the petitioners contend that there are several reasons for grave concern.

The drug is a definite hazard to women's health and a potential hazard to their progeny. The high dose of Net-oen which is to be injected every two months, causes a complete disruption of the hormonal balance maintaining the reproductive system of women. Menstrual CHAOS, which is experienced by 90% of Indian women administered the drug. is just one of the ways in which this is manifested. Neither has the cause of this menstrual chaos been understood, nor has an effective treatment for it been developed so far.

/..2/

WHO, though a proponent of Net-Oen, admits that the safety of the drug is yet to be established with regard to aspects such as: effect on lactation and progeny, cancer risk, long-term sequelea, effects on lipid metabolism and endometrial bleeding.

The drug has a long list of contraindications ranging from breast feeding in the initial six months since delivery, liver disease including jaundice, breast or genital cancer, undiagnised vaginal bleeding, to suspected pregnancy. Women suffering from several other conditions such as diabetes and hypertension, need to be monitored closely. Given the present state of health services in India, the Primary Health Centres (through which the drug will be primarily be administered) are not equipped to screen women with these conditions, administer the injection in a careful and safe manner and deal with complications as and when they arise, Hence, under Indian conditions, the potential hazards of this drug do not justify its introduction into the mass Family Planning Programme.

All the same, in their eagerness to complete the trials on the drug, the centres chosen by the ICMR have been recruiting women through unethical publicity campaigns. Women are being lured by incomplete and biased information which is designed to conceal the experimental nature of the excercise and are led to believe that the drug is already tried and tested.

One of the major fears of the petitioners is that, once introduced, this contraceptive has a high potential for misuse and can recreate the Family Planning Scene of the Emergency era. Unlike then, the unwitting victims may not even be aware that they have become acceptors of this method of contraception because an injection can always be administered under false pretexts.

The petitioners therefore contend that all further experiments on Indian Women with this drug must be stopped and the drug be banned for use in India.

PETITIONERS

Stree Shakti Sanghatana Women's organisation, Hyderabad
Saheli " " Delhi
Chingari " " Ahmedabad
Dr. Shyama Narang, Dr. Kamala S.Jaya Rao, Dr. Davayani Dangoria, Dr. A.K.Vasudevan, Dr. Ramana Dhara, Ms. Vimal Balasubramaniam.

RESPONDENTS:

Union of India through its Secretary, Ministry of Health.
Indian Council of Medical Research through its Director General.
State of Andhra Pradesh through its Secretary, Department of Health and Family Welfare, Drug Controller of India.

ADVOCATES

Petition filed by Mr. Venkataramani;
Appeared before Court: Mr. M.S. Ganesh.

To,

Andy Chetley,

War On Want,

467 Caledonian Road,

London N 7 9 BE, U.K.

October, 30, I990

Dear Andy Chetley,

We are a Delhi-based womens' group, and have been involved in a project related to the contraceptive drug, NET-EN. During the course of our work, we have referred to your document, " NET-EN: The other injectable contraceptive ", published in I984. We are interested in a few of the documents that you have cited in your bibliography. We would be grateful if you could send us the following reprints at your earliest convenience.

1. BENAGIANO, G., "Long Acting Systemic Contraceptives", proceedings of WHO Symposium on Advances in Fertility Regulation, held at Moscow, USSR, 16 - 19 Nov.,1976; paper published by WHO Human Reproduction Unit, Geneva.

2. RINEHART, W. & WINTER, J., "Injectable progestogens- officials debate but use increases", Population Reports, Series K, No. 1, March 1975, Dept of Medical and Public Affairs, George Washington University Medica 1 Centre, Washington, USA, pp K1 - K16.

3. LARRANGA, A., & KESSERU, E.,* "Dos anos de experiencia clinica con el enantato de noretisterano como anticonceptiva injectable de deposito" (Two years of clinical trials with NETEN as an injectable depo contraceptive), Ginecologia y Obstetricia (Peru), 14 (2):Aug. 1968,pp209 -221.

* an English reprint of this reference would be appreciated.

Looking forward to hearing form you soon.

Yours sincerely,

Shilanjana

(For Saheli Collective)

Our address: Saheli Womens' Resource Centre,
Unit Above Shop 105 - 108,
Defence Colony Flyover Market,
New Delhi 110 024, INDIA.

Tel: 616485

6.10. 86

Dear Prof. Mrs. Haupen-Haas,

We thank you for your letter and we are willingly giving information about our depot-contraceptive Noristerat.

The results of clinical tests in the context of Family Planning of some substances for depot contraception and results of scientific publications show advantages for Norethisterone Enanthate (the main ~~ingredient~~ active part of Noristerat):

Norethisterone Enanthate showed the smallest percentage of long-lasting bleeding (8-30 days).

After the cycle following the third injection under the treatment of Noristerat, in most of the cases the release of gonadotropin is restored, while for eg. with Depo-Clinovir the gonadotropin excretion is reduced for a longer period of time.

Only a short time after the injection one can observe a transformation of endometrium through or by means of the effect of the gestagen Noristerar. Through Depo-Clinovir one knows that after longer therapy the lining atrophies in most of the cases which can result in long lasting secondary amenorrhoea.

Disturbances of the carbohydrate metabolism are not seen with M Noristerat.

Amenorrhoea which lasted longer than 6 months were extremely seldom seen. In 60% of the cases the duration and length of menstruation was normal.

3 to 6 months after the last Noristerat injection one can count on the reappearance of the ovulatory cycle. Often the first cycle without treatment will be biphasic. According to experience it will take much longer after Depo-Clinovir in most of the cases.

In respect of cycle and fertility Noristerat should be superior to all other Depo-Gestagens.

Furthermore we willingly give you publications on hormone research and development of the "Pill".

The beginning of hormonal contraception can be seen with the Austrian physiologist Haberlandt who wrote in 1921 on "Hormonal sterilization of female animal bodies" (see enclosure) and who already then saw a method for birth regulation in humans. When in the 1950's in the U.S. it came to the reappearance of hormonal contraception, Haberlandt and his work was forgotten.

Although Gregory Pincus is called the "Father" of the Pill, this

this attribute is not only for him; the Pill has- concerning hormone research- a lot of "Fathers". At that time research in Europe and U.S.A. was going parallel. When for eg. Butenandt in 1929 suceeded in isolation of the follicle hormone, it was independant of the team of Doisy in St. Louis and the Laqueur in Amsterdam who had the same sucess.

The two derivatives, of the 1938 by Inhoffen and Hohlweg for the first time synthesized Ethisterone, namely Norethisterone and Norethynodrel, are even today contents of some hormonal contraceptives. Norethynodrel was the content of the first ever ovulation inhibitor, Envoid, in the today inconceivable high dose of 9.85 mg per dose.

From the enclosed publication it is difficult to decide who has used and synthesized what, when at first and for what reason.

With kind regards

ppa-- has the authority to sign on behalf of the Co. and what he says is binding for the company.

SCHERING

A

Schering Aktiengesellschaft

Frau Professor
Dr. med. Heidrun Kaupen-Haas
Univ.-Krankenhaus Eppendorf
Medizinische Soziologie
Martinistraße 52 -42-

2000 Hamburg 20

Schering Pharma Deutschland

Ihre Zeichen	Ihre Nachricht vom	Unser Zeichen (bei Antwort angeben)	Telefon: (0 30) 3 00 03-0 (0 30) 3 00 03-	Datum
-42-		dr.hr-wi	154	06.10.86

Sehr geehrte Frau Professor Kaupen-Haas,

wir danken für Ihren Brief und informieren Sie gern über unser Depot-Kontrazeptivum Noristerat.

Die Ergebnisse einer im Rahmen der Familienplanung durchgeführten klinischen Prüfung mehrerer Substanzen zur Depot-Kontrazeption und Aussagen in wissenschaftlichen Publikationen lassen für Norethisteronenantat (Wirkstoff des Noristerat) einige wesentliche Vorteile erkennen:

Norethisteronenantat war die Substanz, die den geringsten Prozentsatz an Blutungen von langanhaltender Dauer (8-30 Tage) aufwies.

Nach dem 3. der Injektion folgenden Zyklus ist unter der Behandlung mit Noristerat die zyklische Gonadotropinausscheidung in der überwiegenden Anzahl der Fälle wiederhergestellt, während zum Beispiel durch Depo-Clinovir die Gonadotropinausscheidung für eine längere Zeitdauer reduziert wird.

Schon kurze Zeit nach der Injektion wird durch die Gestagenwirkung von Noristerat eine Transformation des Endometriums beobachtet. Von Depo-Clinovir weiß man, daß nach längerer Therapiedauer die Schleimhautatrophien überwiegen, die langanhaltende sekundäre Amenorrhöen zur Folge haben können.

Störungen des Kohlenhydratstoffwechsels wurden unter Noristerat nicht festgestellt.

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SCHERING

Empfänger	Unsere Zeichen	Datum	Blatt
Frau Professor Dr. med. H. Kaupen-Haas	dr.hr-wi	06.10.86	2

Amenorrhöen, die länger als 6 Monate anhielten, wurden extrem selten gesehen. In 60 % aller Fälle entsprachen Länge und Dauer der Menstruation den normalen Verhältnissen.

3 bis 6 Monate nach der letzten Noristerat-Injektion ist mit dem Wiederauftreten ovulatorischer Zyklen zu rechnen. Häufig verläuft auch schon der erste anwendungsfreie Zyklus wieder biphasisch. Erfahrungsgemäß dauert es nach Depo-Clinovir in der Mehrzahl der Fälle weit aus länger.

Hinsichtlich Zyklusverlauf und Fertilität dürfte Noristerat anderen Depot-Gestagenen überlegen sein.

Ferner überlassen wir Ihnen gern Publikationen zur Hormonforschung und Entwicklung der "Pille".

Die Anfänge der hormonalen Kontrazeption sind bei dem österreichischen Physiologen Haberlandt zu suchen, der bereits 1921 "über hormonale Sterilisierung des weiblichen Tierkörpers" berichtete (s.Anlage) und schon damals eine Methode für die Geburtenregelung beim Menschen voraussah. Als es in den 50er Jahren in den USA zur Wiederaufnahme der hormonalen Kontrazeption kam, waren Haberlandt und seine Untersuchungen vergessen.

Zwar wird Gregory Pincus als "Vater" der Pille bezeichnet, doch steht ihm dieses Attribut nicht allein zu; die Pille hat - was die Hormonforschung angeht - viele"Väter". Die Forschungen liefen seinerzeit in Europa und in den USA parallel. Während z. B. Butenandt 1929 die Isolierung des Follikelhormons gelang, war unabhängig davon den Arbeitsgruppen von Doisy in St. Louis und Laqueur in Amsterdam der gleiche Erfolg beschieden.

Zwei Derivate des erstmals 1938 von Inhoffen und Hohlweg synthetisierten Ethisterons, das Norethisteron und das Norethynodrel, sind heute noch in einigen hormonalen Kontrazeptiva enthalten. Norethynodrel war Bestandteil des allerersten Ovulationshemmers, dem Enovid, in der heute unvorstellbar hohen Dosis von 9,85 mg pro Dragee.

Aus den beigefügten Publikationen werden Sie ersehen, daß es schwierig ist zu entscheiden, wer was wann zuerst und für welchen Zweck synthetisiert und dann verwendet hat.

Mit freundlichen Grüßen
Schering Aktiengesellschaft
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Albring

Dr. med. Albring Dr. H. Herrmann

Anlagen