WARNING TO WOMEN

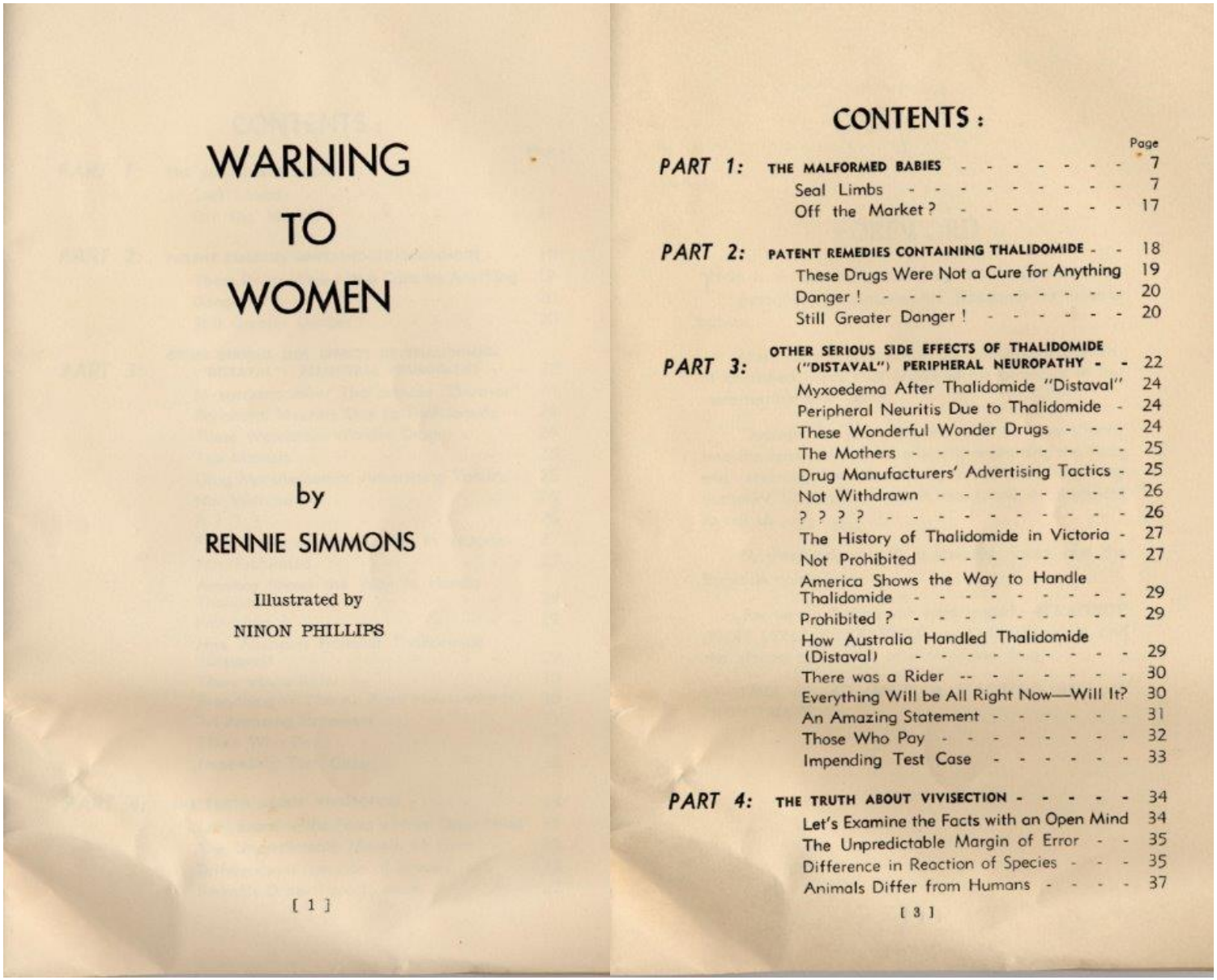
By RENNIE SIMMONS

Illustrated by NINON PHILLIPS

Published by the British Union for the Abolition of Vivisection, Melbourne Branch, 129 Elizabeth Street, Melbourne, Vic., Australia, and endorsed and supported by the Combined Animal Welfare Organisation of Victoria, which comprises 12 major associations.

Obtainable from the above address, price 2/- plus postage.

PRINTED AT "THE AGE" OFFICE, 233 COLLINS STREET, MELBOURNE, C.1.



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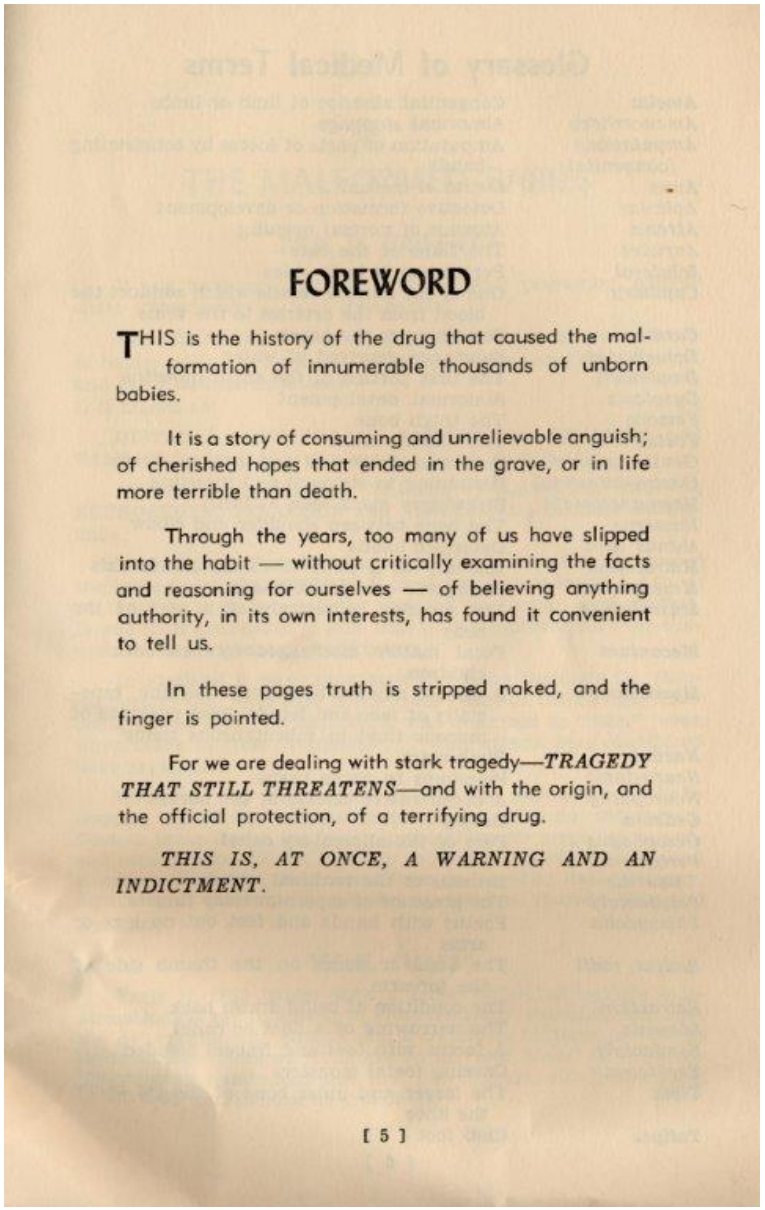

FOREWORD

THIS is the history of the drug that caused the malformation of innumerable thousands of unborn babies.

It is a story of consuming and unrelievable anguish; of cherished hopes that ended in the grave, or in life more terrible than death.

Through the years, too many of us have slipped into the habit — without critically examining the facts and reasoning for ourselves — of believing anything authority, in its own interests, has found it convenient to tell us.

In these pages truth is stripped naked, and the finger is pointed.

For we are dealing with stark tragedy—*TRAGEDY THAT STILL THREATENS*—and with the origin, and the official protection, of a terrifying drug.

THIS IS, AT ONCE, A WARNING AND AN INDICTMENT.

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Glossary of Medical Terms

Amelia	Congenital absence of limb or limbs
Amenorrhoea	Abnormal stoppage
Amputations (congenital)	Amputation of parts of foetus by constricting bands
Anus	Outlet of rectum
Aplasia	Defective formation or development
Atresia	Absence of normal opening
Auricles	The flaps of the ears
Bilateral	Pertaining to both sides
Capillary	One of the minute vessels which conduct the blood from the arteries to the veins
Cardiac	Pertaining to the heart
Dehydrated	Substance deprived of water
Duodenum	The first portion of the small intestine
Dysplasia	Abnormal development
Femora	The thigh bone
Foetus	The unborn child
Genito-urinary	Pertaining to genital and urinary organs
Gastro-intestinal	Pertaining to stomach and intestine
Haemangiomata	Strawberry mark seen at birth
Humerus	The bone between shoulder and elbow
Manus vara	Deformed hands
Malrotation	Inability of a joint to rotate on its axis
Mesenchyme	Embryonic connective tissue
Musculature	The muscles collectively of a part of the body
Meconium	Fecal matter discharged by new-born children
Myxoedema	A disease marked by general swelling, especially of face and hands, from presence of mucous fluid in subcutaneous tissue
Naevus	Birth mark
Neuro-toxic	Poisonous to nerve tissue
Neuropathy	A degenerative disease of the nerves
Oedema	Dropsy
Oesophagus	Part of the alimentary canal
Peripheral neuritis	Neuritis of the terminal nerves
Polydactyly	The presence of supernumerary fingers
Phocomelia	Foetus with hands and feet but no legs or arms
Radius, radii	The bone or bones on the thumb side of the forearm
Retraction	The condition of being drawn back
Stenosis	The narrowing of a duct or canal
Syndactyly	A foetus with toes and fingers blended
Teratogenic	Causing foetal monsters
Tibia	The larger and inner bone of the leg below the knee
Talipes	Club foot

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Part 1

THE MALFORMED BABIES

THIS IS URGENT!

If you have any of these drugs in your possession, destroy them immediately — and irrevocably.

THALIDOMIDE: This is the drug that caused many thousands of babies, all over the world, to be born with horrifying internal and external malformations.
It is known as:

DISTAVAL, CONTERGAN, SOFTERNON, KEVADON and TALIMOL, according to the country in which it is sold.

ASMAVAL, TENSIVAL, VALGIS, VALGRAINE, ISOMIN, NEUROSEDYN, TELARGON and SEDALIS also contain thalidomide.

Produced in West Germany by Chemie Gruenenthal under the trade name of **CONTERGAN,** thalidomide was tested for three years on animals before being released for human consumption. It was then considered so safe that it was approved for over-the-counter sale without a prescription.

In England it was manufactured by the Distillers Co. (Biochemicals) Ltd., who gave it the trade name of **DISTAVAL.** After being tested again on animals it was described as "safe," "even when taken in gross overdosage . . ." Side effects were considered to be negligible.

Within a very short space of time the popularity of thalidomide, under its various trade names, became widespread. Doctors prescribed it freely as a tranquilizer for pregnant women, and consumption soared in many countries, including the United Kingdom, Australia, the Federal German Republic, East Germany, Switzerland, Belgium, Japan, Brazil, Sweden, Canada, Portugal and Italy.

"SEAL LIMBS"

Early in 1958 babies with a large variety of terrible malformations began to appear in West Germany. Prevalent amongst the deformities was phocomelia, a condition hitherto so rare as to be almost unknown. It is known as "seal limbs" because the fragmentary hands and feet are, like flippers, attached closely to the body with little or no arm or leg.

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Many of the babies were stillborn or died within a few hours of birth, but two out of three survived.

"What seemed when it was first tested a few years ago to be the ideal sleeping pill has turned into a frightening medical nightmare." said *"Time"* (23.2.62).

The epidemic increased at an alarming rate and but for the sagacity of a Hamburg University pediatrician, Dr. Widukind Lenz, who discovered that many of the mothers had taken the drug during pregnancy, thalidomide might not have been tracked down as the cause for years.

At a conference, on Nov. 18, 1961, Dr. Lenz voiced his suspicions of the drug. Investigations followed. On Nov. 27, 1961, Chemie Gruenenthal took Contergan and all compound drugs containing thalidomide off the market.

On Dec. 2, 1961, the Distillers Co. withdrew from sale Distaval, Asmaval, Tensival, Valgis and Valgraine.

Reports of phocomelia and other malformations came from many countries. On Jan. 6, 1962, a letter from **Dr. Lenz** appeared in the *"Lancet,"* a leading British medical journal:

"I have seen 52 malformed infants whose mothers had taken 'Contergan' (thalidomide) in early pregnancy . . . Since I discussed the possible aetological role of Contergan in human malformations at a conference on Nov. 18, 1961, I have received letters from many places in the German Federal Republic as well as from Belgium, England and Sweden, reporting 115 additional cases in which this drug was thought to be the cause.

"Though these malformations are variable, they are of a specific nature. It is usually possible to infer from the type of the abnormalities alone whether Contergan has been taken.

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"Typical of a Contergan history are defects of the arms (amelia and phocomelia) with absence of the thumbs and sometimes of other fingers as well, aplasia of the radius, defects of the long bones of the legs, especially the femora and tibia, absence of the auricles, haemangiomata of the nose and the upper lip (wine-spot variety) atresia of the oesophagus, the duodenum or the anus, cardiac anomalies, and aplasia of the gall bladder and the appendix).

"Judging from the case histories of more than 300 women who have borne normal infants, and of whom none had taken Contergan between the 4th and the 8th week after conception, the risk to a foetus of a mother taking Contergan during this period may be definitely more than 20 per cent. I venture the estimate that at least 2000 and possibly more than 3000 "Contergan" babies have been born in Western Germany since 1959."

Universitats-Kinderklinik
Hamburg — Eppendorf,
Germany.

W. LENZ

On August 30, 1962, Dr. Siegfried Stralau, spokesman for the West German Health Ministry, announced that 10,000 infants had been malformed by thalidomide in West Germany. Five thousand of these were born dead or died soon after birth; 5000 were still living. He anticipated that more such babies would appear within the next few months.

The following are extracts from letters which appeared in the "Lancet."

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Dr. N. Freire Maia, *"Lancet,"* Dec. 16, 1961.
Dr. A. Freire Maia,
Universidade de Parana,
Laboratorio di Genetica Humana,
Curitiba Pr. Brazil.

" . . . We have studied 15 cases (9 males and 6 females) of multiple bone aplasias, hypo aplasias and congenital amputations of the extremities. They included abnormalities of different extent, such as manus vara, total amelia, upper extremity amelia, phocomelia and above elbow congenital 'amputation' associated with foot defects. All the parents were normal."

Dr. W. G. McBride, *"Lancet,"* Dec. 16, 1961
Hurstville,
New South Wales,
Australia.

" . . . In recent months I have observed that the incidence of multiple severe abnormalities in babies delivered of women who were given the drug thalidomide (Distaval) during pregnancy, as an anti-emetic or as a sedative to be almost 20%.

"These abnormalities are present in structures developed from mesenchyme — i.e. the bones and musculature of the gut. Bony development seems to be affected in a very striking manner, resulting in polydactyly, syndactyly and failure of development of the long bones, (abnormally short femora and radii.)"

Dr. R. A. Pfeiffer, *"Lancet,"* Jan. 6, 1962.
Dr. W. Kosenow,
Universitats-Kinderklinik, Munster,
Stadtische-Kinderklinik, Krefeld,
Germany.

" . . . Abnormalities include hypoplasia and aplasia of the extremities or individual bones, amelia and phocomelia, but no amputation, like peromelia or single malformation of the hands and feet. We have seen a preponderance of defects of the upper limbs, mostly symmetrical. Both sexes are equally affected. Malformations of other organs (possibly indicating an effect on mesodermal tissues) are often associated: stenosis and malrotation of the gastro-intestinal tract, cardiac defect, dysplasias of the external ears and of the eyes, and anomalies of the genito-urinary system, but not of the nervous system or of the skull or spine. A capillary haemangioma of the upper lips, nose and frontal area seems to be highly pathognomic of this syndrome . . .

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"We have high statistical significance connecting these defects with the taking of thalidomide during the first trimester of pregnancy . . .

With horror piling upon horror — proof piling upon proof that his Company's product had taken the lives of countless children and hopelessly maimed and deformed countless others, causing anguish beyond all imagining, the Managing Director of the Distillers Co. wrote to the *"Lancet"* as follows :

"We are very grateful for the many expressions of appreciation of the value of Distaval (thalidomide) which we have received during the past three weeks.

"Pharmacological studies and clinical inquries are already in hand to determine whether thalidomide taken in early pregnancy can have harmful effects on the foetus . . .

"Although a decision regarding the reissue of Distaval for general use must await further investigations, we are prepared, in response to a number of requests we have received, to make supplies available to hospitals where the administration of the drug and its companion products will be under close supervision and its use in pregnancy avoided."

D. J. Hayman.

The letter showed no sign of even a fleeting sense of culpability — but merely a fixed determination to save Distaval from the wreckage and put it on its feet again.

Even more amazing is the concluding sentence of another letter, this time by:

Dr. D. M. Burley, *"Lancet,"* Jan 13, 1962
Medical Adviser,
Distillers Company (Biochemicals) Ltd.,
London.

" . . . We hope that the problem can be solved without emotion and alarm."

Dr. Lenz, in a letter to the *"Lancet"* (Feb. 3, 1962) written from Hamburg, replied to **Dr. Burley,** "I can hardly imagine that any person will be able to face the facts without emotion and alarm."

The letter reads as follows :

" . . . I have conclusive evidence that Contergan is teratogenic in man. The evidence includes :

"(1) 6 cases in which the mother disclosed before delivery that she had taken thalidomide in early pregnancy and in which the infant showed major malformations at

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birth, of the same type as seen in retrospectively ascertained cases. Four of these cases are part of three unselected series of hospital births in which (a) no case was found in which the mother of a normal infant had taken thalidomide between the third and eighth weeks after conception, and (*b*) no case of the thalidomide type of malformatons was found in which the mother hand NOT taken the drug.

"(2) 55 cases in which the exact date of the prescription and/ for intake of thlidomide is known and coincides with the time of development of the malformed organs.

"(3) Five series of consecutive cases collected independently from hospitals outside Hamburg and communicated to me by gynaecologists and pediatricians.

"The number of cases known to me of malformations and a history of thalidomide intake during the first two months of pregnancy is increasing at present at a rate of 3-10 per day . . . "

W. Lenz.

Here follows an editorial which was published in the *"Lancet"* (Feb. 10, 1962).

"A few months ago we discussed those drugs which may be dangerous to the foetus or the new-born child, and we favoured stricter observation of the administration of drugs to pregnant women, because of their possible connection with foetal disturbances.

"About the same time, concern was mounting in several countries about an apparent increase in congenital malformations. These deformities ranged from absence of the thumbs or other fingers and aplasia of the radius to major defects of the long bones (amelia and phocomelia) and they were often associated with alimentary abnormalities such as atresia, stenosis, malrotation and absent appendix or gallbladder, and also with haemangiomas of the nose and upper lip, dysplasias of the external ears or eyes, and defects in the heart or genito-urinary system.

"Babies with these malformations were born in the Federal German Republic, East Germany, Sweden, Belgium, Switzerland, Australia and the United Kingdom. The number born during the past few years is still unknown, though Lenz has ventured an estimate of at least 2000 and possibly more than 3000 in West Germany since 1959, and he said last week that he is at present receiving information on from 3 to 10 new cases daily. McBride has suggested that the abnormalities were common in New South Wales; at the Birmingham Maternity Hospital . . . doctors were puzzled by a sudden increase in phocomelia (seal limbs) and Speirs* describes an outbreak in Scotland as virtually an epidemic . . .

"On December 2 Distillers Co. (Biochemicals) announced that in view of reports they had received associating the sedative thalidomide with congenital malformation, they were withdrawing their product "Distaval" (which is thalidomide) and also the preparations 'Valgis,' 'Valgraine,' 'Asmaval,' and 'Tensival,' which contain it. A few days earlier, 'Contergan,' another brand of thalidomide, had been withdrawn from the German market.

"McBride then reported what he took to be a close association between thalidomide taken in pregnancy and foetal malformation; and Lenz, in Hamburg, was convinced that the drug caused the abnormalities. But a great many women take sedatives in early pregnancy and thalidomide must have been among the commonest drugs prescribed . . .

"The frequency of deformities may be affected by whether thalidomide preparations are taken continuously or occasionally during limb-bud development . . . Pfeiffer and Kosenow speak of a 'high statistical significance' connecting thalidomide in the first trimester with the type of abnormalities we have described.

"The most recent evidence from Lenz points to a high incidence of malformations among the babies of women who disclosed before delivery that they had taken thalidomide in early pregnancy, and a further group in whom the anatomical abnormalities correspond with the intake of the drug at the time of genesis of the part involved.

"In the Stirlingshire investigation we publish this week, Speirs obtained, by careful questioning and a scrutiny of prescription forms, a history of thalidomide ingestion at the appropriate time in 8 out of 10 cases; and he has established that the drug was a popular sedative in the area.

" . . . And it follows therefore that the withdrawal of thalidomide from the market early in December, 1961, should lead after some months to a fall in the incidence of this malformation to the previous very low figure. There may be many deformed foetuses in utero at present, and the youngest must be of almost 4 months' gestation . . ."

*A. L. Speirs, M.D. (Aberd.), M.R.C.P., D.C.H. Consultant Pediatrician, Stirling Royal Infirmary and Falkirk and District Royal Infirmary, Scotland.

The writer of the editorial is obviously weak on the mathematical side, Dec. 2 - Feb. 10 is 2 months and 1 week, NOT "almost 4 months." His suggestions (which followed) as to the future care of pregnant women, by the medical profession, are laudable; but his casual dismissal of existing dangers is not.

He neglected to mention:

1. That thalidomide, in its various guises of Distaval, Contergan, etc., has been sold in many countries, over the counter, without a prescription — as readily as aspirin.
2. That it has been prescribed with reckless abandon by doctors (who, seemingly, have implicit faith in the propaganda of drug manufacturers), and that it has been recommended by chemists.
3. That it has been sold in bottles of 100, 500 and 1000 tablets (25 or 100 mg.); so that quantities of the drug will still be sitting on the shelves in medicine cupboards in thousands of homes.
4. That, although at the time the editorial appeared it had been known in medical circles for close on three months that thalidomide had caused the malformations in new-born babies, *NO OFFICIAL WARNING, GIVING TRADE NAMES OF PREPARATIONS WHICH CONTAIN THIS DRUG (see Part 2), HAD BEEN ISSUED TO THE PUBLIC BY THE B.M.A., A.M.A., OR ANY OTHER MEDICAL ASSOCIATION IN ENGLAND OR AUSTRALIA.*
   (At the time of writing, August, 1962, this is still true.)
5. That pregnant women, having been kept in ignorance of the evil propensities of the drug *will continue to take the tablets in their possession.*
6. That, by reason of this irresponsible conduct on the part of medical associations, many more piteous, subhuman, armless and legless babies may be born to break the hearts and blight the lives of their mothers and fathers, sisters and brothers.

PREVENTABLE TRAGEDIES !

Did the writer of the *"Lancet"* editorial think that once the drug was taken off the market all responsibility ended?

Here are some more letters from doctors dealing with the subject:

A. Willman, M.B.,
J. G. Dumoulin, M.D.,
South Devon and East Cornwall Hospital,
Plymouth.

British Medical Journal,
Feb. 17. 1962

"A woman, aged 44, who had previously had three normal babies was delivered at term of a baby weighing 3 lb. 10 oz. . . . the baby, which lived only 20 minutes, showed foetal abnormalities which on external examination consisted of

complete absence of arms and small stumps where legs should have been, the femora appeared to be absent and the tibia foreshortened.

"The patient had been taking Distaval (thalidomide) 100 mg. nightly for four months as a sedative, before she became pregnant, and for the first five months of her pregnancy. Thereafter until delivery she had taken 50 mg. nightly.

"The congenital abnormalities in this baby are the same as those described by Lenz, Pfeiffer and Kosenow, Weiderman and McBride, namely, symmetrical aplasia, and hypo-aplasia of the extremities. Their reports from West Germany and Australia include several hundred congenitally deformed infants born to mothers taking thalidomide. As well as abnormalities of the extremities, malformations of many other organs have been found, including the gastro-intestinal and genito-urinary tracts, the ears and the eyes."

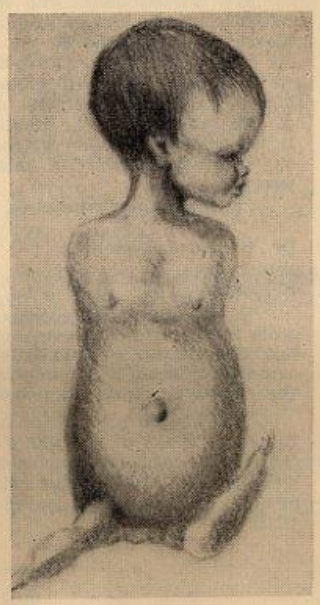
"Lancet," Feb. 24, 1962

Prof. C. Scott Russell, F.R.C.O.G.,
Dr. M. D. McKichan,
Sheffield,

reported the case of a woman whose baby had no arms and only stumps for legs.

" . . . The appearance of the child was very similar to some of those reported by Dr. Speirs (Feb. 10) . . . The baby died in a day or so and postmortem examination revealed many other abnormalities of urogenital, intestinal and nervous systems. The umbilical cord had only two vessels."

The patient had had thalidomide, 100 mg. in the following dosage:
Sept. 27, 1960, 20 tablets.
Dec. 21, 1960, 30? not less than 20 tablets.
Feb. 14, 1961, 30 tablets.
July 8, 1961, 30 tablets.



B. C. Morgan, M.B.,
Bournemouth.

"British Medical Journal,"
March 17, 1962

. . . "On Jan. 22, 1962, a 23-year-old para-2 was delivered of a full-term living female infant weighing 7 lb. 11 oz. . . . From the second to the fourth months of pregnancy Distaval, 100 and 200 mg. at night, had been prescribed for insomnia; a total of 27 tablets — that is 2700 mg. had been taken.

"The baby showed a number of obvious deformities, and . . . bore a striking resemblance to the baby reported by Pfeiffer and Kosenow. On each hand there were five digits and no thumbs, both forearms were bowed. Both lower limbs below the knee were grossly shortened and bowed. There was bilateral talipes. Meconium was passed, but all attempts at feeding were followed by projectile vomiting; gross head retraction developed and the baby became dehydrated and died on the fifteenth day . . ."

Dr. A. W. Ferguson,
Royal Hospital for Sick Children,
Edinburgh.

"Lancet," March 31, 1962

. . . "Thalidomide was administered while she (the patient) was in hospital. She received 100 mg. nightly from March 14 to 16, and 50 mg. nightly on March 17 and 18 . . . on Nov. 20, 1961, she gave birth to a surviving male infant weighing 5 lb. 5 oz., with gross phocomelia of all limbs and a capillary naevus of nose and upper lip. Careful inquiries both of this mother and the family doctor seem to have established that on no other occasion throughout pregnancy did she take any hypnotic or sedative drugs."

NOTE:
(Dr. Ferguson's patient took, in all, 400 mg. Thalidomide.)

Dr. Gerard Rogerson,
Whitchurch,
Shropshire.

"Lancet," March 31, 1962

"A young family recently came to live in this district from Staffordshire, where their first child was born a year ago. This child is a bright little girl, but she was born without arms, there being a rudimentary bud on the left side, and on the right a tiny projection bearing two fingers.

"The mother told me she had been unable to sleep during the early weeks of pregnancy and had been given sleeping tablets. She had given some of them to a neighbour before leaving Staffordshire. This neighbour was asked to send one of the remaining tablets and it proved to be thalidomide (Distaval)."

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"OFF THE MARKET ?"

This bottle of Distaval was purchased on July 9th, 1962, nearly 7½ months after this drug was "taken off the market."

SCENE: Chemist shop in Melbourne.

"Yes?" "A bottle of Distaval, please." "Distaval?" "Yes, D.I.S.T.A.V.A.L." "Oh ! Yes." . . . "How much is that ?" "28/6." "Thank you, good afternoon."

As simply as that — and without a prescription.

AND IN THIS BOTTLE OF 100 25 mg. TABLETS THERE IS ENOUGH THALIDOMIDE TO TERRIBLY AND REVOLTINGLY DEFORM AND/OR DEFORM AND KILL 7 BABIES !

As confirmation of this statement, here is a letter which appeared in the *"Lancet"* (March 17, 1962). It was written by **Mr. Frank Stabler, F.R.C.S.**, of Newcastle upon Tyne :

"A recent patient of mine showed how small a dose of thalidomide is sufficient to cause the typical deformities . . . she was given 50 mg. a day for a fortnight. The patient states that she took the tablets for a week only . . . The baby, weighing 2¼ lb. showed phocomelia and died at 33 hours."

(Mr. Stabler's patient took, in all, 350 mg. thalidomide. Dr. A. W. Ferguson's patient took 400 mg. of this drug.)

THERE ARE OTHER WAYS OF PRODUCING MALFORMED AND STILL-BORN BABIES!

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Part 2

PATENT REMEDIES CONTAINING THALIDOMIDE

ASMAVAL, TENSIVAL, VALGRAINE, VALGIS

When Distaval was taken off the market on Dec. 2, 1961, Asmaval, Tensival, Valgraine and Valgis — products of the same manufacturer, the Distillers Co. (Biochemicals) Ltd. London and Sydney — were also withdrawn.

ALL FOUR CONTAINED THALIDOMIDE.

*Thalidomide Content	*Recommended Dosage
ASMAVAL 12.5 mg. per tablet	1 or 2 tablets 3 times daily. (Six 12.5 mg. tablets represent a daily intake of 75 mg. thalidomide. A total of 375 mg. in 5 days.)
TENSIVAL 12.5 mg. per tablet.	1 tablet twice daily for 4-7 days. (Two 12.5 mg. tablets represent a daily intake of 25 mg. thalidomide. A total of 175 mg. in 7 days.)
VALGRAINE 12.5 mg. per tablet.	1 or 2 tablets, repeat after 2 hours if necessary. (Four 12.5 mg. tablets represent an intake of 50 mg. thalidomide.)
VALGIS 50 mg. per tablet.	1 or 2 tablets at night. (Two 50 mg. tablets represent a daily intake of 100 mg. thalidomide. A total of 350 mg. in 3½ days.)

350 mg. thalidomide caused phocomelia and death in the case of the baby born to Mr. Stabler's patient.

THE ABOVE CHART SHOWS THAT THE DOSAGE RECOMMENDED FOR ASMAVAL, IF TAKEN BY A PREGNANT WOMAN FOR 5 DAYS (total 375 mg. thalidomide) OR THE DOSAGE RECOMMENDED FOR VALGIS IF TAKEN FOR 3½ DAYS (total 350 mg. thalidomide) WOULD BE SUFFICIENT TO DEFORM AND KILL HER BABY.

No limits were placed on the length of time these tablets might be taken.

*Glossary of medical terms page 4.

Here is a letter from Queensland:

Dr. Rodney Lumer,
Paddington,
Queensland,
Australia.

"Medical Journal of Australia,"
June 16, 1962

"I am profoundly disturbed. The reports of thalidomide toxicity in the recent medical Press . . . have brought home to me with a personal case where "Tensival" was given during the first two months of pregnancy — the only occasion I have ever used thalidomide and that a sample which happened to be on my desk.

"The baby was born with phocomelia. In this case both humeri were very short and only one forearm bone was present on either side; both thumbs were missing and only three fingers had developed on one hand, four on the other. There were no other deformities obvious. However, post-mortem examination revealed duodenal atresia as the cause of death . . ."

"TENSIVAL" tablets — according to the manufacturer's instructions — were to be taken for 7 days only. Dr. Lumer would indubitably follow directions when using a sample drug for the first time, in which case *PHOCOMELIA AND DEATH WOULD HAVE OCCURRED AFTER A TOTAL INTAKE OF 175 mg. THALIDOMIDE TAKEN PER "TENSIVAL," HALF THE AMOUNT TAKEN BY MR. STABLER'S PATIENT !*

Medical experts have stated that many phocomelia babies have recently been born to mothers who had not taken Distaval (thalidomide) — *but no enquiries seem to have been made as to whether these mothers had taken* ASMAVAL, TENSIVAL, VALGRAINE *or* VALGIS, *any of which is capable of causing malformation in the foetus.*

THESE DRUGS WERE NOT A CURE FOR ANYTHING !

They merely provided a few hours' temporary relief from such ailments and complaints as the following:
*Headache, toothache, hayfever, bronchitis, migraine, fibrositis, asthma, neuralgia, &c., for which they were sold.

*Particulars of thalidomide content of tablets, recommended dosage and list of complaints for which preparations were used, obtained from "British Encyclopaedia of Medical Practice (Pharmaceutical) 2nd edition, 1961."

"Side effects" says the Encyclopaedia "are uncommon — all disappear on the withdrawal of the drug."

Congenital deformities do not disappear on the withdrawal of a drug, nor do babies who have died come back to life.

And who could wish such babies anything but death?

NO WARNING WHATSOEVER HAS BEEN ISSUED TO THE PUBLIC IN CONNECTION WITH THESE FOUR DRUGS, AND ALL FOUR ARE QUITE AS DANGEROUS AS DISTAVAL (THALIDOMIDE).

DANGER!

When a drug is taken off the market it does not cease to be a potential danger. There is still the home medicine cupboard.

Some complaints, such as asthma, are of irregular recurrence; others such as hayfever, bronchitis, etc., are seasonal.

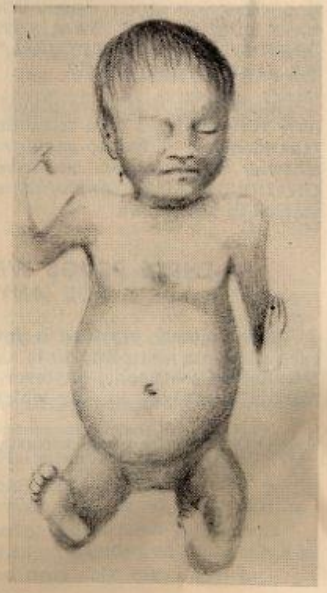
With the first hint of an attack of any kind our automatic reaction is to take off in the direction of the medicine cupboard in search of a remedy.

Neuralgia perhaps, or fibrositis. "There it is, the very thing; "VALGIS" that should fix it! What does it say? Two tablets at night." **If you should happen to be pregnant a few of these tablets could deform and kill your baby.**

Should they have been bought from a chemist, without a prescription, the trade name will be on the label, so you, who are reading this pamphlet are warned.

STILL GREATER DANGER!

But if you are looking for those tablets the doctor ordered for your hay fever last year when the pollen was blowing around, that is a different matter, because *drugs obtained on a doctor's prescription do not have the trade name on the label.* Therefore, all tablets prescribed by a doctor during the past two years for asthma, bronchitis, fibrositis, neuralgia, arthritis, migraine, hay fever, etc., *are suspect and should have the prescription checked before any more are taken.*



Thalidomide — under the collection of trade names listed on page 1 — has been freely prescribed, enthusiastically recommended, and extensively sold and used in many countries. West Germany has released statistical figures of its tragic births. Other countries have not. But information has leaked out.

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The *"Lancet"* editorial (Feb. 10, 1962), mentions an epidemic in Scotland and that such births were common in New South Wales. A Sydney gynaecologist has stated that he has personal knowledge of 30 cases in New South Wales. A report of 500 babies deformed by "Distaval" comes from England where another 800 are expected to be born soon. Baroness Summerskill, herself a doctor and the mother of two children, called on the British Government to assume responsibility for malformed babies whose mothers took Distaval under the National Health Service. Six phocomelia babies have been reported in Queensland and 52 have been reported in Canada. Untold numbers have been reported throughout Western Europe, in South America and Japan.

At present the authorities, out of a desire to cover up the inadequacy of their drug-screening procedures, are sheltering behind the statement that it is impossible to give accurate figures as there is in operation no system of notifying deformed births.

Hospitals keep records, and if officially required the information would be forthcoming within 48 hours.

By suppressing the facts the authorities are protecting the drug companies and imperilling the public.

Pregnant women are not immune to headaches, hay fever, migraine, etc., and it is obvious that **UNLESS AN OFFICIAL WARNING IS ISSUED TO THE PUBLIC GIVING FULL PARTICULARS OF THE DRUGS WHICH CAUSED THIS CALAMITY, MALFORMED BABIES, THROUGH THE MEDIUM OF THE HOME MEDICINE CUPBOARD, WILL CONTINUE TO BE BORN INTERMITTENTLY, HERE, THERE, AND EVERYWHERE FOR YEARS.**

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Part 3

OTHER SERIOUS SIDE EFFECTS OF ("DISTAVAL") THALIDOMIDE

PERIPHERAL NEUROPATHY

In December, 1960, reports began to circulate linking "Distaval" (thalidomide) with peripheral neuropathy in patients who had taken the drug over varying periods of time.

The symptoms described included:

Loss of control in the hands, numbness in the feet and weakness in the legs which made walking difficult, pins and needles in hands, feet and body, red but cold palms, cramp, gradually increasing pain in the limbs, swollen ankles, etc. . . .

The *"British Medical Journal"* (Sept. 30, 1961), carried an article by **Drs. Pamela Fullerton** and **M. Kremer**, giving full particulars of 13 of their patients who developed poly-neuropathy after regular use of "Distaval."

In the same issue of the Journal appeared an editorial entitled *"Thalidomide Neuropathy."* It read as follows:

. . . "More recently Thalidomide ("Distaval") has been tried out in Britain after its development and early use in Germany. It is a safe sedative and hypnotic drug and has the singular advantage of a very low toxicity . . . Now recent reports have described patients who developed a poly-neuropathy after the regular use of this remedy. A further 13 cases are described by **Drs. P. M. Fullerton** and **M. Kremer** in the Journal this week . . . All the patients had been taking the drug regularly for periods of 2 to 18 months in a dosage varying from 50 to 400 mg. each evening before symptoms developed.

"The onset of peripheral neuropathy was marked by paraesthesiae and numbness in the feet spreading later to the hands and associated in some cases with weakness and muscular cramps . . . motor weakness, redness of the palms . . .

A significant feature of this series of 13 patients is that none have shown much improvement in their symptoms or signs on withdrawal of the drug."

This brought forth a spate of letters from doctors confirming the neuro-toxic effects of Distaval as observed in their own patients:

Dr. Philip Howe,
Nuneaton,
Warwickshire.
"British Medical Journal,"
Oct. 21, 1961

"I have for the past 18 months been perplexed by a female patient of 35 who has complained of paraesthesiae in the hands and later in the feet spreading upwards over the months to the groin. There was also gradually increasing pain in the limbs and weakness of the legs with difficulty in climbing stairs and walking.

"Oedema of the ankles has been present on occasions . . . amenorrhoea occurred after starting to take thalidomide in doses of 50-100 mg. nightly."

Dr. K. W. G. Heathfield,
Whipps Cross Hospital,
London.
"British Medical Journal,"
Oct. 21, 1961

. . . "I have seen six cases of neuropathy due to "Distaval" (Thalidomide) this year, in fact it seems that this drug is fast becoming one of the commonest causes of peripheral neuropathy in neurological clinics . . .

"Like Drs. Fullerton and Kremer's cases, mine have so far not improved greatly when the drug has been withdrawn."

Dr. G. A. Powell Tuck,
Dorridge,
Warwickshire.
"British Medical Journal,"
Oct. 28, 1961.

. . . "Early this month he (the patient) complained of "fumbling" the papers on his desk and said his hands and feet felt peculiar — that he had noticed numbness of the three middle toes of his feet. He was not addicted to alcohol . . .

"His condition puzzled me and I had already suggested a neurologist's opinion when he asked for a repeat of his "Distaval" (Thalidomide) . . . He was advised to stop thalidomide."

Dr. P. K. Cahill,
Mansfield, Notts.
"British Medical Journal,"
Nov. 4, 1961

"The patient . . . has taken 100 mg. "Distaval" (Thalidomide) nightly for the past seven months. During that period he began to complain of "pins and needles" in his fingers, burning sensations in his toes, and weakness in his legs causing interference with his walking. His palms were red but felt cold. The patient has been suffering from cramps in his calves for about 18 months (onset therefore prior to treatment with Thalidomide), but these cramps became more severe during the past six months or so and started to affect the neck muscles . . .

"On reading the article by **Drs. Fullerton** and **Kremer** I immediately stopped prescribing Thalidomide to this patient . . . so far there has been a very slight alleviation of symptoms . . ."

J. A. Simpson, F.R.F.P.S.,
Neurological Unit,
Northern General Hospital,
Edinburgh.

"British Medical Journal,"
Nov. 11, 1961

"I also wish to confirm their (Drs. Fullerton and Kremer) conclusion that sensory neuropathy at least does not resolve rapidly after withdrawal of Thalidomide."

It will be seen from the above letters that all those doctors who had ceased to prescribe "Distaval" for their patients for a time, had noticed little appreciable change in their condition.

Here's another letter from the last writer:

J. A. Simpson, F.R.F.P.S.,
Neurological Unit,
Northern General Hospital,
Edinburgh.

"British Medical Journal,"
Jan. 6, 1962

***MYXOEDEMA AFTER THALIDOMIDE "DISTAVAL."**

. . . "One of my cases of Thalidomide neuropathy . . . has symptoms and signs suggestive of myxoedema. She is a woman aged 58 who has taken "Distaval," 100 mg. nightly, for at least a year.

"For nine months she has complained of numbness, coldness, and pins and needles of hands, feet and legs, but in addition has increasing slowness and stiffness of movement and is gaining weight. Ankle jerks are depressed, calf muscles tender, and light touch sensation is impaired on the feet."

**MYXOEDEMA*. A disease marked by general swelling, especially of the face and hands, from presence of a mucous fluid in subcutaneous tissues.

"British Medical Journal," Question page, April 7th, 1962.

PERIPHERAL NEURITIS DUE TO THALIDOMIDE.

Q. I have a patient with peripheral neuritis due to Thalidomide. Is there at the present time any known effective therapy for this condition?

A. The mechanism whereby Thalidomide causes peripheral neuritis is not yet known . . . At present, therefore, there is no specific therapy available.

THESE WONDERFUL WONDER DRUGS.

Elsewhere attention was drawn to the fact that **DISTAVAL, ASMAVAL, TENSIVAL, VALGRAINE** and **VALGIS** are not cures for anything, and that they merely provide a few hours temporary relief from whatever the patient's complaint happens to be.

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Analysis of the facts disclosed in Part 3, leads to the startling discovery that *after having taken any one of the above drugs for a time, the patient not only still has his own complaint but he has all the symptoms of poly-neuropathy as well!*

And although the relief provided by these drugs is fleeting, it would seem that the poly-neuropathy they cause is not.

So now he needs to find another wonder drug to provide relief from poly-neuropathy. Possibly the drug manufacturer already has such a one in preparation.

All this leads to another cause for alarm!

THE MOTHERS

Exhaustive research has failed to bring to light any information as to the condition of the mothers of the malformed babies.

Indubitably, those who had taken Distaval (Thalidomide) regularly will be suffering — or will have suffered from the poly-neuropathic symptoms described by doctors in their letters.

In the circumstances such symptoms might very easily be attributed to shock!

DRUG MANUFACTURERS' ADVERTISING TACTICS.

Just how much reliance can be placed on the claims of drug manufacturers may be judged by the fact that despite the British Medical Journal's editorial entitled "Thalidomide Neuropathy" (Sept. 30, 1961), and numerous letters in medical journals (written by doctors who described in detail the harmful effects Distaval had had on their patients), a full-page advertisement appeared in the British Medical Journal (Nov. 4), 5 issues later, claiming that there was no case on record in which Distaval had had "harmful results."

The following letter written by **Dr. Eric C. O. Jewesbury,** London, (B.M.J. Nov. 11, 1961), deals very effectively with the matter:

"**Drs. Pamela M. Fullerton** and **M. Kremer** (Sept. 30, 1961) have described the neurotoxic effects of Thalidomide ("Dis-

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taval") in 13 patients; they stated that "the disorder was predominantly a sensory peripheral neuritis, but there was evidence of more wide-spread effects on the nervous system" . . . since then, further cases have been brought to light by a series of letters in your columns; one correspondent stated that he had seen six cases of neuropathy due to "Distaval" this year.

"In your current number (Nov. 4), three more letters describing cases are published. It is therefore the more surprising that an advertisement for Distaval, occupying a full page of the same issue, underlines the safety of the drug, and concludes, 'There is no case on record in which even gross overdosages with Distaval has had harmful results. Put your mind at rest. Depend on the safety of Distaval.'

"The references cited in the advertisement do not yet include the article by Drs. Fullerton and Kremer, and, although the makers may take satisfaction from the lack of any frankly lethal effects of their drug, their advertisement appears remarkably out of touch with recent observations, and might at least be suitably revised if it is to continue to appear."

* * * *

"Doctors haven't time to evaluate the new drugs" said **Dr. Donald Cheek,** Senior Research Fellow at the Royal Children's Hospital, on his return from abroad (Melbourne *"Age"* June 10, 1962), "they can only go on what the manufacturer says about the drug."

He was warning on the potential horrors of new drugs being introduced into Australia unchecked. He said that Distaval had caused babies to be born without arms or legs, and that similar abnormalities had occurred in Australia.

NOT WITHDRAWN

ALTHOUGH THE NEURO-TOXIC EFFECTS OF DISTAVAL (THALIDOMIDE) HAD BEEN ESTABLISHED BEYOND DOUBT BY AUGUST, 1961, THE DRUG WAS NOT WITHDRAWN FROM SALE BY THE MANUFACTURER UNTIL DEC. 2 OF THE SAME YEAR, AFTER IT WAS FOUND TO HAVE CAUSED THE MALFORMATION AND DEATH OF COUNTLESS BABIES.

? ? ? ?

1. Do the hours of sleep which Thalidomide gives in the night compensate the patient for the torment he suffers during the day, from the neuro-toxic symptoms caused by the same drug?
2. Doctors in Europe and America are alarmed by the possibility that future children of the mothers of phocomelia babies might be similarly affected.
   Is there any certainty that we have yet plumbed the depths of the danger latent in Thalidomide?

3. That Distaval damages the nervous system is an established fact. "This drug ("Distaval" [Thalidomide]) is fast becoming one of the commonest causes of peripheral neuropathy in neurological clinics," said Dr. K. W. G. Heathfield, London.
   In all reports of the poly-neuropathic effects of Distaval upon their patients, doctors have described the symptoms as gradually increasing in severity. How does poly-neuropathy end?
4. When poly-neuropathic symptoms become so severe that Thalidomide must be withdrawn, what happens to the patient who, as well as his own complaint, now has poly-neuropathic symptoms so severe that Thalidomide had to be withdrawn ?

An eminent English doctor said recently:

"Apart from the fact that Distaval (Thalidomide) is an effective sedative, little or nothing is known about it excepting:

(a) That is has caused thousands of babies to be born without arms or legs.
(b) That it has caused thousands of babies to be stillborn as a result of gross malformation of the internal organs, and
(c) That it causes severe peripheral neuropathy and also myxoedema when taken for any length of time."

THALIDOMIDE'S ONLY CLAIM TO USEFULNESS IS THAT IT ACTS QUICKLY AND GIVES 4-5 HOURS' SLEEP.

THE HISTORY OF DISTAVAL (THALIDOMIDE) IN VICTORIA.

March 1961:	Declared a potent drug. This restricted its sale to chemists.
October 1961:	Approved for sale over the counter without a prescription.
November (late):	Withdrawn from sale by the manufacturer.
April 1962:	Classified as a drug to be sold only on doctors' prescription.

NOT PROHIBITED

Although it was known in November, 1961, that thalidomide had caused the malformation and death of thousands of babies *the drug was not prohibited in any State of Australia.* It was left to the manufacturer to do as he pleased about withdrawing or reissuing it, and (after April, '62) to the doctor to do as he pleased about prescribing it — if or when the manufacturer pleased to reissue it; or if and when the doctor could get his hands on it. (Not an insuperable difficulty this last !).

According to **Dr. R. J. Farnbach,** Deputy Chief Health Officer of the Health Department, it was up to the doctor to decide whether to give the drug to his patient or not.

According to **Mr. F. C. Kent,** Secretary of the Pharmacy Board, its use was left to the judgment of the doctor.

Doctors have no time, we have been told, to evaluate the new drugs, they must rely on the claims of the drug manufac-

turer. And judging from the number of phocomelia babies (resulting from the prescribing of thalidomide under its various trade names) which have been reported from all over the world, it is impossible to doubt the accuracy of **Dr. Cheek's** statement.

Considered in the light of the Distaval advertisement mentioned under "Drug Manufacturers' Advertising Tactics," and of the completely false claim that the drug was "safe" "even when taken in gross overdosage . . . " the danger of accepting such claims should be obvious.

As doctors rely on the claims of drug manufacturers, aren't the authorities (in such cases) relying on the drug manufacturers' claims rather than on the doctors' judgment? In other words, is it possible to rely on the judgment of a doctor who relies on the claims of a drug manufacturer ?

Numerous requests for Distaval have come from hospitals and from doctors, the Managing Director of the Distillers Co. informs us. Its quietening effects would contribute greatly to the smooth running of a hospital. But doctors who would still use it should cultivate a sense of proportion, there are other methods of inducing sleep which do not damage the patients' nervous system.

That protests against the withdrawal of Distaval have come from doctors we know, we have read some of them in medical journals.

Here is one from New South Wales :

Dr. H. Lindsay Thompson, *"Medical Journal of Australia,"*
53 Railway Parade, April 7, 1962
Lakemba.

" . . . I have found this drug of considerable use in practice, particularly the pediatric suspension. This suspension became an essential item in our children's drug cupboard ensuring a good night's rest for my wife and me.

"Alarmed by the prospect of frequent frivolous night calls to be expected if the proposed changes in the Medical Practitioners Act (N.S.W.) are implemented, I wrote to the Distillers Company stating that I could see no reason why 'Distaval' should not re-enter the market, provided practitioners were warned against its use in women during the reproductive period. In reply, the company states that in response to a large number of requests they have decided to make 'Distaval' available to hospitals once more."

OFF THE MARKET ?

"The Age," August 9, 1962. (4 months later.)

"CANBERRA. — The Minister for Health (Senator Wade) said today no action was necessary on the drug thalidomide — sold commercially as Distaval — because the manufacturer had withdrawn it from the market." (! ! !).

Because "no action" was taken on thalidomide it was possible to walk into a chemist shop in Melbourne and buy 100 tablets, 7½ months after "the manufacturer had withdrawn it from the market."

And because "no action" was taken it was possible for the manufacturer to make supplies available to hospitals at any time.

Eminent doctors in Europe and America have expressed the fear that future children of the mothers of phocomelia babies might also be malformed and that thalidomide taken prior to pregnancy might deform a foetus conceived months or even years afterwards.

It seems incredible to the lay mind, that in spite of the evil history of Distaval (thalidomide), both in its teratogenic and its neuro-toxic action, doctors should still wish to prescribe it for their patients.

THE KNOWN HISTORY OF THALIDOMIDE IS HORRIFYING — ITS UNKNOWN HISTORY IS YET TO BE WRITTEN.

AMERICA SHOWS THE WAY TO HANDLE THALIDOMIDE

On August 1, 1962, President Kennedy swung into action. He alerted the people of America to the dangers of thalidomide, called for a nationwide search of every home and every medicine cabinet in the country, and for the destruction of every thalidomide tablet found.

He made a personal appearance on television to emphasise the terrible effects of the drug; had warnings flashed on the television screen and over the air at intervals throughout the day and night for weeks.

Determined to clear the last one of these pills out of U.S. he detailed 200 men to track down every doctor who might have obtained supplies of the drug from outside sources and gave orders that all the thalidomide they located was to be confiscated and destroyed on sight.

CANBERRA STIRRED UNEASILY !

PROHIBITED ?

HOW AUSTRALIA HANDLED THALIDOMIDE (DISTAVAL).

On August 9, 1962, the Minister for Customs, Senator Henty, announced in Canberra that the Federal Government had prohibited the importation of thalidomide and preparations which contain it.

Let us not be lulled into a false sense of security.

THERE WAS A RIDER

"Future importations (of the drug) would be approved only on the recommendation of the Minister for Health and subject to safeguards." (*"The Age,"* Aug. 10.)

What this means precisely, is that although the importation of thalidomide (Distaval) is prohibited by law, it will still be possible for supplies of the drug to enter Australia on the recommendation of the Minister for Health !

This is what is known as a "double finesse." The people are satisfied because they think the importation of thalidomide is prohibited — the doctors are satisfied because they know it is not !

WHO IS BEING FOOLED ?

EVERYTHING WILL BE ALL RIGHT NOW — WILL IT ?

On August 6 (*"The Age,"* Aug. 7, 1962) Senator Wade, Federal Minister for Health, stated in Canberra that the Commonwealth Department of Health would supply 12,000 Australian doctors regularly with copies of *"Prescribers' Journal,"* a periodical which, it was said, contains "early and reliable information on new pharmaceutical products." This "would enable doctors to appraise the value of drugs for use in general practice and in hospitals."

"Prescribers' Journal" is published "under the guidance of an advisory panel of experts, most of whom are professors of medical specialities in leading British universities."

Our politicians have evidently missed the fact that this is the same panel of experts under whose guidance the British National Health Service handed out Distaval (thalidomide) to expectant mothers, resulting in an estimated 1,200 babies being horribly malformed and/or malformed and killed.

If Australian doctors are to be guided in the way to appraise new drugs by experts such as these, can we hope to escape like tragedies from new drugs in the future ?

It is alarming to find that on that advisory panel there was not a single "expert" with sufficient discrimination to apprehend the fact that thalidomide was not a harmless drug.

Yet Dr. Frances Kelsey, pharmacologist of F.D.A. (*America's Food and Drug Administration*)—the woman who saved United States from calamity — spotted its potential danger on sight, and because she was convinced of her opinion that the neuropathic symptoms caused by thalidomide might portend danger to the unborn child, she resisted and defeated the terrific pressure brought to bear upon her by the drug company anxious for a permit to market this "gold mine."

By issuing a 60 day postponement every time application was renewed, she held up the licence for over a year, by which time thalidomide was found to have caused the greatest tragedy in the history of wonder drugs.

Surely, if our doctors are to receive guidance it should be from F.D.A. rather than the somnolent *"Prescribers' Journal."*

AN AMAZING STATEMENT

Dr. J. G. Hunter, N.S.W. Secretary of the *Australian Medical Association*, stated (*"The Age,"* Aug. 13, 1962) that Distaval (thalidomide) has a disastrous effect only on women who are pregnant.

This statement is not true.

That thalidomide (Distaval) causes peripheral neuropathy and myxoedema is a well established fact which has been recognised in the medical world for over a year.

Dr. Hunter should study the following, which appeared in the *"British Medical Journal,"* Sept. 30, 1961.

"Neuropathy after Intake of Thalidomide," by **Pamela Fullerton**, M.A., B.M., M.R.C.P. Registrar, and **Michael Kremer**, M.D., B.Sc., F.R.C.P., Physician, both of the Department for Nervous Diseases, Middlesex Hospital, London.

Editorial entitled *"Thalidomide Neuropathy."*

Also papers and reports dealing with the neuro-toxic effects of Distaval, from hospitals and neurological clinics; and letters written by neurologists, surgeons and physicians which have appeared in medical journals since December, 1960, extracts from some of which are quoted in this pamphlet.

In these letters doctors have described in detail the very distressing symptoms contracted by their patients after Distaval therapy; in some instances they have supplied case histories as well.

That the neuropathy is not confined to the period of intake of this drug has also been clearly established. Reports and letters confirm this:

Dr. Ivan Pirrie,
Maldon,
Essex.
"British Medical Journal,"
December 2, 1961.

"I have followed the correspondence concerning thalidomide with special interest because I am one of the unfortunate ones who developed a peripheral neuropathy . . .

"It is now over 10 months since I stopped taking Distaval and my symptoms are no better. I find the condition more trying over a period of time than other departures from health of a more serious nature which have been my lot of recent years."

J. A. Simpson, F.R.F.P.S.,
Neurological Unit,
Northern General Hospital,
Edinburgh.
"British Medical Journal,"
November 11, 1961.

" . . . Sensory neuropathy at least does not resolve rapidly after withdrawal of thalidomide. None of the patients

referred to in our original letter (Jan. 28, p. 291) is yet symptom free."

(Over 9 months later.)

It is disturbing to find that in spite of the abundance of evidence on this subject, published in medical journals during the past 18 months, the N.S.W. Secretary of the A.M.A. has not yet caught up with the fact that thalidomide (Distaval) causes severe poly-neuropathy (which damages the nervous system) and also myxoedema.

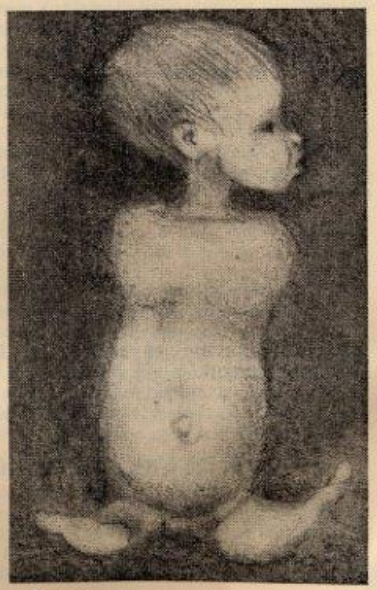
"The Age," Aug. 13, quoted **Dr. Hunter** as having said it was hard to foresee the ultimate side effects of new and complex drugs. Just so. *It would help, however, to keep up to date with information which is readily available in medical journals.*

The public should be educated in the proper use of drugs, said he.

After reading **Dr. Hunter's** statements it is obvious that not ALL responsibility for the misuse of drugs can be blamed on the public.

THOSE WHO PAY

When a young Belgian mother, crazed with shock, killed her armless baby daughter, she was arrested and charged with murder — but no charge of murder, or of manslaughter — or of anything at all, has been laid against the drug manufacturers whose products have deformed and killed countless thousands of babies throughout the world, and who were directly responsible for the young mother's act.



All through this terrible time no hint of blame has attached itself to the manufacturers who unloosed this fearsome massacre upon the world. All the weight of suffering bears down upon the parents of the deformed and dying un-

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born children, and of longed-for children who were born only to die within a few hours; on mothers whose hearts are breaking with despair and fear for the pitiable, misshapen babies who have lived to face the future, bereft of all hope.

Every time calamities and fatalities have followed on the introduction of a new drug, the manufacturer has run for cover, and, protected by the silence of the medical associations and the authorities, he has come through unscathed.

But recent happenings indicate that an end might come to this time-honoured immunity.

Early in 1962, **Mrs. Carney Love** of California, mother of two children, sued **Dr. John Wolf** and **Parke Davis** (drug manufacturers) for damages.

Mrs. Love (stated *"Time,"* March 30, 1962) was an attractive healthy young woman, but after being treated by her doctor with Chloromycetin for bleeding gums following on tooth extraction, her face became beet red, lumpy and scarred. She developed enormous muscles and a coat of hair which made it necessary for her to shave daily.

A few months after taking Chloromycetin she developed aplastic anemia, in which the bone marrow fails to make an adequate supply of blood cells.

Sixty transfusions and "vigorous treatment with cortisone and testosterone kept Mrs. Love among the 25% of patients who get aplastic anemia and survive."

IMPENDING TEST CASE

IN MARCH, 1962, A JURY AWARDED MRS. LOVE $334,046 DAMAGES FROM DR. JOHN WOLF AND PARKE DAVIS & CO., THE MANUFACTURERS OF CHLOROMYCETIN.

From reports which have appeared in the press it appears that parents of thalidomide babies are at present taking legal advice with a view to commencing law suits for damages against the manufacturer of the drug.

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Part 4

THE TRUTH ABOUT VIVISECTION

For over half a century eminent doctors and surgeons, all over the world, have warned of the danger of applying the results of experiments made on animals to human beings.

Now, the proof that they were right is there for all to see. Thalidomide, and all the drugs compounded of thalidomide, had been thoroughly tested on animals for 3 years in Germany. Later, they were tested for years in England.

They were then described as "safe" "even when taken in gross overdosage . . . " Side effects were said to be "uncommon" and to "disappear on withdrawal of the drug."

Such fantastic misstatements and miscalculations are inevitable in animal experimentation.

LET'S EXAMINE THE FACTS WITH AN OPEN MIND

Dogs, cats, kittens, monkeys, mice, sheep, pigs, rats, goats, hedgehogs, doves, guinea pigs, fowls, rabbits, sparrows, etc., are the vivisectors' stock in trade. These must be classified into 3 groups :

Carnivorous, meat eating.

Graminivorous, grass eating.

Omnivorous, feeding on anything available.

The chemical composition of the tissues, the gastro-intestinal and digestive processes and the metabolism of these animals vary from group to group.

The degree of susceptibility or resistance to drugs, stimuli, toxins, sex-hormones, anti-biotics, etc., which governs the multiplicity of hazards upon which deductions must be based varies not merely from group to group, but from species to species and from strain to strain of the same species.

Size, weight, physical condition, sex, age, background, health — and the various combinations of these — set up a formidable array of variables which, because they cause a diversity of reactions, must all be taken into consideration if any degree of accuracy is to be attempted in assessing the result of an experiment. The following extract from *"The Biological Estimation of Toxicity"* confirms this. It appeared in the *"Lancet,"* March 16, 1929 :

" . . . The work was further complicated not only by the suspicion of variations in sensitiveness between individual animals, but the possibility of variations due to age, strain, parentage, dietetic history, sexual development, seasonal changes and sex. Not even weight could be excluded . . . for it was discovered that small immature mice had more resistance than mature ones . . . "

The varied experimental techniques employed and the conditions under which animals live in laboratories also combine to add complexity to every computation:

On this subject *"Evans' Journal"* (New Series), Vol. 4, No. 2 (Nov., 1938) reads as follows :

"In all biological tests very many different factors have to be taken into consideration, the chief being animal variation. There is always in the living animal, variation in susceptibility to any condition, this variation often being very inconsistent, altering from day to day, season to season and according to the conditions under which the animals are fed and kept. The result of the summation of such variable factors alone renders it impossible accurately to standardise a preparation in terms of units as dog, cat, pigeon units, etc. . . . "

THE UNPREDICTABLE MARGIN OF ERROR

Dr. Chalmers Watson.
— *"Scottish Journal of Agriculture,"* October, 1933.

"Professor Drummond pointed out from an investigation into the potency of various cod-liver oil preparations in Vitamin A that even if five times the number of animals are employed for biological tests than were used in the official tests the margin of error is still 100 per cent . . . "

* * * *

"British Medical Journal," March, 1932, pp. 481-2.

"Tests of the toxicity of mercurochrome made in two Institutions differed by no less than 50 per cent., and this difference was found to depend on the fact that mice in one Institution were fed on mixed grain, and in the other on bread and milk."

DIFFERENCE IN REACTION OF SPECIES

"Brown-Sequard removed adrenals from dogs, cats, rabbits and guinea-pigs and found that they pined away and died . . . Two other investigators repeated Brown-Sequard's experiments but . . . selected white rats as subjects. The animals survived in excellent health . . . "

"The Tides of Life," by **R. G. Hoskins,** Ph.D., M.D., (Kegan Paul, 1933) pp. 31-2.

"The pulmonary reactions of the dog, pig, and guinea-pig to nerve stimulations and to drugs differ from one another and there may even be wide variations in animals of the same species."
Leading article, *"Lancet,"* April 16, 1938, p. 898.

* * * *

"Ordinary laboratory animals such as rabbits, guinea-pigs, cats and dogs cannot be infected in the conjunctiva . . . Chimpanzees, Barbary apes and macaques have given different results to different observers."
F. H. Stewart, M.D., *"British Journal of Ophthalmology,"* Vol. 23, 1939, p.378.

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" . . . except the guinea-pig, which for reasons that have not been worked out can be killed by quite small doses of penicillin . . . "
Sir Howard Florey, M.D., F.R.S., *"The Advance of Chemotherapy by Animal Experiments," "Conquest,"* January, 1953, p.12.

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" . . . penicillin does not produce dramatic improvement (in leptospirosis) in man, as it does in dogs . . . "
Leading Article, *"Canicola Fever," "Lancet,"* December 22, 1951, p. 1170.

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" . . . Susceptibility varies enormously between organisms of the same and different species. Dogs are killed readily, frogs are immune, while birds, rabbits, guinea-pigs, rats and mice are intermediate . . . "
M. Hilary E. Long, M.Sc., M.B., B.S., F.R.C.S. *"Medical Press,"* Aug. 21, 1935.

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" . . . actually any individual animal may be killed by an amount which is much smaller than this, or it may require a considerably greater amount . . . some cats require more than two and one half times the dose required for others."
Dr. Erwin Nelson, Presidential Address to the Section on Pharmacology and Therapeutics, Annual Sessions of the American Medical Association, 1939.

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"Certain species of animals tolerate quantities of drugs which would be fatal to others of the same size. In fact, so frequently is this the case that it is impossible to determine the fatal dose of any drug from experiments on others of a different species, even though it be nearly related.

"One of the most remarkable examples of this form of tolerance is met with in the hedgehog, which resists large doses

of very active poisons. Another well-known example is the tolerance of the rabbit of large quantities of atropine."
Professor Cushny, Chairman of Chemical Warfare Committee, April, 1918. *Textbook of Pharmacology and Therapeutics,* 10th Ed. 1934.

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Having established the fact that animals differ and even conflict in their reaction to drugs, a significant and crucial question arises. It is this :

FOR AN EXPERIMENT, DOES THE VIVISECTOR SELECT A SPECIES BECAUSE OF ITS SUSCEPTIBILITY TO THE DRUG BEING TESTED OR BECAUSE IT IS IMPERVIOUS TO IT?

UPON THIS CHOICE HINGES THE ACCURACY OF EVERY CALCULATION MADE IN AN EXPERIMENTAL LABORATORY, FOR BY REASON OF IT, DEDUCTIONS COULD VARY BY AS MUCH AS 100 PER CENT.

NOR COULD THIS IMPASSE BE OVERCOME BY EXPERIMENTING ON A COLLECTION OF ANIMALS OF MIXED SPECIES, FOR THEIR HETEROGENEOUS REACTIONS WOULD MERELY RESULT IN A CONFUSION OF CONFLICTING DEDUCTIONS, ONE CANCELLING OUT ANOTHER.

Perhaps the following quotation supplies the answer :

" . . . the claptrap and sales-talk of animal experimentation can be had for the asking, and can be served up to support any theory, however bizarre, and any operation, however unsound."
Sir W. Heneage Ogilvie, K.B.E., M.A., M.Ch. (Oxon.), F.R.C.S., Consulting Surgeon to Guy's Hospital, *"Lancet,"* Jan. 21, 1956.

ANIMALS DIFFER FROM HUMANS

That the physiology of a human being differs from that of animals has been stressed again and again. Here are some medical opinions on the subject :

"It cannot be denied that many of the weird animal experiments recorded in the medical journals are extremely misleading when their results are applied to man, who is not a rodent, not a mouse, rat, guinea-pig, rabbit, cat or dog, but a human being. Diseased conditions in man cannot be correctly imitated in experimental animals, so why persist in making such experiments, which are sometimes of the most absurd and hopelessly valueless kind."
James Burnett, M.A., LL.B., M.D., F.R.C.P.E., *"Medical World,"* May 18, 1945.

"My own conviction is that the study of human physiology by way of experiments on animals is the most grotesque and fantastic error ever committed in the whole range of human activity."

G. F. Walker, M.D., M.R.C.P., *"Medical World,"* October 6, 1933.

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"Even when a drug has been subjected to a complete and adequate pharmacologic investigation on several species of animals and found to be relatively non-toxic it is frequently found that such a drug may show unexpected toxic reactions in diseased human beings."

"These statements are based on the fact that many toxic reactions are seen in patients when the drug is administered which could not be predicted from animal experimentation."

E. K. Marshall, Ph.D., M.D., Baltimore :
"Journal of the American Medical Association," Jan. 28, 1939.

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"Experimental pharmacology is now receiving State aid, but the results of drug experiments upon animals are, as far as their application to man is concerned, absolutely useless and even misleading."

W. Mitchell Stevens, M.D., F.R.C.P.:
"Medical World," December 1933, p.335.

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"The entire teaching of pharmacology is wrong at the present time. The reason is that it is being taught by experimentalists accustomed to the laboratory and animal experiments instead of, as it should undoubtedly be, by clinicians with experience of human disease." — Editorial, *"Medical Times,"* July, 1938.

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"Take for example the action of drugs. Until recently the teaching of therapeutics was subordinated to that of materia medica and applied pharmacology. As a result of experiments on laboratory animals of a different species, employing doses of an entirely different order, and experimenting on animals not suffering from the malady in question, the mode of action of certain drugs had been worked out. To apply these results without more ado to the treatment of disease in man is a procedure so full of fallacies as to need no comment. Yet it was held to be scientific."

Professor G. W. Pickering, M.A., M.B., F.R.C.P. Presidential Address to the Section of Experimental Medicine and Therapeutics, Royal Society of Medicine, Oct. 19, 1948. Proceedings of the *Royal Society of Medicine*, Vol. XLII. Ap. 1949.

". . . it was true that the bodies of different living creatures were not all alike, and experiments on animals could never completely show what happened in bodies like our own . . ."

Professor E. D. Adrian, O.M.: Stephen Paget Memorial Lecture, Nov. 22, 1950. *British Medical Journal*, Dec. 16, 1950. P.1385.

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"The mere fact that something has been injected into mice or rats, and some easily misinterpreted results derived therefrom, does not always imply good work or yet the conclusion that human beings similarly treated would behave in rat fashion."

Dr. Norman F. Miller, Chairman of the section of Obstetrics and Gynecology, at the 92nd session of the American Medical Association: Journal of the *American Medical Association*, Vol. 117, Sept. 13, 1941. P.905.

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"Reputable manufacturers submit any new substance of promise to exhaustive pharmacological investigation and to clinical trial, but there is a wide species variation in response to drugs and the results of animal experiment cannot be assumed to be true for man."

Thomas N. Morgan, M.D., M.R.C.P., Senior Lecturer in Materia Medica and Therapeutics, University of Aberdeen: *Practitioner*, August, 1953, P.196.

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"One of the newer antibiotic drugs, chloramphenicol, has been recorded as a cause of fatal aplastic anemia in human beings. But extensive experiments on dogs have failed to show any evidence of injury or disease to the canine species."

Bulletin, Easton, Mass., U.S.A., April 2, 1953.
(Chloramphenicol is "Chloromycetin" the drug which gave Mrs. Carney Love aplastic anemia. There have been many deaths caused by this drug.)

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"Very effective as is this preparation in the case of the rabbit, we have found it impossible to use it on human patients owing to its great toxity in them . . ." (The drug Benzene Sulphonyglycinate.)

W. Blair Bell, B.S., M.D., F.R.C.S.: *The Practitioner*, Aug. 1931, P.231.

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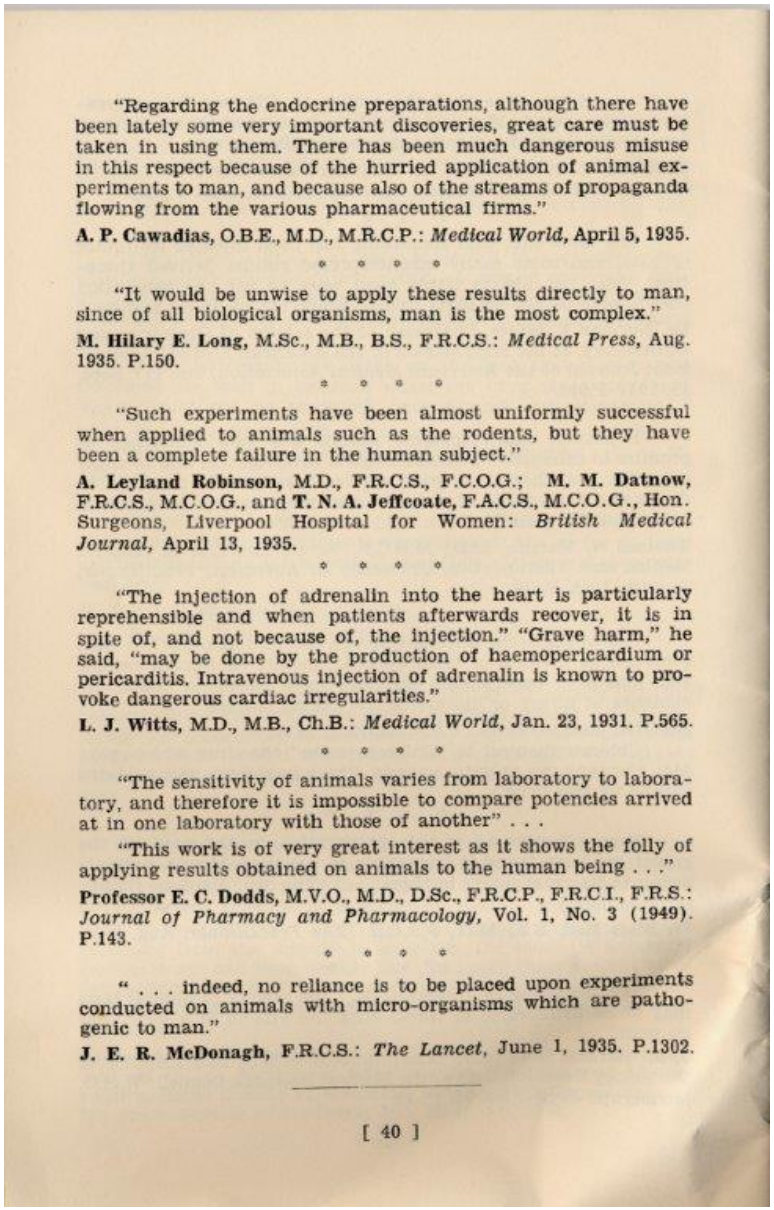
"It must never be forgotten that the results of animal tests may be of little value in forecasting the effects of a substance on man."

J. M. Barnes, B.A., M.B., Consultant to W.H.O. and Director of Toxicology Research Unit of the Medical Research Council: W.H.O. Monograph Series, No. 16. P. 10.



"Regarding the endocrine preparations, although there have been lately some very important discoveries, great care must be taken in using them. There has been much dangerous misuse in this respect because of the hurried application of animal experiments to man, and because also of the streams of propaganda flowing from the various pharmaceutical firms."

A. P. Cawadias, O.B.E., M.D., M.R.C.P.: *Medical World*, April 5, 1935.

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"It would be unwise to apply these results directly to man, since of all biological organisms, man is the most complex."

M. Hilary E. Long, M.Sc., M.B., B.S., F.R.C.S.: *Medical Press*, Aug. 1935. P.150.

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"Such experiments have been almost uniformly successful when applied to animals such as the rodents, but they have been a complete failure in the human subject."

A. Leyland Robinson, M.D., F.R.C.S., F.C.O.G.; **M. M. Datnow**, F.R.C.S., M.C.O.G., and **T. N. A. Jeffcoate**, F.A.C.S., M.C.O.G., Hon. Surgeons, Liverpool Hospital for Women: *British Medical Journal*, April 13, 1935.

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"The injection of adrenalin into the heart is particularly reprehensible and when patients afterwards recover, it is in spite of, and not because of, the injection." "Grave harm," he said, "may be done by the production of haemopericardium or pericarditis. Intravenous injection of adrenalin is known to provoke dangerous cardiac irregularities."

L. J. Witts, M.D., M.B., Ch.B.: *Medical World*, Jan. 23, 1931. P.565.

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"The sensitivity of animals varies from laboratory to laboratory, and therefore it is impossible to compare potencies arrived at in one laboratory with those of another" . . .

"This work is of very great interest as it shows the folly of applying results obtained on animals to the human being . . ."

Professor E. C. Dodds, M.V.O., M.D., D.Sc., F.R.C.P., F.R.C.I., F.R.S.: *Journal of Pharmacy and Pharmacology*, Vol. 1, No. 3 (1949). P.143.

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" . . . indeed, no reliance is to be placed upon experiments conducted on animals with micro-organisms which are pathogenic to man."

J. E. R. McDonagh, F.R.C.S.: *The Lancet*, June 1, 1935. P.1302.

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