Dear Gentle Reader

Below is a preliminary draft of Part 2 of a project I'm developing with Susanne Klausen of Carleton University, and perhaps other colleagues, which attempts to raise and then answer the question 'why was there no epidemic of thalidomide in (South) Africa'? Part 1 deals with the general background to the history of thalidomide; Part 3 will look at two 'moments' in South African history when thalidomide - or the 'spectre' of it - featured in political debates here, one concerning race, apartheid and abortion; the second will be concerned with the linkages between thalidomide and the origins of the 1965 Medicines & Related Substances Control Act of South Africa which established the Medicines Control Council; Part 4 - if there is information out there - will look at thalidomide in other Africa countries; Parts 5 and 6 could bring us into the present, covering thalidomide in the treatment of conditions associated with Hansen's disease (leprosy) in the 1960s-1990s and, from the 1990s, in some cancers and other severe afflictions, including HIV, especially as it would seem that thalidomide analogues are being used in research today into HIV/AIDS and TB here in South Africa. We are at the very beginning of our research and I am not qualified to discuss the scientific, chemical or medical properties of thalidomide.

***Some background information**: Thalidomide – N-Phtalylglutamic Acidimide (chemical name: phthalimido-glutarimide) or K17, as it was initially dubbed by its creators, German firm Chemie Grunenthal - was produced as one of the many hundreds, if not thousands, of medications created in the context of the hugely profitable post-War boom in synthetic drugs, and vigorously marketed from the mid-1950s to late 1961 for multiple uses and on a vast scale, by expanding multinational corporations diversifying their products from alcoholic drinks and cosmetics to pharmaceuticals. Under its dozens of brand names --, Asmaval (for asthma), Tensival (for hypertension), Valgraine (migraine), Contergan, Distaval, Pscycholiquid, Kevadon, Softenon are just a few -- it rapidly brought Grünenthal, and the distributors elsewhere in the world, very substantial profits.*

Advertised as being "completely non-poisonous, completely safe", instead, this "wonder drug" rapidly led to serious complications of peripheral neuritis in many hundreds of patients. More widely known, and more notoriously, across a swathe of countries – Australia, Germany, the United Kingdom, Ireland, Sweden, Japan, Canada, Japan, Belgium, Switzerland, Lebanon, Israel, Peru, Brazil, though not in the USA, Turkey, India or South Africa – it caused a pharmaceutical plague, and an epidemic of terribly deformed babies. By the time the connection had been made, in Australia, between the ingestion during the first trimester of pregnancy of the drug, and the varied, yet characteristic, attenuated or missing limbs, fingers and toes, eyes, ears, and even more severe internal abnormalities, and its withdrawal by Grunenthal from the market (though tragically not from circulation in some places) in late 1961, there were an estimated 8,000 to 10,000 living children whose congenital disabilities were labelled as a form of phocomelia, a consequence of the 'monster drug', the teratogen, thalidomide.[1]

[1] This is, very much, work-in-progress. Please do not quote or cite without the prior permission of Julie Parle (parlej@ukzn.ac.za) or Susanne Klausen (Susanne.Klausen@carleton.ca). The references/footnotes require attention. And, I have no doubt that by the time I present this paper to the HASS I shall need to revise some of my preliminary deductions. We would like to thank several people who have assisted us in pointing to sources – especially Alex Niblock, Kali Wilde, Carolyn DesForges, Dr Opiyo Oloya, Dr Martin W. Johnson, Geoff Adams-Spink, Jose (Pepe) Riquelme, Tobias Arndt; and Virginia Kilyobo for research assistance in Pietermaritzburg.

Phocomelia: [via New Latin from Greek *phōkē* a seal + *melos* a limb] "Teratology: A congenital malformation characterized by attachment of a hand to the shoulder or foot to the pelvis, imparting a seal flipper appearance, classically associated with exposure of a developing fetus to thalidomide. Cf Thalidomide." McGraw-Hill Concise Dictionary of Modern Medicine. © 2002 by The McGraw-Hill Companies, Inc.

Dysmelia: [*dys-* + G. *melos,* limb] is defined as "Congenital abnormality characterized by missing or foreshortened limbs, sometimes with associated vertebral column abnormalities; caused by metabolic disturbance at the time of primordial limb development." Medical Dictionary for the Health Professions and Nursing © Farlex 2012, both definitions from http://medical-dictionary.thefreedictionary.com.
Perhaps the most well known example of a person often thought to be, but not, thalidomide-affected is artist Alison Lapper, the famous 12 foot white marble sculpture of whom – naked and pregnant – featured in London's Trafalgar Square between 2005 and 2007.

Teratogen: terato-Origin: Ancient Greek τερας (teras, "monster").en.wiktionary.org/wiki /terato- http://www.memidex.com/teratogen. *n.* (Medicine) any substance, organism, or process that causes malformations in a fetus. Teratogens include certain drugs (such as thalidomide), infections (such as German measles), and ionizing radiation. Collins English Dictionary – Complete and Unabridged © HarperCollins Publishers 1991, 1994, 1998, 2000, 2003.

"*Okapia johnstoni*, is a giraffid artiodactyl mammal native to the Ituri Rainforest, located in the northeast of the Democratic Republic of the Congo, in Central Africa. Although the okapi bears striped markings reminiscent of zebras, it is most closely related to the giraffe…. The animal was brought to prominent European attention by speculation on its existence found in popular press reports covering Henry Morton Stanley's journeys in 1887. Remains of a carcass were later sent to London by the English adventurer and colonial administrator Harry Johnston and became a media event in 1901. [Called 'the African unicorn' it was long thought to be extinct or mythical]. Today, about 10,000–20,000 remain in the wild and as of 2011, 42 different institutions display them worldwide. From https://en.wikipedia.org/w/index.php?title=Okapi&printable=yes: accessed 7 May 2013.

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Searching for the okapi: is there a history of thalidomide in (South) Africa? [2]

ABSTRACT

Work-in-genesis, work-in-progress, this is an attempt to sketch the background to an emerging research project the outcomes of which are as yet uncertain, but which will explore an absence, a curious incidence of something that did not happen. For, in the absence of bodies characteristic (though variously formed) of the *in utero* presence of the substance, it has become conventional wisdom that there are no histories to be told of thalidomide in South Africa, or in the continent more widely. This paper begins to question that view and asks, if there was indeed no 'epidemic of thalidomide' in the continent in the late 1950s and early 1960s, why not, for Africa was certainly projected as a market for the drug. Moreover, it can also be asked (though not answered or explored in any depth in the current paper) why it is that there are no officially reported instances of disabilities arising from the use of thalidomide in the continent for the treatment of leprosy in the 1970s and 1980s; or more recently, in treatments for some cancers and conditions associated with HIV/AIDS? The answers are not self-evident and indeed are themselves of interest not merely as counter-factual histories, but as explorations in their own right of several aspects of African history: inter alia of Cold War and Commonwealth era flows of capital and pharmaceuticals, which in turn were linked to imperial economies of under-development; of the penetration of biomedicine and its institutions; of the statistical state and the monitoring of and local response to children born with birth defects; of debates about eugenics and reproductive rights; and of course, of the histories in Africa of pharmacology and public health.

[2] The phrase was suggested to me by Dr Opiyo Oloya in email correspondence, 1 March 2013. This will be elaborated below.

Tales of the teratogen

Even in the better documented regions where we know thalidomide was sold or dispensed, establishing exactly the number of persons adversely affected by the drug – adults with complications of peripheral neuritis; pregnant women who were prescribed or who were given samples,[3] or who purchased it over-the-counter in countries from Germany to Brazil; or who bought it illegally; ingested it accidentally; or who took it in ignorance; or *in utero*, – is impossible.

Moreover, and as discussed in Part 1, the histories that we do have do not necessarily map directly onto to the actual instance of the numbers of victims. In Canada and Sweden, for instance, the tales of the teratogen are well publicized, although the actual numbers directly affected (153 in Sweden and 115 in Canada) are far below those of the estimated 3,000 Spanish thalidomiders about whom far less is known, at least in the English-speaking world.[4] On the other hand, we know a great deal about thalidomide in the USA precisely *because there was no large-scale disaster there.*

And, what of our continent: what of thalidomide in Africa? Assertions of the drug's presence here are both ubiquitous and elusive.[5] So far, my search has been akin to what the Ugandan columnist and Canadian educator, Dr Opiyo Olyoa, suggested to

[3] On occasion these included women physicians; but more usually, samples were distributed via sales representatives who liberally dished them out (mostly male) pharmacists, doctors, dentists or other medical personnel, by Grunenthal or Distillers, the British distributors of thalidomide; or rather their subsidiary, Distillers Company (Biochemicals) Ltd, DCBL.

[4] 'Contergan (and its derivatives) in some countries in Europe and America'http://www.avite.org/cifras2.htm, accessed 8 March 2013 – JP needs to verify exact sources of the several remarkably damning tables in this Spanish website (translated by Google!), but the information is cited in the original.

[5] In correspondence about her book *Medical Apartheid: The Dark History of Medical Experimentation on Black Americans from Colonial Times to the Present* (New York: Harlem Moon, 2006), p. 391, American author Harriet A Washington does not state that the drug has led to disabled children being born in Africa, but, rather situates her concern against the long history in the continent and elsewhere of racist malpractice and ethical dereliction by pharmaceutical companies and imperial agents. She states: "Medications considered far too dangerous or too hopelessly tainted for testing in the West have been introduced into clinical trials with unsuspecting African patients. Within the past decade, even the infamously teratrogenic drug thalidomide has been tried on Africans as a treatment for leprosy – forty years after it produced twelve thousand horribly deformed babies around the world." See also *NY Times*, 2007, where she asserts that "Thalidomide is indeed being given to black women subjects in Africa, and researchers fear that its presence in semen may make its use in men hazardous."
http://www.nytimes.com/2007/03/18/books/review/Letters.t.html?pagewanted=1&_r=0http://www.nytimes.com/2007/03/18/books/review/Letters.t.html?pagewanted=1&_r=0

me: a search for the 'extinct okapi'; a tantalizing hunt for something that may or may not exist somewhere in Africa, although, in his view, in the light of the persistent rumours, "somebody must know something".

Indeed, assertions that there have been, and still are, 'thalidomide babies' being born in this continent are not hard to find, though whether they are based in factual existence or discursive stratagems is sometimes hard to discern. For instance, according to information on the website of the Swedish Thalidomide NGO "[At] this very moment, new babies are being born with thalidomide embropathy in countries such as Argentina, China, Peru, Cuba, Nigeria, as-well in other African countries…"[6] In 2009, scientist Neil Vargesson is reported to have told *Nature* that "[i]t was while watching a television news report about African children born to mothers who had taken thalidomide to treat leprosy that … [he] decided he wanted to study the drug. "I looked at that and thought, 'well that has to be stopped'," he says. "You can't have this drug out there doing that."[7]

Even more recently, in February 2011in the Ugandan web publication *The New Vision*, Dr Olyoa drew links between the expanding operations of the multinational Monsanto and its promotion of genetically modified crops, and a history of unrecognised and uncompensated thalidomide victims in Africa:

> For instance, between 1957 and 1962 the German drug manufacturer Chemie Grünenthal marketed the drug Thalidomide under various labels such as Asmaval and Distaval to pregnant women to stop symptoms associated with morning sickness. The wonder drug was sold in Angola, Ghana, Guinea, Sudan, Mozambique, South Africa, Eritrea, Ethiopia, Egypt and Nigeria…By 1962, African women started giving birth to children with no arms and legs. These deformed children had flimsy flippers where their limbs should have been. The drug was never licensed in the US because a conscientious FDA scientist considered the drug harmful. The African victims [have] never been compensated.[8]

[6] http://ffdn.se/web/against-leprosy/. I have asked for verification of this statement (the date of its composition is not given), but as yet have had no response to this question.

[7] Heidi Ledford, 'How Thalidomide Makes its mark', http://www.nature.com/news/2009/090511/full/news.2009.462.html, published online 11 May 2009.

[8] Uganda: How Much Has Monsanto Paid Scientists for the GMO Experiments?, *By Dr Opiyo Oloya, 1 February 2011* at http://www.newvision.co.ug/D/8/20/745462.

When asked for corroboration, Dr Oloya replied:

> I first wrote a newspaper article about Thalidomide in Africa about seven or eight years ago--this was in response to news of another drug that had been distributed in Nigeria and caused many child deaths. At that time I was contacted by two or three people on the continent either who knew someone who had been affected or was related to someone who knew someone affected by the drug.
>
> I do recall carrying out some email correspondence with one of the contacts over some time (from Ghana or Sudan?)--trying to help her get compensation. … The biggest hurdles that victims of Thalidomide in Africa likely faced were cultural taboos around deformity/disability, lack of systematic documentation of the anomaly of children born without limbs (in Europe and Canada, these children were carefully catalogued so there are records), and lack of proper medical and social support that likely meant that the African Thalidomide children perished within a few days/months/years of birth. I suspect we have some survivors out there, perhaps not many, but definitely there as was indicated in those emails I received years ago….[9]

'No credible claimants?'

In the absence of conclusive documentation, and given that children are born with naturally-occurring phocomelia, it is impossible to prove that thalidomide was responsible for the disabled children being reported to Dr Olyoa in the late 1990s or early 2000s, in other words as a consequence of the drug being in circulation outside of leprosy treatment programmes on the continent.[10] On the other hand, the possibilities of old or imported (illegal) stock cannot be ruled out entirely, and much more research, including into – if and where possible – birth defect and infanticide records in areas where there are leprosy treatment centres needs to be done.

The Thalidomide Trust in the UK (responsible for the support of thalidomiders born in the UK or whose mothers had taken thalidomide distributed by DCBL or its representatives) has in recent years facilitated the examination of one child from Kenya, Freddie Museveni, by its specialist medical advisor, Dr Claus Newman. As

[9] Email correspondence, Opiyo Oloya [Opiyo.Oloya@ycdsb.ca] to Julie Parle, 1 March 2013.

[10] I am still tracking down the 62 centres where thalidomide was used in leprosy treatments/trials from the mid-1960s; it is highly likely that there were several in Africa as well as in Asia.

the Director of the Thalidomide Trust, Martin W. Johnson, wrote to me earlier this year (2013)

> we had the story a few short years ago of Freddie Museveni, a child born in Kenya whose case was taken up by an English woman (Dee) who was running some kind of care centre. The mother rushed little Freddie to Dee, as his father was going to kill him straight after birth. Freddie had severe four limb damage, and was examined by Dr Newman [medical advisor to the Thalidomide Trust] in London, who concluded that his damage was highly consistent with thalidomide. Freddie died at 18 months. Dee said she had heard a number of stories of other children born with limb defects - killed at birth, but we heard no more about this.[11]

Johnson also relayed that

> Both Grünenthal and Distillers deny ever distributing in South Africa, and we have had no credible claimants coming forward from SA. We get a few from the region, but every time I have seen one, they have damage inconsistent with thalidomide. We have two beneficiaries from Uganda - and therefore a history of some supply to that country (one of the beneficiaries' fathers was a doctor, so that helped). I believe there's one case of a beneficiary born to an expat family in a West African country, whose mother got the drug from a company doctor fresh from London.[12]

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[11] Email correspondence from Martin W. Johnson, to Julie Parle, 16 January 2013 06:04 PM. In a story 'Why I fought for little Freddie' carried by the *Evening Chronicle* (Newcastle), England, on 2 July 2005, Dee Knott-Mtile states that she was based at "a small village Kiboaoni, just outside of Malindi." And that I first came across Freddie when a children's officer came to see me and he informed me of a baby who had been born in one of the villages. He told me the child had been born without any arms or legs. …I asked the officer if they had a placement for this new baby. He said `no', so I said: `You do now'. …The following day I saw Freddie lying on the bed and, for one second, I wondered if I could do it. But I decided he needed my help. …I took him home and from there we got on with our lives. He was ten days old and now he's 14-months." There is no mention in this article of the threat of infanticide. http://www.thefreelibrary.com/Why+I+fought+for+little+Freddie.-a0133731207

[12] Johnson to Parle, 16 January 2013. In bombshell news received whilst editing this paper for the UJ seminar on 14 May, I was sent a document showing that Grunenthal took out patents, including for thalidomide, in South Africa from as early as 1956. Moreover, South African Professor of Pharmacology and Toxicology at the University of Pretoria, Douw G Steyn, wrote to the West German lawyers prosecuting Grunenthal in 1967 enclosing a letter with his article in the *SAMJ* of 2 January 1954, 'Disturbances of Mitotic Processes and Teratism' "in which he warned of drugs for pregnant women. Before that time and since "I have constantly impressed this danger on my medical students and pleaded that all drugs likely to be administered to pregnant women should be tested for their possible teratogenic effects.. The teratogenicity of thalidomide could have been established on animals (mice, rabbits, monkeys) and there was no need to run the grave risk by experimentation on pregnant women." " Folder 385 (Düsseldorf) pages not numbered: Signed letter from Dr Steyn in South Africa to Sjostrom - 26.5.67. I am indebted to Tobias Arndt, Chief Operating Officer of EDRIC (European Dysmelia Reference Information Centre), for this citation: I had found the quotation from Steyn, albeit unreferenced, some while back in Bette Overell's book 'Animal Research Takes Lives', but am pleased to have confirmation of Steyn's correspondence.

K17: Commonwealth and other Circuits

Establishing a history of supply, then, remains a vital part of the thalidomide puzzle, and the small numbers of proven claimants were, like many of those in West Germany, in some way directly connected with the medical profession, or alternatively were in the employ of British-based multinational corporations such as British Petroleum. As one thalidomider confirmed: "My mother was given Thalidomide following a car accident in Nigeria in 1959. I was born there in 1960, as my father worked for BP. It was probably distributed by the BP clinic but I always got the impression the drug was used earlier than in the UK."[13]

Indeed, thalidomide – under the names Asmaval, Distaval, Valgraine, amongst others - was available in "'West Africa' and 'Ghana'" in the late 1950s and early 1960s, though it is difficult to pin down with certainty the date of its first marketing. (See Appendices below). Extensive research by Canadian Thalidomide Victims' Association's Randy Warren has also established that thalidomide was licensed if not distributed at that time in several other African countries, including Angola, Ghana, Guinea, Mozambique, Somalia, Sudan, and South Africa. He adds that

> In the places [in the list that follows], indicating the presence of the names of "brand" of thalidomide and / or victims who acquired it from some unspecified way, [who] probably got the[m] drugs such as medical samples, and the dates of their availability can not be confirmed, what is clear is [however is] that the drug could not [have been] available before October 1, 1957: Afghanistan, Bahrain, Bolivia, Burma, Chile, Curacao, East Germany, Ecuador, Egypt, El Salvador, Eritrea, Ethiopia, Gaza, Goa, Greece, Haiti, Kuwait, Nicaragua, Nigeria, Panama, Paraguay, Qatar, Rhodesia, South Africa, Thailand.[14]

Moreover, according to the Swedish Thalidomide Society, Chemie Grunenthal's own records (see Appendix) reveal that between 1985 and 1992, more than half a million thalidomide pills were exported to African countries, including Cape Verde (10,000), Ethiopia (15,000), Liberia (25,000), Mali (60,000), and Morocco (a staggering 400,000).[15] At the time of writing, I cannot verify these figures. If they are even

[13] The correspondent now lives in the UK. Personal correspondence, 13 March 2013.
[14] TVAC 'The Many Faces of Thalidomide' See Appendix below
[15] http://ffdn.se/web/chemie-grnenthal-1/ accessed 4 April 2013. NB: I do not know how reliable these stats are: I am still in the process of verifying them.

remotely accurate, there would appear, statistically, to be very real grounds to doubt that there have been no thalidomide-related disabilities in Africa since the late 1950s/early 1960s.

More definite evidence of the teratogen's extended reach into East Africa appears – or was at least strongly suggested - in the Correspondence pages of the *British Medical Journal* in November 1962 by Dr Ashfaq Alam Khan of the Department of Paediatrics and Child Health, Makerere University College, Uganda. In his submission 'Phocomelia in Three Ugandan Children', he noted that there had been three recent cases in the capital Kampala, two of whom had been born at Mulago Hospital "within the short space of a fortnight". "Case 1" he described as

> 1.-An African multipara (of a high socio-economic group) delivered a full-term male child in mid-August. 1962… The child's general condition was good at birth with a good Apgar index. The right limb bud showed an absence of the hand with rudimentary digits (Fig. 1). Radiography showed a reduction in the size of both radius and ulna and the metacarpals were absent. Clinically there was no other abnormality. The child was discharged after 10 days, having regained his birth weight.[16]

Dr Khan added that "The mother suffered from abdominal discomfort during the second month of pregnancy. She had received a "'course" of injections and sedative tablets, prescribed by her doctor, which she took thrice daily. There is reasonable evidence to suggest that the sedative tablets taken were thalidomide."

The second child born with phocomelia resembling thalidomide-impairment – "a virtual absence of the left limb bud, with four small deformed fingers attached to a short, fleshy stump measuring 2cm in length arising from the left shoulder (Fig 2)" – was the first-born child of another African woman, but this time of "a low socio-economic group)." She had given a "history of a rather stormy 'pregnancy with many episodes of vaginal bleeding. She consulted a doctor at 14-16 weeks of pregnancy who gave her some sedative mixture to drink. The child made a normal progress and was discharged after 10 days."[17]

[16] Dr. A. A. Khan, 'Phocomelia in Three Ugandan Children', 'Correspondence', British Medical Journal, Nov 17 1962, 1326-7.
[17] Ibid. [JP: is this outside of the 'sensitive' phase?]

The third child – described as "an Asian" was not born at Mulago; and in her case there was a "definite history of the mother having taken a thalidomide preparation during early pregnancy". Circumstantial evidence points to this child being the daughter of a doctor who had acquired thalidomide from outside of Uganda. Indeed, and as Dr Khan acknowledged, it was not possible to know the "true aetiology" of the phocomelia and there had been examples of "Reduction deformities of the limbs … … occasionally … in the past". He added that

> The absence of reported cases of drug-induced phocomelia from the developing countries of the world can be attributed partly to the lack of medical facilities and also to the high cost of such drugs, which are beyond the reach of most patients. In East African hospitals thalidomide preparations have never been on the approved list of drugs, and these preparations were withdrawn from the local market in December, 1961. The appearance of these three cases over a short period of time, and the apparent absence of such deformities previously, could be just a coincidence. However, in view of the evidence of a thalidomide preparation being taken by the mothers of two affected children it seems likely that this drug was the cause of the malformations in them. Because of the poor history it is not possible to comment on the exact cause of the malformation in Case 2.
>
> As a result of the increased speed of modern communications, it is apparent that iatrogenic epidemics due to the use, abuse, or misuse of drugs can occur on a global basis. The occurrence of phocomelia in Uganda well illustrates this point.[18]

That the British distributors of thalidomide had intended to target significant regions of Africa for sales is shown in documents recently available to researchers, through the archival research conducted on behalf of Australian thalidomider Lynette Rowe.[19] They reveal a terse and determined competition to establish global markets for the drug, and both cooperation and competition between Grunenthal and Distillers for sales territories, including in Africa.

Teasing out this history will have to wait for further research and access to Grunenthal, Distillers and the *Sunday Times*' archives, but from the Rowe discovery papers we learn that by July 1959 DCBL had a "A Plan For Developing Hospital

[18] Ibid. The significance of Ugandan and other African countries' political independence and shift in health care ideologies as well as drug regulations (reductions) will be the subject of future research.

[19] For the background to this case see http://www.guardian.co.uk/business/2012/jul/18/australian-woman-settlement-thalidomide-distributor

Business" which "considered that there should be a worthwhile amount of business for Distaval, particularly the 100 mg tablets, in leading hospitals overseas [ellipses in Rowe Discovery documents…]"[20] which then goes on to suggest that

> … sole importers are to be told of our wish to explore this avenue and asked to supply the names and addresses of suitable hospitals together with the names and qualifications of one or more doctors who would be likely to prescribe Distaval. This would give us our mailing list and indicate the quality of the samples required.

After this, each doctor would be sent a "suitable letter" mailed from England; copies also would be sent to the CMO [assume this is the Chief Medical Officer] "for courtesy"; another letter would then be sent to "all sole importers", who would reproduce the text on their own letterheads and send to pharmacists, giving details of the pricing of Distaval and indicating that "a sample pack for trial by the doctors would be given to the Pharmacist".

> The suggested sample pack would be 1 x 100 x 100mg Distaval Forte. For mental hospitals possibly 25 mg tablets would also be sent. The Sole Importer's representative would be required to call at the hospital about three days a week after the doctors and pharmacist receive the letters mentioned above hand over the sample to the pharmacist with the express intention of persuading them to allocate several suitable patients to the trial of the sample tablets …[21]

By mid-1960, thalidomide was being distributed in Australia. Personal contacts, influential physicians and networks of marketers and national and Commonwealth-linked connections seem to have played an important role in getting entrees to potentially lucrative markets. That these extended across Africa too can be glimpsed in an excerpt from a letter from Brown of DCBL to Michael Gelfand, who became Zimbabwe's (then Rhodesia) most well-known medical scientist, author, and historian of medicine of Southern Africa in 1959:

> It is almost three years since I had the pleasure of meeting you … I remember your interest in new drugs so I thought that you might like to hear about thalidomide … If you are interested in this type of preparation, I shall be glad to arrange for supplies of material to be made available to you, so that you can assess it for yourself. Your opinion of its effectiveness would be of great help to me.[22]

[20] Thalid4_jp. DIS.701.186.0001: 7 July 1959, Poole. [p.143]
[21] Thalid4_jp. DIS.701.186.0001: 7 July 1959, Poole. [p.143-4]
[22] Thalid3_jp. DID701.707.0001 at 0003. [pp. 47-48] 2 December 1959. Brown to Gelfand (in Rhodesia)

I do not as yet know whether Gelfand replied. However, elsewhere unregulated and unsystematic trials of thalidomide were being conducted, in addition to those on including on pregnant Australian women and on psychiatric and geriatric patients in care in Germany and Britain, other British dependencies including Malta and the West Indies.[23] Indeed, in February 1960 marketing men in DCBL pushed for "overseas trials for reasons of prestige and for the sales promotional value of resulting publications in local journals". They suggested

> that the products suitable for such trials are (a) Distaval… it was decided that the areas for which such trials would be of the greatest value would be as follows:-West Indies, South Africa, Australia… [and] The discussion progressed to the process to be followed when organising a trial, having determined that the West Indies was the best place for the trial to occur…. (c) Medical Department to contact the doctor recommended to supervise the trial. (d) A visit from a member of the Medical Department either (i) with a member of the Export Sales Department, or (ii) with the DCBL permanent representative for the West Indies to attend the supervision of the trial and to the compilation of the results."[24]

In August 1960, there were further requests "… for trials to be carried out in certain Commonwealth territories to ascertain whether we could establish any tangible difference between conditions here [Australia?] and in the UK".[25] In correspondence between Grunenthal and DCBL in January 1961 it was noted that "clinical tests with K17" were being conducted in "the West Indies, Malta, and Australia". Distillers also reported that its sales areas "in all contract market areas [were] good" and gave the following information:

> At the beginning of 1960 the turnover was £400 per month, now it is about £4000 per month.
> The following figures are estimates for 1961 for the current tablet formulations – without syrup:
> Central Africa £7000
> East Africa £12000
> West Africa £8000
> British West Indies £9000
> Cyprus £1000
> Malta £1500
> Pakistan £1500
> £400000

[23] Thalid1Jp, p34 27 January 1961

[24] Thalid4_jp.DIS701.977.0001 at 0025: 17 February 1960, p.141-2] 'Minutes of Meeting to discuss the promotion of overseas clinical trials', attended by Burley, Flawn and Mitchell. pp

[25] Thalid4_jp. DIS 034.001.0179: 10 August 1960. Memorandum from Hayman to Brown. [p.87]

[handwritten note: Australia/ New Zealand?]

The Rowe legal summary continues:

> No sales have been possible in India, because governmental approval has not come through yet. However, they are optimistic they will receive it and will also be granted the relevant import licences.
>
> Distaval has been on the market in Australia and New Zealand since 1.10.1960. We have received advice about prices in the meantime. …
>
> The first attempt to have K17 placed on the so-called 'free-list'[26] of the Australian government failed. By visiting the government official in person it was possible to change his personal opinion. However, there was still no approval by the government. In order to gain an approval, further clinical tests are underway in Australia at the moment. Then a new application will be filed.
>
> Doriden is not on the free list in Australia.
>
> All tests and the inclusion in the free list can later be transferred to our logo and used by us.
> …
> According to the letter by Mr Hayman, a request for more sales areas was voiced:
>
> Hong Kong
> Thailand
> Malaysia and Singapore
>
> Distillers feels they are in a strong position to achieve the following annual turnovers:
>
> Hong Kong £2000
> Thailand £6000
> Malaysia)
> Singapore £2500
>
> We promised to investigate the issue for the pure substance, as well as the request to be able to sell the Distillers-Contergan combination in these additional sales areas, however, we did not give them much hope….[27]

[26] Again, I need to establish this with certainty, but the 'free list' appears to refer to preferential import rates and/or preference for state pharmaceutical tenders in Commonwealth and other British commercially connected countries.

[27] http://images.theage.com.au/file/2012/07/26/3492315/thalid4.pdf?rand=1343304467483. GRT. 0001.00030.0155: 27 January 1961. File note concerning a discussion at Distillers in England between Distillers and Grt. [Note this is from the 2012 summary; later, I will analyse the duplicated documents in more detail]. This information is corroborated by Tobias Arndt in correspondence to Parle 5 to 7th May 2013.

For our purposes, what is especially notable is that in 1961 substantial sales of thalidomide were projected in Africa,[28] most likely in contracts to multinational corporations such as BP, public hospitals, and British Commonwealth agencies based in the continent. Whether significant amounts of the drug were actually *exported* and *dispensed* has yet to be established. Moreover, and for reasons I have yet to determine exactly, but which are likely to lie in delays in licensing agreements, South Africa is not listed as an area of projected sales in the January 1961 documents cited above. This does not mean that no markets were anticipated there. On the contrary, in addition to the references to the possibility of conducting "trials" in South Africa, as early as October 1957 DCBL had written to Grunenthal

> We are very disturbed that you have not found it possible to grant us any rights in respect of Australia, New Zealand and South Africa, particularly as we had firmly gathered the opinion from our previous discussions that some of these territories, if not all, would be allocated to us. We felt then, as we do now, that as these countries are our legitimate field and the export countries in which our organisation is at the strongest, that we should have received more urgent consideration of our claims. We therefore earnestly hope you will be able to see your way clear to giving us some kind of interest in these territories.[29]

Two years later, in 1959, DCBL was still pushing Grunenthal with regards to

> your reactions following our discussions as soon as possible, particularly in respect of South Africa, New Zealand, and Eire. I cannot emphasize too strongly that so far as Australia and New Zealand are concerned a great deal of preparatory work has to be undertaken to get Thalidomide accepted as a free of charge [drug] under the respective National Health schemes before one can anticipate a reasonable measure of sale at all."[30]

Even in March 1960, the two were still locked in discussions about an "omnibus deal" covering four main points, the first of which was "(a) the granting to us of licences to sell Distaval in Australia, New Zealand and South Africa."[31] Even formal agreements

[28] This is borne out by documentation sent to me by Jose (Pepe) Riquelme of Spain's AVITE. It will be incorporated into subsequent versions of this chapter/section.

[29] http://images.theage.com.au/file/2012/07/26/3492315/thalid4.pdf?rand=1343304467483, p. 126:DIS. 040.004.0138: 24 October 1957. Letter from DCBL to Leufgens. JP get full reference and cross check this date thalid4jp. P. 126

[30] http://images.theage.com.au/file/2012/07/26/3492315/thalid4.pdf?rand=1343304467483, p. 128. DIS. 034.002.0172: 3 November 1959. Letter from Hayman to Leufgens thalid4jp. P. 128

[31] http://images.theage.com.au/file/2012/07/26/3492315/thalid4.pdf?rand=1343304467483, p. 128-129. DIS. 034.002.0172: 3 November 1959. Letter from Hayman to Leufgens. Unfortunately, points b and c are omitted from these documents.

however were no guarantee of business practice. DCBL had already jumped the gun by launching sales of Malta as early as 1958 and in November 1960 found itself obliged to apologise to Grunenthal, admitting that Malta was

> not one of the markets specifically listed in our agreement... I can only come to the conclusion that this is a genuine misunderstanding on our part, arising possibly from our Export Department's belief that we enjoyed rights in the British Commonwealth with the exception of those markets such as Canada and South Africa which were clearly excluded from the outset….[32]

In anticipation of being given preference in Commonwealth markets, in 1958 DCBL had created Distillers Biochemicals Australia to act as its agent, though the parent company retained *de facto* control over policy and decision-making. The delay in getting Distaval available in Australia was at least in part a consequence of DCBL's attempts to manoeuvre the most favourable terms of trade in terms of the Commonwealth's "free list" and to have thalidomide preparations prescribed through the national health schemes.

In New Zealand, as late as May 1961, there were still pressures to have Distaval "to be admitted to social security from 1st November BUT with the proviso that it shall be available from hospitals only … it was not the price factor which made them place this restriction on the product but … the peripheral neuritis factor".[33] Barely a little more than six months later came notice of the suspension of sales of Distaval, Valgris, Tensival and Valgraine, in Australia and New Zealand, despite, or so claimed, the "the evidence of which [these reports are based] being circumstantial … and pending further investigation".[34] An estimated 15 thalidomide-affected persons were born in New Zealand nonetheless.

After March 1960, I have as yet no references in the Rowe documents to South Africa, though these have been edited so as to focus on the remit of the case, Australia and New Zealand. What is incontrovertible is that in the late 1950s it was anticipated that South Africa would be a market for thalidomide, presumably through a "Sole

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[32] http://images.theage.com.au/file/2012/07/26/3492315/thalid4.pdf?rand=1343304467483, p. 130.GRT. 004.02534.0944: 1 November 1960, Hayman to Block.
[33] Thalid4_jp.pdf. page 77. DIS.701.207.0001 at 0007: 5 June 1961. Dr J A Harrison to Wolverridge.
[34] See 'Letter to Matrons, pdf 8 December 1961', found at http://www.health.wa.gov.au/circularsnew/pdfs/5877.pdf

Importer" or subsidiary of DCBL. In its subsequent controversial financial settlement and establishment of the body to administer the settlement, The Thalidomide Trust, reached in 1973, DCBL recognised its legal obligations to beneficiaries whose mothers had taken "the preparation" [defined as] … any preparation manufactured by The Distillers Company (Biochemicals) Limited in the United Kingdom containing the drug known as Thalidomide".

> (d) "Beneficiary" means any person (whether of full age or not) now living (i) who was born in the United Kingdom **or** (ii) whose mother took the preparation in the United Kingdom during pregnancy **or** (iii) whose mother took the preparation during pregnancy and who was on 22nd February 1973 domiciled or resident within the United Kingdom or any countries specified in the First Schedule hereto

The 'First Schedule' comprised

Channel Islands
Kenya
Republic of South Africa
Canada
Cyprus
Jamaica
Republic of Ireland[35]

Oblivion C: Sedating South Africa

But, thalidomide was never actually marketed in South Africa. Further research is needed to establish whether local administrative hurdles – technical or scientific – hindered processes of application; or whether the failure to launch the sedative here was more serendipitous, perhaps the fortuitous consequence of a single person's encounter with the drug. Reviewing the announcements for new pharmaceutical products – thinly veiled advertisements – appearing in every volume of the *South African Medical Journal* (*SAMJ*) reveals that sales of sedatives and tranquillizers – as well as antibiotics – to South Africa were on the rise in late 1950s and early 1960s.

A number of international pharmaceutical companies were looking to expand into the region either directly or via local subsidiaries. Indeed, in July 1959 came news that

[35] http://www.thalidomidetrust.org/docs/deed.pdf#page=2&zoom=auto,0,791 Revised Deed of the Thalidomide Trust, 4 July 2008. Interestingly, in the 1973 Offer of Settlement by DCBL, these countries were listed as the 'Second Schedule'. There is no mention of Uganda or any West African country. Indeed, it seems that Grunenthal may well have dealt directly with sales to West Africa.

US pharmaceutical manufacturers, Wyeth International Ltd, was constructing a "modern combination production-laboratory and administration building at Isando, near Johannesburg", which would employ more than one hundred South Africans. The plant would "manufacture and package the tranquilizing agents equanil, sparine and prozine…" as well as treatments for hyperacidity; analgesic creams; an anti-diarrhoeal preparation; and "zactirin, a new pain reliever."[36]

Distillers itself had a direct interest in at least one South African company, National Chemical Products (NCP), having in 1940 bought a "large minority stake" in the enterprise.[37] In 1953, Distillers' chairman, Sir Henry J Ross, included Australia, New Zealand and South Africa in his tour of territories comprising a global circle of "widening influence" for the company and reported that in South Africa "our associated company National Chemical Products Limited had had a good year and the expansion schemes in the range of chemicals and plastics have made satisfactory progress."[38] Also doing well was the Distillers' flagship Gordon's Gin, which was being locally produced at Isando, Johannesburg. Ross's visit no doubt was intended to persuade South African authorities to facilitate Distillers' interests in the region. In April 1953 he had commented that

> we are still faced with problems and difficulties regarding exports to certain overseas markets. In some instances the extent of our trade is regulated by annual trade agreements in which specified import quotas are related to various United Kingdom exports. In others, such as Australia and South Africa, a limited amount of sterling is made available to importers and our exports are restricted accordingly.

In the same report, he explained that the Biochemicals Division of Distillers "despite intensive competition both at home and abroad our factory at Speke has enjoyed a

[36] *SAMJ*, 4 July 1959, p. 571. Wyeth produced Equinal, or Miltown http://books.google.co.za/books?id=eSBDF5_L3BgC&pg=PA293&lpg=PA293&dq=1950s+percentage+of+americans+tranquilizers&source=bl&ots=Xi-28VNBsm&sig=FmtlVlUr7lgQvFX2kFv8Q1hGGqE&hl=en&sa=X&ei=z7dyUZu_NIyYhQeYwYC4AQ&sqi=2&ved=0CFAQ6AEwBA#v=onepage&q=1950s%20percentage%20of%20americans%20tranquilizers&f=false

[37] Zavareh Rustomjee, 'The Development of South Africa's Chemical Industry and its Implications for Chemical Sector Development in Southern Africa', paper for the inuaugural conference of the Instituto de Estudos e Economicos (IESE), Mozambique, 19 September 2007, p. 23.

[38] The Glasgow Herald, 19 August 1954: http://news.google.com/newspapers?id=qz1AAAAAIBAJ&sjid=VlkMAAAAIBAJ&pg=2125,4908291&dq=distillers+south+africa&hl=en

reasonable level of production of penicillin and streptomycin…"[39] In the UK, a new production plant had almost been completed, enabling consumer demand to be met.

> New forms of these two stable antibiotics have been marketed and well received by the medical and pharmaceutical professions. … [However] due to progressive process development and rising consumption there have been a series of major reductions in selling prices over the last few years. Competition remains very keen, particularly in the export markets where prices are still falling, but our modern plant and technical resources should help us to meet these conditions and secure a proper share of the business.[40]

In short, in the quest for new markets and greater profits, overseas markets, including those in South Africa, were extremely important to Distillers Company Ltd. In turn, its South African associated company, NCP had interests in other African countries, including Kenya, where it sold animal feed supplements, another product area in which Distillers had worldwide interests.[41] Despite these expansionary pressures and despite the acquisition of the licence to sell thalidomide-related products and the attendant bombardment from Distillers of promotional materials, advertisements, and approaches to hospitals, doctors, pharmacists and hospital managers, a search of the pages of the *South African Medical Journal* between 1958 and 1961 has not turned up an announcement of the impending launch of Distaval or any of the other brand-named sedatives sold by DCBL.

This seems all the more curious when we learn that DCBL was active in the country. For instance as early as February 1956, the 'New Prepaations and Appliances' column in the SAMJ carried notice that "British Drug Houses are now distributing 'Distaquaine' V tablets in South Africa, manufactured by The Distillers Company (Bio-chemicaJs) Ltd. [who] submit the following statement: 'Distaquaine' V tablets

[39] The Glasgow Herald, 20 August 1953, viewed at http://news.google.com/newspapers?nid=2507&dat=19530820&id=5EdAAAAAIBAJ&sjid=koUMAAAAIBAJ&pg=5908,938016

[40] The Glasgow Herald, 20 August 1953, viewed at http://news.google.com/newspapers?nid=2507&dat=19530820&id=5EdAAAAAIBAJ&sjid=koUMAAAAIBAJ&pg=5908,938016

[41] The Kenya Gazette, 18 December 1962, p.1414, viewed at http://books.google.co.za/books. Two more interesting points strike one just through glancing through the range of products being advertised in this volume alone. The first is that NCP's legal advocates in Nairobi are listed as 'Messrs Kaplan and Stratton'; and that Glaxo Laboratories advertised PREGAMAL, "Pharmaceutical preparations for use in pregnancy", see p. 1412.

consist of phenoxymethylpenicillin, a new form of penicillin which is stable in an acid medium and therefore requires no added buffer to 'prevent its destruction by the gastric contents."[42] Similarly, in January 1960, it was the introduction by British Drug Houses (South Africa) (Pty) Ltd, of Zynocin, an "antiseptic and sore throat lozenge … The first preparation of its type to incorporate the new antibiotic xanthocillin …" was announced.[43]

There was certainly a potential market for Distaval, as can be seen in the announcements of new sedatives and tranquillizers that were also placed by companies other than British Drug Houses or DCBL at the time. For instance, in 1961 the *SAMJ* carried an announcement by Merck Sharp & Dohme (Pty) Ltd in Johannesburg about the "discovery and development" of Tryptanol, which, it said "represents a significant advance in the treatment of depression and especially depression accompanied by anxiety". It went on to add "…unlike other potent psycho-pharmacological agents, Tryptanol achieves its wide range of therapeutic goals with a remarkable degree of safety.[44]

A few months earlier, SKF Laboratories (Pty) Ltd, also of Isando, had announced, in the *SAMJ*, two new medications: the first, "Parnate tablets … for the treatment of pure depression (reactive, endogenous), involutional melancholia, manic-depressive psychosis (depressive phase), and psychotic depressive reactions." The drug, it claimed

> had no serious side-effects, and the action of the drug persists for only 48-72 hours after withdrawal".[45] Parstelin tablets, similarly, were recommended for the treatment of: (1) Symptoms of depression and anxiety appearing concurrently; (2) emotional fatigue; (3) menopausal syndrome; and (4) emotional states, secondary to organic illness, and psychosomatic illnesses with symptoms of depression and anxiety…. Parstelin enables the physician to control with a single preparation the symptoms of depression and anxiety when they appear concurrently. The need for such a product has long been realized. The association of Parnate, a new anti-depressant agent that is particularly effective in mild and moderate depressions, with Stelazine, a

[42] *South African Medical Journal* (*SAMJ*), 11 February 1956, p. 140.
[43] *SAMJ*, 23 January 1960, p. 79. On the same page, medical products by Glaxo-Allenburys (S.A.) (Pty) and Johnson & Johnson (Pty) Ltd are also advertised. The next phase of research will cover a search of the *South African Pharmaceutical Journal*.
[44] *SAMJ*, 17 June 1961, p. 506: 'New Preparations and Appliances'.
[45] *SAMJ*, 4 March, 1961, p. 183.

> phenothiazine tranquillizer outstandingly effective in treating anxiety, is a logical development in the field.

And, in the same volume, came the announcement of from Evans Medical of "Dormwell Tablets and Paediatric Tablets, manufactured by Smith & Nephew (Pharmaceuticals) Ltd … England … Dormwell is a dichloralphenazone. It is a safe, non-barbituate sedative and hypnotic", and was said to be "particularly suitable for elderly patients since they cause no restlessness or mental confusion. The paediatric tablets are very well tolerated by children and babies." Both literature and samples could be obtained by writing to Evans Medical in Johannesburg.[46]

This was not the only sedative for children being marketed in 1961: Neo-Choral-Ped, sold by Westdene Products (Pty) was

> a safe mild hypnotic for children, … available in tablet form… Neo-Chloral-Ped is a product of South African Research manufactured by Pediatric Laboratories (Pty) Ltd., Cape Town. It contains a complex organic salt of chloral-hydrate possessing no unpleasant flavour whatsoever. It is a safe, mild hypnotic giving a natural sleep from which children can be easily awakened. There are no after-effects and painful conditions are not masked…. Neo-Chloral-Ped has been available for some time as an elixir and the increasing demand for this has encouraged the introduction of a tablet form for older children.[47]

Westdene Products (Pty), were also already selling in South Africa a drug manufactured by British Schering of London, named 'Oblivion-C'. In terms almost spookily close to the descriptions of thalidomide, Oblivion-C was, readers were assured

> a particularly safe drug which has proved very effective in the treatment of those conditions in which anxiety is the dominant factor. In the day-to-day management of anxiety states, anxiety neuroses, phobic conditions, functional and psychosomatic disorders, Oblivion-C effectively relieves the stress factor in these cases by its specific action on anxiety. … Oblivion-C is the most suitable tranquillizer for use in general practice because of its reliable action and its freedom from side-effects. There are no contra-indications to its use. … Oblivion-C is available in the form of oval tablets specially shaped to make them easy to swallow, and is supplied in containers of 25 and 100 ovets. Each ovet contains 100 mg. of Oblivion-C (methylpentynol carbamate). …. *Oblivion elixir* is a shorter-acting tranquillizer than Oblivion-C. Oblivion elixir rapidly allays fear and reduces tension before minor medical and surgical

[46] *SAMJ*, 4 March, 1961, p. 184
[47] *SAMJ*, 28 January 1961, p. 77.

> procedures. It plays an important role in dentistry and pre-anaesthetic medication. The elixir is presented as a palatable liquid in bottles of 100 ml. and is particularly suitable for children and old people. … Samples and further information may be obtained from the sole South African distributors, Westdene Products (Pty) Ltd….[48]

Moreover, Westdene Products were also the "sole South African agents for Astra International of Sweden", a major pharmaceutical company which had also enjoyed great success with xylocaine, a spectacularly successful local anaesthetic. In 1960, Astra had more than 2,000 employees at its home factories and "in the 14 subsidiary companies in various parts of the world", manufacturing programme covering "no less than 400 different products". The September 1960 infomercial in the *SAMJ* announced that "… many more products of original research from the Astra Laboratories will be reaching South Africa during the coming months as a result of the new link with Westdene's Ethical Division."[49] At the time, Astra Laboratories was the Swedish distributor of the prescription-free sedative, Neurosedyn: thalidomide.

"A man had a headache in South Africa, and thus was the country spared the horror."

At this juncture of our research, I have only hypotheses as to why DCBL did not launch Distaval, Asmaval or any other thalidomide preparation in Southern Africa in the late 1950s or early 1960s. These suggest lines of further research, which will require attention to the political context of the times. After all, the early 1960s were, of course, years of tremendous turmoil in South Africa. In the first year of the decade, black opposition groupings escalated protests and on 21 March a large gathering of people at Sharpeville, a township in the southern Transvaal province, was met with violence by white South African police. Official statistics would put the death toll at 69, with nearly 200 injured. Infamously, many people were shot as they attempted to flee, sustaining bullet wounds in the back. In the weeks that followed, both protests and repression escalated. By the end of March a State of Emergency had been declared; around 18,000 people arrested; and international condemnation of apartheid became more vocal. The following year, South Africa became a Republic and

[48] *SAMJ*, 30 May 1959, p. 465.
[49] *SAMJ*, 10 September 1960, p. 793.

accelerated state support for national independence in industrial manufacturing and energy supplies.

By the time the Commission of Inquiry into the Pharmaceutical Industry reported in 1978, there was official interest in the support too of the domestic manufacture of chemicals and medications "in case of boycott or war".[50] In the intervening years, what had been the commercial and financial consequences of exclusion from the Commonwealth, and how had this affected licensing and patent applications for new pharmaceuticals?

Along with much of the rest of the world, *after* the extent of the thalidomide epidemic had become known, South Africa tightened up on its requirements for the testing, licensing and marketing of medications. A Commission of Inquiry into the High Costs of Medical Services and Medicines came in 1962; and in 1965 the Medicines and Related Substances Control Act (Act No. 101 Of 1965) established the Medicines Control Council, to "oversee the regulation of medicines in South Africa." However, for more than a decade before this, the South African Bureau of Standards had been flexing its muscles. In early 1961, the SAMJ published an article by SABS member, J H Rauch, M.B., CH.B. (DUBL.), D.P.H., D.T.M. & HY (RAND), titled 'The Testing and Control of Pharmaceutical Products', which described how the Bureau was preparing "specifications…for intravenous fluids, vitamin preparation, surgical sutures, insulin injections and other forms of drugs …".[51]

He noted the increasing number of "overseas principles [who had] established their own factories in this country or have made arrangements with organizations to manufacture for them. As a result of this increasing industry the Bureau of Standards has been called upon more and more to provide test facilities for a very wide range of manufactured pharmaceutical products, especially ethical preparations." A significant demand on the Bureau's services came in the need to test products "submitted against tender for Government use." Rauch reported that, right "from the beginning" they had had to "submit frequent reports on the failure of many of the preparations

[50] R.P. 38-1978, Report of the Commission of Inquiry into the Pharmaceutical Industry, January 1978
[51] SAMJ, 7 January 1961.

submitted…" As a result of this vigilance, a greater number of "the importing agents of overseas companies…and…more and more products have been, and are continuing to be, submitted… for control purposes." The outcome was, he said, that the

> medical profession are getting tested products of high quality and performance, and, in addition to this, there has certainly been a decrease in the number of failures experienced in tender contracts ….The Union Health Department, whose responsibility includes the administration of the Food and Drugs Act and the Therapeutic Substances Act, has been seeking the assistance of the Bureau in the field of testing, and today frequently submits varied samples drawn in terms of the administration of these two Acts. This work from the Union Department of Health continues to show steady increase.[52]

Perhaps Distaval had been caught up in the administrative requirements of the SABS?

An alternative hypothesis is to follow the claim made in an article in the Weekend Argus in late 1979 by Mr Frank Wayne, who told reporter D. Birch that he

> the marketing executive of the British company to which Thalidomide was licensed by the German manufacturers, had some trouble sleeping while on his travels. He took Thalidomide samples. He developed a headache and this made his approach to the pills more guarded. And, after a few months, when he used the pills again and got another headache he was puzzled.
>
> He subsequently received a report about a side-effect of Thalidomide and he decided to think the whole matter over very carefully.
>
> There were delays, and the new drug remained unlaunched in South Africa.[53]

The Weekend Argus ran the byline "A man had a headache in South Africa, and thus was the country spared the horror …"

The statement that thalidomide was not launched in South Africa seems to be corroborated by a letter to the *SAMJ* from W. Leigh, Senior Lecturer in Pharmacology at the University of the Witwatersrand in November 1962. Leigh wrote to the Editor that:

> Most of these preparations were not introduced in the Republic of South Africa, but it is possible that an odd one may be circulating as a 'clinical trial' substance, or might be unwittingly introduced later." Leigh then lists the 50 or so names under which thalidomide preparations were registered (see Appendix) and then added "The following substances are closely related in

[52] *SAMJ*, 7 January 1961.
[53] D. Birch, 'Twenty years ago … the horror of THALIDOMIDE', *Weekend Argus*, 22 December 1979.

> molecular structure to thalidomide. However, activity or function relationship concerning teratogenesis have not been proved and the names appearing hereunder represent a chemical guide: Glutarimide, Glutethimide (Doriden), Bemegride (Megimide), Methyprylon (Nolundar).[54]

The reader will note that Leigh did not rule out thalidomide samples having been distributed, or, the drug having been obtained outside of the country. Indeed, according to the *Weekend Argus*' story,

> In August 1962, the first 'Thalidomide baby' in South Africa was born – perfectly normal – at a Johannesburg maternity home. The mother came from Lourenco Marques and took the drug throughout her pregnancy.
>
> A doctor at the maternity home said that the abnormality rate with the new drug was 30 percent which was dangerously high. However, he explained, this did not mean that one in three women had the chance of giving birth to a normal baby. 'This woman was one of the lucky ones', he said, referring to the mother from Lourenco Marques.

This is intriguing. According to Randy Warren of the Thalidomide Victims' Association of Canada, which has conducted extensive research into the sales of thalidomide, the drug was available in Mozambique between 1960 and 1961. (See Appendix below). Indeed, according to a 1983 study,

> before independence [in 1975] there were some 26,000 brand-name products registered in the country and about half of that number of pharmaceutical preparations were actually on the market. Importation was in the hands of private agencies representing various manufacturers and representatives of some transnational countries. Import licences were required but there was no effective import control: a search through the Ministry of Health records revealed only thalidomide being prohibited from importation. Pharmaceuticals were bought mainly from Portugal and South Africa, and to a lesser extent from Western Europe and the USA. There was no pharmaceutical industry.[55]

Whether thalidomide was the only banned pharmaceutical in Portuguese-ruled Mozambique because of response to the drug in the metropole, is yet to be established. It is certainly not inconceivable that some settlers, including doctors, pharmacists, and drug company representatives, had knowledge of and access to Distaval. As Mazagão and Segal comment, in Mozambique "before independence"

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[54] W. Leigh, Senior Lecturer, Department of Pharmacology, Medical School, University of the Witwatersrand, Johannesburg, 19 October 1962; letter titled 'Thalidomide' to The Editor, *SAMJ*, 3 November 1962, p. 928.

[55] Carlos Mazagão and Malcolm Segal, 'Drug Selection in Mozambique', originally published in World Development, 11, 3 (1983): 205-216, and reproduced in Surendra J Patel (ed), *Pharmaceuticals and Health in the Third World* (Oxford: Pergammon Press, 1987). The quotation is on p. 207 of the Patel book.

> there was one drug company representative for about every 5 doctors in the country. Doctors (and in some circumstances even nurses) often prescribed the latest fashionable drugs especially, but not exclusively, in private practice. … Doctors brought into the country for 2-3 years by the army added their personal preferences to the multiplicity of product lines. Self-medication with expensive OTC (over-the-counter) preparation was prevalent, especially in the major towns which contained private retail pharmacies.

They add that "the distribution of drugs to rural health units was very irregular and poorly planned, the choice of products for an entire area often being at the whim of an individual doctor. The absence in health units of basic essential drugs could coincide with the presence of sophisticated products for rare disorders. Drugs were sold to the rural population without control."[56] Given this chaotic state of affairs in the decades before independence, and given the distribution of Distaval/thalidomide in Portugal (and possibly in Angola), it seems almost impossible that there was no (reported?) epidemic of deformity there.

Moreover, as we have seen, long before 1975, thalidomide was being investigated by researchers for its use in the treatment of ENL (a complication of Hansen's disease/leprosy). And, whilst also banned in South Africa, it had been cleared as early as 1968 (if not earlier) for experimental use in other path-breaking medical research. In a country and city abuzz with the exhilaration of having achieved the world's first successful human heart transplant in late 1967, it was reported in the international press that

> The controversial drug thalidomide is being tested at [Cape Town's] Karl Bremer Hospital here as an immuno-suppressive serum in baboon kidney transplants and skin grafts on rabbits. Immuno-suppressive drugs are designed to prevent the body's natural rejection of transplanted organs.
>
> Thalidomide is banned in South Africa, but can be imported for research, a spokesman said. He said "it compared satisfyingly" with other immuno-suppressive drugs."[57]

A decade later, the *Weekend Argus* reported

> In 1968, doctors found that Thalidomide was capable of delaying or preventing the donor skin from being rejected as foreign tissues. Experiments carried out on animals revealed this new, unexpected property in the drug.

[56] Mazagão and Segal, 'Drug Selection in Mozambique', Patel (ed), *Pharmaceuticals and Health in the Third World,* p. 208.
[57] *Reading Eagle*, Sunday 24 November 1968, 'Thalidomide May Still Be Useful'.

> Thalidomide, it was reported, was being used successfully to depress serious reactions during the course of treatment for leprosy, and doctors felt, at the time, that this was direct evidence that Thalidomide could also be used in man as an immuno-suppressive. But because of the danger to unborn children, the drug has been used only with male patients or females beyond the child-bearing age.[58]

Neither of these reports states when thalidomide was cleared for testing in South Africa, or at whose behest.

Has the okapi been spotted, at last, in Cape Town?

[58] D. Birch, 'Twenty years ago … the horror of THALIDOMIDE', *Weekend Argus*, 22 December 1979.

APPENDICES

A.

Tables from http://www.avite.org/cifras2.htm accessed 8 March 2013 (translated by Google). Writer: Carlos Gamero Esparza, from Lima, Peru
Special AVITE
Adapted from the article "Pills in His Labyrinth":

WATCH OUT FOR THESE DRUGS

Thalidomide, pure or mixed with other drugs, has been selling at least 52 names, which we list below. If you have in your possession any drugs, get rid of it or give it to your doctor.

Algosediv	Imidan	Poly-giron	Sedoval-K17
Asmadion	Imidene	Poligripan	Slip
Asmaval	Imidene hypnotic	Prednisone sediv	Softenil
Bonbrrin	Isomin	Profarmil	Softenon
Calmorex	Kevadon	Psycholiquid	Talarfan
Contergan	Lulamin	Psychotablets	Talimol
Coronarobetin	Neo Nibro	Quetimid	Tensival
Distaval	Neosydyn	Quietoplex	Thalin
Ectiluran	Neurosedyn	Sanodormin	Thalinette
Enterosediv	Nevrodyn	Sedalis	Theophilcholine
Gastrimide	Noctosediv	Sedimida	Ulcerfen (*)
Glutanon	Noxodyn	Sedin	Valgis
Grippex	Peracon Expectorans	Sediserpil	Valgraine

Source: LIFE Magazine in Spanish - September 17, 1962.

Total production of thalidomide sold by Chemie-Grünenthal (WHO) between 1985 and 1992

Country	Number thalidomide tablets x country
Germany	141,500
Austria	1,600
Belgium	1,000
Bolivia	20,000
Bulgaria	4,900
Cape Verde	10,000
Czechoslovakia	3,600
Cyprus	20,000
Comoros	10,000
Korea	130,000
Cuba	39,300
Denmark	29,600
U.S.	155,200
Ethiopia	15,000
Finland	10,400
Greece	65,000
Haiti	5,000
Hong Kong	4,000
India	316,500
Israel	6,000
Italy	15,400
Liberia	25,000
Malaysia	1,000
Mali	60,000
Morocco	400,000
Mexico	130,000
NZ	28,000
Netherlands	11,500
Pakistan	10,000
Paraguay	30,000

Peru	200,000
Portugal	20,000
Singapore	60,000
Sweden	33,100
Switzerland	46,900
Surinam	100,000
Traskei	5,000
Turkey	5,000
Total 38 countries	2169500

Source: Chemie-Grünenthal / Thalidomide.org

B. Brand names that took Thalidomide and countries were available:

Source: National language version of "The Many Faces of Thalidomide"

MARK THALIDOMIDE	COUNTRIES WHERE AVAILABLE
Algosediv	Portugal, Switzerland, Germany
Asmadion	Italy
Asmaval	Angola, Australia, Ghana, Great Britain, Guinea, New Zealand, West Africa
Bonbrain	Japan
Calmorex	Italy
Contergan	Portugal, Germany
Forte Contergan	Germany
Saft Contergan	Germany
Contergan-Suppositorium	Germany
Corona-Robetin	Italy
Distaval	Angola, Australia, Ghana, Great Britain, Guinea, New Zealand, Portugal, West Africa
Forte Distaval	Britain
Ectiluran	Brazil
Enterosediv	Belgium, Finland, Ireland, Netherlands, Portugal, Switzerland (Note 2)
Gastrinide	Italy
Glutanon	Japan
Grippex	Germany
Imide-Lab	Portugal
Imidan	Spain
Imidene	Italy
Hypnotic Imidene	Italy
Isomin	Japan
Kevadon	Canada, Portugal, United States
Lulanin	Denmark
NeoNibrol (also: New Nibrol)	Japan
Neosedyn	Denmark
Nerufatin	Japan
Neurosedyn	Norway, Sweden
Nevrodyn	Norway
Noctimid	Belgium
Noctosediv	Finland, Ireland, Netherlands, Portugal, Switzerland

Noxodyn	Sweden
Noxosedyn	Sweden
Ondasil	Brazil
Pantosediv	Germany
Peracon	Finland
Peracon-Expectorans	Germany
Poli-Gripan	Hong Kong, Ireland, Malaysia, Pakistan
Prednisediv	Finland, Ireland, Germany
Proban-M	Japan
Profarmil	Italy
Quetimid	Italy
Quietoplex	Italy
Sanodormin	Japan
Sedalis	Brazil (Note 2 b)
Sedi-Lab	Portugal
Sedimide	Italy
Sedin	Brazil
Sediserpil	Italy
Sedoval K-17	Italy
Shin-S-Naito	Japan
Shin Nibrol	Japan
Sleepan	Japan
Slip	Brazil
Softenil	Argentina, Peru (Note 2 c)
Softenon	Austria, Belgium, Cyprus, Finland, Ireland, Malta, Netherlands, Portugal, Spain, Switzerland, Germany
Forte Softenon	Germany
Talargan	Mexico
Talimol	Canada
Tensival	Angola, Australia, Ghana, Great Britain, Guinea, New Zealand, West Africa
Thalin	Israel
Thalinette	Israel

Theophyl-theophyl-Choline	Italy
Ulcerfen	Italy (Note 2 d)
Valgis	Angola, Australia, Ghana, Great Britain, Guinea, New Zealand, West Africa
Valgraine	Australia, Ghana, Great Britain, Guinea, New Zealand, West Africa
Valip	Italy
Verdil	Brazil

The original texts of nomenclatures and explanatory notes that follow have been modified and adapted for this purpose.
Note 1: In Peru is suspected, the drug also mentioned drugs have also circulated and Enterosediv Sedalis (Whole-Sediv). Furthermore, LIFE magazine reports that the drugs were sold in Latin America, but does not specify the countries, and notes - also omitting names-that in Peru "the drug was banned in June" (1962), without giving further details. The same publication also mentions the Ulcerfen - in the list of TVAC listed as available only in Italy, which, although no data on its sale in Peru, is now known to be produced and sold in Argentina.
Note 2 (a): Drug for stomach derangement.
As an extension of Note 1, although there is no way to confirm the sale in Peru, some acquaintances of the writer reported having used or seen in the Enterosediv drugstores and pharmacies. What is strange that while Softenil Sedalis and preferably marketed drugs were in Brazil, Argentina and Peru, the Enterosediv was apparently brought from Europe to be sold in Peru-know whether this also occurred in other Latin American countries. The only certainty is that this drug was a showcase for many years and sold virtually no medical straight in Lima and other Peruvian cities, but health officials do not seem to have shown interest, despite being a drug risk. What I can say is that at the time these drugs have been on show-and post-'60s there was no effective control of medicines in Peru, even worse, the bottles and packaging of most drugs did not even have an expiration date.
Note 2 (b): Sleeping pills. Possible sale in Peru, which is very likely because he was also a massive drug use in Brazil.
Note 2 (c): The only officially recognized drug sold in Peru in the early '60s, as can be seen in the list published by LIFE for many years.
Note 2 (d): Now is manufactured in Argentina. With the suspicion of having circulated in Peru. It is a drug for stomach ulcers.
Note 2 (e): According to Dr. Rodolfo Maino (5), Thalidomide was produced in large quantities and exported to other eleven European countries, seven Africans, seventeen and eleven Asian Americans, excluding U.S. where never marketed, until many years later, by the action of Dr. Frances Kelsey, who, you will recall, was suspicious of the safety of the substance.

Contergan FIGURES (and its derivatives) in some countries in Europe and America

Country	Distributor	Brand	Marketed	Retired
East Germany	Chemie-Grünenthal (the manufacturer of the original drug).	Algosediv, Contergan, Contergan Forte, Grippex, Peracon-Expectorans, Softenon, Softenon Forte, Pantosediv, Prednisediv	October 1, 1957	Retirado27 November 1961 Available over the counter (without prescription)
Spain	PEVYA UCB, SA (*) (After UCB Pharma). Nessa Pharmaceuticals Medinsa (as Chemie-Grünenthal representative).	Imidan, Varial, Gluto Naphthyl, Softenon, Noctosediv, Enterosediv (tablets), Enterosediv-Supen (Solution)	≈ 1960	Retired January 21, 1963 Sold without a prescription
U.S.	William S.Merrell Inc. (Richardson-Merrell or (**)	Kevadon	Never. Although Richardson-Merrell 2,528,412 tablets distributed to 1,627 American doctors for clinical trials, which in turn received some 20,000 patients	
Sweden	Astra	Neurosedyn, Noxodyn	? 1957?	Retired quietly on December 12, 1961, but made official on March 14, 1962, after the birth of five babies unnecessarily deformed
Switzerland	¿?	Noctosediv	¿?	¿?

(*) Website UCB Pharma: http://www.ucb-pharma.com/
(**) The Dow Chemical Company, formerly William S. Merrell (Richardson-Merrell), founded in 1897, currently based in West Virginia and a presence in 170 countries. (6 - 7)
Sources: "Suffer the Children: The story of thalidomide" by The Sunday Times of London. 1979 (8)
Department of Pharmacy & Medicine, 1981. (Spain)
Editor's Note: Could not find direct references Medinsa web (International Drug SA), Nessa Laboratories or Spain.

http://www.thalidomide.ca/many-faces-of-thalidomide/

http://www.thalidomide.ca/many-faces-of-thalidomide/
The Many Faces of Thalidomide (from 1957 to 1966)

compiled by Randolph Warren
May 7, 1999

As much as possible, this document strives to list all of the brand names thalidomide was available under, and provides a comprehensive list of all the countries thalidomide was available in. Whenever possible, the dates of thalidomide availability in each country is also provided.

In some cases, the "Brand Names" are blank, but it is known that thalidomide was present in the country as proven thalidomide victims are located in that country and the mothers got the drug from there either as samples or from some other source. Some countries have no "Dates Available" reference, but again, the drug was not licensed there and therefore there can be no accurate rendering of when samples were first available. In these cases, the drug could not have been available before October 1, 1957, West Germany's marketing launch date.

It is virtually impossible to completely list all the brand names and every possibility that thalidomide was available in a certain country when it wasn't licensed there, but what follows is a compilation from many sources to the best of our ability:

Country**	Brand Name of Thalidomide	Dates Available
Angola	Asmaval, Distaval, Tensival, Valgis	
Argentina	Softenil	Withdrawn March 1962
Australia	Asmaval, Distaval, Tensival, Valgis, Valgraine	April 1958 - Dec. 1961
Austria	Softenon	1958 - Dec. 1961
Belgium	Enterosediv, Noctimid, Softenon	1959 - 1962
Brazil	Ectiluran, Ondasil, Sedalis, Sedin, Slip, Verdil	March 1959 - June 1962
Canada	Talimol, Kevadon	Late 1959 - April 1, 1961 as samples, then licensed and withdrawn on March 2, 1962
Canary Islands		1959 – 1961
Cyprus	Softenon	April 1961 -
Denmark	Lulanin, Neosedyn	Oct. 1959 - Dec. 1961
Dominican Republic		not licensed
Finland	Enterosediv, Noctosediv, Peracon, Prednisediv, Softenon	Sept. 1959 - Dec. 1961
France		not licensed
Ghana	Asmaval, Distaval, Tensival, Valgis,	

	Valgraine	
Great Britain	Asmaval, Distaval, Distaval Forte, Tensival, Valgis, Valgraine	April 1958 - Dec. 2, 1961
Guinea	Asmaval, Distaval, Tensival, Valgis, Valgraine	Withdrawn in 1961
Hong Kong	Poli-Gripan	
Hungary		not licensed
Iran		1959 - 1966
Iraq		1960 - 1961
Ireland	Enterosediv, Noctosediv, Poli-Gripan, Prednisediv, Softenon	May 1959 - January 1962
Israel	Thalin, Thalinette	for a few weeks only
Italy	Asmadion, Calmorex, Corona-Robetin, Gastrinide, Imidene, Imidene ipnotico, Profarmil, Quetimid, Quietoplex, Sedimide, Sediserpil, Sedoval K-17, Theophyl-Choline, Ulcerfen, Valip	still on sale ten months after German withdrawal
Japan	Bonbrain, Glutanon, Isomin, NeoNibrol (also: New Nibrol), Nerufatin, Proban-M, Sanodormin, Shin-Naito-S, Shin Nibrol, Sleepan	January 1958 - 1963 Available Over-The-Counter.
Jordan		1959 - 1961
Lebanon		1959 - 1961
Malaysia	Poli-Gripan	
Malta	Softenon	
Mexico	Talargan	1959 - 1962
Mozambique		1960 - 1961
Netherlands (Holland)	Enterosediv, Noctosediv, Softenon	January 1959 - Nov. 1961
New Zealand	Asmaval, Distaval, Tensival, Valgis, Valgraine	
Norway	Nevrodyn, Neurosedyn	Nov. 1959 - Dec. 1961
Pakistan	Poli-Gripan	
Peru	Softenil	
Portugal	Algosediv, Contergan, Distaval, Enterosediv, Imida-Lab, Kevadon, Noctosediv, Sedi-Lab, Softenon	August 1960 - Dec. 1961
Saudi Arabia		1959 - 1961
Singapore		
Somalia		
Spain	Imidan, Softenon	May 1961 - May 1962 (?)
Sudan		1959 - 1961
Sweden	Neurosedyn, Noxodyn, Noxosedyn	Sept. 1958 - Dec. 12, 1961, withdrawn a second time March 14, 1962 as first withdrawal was done quietly and not heeded.

Switzerland	Algosediv, Enterosediv, Noctosediv, Softenon	Sept. 1958 - Dec. 1961
Syria		1959 - 1961
Taiwan		Sept. 1958 - 1962
United States	Kevadon	1958 - December 1961 as samples only
West Africa	Asmaval, Distaval, Tensival, Valgis, Valgraine	October 1, 1957 - November 28, 1961
West Germany	Algosediv, Contergan, Contergan Forte, Contergan Saft, Contergan-Suppositorium, Grippex, Pantosediv, Peracon-Expectorans, Prednisev, Softenon, Softenon Forte	* This is where it all started! There were reports of babies being born as early as 1956 but ONLY to employees of the drug company.
Yugoslavia		not licensed

** The following countries have reported the presence of thalidomide and / or thalidomide victims having been born there, but the actual brand name that was available, likely as samples, and the dates of availability cannot be confirmed; What is clear is that the drug COULD NOT be available before October 1, 1957:

Afghanistan, Bahrain, Bolivia, Burma, Chile, Curacao, East Germany, Ecuador, Egypt, El Salvador, Eritrea, Ethiopia, Gaza, Goa, Greece, Haiti, Kuwait, Nicaragua, Nigeria, Panama, Paraguay, Qatar, Rhodesia, South Africa, Thailand.