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WHO'S AFRAID OF  
A CURE FOR CANCER?

*The struggle for an alternative cancer drug*

Translated from the German by Steve Gander

Millions of people all over the world die of cancer each year.

According to statistics from the International Agency for Research on Cancer (IARC) Globocan, the figure was 5,182,632 in 1998. Of these, 921,194 died of lung cancer, three times as many men as women; 627,850 died of stomach cancer, 426,934 of cancer of the liver, also three times as many men as women.

In Austria a total of 18,955 died of cancer in 1998, 3,123 of lung cancer. Here too, men account for three times more deaths than women. Breast cancer killed 1,677 women.

Incidence of lung, breast and stomach cancer is increasing worldwide. Oesophageal cancer is on the increase. After the age of 55 the number of deaths from cancer rises dramatically.

## Introduction

Who in the world is afraid of Ukrain? – And who must be protected from it at all costs?

These are the main questions to be investigated in this book. It is also the story of the way in which the emergence of a promising anti-cancer drug has been obstructed – perhaps for reasons which are not always so mysterious.

It is also the first and only drug which destroys cancer cells while leaving healthy cells undamaged, as proven by, among others, the US National Cancer Institute (NCI), an internationally recognised research institute. The mechanism of action of the drug was deciphered at St. John's University, Newfoundland in Canada.

At international cancer congresses, doctors and researchers from all over the world have reported their successes in using Ukrain. There is certainly no shortage of success stories. Hundreds of case histories prove that Ukrain has been effective, even in apparently hopeless cases where conventional medicine had failed.

However, Ukrain is no wonder drug. There are also cases in which it has failed, especially when the disease is too far advanced; although even then, in not just a small number of cases, significant prolongation of life can be expected and particularly a decisive improvement in the general condition. All patients so far have agreed on this: the quality of life during and after treatment increased in a way they had not known previously - in contrast to conventional chemotherapy which also destroys healthy cells and weakens the immune system. Cancer patients and their relatives know the suffering of undergoing 'chemo' and how many additional drugs must be taken to reduce that suffering as much as possible – i.e. make it to some extent tolerable.

The anti-cancer drug Ukrain is interesting because it is completely non-toxic, as proven decades ago at the Pharmacological Institute of the University of Vienna and later confirmed by numerous researchers and doctors worldwide. Furthermore, it has no damaging side effects such as hair loss or extreme nausea and therefore needs no extra drugs to combat the side effects.

Ukrain appears to be especially effective where conventional medicine has unfortunately so often failed, such as with lung cancer with metastases, colon cancer, melanomas or types of cancer which form metastases in the liver and intestines. Many cases will be described in more detail in this report.

The layman may ask why, if Ukrain is so promising, is it not long-established in general cancer therapy?

That is the question.

Its inventor, Wassil Jaroslaw Nowicky, an Austrian citizen originally from Ukraine, has been struggling to obtain official approval for more than twenty years – approval which the Austrian Ministry of Health has stubbornly refused.

Tirelessly Nowicky has repeatedly submitted documentation which the authorities have demanded, only to then be told that they are still not satisfactory. Like Don Quixote he has struggled against a bureaucracy which, as we shall see, does not want to register his drug.

But Nowicky has not given up. He has a deep streak of stubbornness. He is likeable and ready to help others but when it is a question of his invention he is imperturbable, hard-headed and liable to flare up. He will not let it out of his own hands. He has devoted his entire life to his research and he is utterly convinced of its value – and events have proven him right.

His misfortune is that he can only be granted registration of a medicine in the country of which he is a citizen.<sup>1</sup> His even greater misfortune is that the authorities responsible refuse to grant it.

Without registration a drug may only be dispensed at a chemist in exceptional circumstances, which are precisely defined under medical law. It is of no importance whether it is effective or whether it cures patients or not. The law particularly demands that a drug, when properly used, has no damaging effects beyond those that can be justified according to current medical knowledge. This means that when a drug is registered, damaging effects (risk) must be accepted when the sum of desired effects (benefit) is greater.

In general, when dealing with cancer drugs, this relationship between risk and benefit is very generously defined by the registration authorities. Since 1980 several highly toxic substances with a relatively low response rate and low efficacy have been registered in Austria. Despite the fact that these substances not only constitute great potential danger for cancer patients, but also for medical personnel. (More about these drugs later.) In addition, with many cytostatica a relatively low margin of dose error can prove fatal.

Therefore a cancer drug which was completely harmless and without side effects would be of enormous importance. It would also have a very favourable effect on the costs of cancer treatment. (The National Cancer Institute estimated the costs for 1990 at 104 billion dollars.)

In view of these facts, any country and its ministers, authorities, health insurance institutions and doctors ought to be grateful if a drug is developed in their country which fights cancer without damaging health in any way. For this reason there is an accelerated procedure for these cases in many EU states and in the USA to make such a drug available to patients as quickly as possible. The dilemma of conventional cancer treatment with chemotherapy is that these drugs principally consist of cell toxins which kill or inhibit the growth of all fast growing cell systems, both healthy and malignant alike.

It is therefore totally incomprehensible that over a period of twenty years an inventor has not been able to register an anti-cancer drug which on top of all other factors was also developed with considerable support from the Austrian Ministry of Science. In this case there can be no doubt about a positive risk-benefit ratio.

At therapeutic doses Ukrain is non-toxic (it can even be drunk if it is not possible to inject it); it has no damaging side effects and its therapeutic efficacy is greater than conventional cytostatica. This has been confirmed in over one hundred scientific studies, clinical studies abroad and in numerous case reports.

The inventor of this substance has been honoured worldwide (with the exception of Austria) with a total of 45 international and national awards. Papers on his drug have been presented at international cancer congresses. At the International Congress on Chemotherapy in July 1997 in Sydney, Australia a complete conference sequence was dedicated to Ukrain.

'It is certainly no quack remedy,' was even confirmed years ago by one of the civil servants responsible for registration. However, there can be no question of it being registered. The same ministry and the same civil servants who certified a positive risk-benefit ratio for such highly toxic substances as Taxol and Cisplatin for cancer treatment have fought against Ukrain with almost religious zeal. Whereby the facts of the case for registration are extremely simple: the preparation is not toxic and therefore not dangerous. The Ministry of Health has had the relevant proof for a long time. The therapeutic efficacy has been clearly demonstrated in studies on cell cultures (in vitro), in animal experiments (in vivo) and in clinical studies. In addition, the economic importance of such a preparation should also be considered. It would be an excellent product for export with an enormous world market and, as an intelligent product is apparently what the Austrian government so much wants to support. Since the raw

<sup>1</sup> The only exceptions are Ukraine and Belarus, which suffering from the effects of Chernobyl successfully tested Nowicky's cancer drug and granted him registration.

materials for Ukrain come from plants there would also be benefits to agriculture. There are reasons why its inventor has been offered millions by powerful international concerns for his worldwide patent and the relevant know-how.

So why has this drug been persecuted by the registration authorities as though it were an enemy? This persecution culminated in the statement by one of the top civil servants at the registration authorities to interested parties from other countries who were interested in licencing agreements: 'Ukrain will never be registered in Austria.'

The fact that such a standpoint of one of the civil servants can amount to an almost insuperable hurdle lies in the nature of Austrian medical law. This uses expressions such as current scientific knowledge, practical experience, state-of-the-art and others. However, it does not define what state-of-the-art actually is. It is therefore subject to the discretion of the civil servants interpreting the law, who can therefore subvert its intention, namely to protect patients.

In this way the registration procedure can be drawn out to eternity by continually demanding new proofs, even when they are not required. This prolongs the procedure and uses up the time in which the patent is in force. At the same time the gathering of experience of the use of the preparation has been purposely obstructed by the ministry by putting pressure on doctors who successfully use the drug and not repealing edicts which are in contravention of the law or have misleading contents even when their incorrectness has been acknowledged by the ministry in writing and recognised by the highest court in the land. As a result, the health insurance institutions do not compensate patients for treatment costs even when treatment was obviously successful.

The question arises as to who finally benefits from the ministry's attitude. The patients need not be protected because the drug is not dangerous. The Austrian economy can only be damaged: delaying registration shortens the time for which the patent is effective and therefore also reduces economic profits and tax revenues.

The solution to the puzzle is perhaps closer if the question is turned around: who is damaged by the registration of a drug?

The question is aimed directly at the financial interests of international pharmaceutical companies. Perhaps here is the solution to the puzzle and the story of this incomprehensible delaying action suddenly turns out to be less mysterious. After all, an American doctor had expressed the opinion that this new drug could replace most current chemotherapeutics.

During the course of my research this report has turned more into a crime story. Acts such as theft, telephone tapping and even direct threats cannot be attributed to coincidence for long. The obstruction, for which civil servants at the Ministry of Health and Consumer Protection (in the text below named Ministry of Health) are shamefully to a great extent responsible, has taken on ever more brutal forms over the course of the years so that once even the secret service became involved.

I have spoken with those who are for and against, with doctors and with scientists and collected the evidence which is now part of this crime story. The two special issues of the medical journal 'Drugs Under Experimental and Clinical Research' from 1992 and 1996 and the 'Documentation of Research Work on Ukrain' under project director Dr. Peter Locatin, all sponsored by the Austrian Ministry of Science have been particularly helpful in covering the scientific aspects. I would also like to express my thanks to Dr. Heinz Talirz for his valuable thoughts on the practice of drug registration.

In order to make the book more easily readable for laymen, I have kept specialist terms to a minimum.

## Our First Meeting

Our first meeting was brief and disappointing.

I was sitting in my office with my desk overflowing with paper. It was just before six o' clock. I had urgent work on hand and another appointment in the evening. There was a knock at the door and a shy, almost frightened-looking man came in. He introduced himself as Jaroslaw Nowicky. In excruciatingly bad, grammatically almost unintelligible German, he tried to explain to me what he wanted. He was working on the development of a substance that could revolutionize the treatment of cancer. Since I was the newspaper's science correspondent, I should be interested.

Another fantasist, I thought, used to the most incredible 'scientists' turning up at my office. On top of that, I was becoming increasingly irritated by his adventurous German. It came at me like machine gun fire, made no useful sense and, in view of being pressed for time, induced in me a paralyzing mixture of desperation and impatience.

To get a moment's air, I asked my uninvited guest to leave me the most important papers from his full-to-bursting briefcase. I would look at them in peace and then call him. After giving me his address and telephone number, he said goodbye.

Later he told me of his bitter disappointment. He had been advised to come to me because I was the only one who would listen to him and write the article he so hoped for. He had already made unsuccessful approaches to other newspapers and now he expected that I too would somehow file his documents and forget about them.

I almost did.

But a few weeks later I had finished what I had to do earlier than expected and began a sporadic inspection of the mountains of paper on my desk – which mostly meant throwing away out of date news reports, invitations, notes, magazines and so on. I eventually worked my way down to a 'potentially usable' pile in which Nowicky's documents awaited their exhumation. Out of fairness to him, I was just going to look through them quickly and let him know. I did not really expect to find anything newsworthy. However, I knew from experience that from time to time you strike lucky.

And I did here.

The papers were clear and comprehensible and, as far as I was able to judge on a quick first reading, did in fact contain sensational material in the field of cancer research – if it would all stand up to thorough investigation.

Many people are interested in reading news about medicine – especially articles about cancer – so a journalist can count on receiving special attention. Maybe I had a scoop. I called the number Nowicky had left me and arranged a meeting.

He came. Once again loaded with piles of paper. I had armed myself with patience – a scarce commodity in my case – and with the necessary stern expression, requested him simply to answer my questions at first without expanding on them too much since an information overflow would only lead to confusion.

Of course, I had to interrupt him repeatedly because I was having a problem understanding his grammar. He submitted himself to my questioning with great patience. After almost two hours, I had discovered the essentials.

And that was sensational enough. Jaroslaw Wassil Nowicky had developed a substance from the plant greater celandine which, when intravenously injected, accumulated in tumours. Due to its auto-fluorescence, it could make tumours visible under ultraviolet light. The same phenomenon could be observed with metastases.

This demarcation of the tumour would be a great help to surgeons who must cut deep into healthy tissue. Furthermore, veterinary surgeons had reported that tumours were easy to remove when animals had been injected with this preparation.

The fact that oxygen consumption in cancer cells is increased for fifteen minutes and then leads to the death of the cells while the oxygen consumption of healthy cells is increased for five minutes and then returns to normal was a most remarkable discovery.

If this phenomenon had been given attention in 1980 and this process observed under the microscope, we would have discovered what, seventeen years later, under the name 'angiogenesis', was to bring new findings about cancer to international cancer research. And it could have been realised at that time how Nowicky's substance Ukrain can prevent the formation of metastases.

In view of the fact that cancer is still the number two cause of death worldwide, one might have thought that medical science would have at least taken an intensive interest in the phenomenon of the increased oxygen consumption and subsequent death of tumour cells. In addition, there were indications that in some cases even tumour regression had been observed. In any case, Nowicky's substance was the first and only one which attacked cancer cells without destroying healthy cells.

However, there can be no talk of any interest from the authorities responsible. On the contrary. In the course of subsequent years, I was witness to not only indirect but sometimes criminal persecution of this outsider who had had the audacity to discover something that others, with enormous funds at their disposal, had been searching for in vain. He would now be punished by having his research findings consistently ignored.

He was chased out of one university laboratory only to suffer the same fate at the next, as though he should be made a living example of the proverbial fate of inventors.

After I had observed these perfidies for a few years, though I must admit that initially I even secretly believed that Nowicky was paranoid, I decided to document this persecution until I had concrete evidence.

In the meantime, eighteen years have passed since my first article appeared in the now defunct Austrian news magazine 'Wochenpresse'. Since then, medical reports of cures brought about by Ukrain have been piling up but there is still no end to the suppression of this invention. No clinical study has been carried out in Austria, foreign studies are not recognized and conspiratorial vested interests, both inside and outside the Ministry of Health, are still directed against the registration of this drug which has been tested worldwide and presented at well over two hundred international congresses by researchers from all over the world. Wherever possible, obstacles have been put in the inventor's way and the authorities have even used illegal means to threaten his livelihood. As persistently as this persecution has been continued, the inventor has steadfastly continued his work.

Until recently, I thought that my articles and all the others in various newspapers had achieved absolutely nothing. However, now I know that these publications were the impetus for the fact that since 1984, whenever the need was the greatest, crucial assistance was at hand – certainly not from the Ministry of Health, which was responsible - but from the Ministry of Science.

What follows, is a documentation of this assistance and the methods used by the opponents of Nowicky's drug, Ukrain.

## Nowicky Leaves the Country of His Birth

When I first met Jaroslaw Nowicky, he had already been in Vienna for nine years. He not only had a turbulent past behind him but also his first experiences of the life of an outsider scientist.

He was born on 15 October 1937 in a small village in Galicia. It was not the best time to grow up. He was just seven as he and his parents were deported west to a concentration camp. He spent most time behind barbed wire at the Neumarkt camp near Nuremberg. His father had hidden a Jewish friend, a capital crime under Nazi rule, which had extended over Poland and Ukraine since the beginning of the war.

At the end of the war, they returned to their 'liberated' home country but Stalinist Russia was also not the safest of places. At first, Nowicky's family lived apart to avoid deportation to Siberia. Whoever had spent too long in the West, even as a prisoner, had to be ideologically 'cleansed' and polished up in accordance with communism. The gulags were full of such people. Thanks to the family's separation, young Jaroslaw was able to graduate from high school in Broschniv-Osada and subsequently studied at the radio technology faculty of the Technical Academy in Lvov. Because he was the only one who was not a member of the Comsomol - also highly suspicious in the period following Stalinism - he was sent to work in a factory in Petropavlovsk in Kazakhstan. Since under dictatorships it is often the case that one office does not know what the other is doing, the grotesque situation arose in which Nowicky was sent to a top-secret military factory where he was refused permission to pass even the first perimeter fence. The politically suspect were not allowed even to set foot inside a restricted area. Because nobody knew what to do with him, he was just sent away. No other camp, no forced labor, simply free - but thousands of miles away from Lvov. He had to find work somewhere in order to survive. This intermezzo lasted four months until he arrived back at his starting point of Lvov.

In 1961, as a qualified engineer, he began work in a television factory, which he left just one year later as chief engineer. He then taught in Lvov at a technical high school where he lectured both in Russian and Ukrainian - which promptly led to his suspension. Illegally - for although Russian was the language used in all schools throughout the Soviet Union, it was not expressly forbidden to speak Ukrainian. Nowicky often used Ukrainian so that students from less educated backgrounds, who knew little Russian, could follow his lessons. But now politics gave him a four-year break.

Not for the first time, Nowicky proved his incredible endurance. Once he got his teeth into something, he never let go. As he was turned down for every other teaching job on the grounds that he was no longer to be trusted to speak in front of young people he quoted the law which said that the Ukrainian language was indeed allowed in the Soviet Union and that he therefore had the right to teach in that language. Ukrainians were secretly longing to become independent and, despite all obstacles, would not give up their language.

Nowicky began to be a thorn in the side of the authorities. And this time, also the KGB. At first his efforts were in vain. However, because he did not give up, the KGB began to harass his father. For Nowicky this was too much.

He traveled to Moscow to inform the head of the KGB, Yuri Andropov, of these injustices personally. After checking in to a small hotel in the capital, he went to the headquarters of the KGB close to the notorious Lubyanka. He told the guards that he had to speak to Andropov personally.

'On what business?'

'I will tell Andropov myself,' said Nowicky.

'If we don't know what it's about, you can't make an appointment with him.'

‘When a Soviet citizen has something very important to say to the head of the KGB he ought to be allowed to say it,’ answered Nowicky.

He was accompanied to the door. He left his name and the address of the hotel.

Next day he appeared again.

The boss was not there.

Nowicky would wait.

‘What’s it about?’

‘I will tell him personally.’

Next day he was there again.

The boss is away on business.

Nowicky would wait.

This scene was repeated for twenty-seven days. On the twenty-eighth day a letter was waiting for him at his hotel. He should make himself ready to be picked up at ten o'clock. On the dot of ten a big black KGB car arrived in front of the door and took him to the Lubyanka.

And then he was standing in front of Andropov to say something ‘very important’ to him - that his subordinates were not obeying the law, that they had suspended Nowicky without good reason. His father had even been threatened, without any justification, by Andropov's own people.

Suddenly Andropov stood up, his face red, and banged on the table with his fist. Nowicky was also overcome with anger and banged on the table. He protested against being punished without reason. ‘I'm a human being, just like you are!’

The head of the KGB calmed down. Glancing at his watch, Nowicky got up to go.

‘Stay here,’ Andropov barked at him.

‘I asked you for three minutes and the three minutes are up. I had to wait twenty-eight days for these three minutes.’ Nowicky turned to the door and went out. Andropov called him back but he continued on his way. In the outer office Andropov's staff were talking excitedly but Nowicky remained unflustered and left the building in which he had stood up to the most powerful man in the Soviet Union.

Back in Lvov, he was told that after four years he had been rehabilitated and even that some people who had reported him, including fellow teachers, had been punished.

However, what sounds like a success story, nevertheless cost several years and very much in energy and effort. Even today, when Nowicky talks about these times, there are almost tears in his eyes, so strong are the memories.

The minor government officials in Lvov had not reckoned with his tenacity. They were later also to discover that they should not underestimate his perseverance.

Nowicky did of course use these apparently lost years for other purposes. With a group of scientists from the medical faculty in Lvov, he began working on the development of a treatment for cancer. This was triggered by his brother being diagnosed with testicular cancer. Nowicky recalled that in his country, herb women had always used greater celandine against cancer and had reported cases in which skin cancer had been cured through the long and repeated application of the milk of *Chelidonium majus* L. (greater celandine), whose popular name in his language was ‘wart herb’.

Nowicky discovered that a young assistant doctor in Ivano-Frankivsk (previously called Stanislav) was working with greater celandine and had achieved some interesting results with some patients and also with animals. The doctor, Anatoli Ivanovich Potopalsky was producing an injection solution from greater celandine and Thiotepa, which he called ‘Amitosin’.

At first, the doctor denied having such a drug but Nowicky was not willing to leave empty-handed.

‘I know that you have a drug. If you don't give it to me, I'll break into the institute,’ he threatened. ‘I only need the extract.’

'Who will inject it?' asked the doctor.

'I will,' said Nowicky emphatically.

'Can you do it?'

'I'll learn.'

He then learnt how to give injections by practicing on apples. However, it was not so easy to give his brother intramuscular injections. He was in a hospital ward surrounded by other patients. With the help of a friend who stood guard, Nowicky gave his brother injections in the toilet.

The patient went into a high fever, up to forty degrees. However, his condition improved. Nowicky took his brother home and continued the series of injections for two months. When it then appeared that the tumour had disappeared, he took his brother to Lvov and from then on dedicated himself to the yellow milk of *Chelidonium majus* L., greater celandine, an ordinary plant with yellow flowers which grows on walls and wherever it is not weeded out.

Nowicky was by no means the first person to investigate the milk of this plant. It had been known for a long time that it was made up mainly of alkaloids, basic nitrogen compounds from which 32 different alkaloids have so far been isolated. Some have been found to be cytotoxic, which means that they damage cells. Cancer researchers were very interested in these, and with good reason, but of course without coming up with any special results. Other alkaloids in the plant were ignored.

Nowicky studied case reports from natural medicine. He noticed that whenever cures were reported it was always when the milk of greater celandine was used from plants which had been picked in winter. The proportions of the individual alkaloids, their quantity and quality, depends on the seasons. In winter the plant contains some alkaloids which almost disappear in summer. Nowicky concentrated his research on a group of eight of these winter alkaloids.

However, it would not be possible for him to carry out this research in Lvov and at this time he decided to emigrate to Vienna.

As a Ulan, his father had fought in the army of the former Hapsburg monarchy and had told stories painting Austria and Vienna in glowing colours, so that without any idea about what really awaited him the son staked everything on being allowed to emigrate. In the former Soviet Union this was an almost hopeless cause. Nowicky's thick skin and tenacity were required once again.

In 1956, Nowicky had worked as an interpreter for Polish at an international youth festival in Moscow. There he had met a woman from Vienna named Anna who worked at the Atlas publishing house. They had become friends and had later kept in touch. Nowicky suggested that they went on holiday together to the Black Sea resort of Soshi. There he asked her to help him emigrate. The only possible way to do this was by getting married. Anna agreed and it was then left to Nowicky to fight for permission to leave the country in order to get married.

Not unexpectedly, this was at first refused. He wrote a total of 380 complaints to various authorities. Once again the KGB became interested and summoned him for questioning - even with his mother. The official wanted to force her to use her influence over her son.

'Do you have children?' she asked him.

'Yes, three.'

'And do they do what you tell them to do?' she asked.

A shrug of the shoulders was the answer.

Finally, the military became involved and Nowicky had to submit to questioning by a general.

'Why can't you marry in Lvov?' he asked.

Nowicky insisted that he must get married in Vienna and asked the general how his wedding had been.

Completely normal, he said. He had met his wife-to-be in Siberia during the war and later gone back to her home village and married her there in Siberia.

'Exactly,' said Nowicky, 'Cows may be brought to a bull but a man goes to the bride's village for their wedding.'

However, all this inventiveness would have been useless if Anna had not at the same time set all wheels in motion in Vienna. She did what many people did at that time in cases which appeared hopeless, she turned to the Chancellor of Austria, Bruno Kreisky. His help was decisive and in 1974 Nowicky was finally allowed to emigrate to Vienna, the city from which he expected so much and which was later to disappoint him so bitterly.

## An Uninvited Guest in Vienna

Now that he was in Vienna, Nowicky felt more lonely than he had ever imagined. People were far less communicative than in his home country, where it was much easier to make contact. In Vienna people wanted to keep to themselves and were not open to a newcomer.

One of Nowicky's first visits was to Chancellor Kreisky who he thanked for his assistance and presented with a small gift. He had also brought his first patent with him, which he and a colleague had taken out in Lvov for research into a particular alkaloid. This patent already contained the words, 'The drug demonstrates a considerably greater inhibition of the growth of various carcinomas than the alkaloids used in the production of adducts.'

'I have very important work to do,' Nowicky told the Austrian Chancellor. 'Please help me.'

Once again, Kreisky came to his assistance. Thanks to his intervention, Nowicky was able to begin research at the Boltzmann Cancer Research Institute. The head of the institute at the time was Professor Heinrich Wrba, who assigned him to a laboratory run by Georg Saueremann, the current head of the institute.

It was here that the first harassment began, much more was to follow. At the institute, Nowicky became friends with the student, Walter Hiesmayr. One day, as they were having lunch together in the canteen, Professor Wrba walked past and brusquely demanded to know what Nowicky was doing there. The canteen was for employees only, he said, and threw Nowicky out.

That was the first, but by no means the last, kick in the teeth which the immigrant researcher had to take.

Seeing Nowicky's overflowing work-space in the laboratory, the later Professor Saueremann allowed himself an especially nasty joke at Nowicky's expense.

'You don't have enough space here,' he said. 'I'll put you opposite on the eleventh floor.'

Nowicky thanked him. However, as he later asked the cleaning lady what was over there on the eleventh floor, he discovered that it was the psychiatric department.

Soon afterwards, on the orders of Professor Wrba, he was forced to leave the institute. He was never told why.

He was then allowed to work for a short time under Professor Karlheinz Kärcher at the Institute for Radiotherapy after the autofluorescence of his drug had been discovered. This could be seen in cancer tissue under ultraviolet light, enabling malignant growths and metastases to be localized.

In the long term, the radiotherapy institute was not the most suitable for him. Since there were no other offers he took his things and continued working at home. His wife Anna had provided him with a small flat and he made ends meet by selling stamps, coins and first editions of books which he had brought with him from Ukraine. He had agreed with Anna that they should find out whether living together would be at all possible under the circumstances.

It very soon became apparent that Nowicky's work mania made any sort of togetherness impossible. He was not only researching in the laboratory like a man possessed – in 1975 he took out a new patent - he also registered to study pharmacology at the university. The head of pharmacology then was Professor Jentzch, the father of the civil servant who is today responsible for the registration of drugs at the Ministry of Health. Nowicky contacted all scientists who had published articles about greater celandine. It was inevitable that he would run across Professor Kubelka, who allowed the first-year student to work in his laboratory. At the Institute of Pharmacology he also met the since deceased alkaloid specialist

Professor Friedrich Kuffner, who further helped him with his research. In his home laboratory, Nowicky had a whole collection of alkaloids.

One day as he returned home he found his flat door had been forced and the police, who had been called by a neighbour, in his flat. Everything had been stolen. The thief was never found.

However, once in a while there were also rays of hope. One of these came from the Ministry of Trade where the head of the research department, Dr. Norbert Rozsenich, became aware of this 'student'. He supported his work with a commission worth €22,000, which came to Nowicky via Professor Kuffner for further research into greater celandine alkaloids.

Nevertheless, there was also resistance at the Institute of Pharmacology. Nowicky was forbidden to carry out in vitro experiments because, as he found out from a colleague who wanted to write his thesis on the preparation developed by Nowicky, the Ministry of Health had intervened - despite the fact that it was not responsible for university matters.

Then once again he had to leave his laboratory table within two hours without explanation. He later discovered from the laboratory assistant Walter Oparski that he had been reported as a spy.

Professor Kuffner, who obviously did not have the power to retain his talented protégé, found a place for him with Professor Bancher, a botanist, at the Technical Academy, where he was able to work for a while before he was once again sent away from the laboratory without explanation.

During this period, the pharmaceutical company La Roche offered him space at their Vienna laboratory. However, Nowicky was not prepared to accept the condition that everything he discovered there would belong to La Roche.

Nowicky could not explain the continuous harassment to which he was subjected. He thought back in vain, looking for connections. The only thing he could think of was about the time when his difficulties had begun. That was very soon after his arrival in Vienna. The Chancellor had not only put him in touch with Wrba, but also with the Minister of Health, Ingrid Leodolter. In 1976 there had been a meeting at the ministry where, besides Nowicky and the minister, a civil servant from the registration department and the doctor, Professor Karer, who carried out clinical studies for the pharmaceutical industry, were present. The subject of the discussion was Nowicky's 'discovery'.

Karer had said that Nowicky's patent was 'nothing special' and that it was not worth undertaking further work on the drug. 'That's of no interest,' he said, as Nowicky still irately remembers - and that he flared up.

'How can you say that when my substance is three hundred times less toxic than normal cytostatica?'

At that time, Walter Hiesmayr had already tested the substance, which Nowicky had named after his home country 'Ukrain', in vitro and on rats and mice and also discovered its fluorescence.

The Minister of Health did not appear impressed by any of this, she merely wanted to calm everybody down. 'Gentlemen, please stop arguing.' And that is as far as it went.

Immediately afterwards, Nowicky was forced to leave his first laboratory. His brooding led him to the conclusion that it was the Ministry of Health, of all places, that had begun placing obstacles in the way of his work. If this was true, the auspices were extremely depressing. Nowicky was deeply discouraged.

To take his mind off all this, he booked a cheap bus trip to Paris for Easter. On Easter Sunday he was walking through town visiting churches. That year the Catholic and Orthodox Easters fell on the same day. Nowicky was a member of the United Church. He stayed for a mass in Notre Dame and then wandered through Saint Germain. From the church of Saint Germain he suddenly heard Ukrainian singing, went in and stayed until the end of the service. A woman spoke to him and invited him, as was the tradition, to an Easter meal with many

other Ukrainians. Nowicky told his story and also spoke about his discovery of greater celandine alkaloids as an anti-cancer drug.

He was told that he absolutely had to meet Professor Musianowycz. He was extremely interested in Nowicky's discovery. He had himself written his thesis on greater celandine. He wanted to try out Ukrain on seventeen patients who had been through conventional therapy to no effect and whose conditions were hopeless.

On returning to Vienna, Nowicky sent him the required quantity of the drug and waited.

After six weeks, trembling with excitement, he called Paris. 'You're right,' said Musianowycz. 'In some patients the tumour has become smaller and the others are at least not in pain.'

Some of the patients from this clinical study are still alive today.

This positive news from abroad was a great encouragement. In 1978, the daughter of the Polish ambassador to Paris was diagnosed with cancer. She had seen her best friend come to a miserable end with breast cancer and refused the normal treatment. Her father turned to Professor Musianowycz who injected Ukrain on her express wish of the patient – with complete success. She is still alive today.

In Lublin, the astonishing effect of Ukrain on a thyroid carcinoma was observed and it was proposed to carry out a clinical study. Nowicky would not have to pay but only to deliver the required amount of Ukrain. Since drug manufacturers have to pay enormous sums of money for such studies (at that time it was over €7,200 per patient, today it is over €70,000) this was an exceptional offer. However, Nowicky was unable to accept because he was not in the financial position to deliver Ukrain free of charge.

Nevertheless, at this time more and more positive reports about Ukrain began to arrive. The National Cancer Institute in the USA carried out in vitro experiments and observed interesting reactions in all the cell cultures tested. The scientists there also discovered that in rats and mice reactions could only be expected when the drug was injected intravenously. Nowicky was now certain that he had found an alternative to the destructive method of fighting cancer used in conventional medicine because of a lack of any viable alternative. It could not be denied that scalpel, radiotherapy and chemotherapy, which put a great burden on patients without curing them, were not satisfactory methods of treatment for cancer. Since then, little has changed.

With the product of his research, a semi-synthetic, non-toxic alkaloid derivative, Nowicky believed that he had found a treatment for cancer which would not harm patients and which was more successful than conventional therapies. He then registered Ukrain, this glass-clear injection fluid, as a new pharmaceutical speciality, for a worldwide patent.

He now believed that medical institutes would be very interested in the extremely promising results of his research. After all, the Pharmacological Institute of the University of Vienna had confirmed that his preparation was non-toxic and with Walter Hiesmayr he had discovered its fluorescence when it was intravenously injected. The fact that this made it possible to see the exact limits of cancerous growth would surely make oncologists and surgeons sit up and take notice.

Full of hope he sent his results to the heads of Vienna clinics and consultant surgeons with the words:

'Please find enclosed a report about my recent discovery that after treatment with this preparation malignant tissue fluoresces under UV light.'

An assistant doctor in Lainz Hospital was the first to confirm the UV light test. After this result, what else could one do (with the knowledge of the head of the clinic and the agreement of the patient) except to inform the head of the Radiotherapy Clinic, Professor Karlheinz Kärcher?

In his most pessimistic times, Nowicky could not have imagined what would now happen.

The head of the surgical department at Lainz Hospital, where this light test had been carried out, Professor Helmut Denk, a well-known surgeon, threatened Nowicky not only that he would report him to the police but also with immediate deportation from Austria. He described the fact that the discoverer of the UV test had shown it to the board of the University Radiotherapy Clinic as a 'gross illegality'. In a short letter of eleven lines he accused Nowicky of misappropriating an internal letter and, because he had showed it to Professor Kärcher, also of breaking data protection laws. 'For this reason,' he wrote in an indeed original closing phrase, 'allow me to report you immediately to the police.'

He did not do so.

The surgeon did not spare one word for the potentially helpful discovery. There was just as little reaction from all the heads of clinics and consultant surgeons in Vienna to whom Nowicky had sent his report.

With just one notable exception.

## The Family is Evicted

Professor Hans Peter Spengler, son of a well-known Austrian surgeon, who worked as a surgeon at the Sanatorium Hera in Vienna, studied the fluorescence effect of Ukrain over a period of two years. When I contacted him as I was writing an article in 1984 he confirmed Nowicky's observations.

'I have seen just as many effects as non-effects. I suppose that it is only effective in cases of specific changes. That must be tested. Tests must be carried out according to norms and be reproducible. It would certainly be worth testing this preparation properly – not just here and there. That does not give a full picture.' About Nowicky he said, 'He is definitely a good researcher.'

However, since the oncologists at the established Vienna clinics were not prepared to take notice of his discovery, he had no choice but to collect his data 'here and there'.

For a short time, there was a ray of hope from the hospital in Klagenfurt when some breast cancer patients were treated with Ukrain in the surgical department run by Professor Fritz Judmaier. At first, there was not much more to report except that cancer reacted to Ukrain. However, the final report stated:

'Results so far appear to justify further clinical study, whereby we shall include somewhat younger patients who have not previously received polychemotherapy.'

Of course, no such thing ever happened. A short time later, Judmaier left his post and retired.

The explanation often heard in medical circles about new drugs, that they only work if the patient believes in them, could be refuted from the start. The Viennese vet, Helmut Forcher, reported a spectacular case. One of his four-legged patients was a poodle named Jason which had been brought to his surgery and operated on for a bone sarcoma in the lower jaw. When the swelling returned, because a second operation was not possible, Ukrain was used.

'It was somehow extremely remarkable,' Forcher described the case. The cancer growth was encapsulated, making a second operation possible. In addition, the vet observed, 'it was becoming necrotic from the inside'. 'This drug has got something.' Further research was necessary.

Now that more reports about promising results with patients treated with Ukrain were coming in, Nowicky worked at his research with new heart.

Then, out of the blue, he received notice to leave his flat.

He had moved in two years previously after he and Anna had recognised that family life was not possible in view of his round-the-clock work. The two of them split up but have remained good friends to this day.

In 1978 Nowicky moved out of Anna's small flat and rented a sub-standard flat in the Laimgrubengasse in the sixth district of Vienna. With friends, he modernised the apartment, installed central heating, tiled the bathroom and he bought a fitted kitchen.

It was the year of many hopeful beginnings. Not only did he have a new apartment but Professor Kuffner had also put him forward for a €22,000 commission from the Ministry of Trade. In fact, Ukrain had not only proved itself to be the only known malignocytotoxic (cell growth inhibitor) which attacked only cancer cells while leaving healthy cells undamaged, but also a stimulator of the body's immune system. No previous cancer drug had these properties.

All the greater was the shock when only two years after moving in to the now renovated flat, notice to leave arrived, on the grounds that the other people who had flats in the building were disturbed by noise from Nowicky's apartment, whereby a whistling kettle, which he had never owned, played a special role. Nowicky appealed.

What now took place and stretched until Nowicky's eviction in 1988 is no glorious chapter in the history of justice in this country.

Nowicky had remarried in 1986 and in Mira, who came from Poland, had found a valuable helper who brought order into the chaos of the brilliant but absent-minded researcher and with him bravely endured the injustice to which they were subjected – including the eviction on 10 February 1988.

That this should be officially ordered in the middle of winter, putting a pregnant woman and a one-year old toddler on the street is another ugly detail. Although statements by witnesses in the appeal court did not stand up to examination, a document proved to be a fake and in addition to much other proven incorrectness 'police interventions', which never happened, were stated as grounds for the verdict. It was always the noise supposedly caused by Nowicky and his guests which was put forward as the reason for these measures. The flimsiness of the evidence of the witnesses can be seen from the fact that the Nowicky family was taken in by a market trader who lived one floor above them and who now also received notice to leave – which was never implemented. None of the neighbours, who had wanted Nowicky evicted because of the unacceptable noise level, raised even the slightest objection against the family remaining in the house. They were now forced to live for many years in an extremely confined space.

Understandably, Nowicky was incensed by the whole procedure. During the whole case he had been illegally refused permission to look into the files – it was only after the eviction that he was allowed to do so. He sued the appeal commission of the civil court.

The reaction of the authorities was just as baffling as it was illegal. Nowicky received a letter dated 30 May 1990 from Dr. Peter Krieger, a specialist in neurology and psychiatry working for the courts.

'The Vienna Criminal Court has commissioned us to draw up a report.

Please come for an examination on Monday, 18 June 1990 at 14.00.'

He was also asked to come alone.

Nowicky was incensed by this, as anyone might be. This was the reaction because he had dared to sue the authorities. Already having learned from experience of the tricks of officialdom, Nowicky first asked that the appointment be postponed in order to give him time to inform himself of the law. He discovered that he could not be forced to undergo any sort of medical, not to mention a psychiatric examination.

He was therefore considerably less shocked when he received a 'Summons of the defendant in preliminary hearings' dated 12 September 1990 – he had suddenly transformed from the plaintiff to the defendant – in which he was ordered to come to the criminal court for a 'psychiatric examination' on 25 September at 08.45.

To clear up any misunderstandings the summons went on:

'You will be questioned by this court as the defendant.'

He was threatened that a warrant could be issued to force him to appear. However, Nowicky arrived punctually and discovered that the authorities obviously reckoned with the fact that citizens were ignorant of the law. As he referred to the relevant paragraphs according to which, 'witnesses or defendants are not obliged to undergo medical examinations' he was able to leave unmolested for the moment.

While Nowicky fought for his rights and tried in vain to prevent the eviction, he also lost his third laboratory place under Professor Bancher at the Technical University. Again without any reasons being given. Later Nowicky said that he was followed by a white and a black angel, whenever he took a beating from the black angel, the white angel came to his assistance shortly afterwards.

And so it was this time too. A cancer patient who had asked her doctor to treat her with Ukrain and had been cured, put the inventor without a laboratory in touch with Professor Viktor Gutmann who held a professorship in inorganic chemistry at the Technical University.

This contact turned out to be a fortunate one. On the day of his eviction, which took place at 10.00, he had his first appointment with Gutmann at 13.00. It seems that on this day, both angels were at work.

The eviction could not be stopped but Nowicky's 'white angel' was waiting for him at the Technical University. The professor did not only offer him a laboratory place, he also agreed that he should oversee Nowicky's work for his doctorate. And as Nowicky was summoned for psychiatric examination, Gutmann spontaneously offered to accompany him as a witness.

## Congresses, Successes and Dirty Tricks

Parallel to all the harassment good news was also coming in. The news that cancer patients reacted surprisingly well to Ukrain had slowly begun to spread through international specialist circles. As a result, Nowicky was invited more and more frequently to relevant medical congresses.

The first time he spoke in front of international cancer specialists was at the 13<sup>th</sup> International Chemotherapy Congress in Vienna in 1983. It was not, however, at the request of the Vienna medical community but at the invitation of the World Health Organization (WHO), the sponsor of the congress. Nowicky was nominated as a speaker and subsequently invited to a world congress in Cairo the following year.

In May 1984, at the invitation of the president of the Italian Pharmacological Society, Nowicky spoke in front of 500 cancer researchers from all over the world about cancer cases in which sometimes spectacular cures had been achieved. Nowicky was promptly invited to an enormous congress with 4,000 participants on Rhodes in October of the same year by the president of the Greek Chemotherapy Society, George K. Daikos.

In the meantime, there were now hundreds of case reports from Canada, USA, France, Poland, but also Austria which could certainly bring hope to cancer patients. However, any interest from the Viennese medical establishment remained extremely modest. A documented case of a cure brought about by Ukrain treatment was labeled a 'spontaneous cure' – despite the fact that this is extremely rare, as proven by international statistics. Such a case occurs in only one out of 100,000 cancer patients.

In order to put a stop to the numerous 'spontaneous cures' in Austria, in 1986 the Ministry of Health began sending out edicts forbidding the use of Ukrain in order to intimidate doctors who were prepared to use it.

At the suggestion of Professor Ingeborg Eichler, Dr. Werner Brüller from the Federal Institute of Experimental Pharmacology investigated the effect of Ukrain on oxygen consumption in cancer cells and confirmed what was already known – that Ukrain causes a significant increase in oxygen consumption and thereby brings about the death of cancer cells. He was initially enthusiastic and then, as Nowicky noticed, suddenly lost interest. Later, however, the Ministry of Science persuaded him to deliver a report for a special edition of 'Drugs Under Research' sponsored by the research department. There he also wrote that further tests should be undertaken to confirm the destructive effect of Ukrain on cancer cells while leaving healthy cells undamaged. His contribution concluded, 'No toxic symptoms have been found in normal cells after Ukrain administration, not even at doses around one thousand times higher than the normal dose.'

It was thereby confirmed by an independent specialist that Ukrain had no kind of toxic side effects. However, proof of this was still demanded by the registration authorities as grounds for refusing registration.

Professor Eichler, the predecessor of official expert witness Pittner, who submitted negative reports on Ukrain to the ministry, wanted to test cell cultures very early on but then, as Nowicky remembers today, she 'suddenly had difficulties' and gave up.

In a conversation on 1 April 1998, she could no longer remember this. Only that Nowicky was extremely difficult and mistrustful and that he did not make it easy even for people who wanted to help him. Nowicky also says now that it was she who gave him the advice to register Ukrain as a homeopathic drug because the step to conventional medicine was easier from there. However, today Eichler believes it was extremely unlikely that she gave him this advice and that Nowicky must have misunderstood.

Whatever: 'It was very good advice. I only understood that later,' is Nowicky's comment.

In the following period it seemed that a secret ban had been put on Ukrain, that even research into its mechanism of action should be stopped. It also did not help much that a particularly interesting case found its way to the then Minister of Science and later speaker of the Austrian parliament, Heinz Fischer. It was a patient suffering from a melanoma, a specially malignant fast-growing form of cancer, who was in the Rudolfinerhaus hospital in Vienna and who doctors had given only a few weeks to live since melanin had already been found in his urine, a sign that the cancer was far advanced. No remissions had been heard of at this stage.

Professor Peter Wodnianski, who had been brought in as a skin specialist, was so impressed with the results of Ukrain treatment that in June 1984 he wrote to the Minister of Science. After the introductory case report he wrote:

‘During the course of the following nine months I saw Mr. R.I. several times and examined him. He gives the impression of being healthy – or cured. This extraordinary result – life expectancy of melanoma patients who excrete melanin in their urine can rarely be counted in months – has impressed me so much that I wish to support the application for further funding.’

The ‘postoperative record without pathological findings’ from the hospital on 13 June 1984 stated coolly:

‘The cyst growth described at the last examination on 13 March 1984 could not be seen at today’s examination.’

The fact that, thanks to Ukrain, an initially inoperable tumour became operable and no metastases could be detected and particularly that a moribund patient who had been given up by the doctors gave the impression of being ‘healthy’ or ‘cured’ had no influence on the ban or prevention of Ukrain.

At that time, it had already been proven that Ukrain accumulates between healthy and malignant tissue and that its autofluorescence allows the limits of a tumour and surrounding healthy tissue to be seen.

Furthermore, it had also been demonstrated that Ukrain caused a reduction in tumour tissue and metastases without all those disadvantages for patients caused by the side effects of conventional cytostatica. One did not have to be afraid of damage to normal cells or mucous membrane or of hair loss. There was also no intolerance. Various reports from researchers abroad had confirmed that under the influence of Ukrain the oxygen consumption of cells increased significantly but that it returned to normal levels in healthy cells within fifteen minutes but that cancer cells stopped ‘breathing’ during this time and died.

Was that not exactly what so many researchers had been looking for? In the documentation supplied to the Ministry of Science this fact was emphasised: ‘This specific pharmacological effect on malignant cells has not been described for any other substance in the literature.’

This documentation was, of course, also known at the Ministry of Health and in the best local tradition of the playwright Nestroy, was ‘not even ignored’.

Dr. Norbert Rozsenich, head of the research department at the Ministry of Trade was the only person interested in promoting the promising new cancer drug and did not leave the researcher in the lurch and smoothed paths for him as far as possible. However, the Ministry of Health was solely responsible for the registration of the drug and, until now, their strategy had been merely defensive.

When my second article on Ukrain was published in the *Wochenpresse* on 27 November 1984, the Austrian medical association reacted by initiating disciplinary proceedings against doctors named in the article. However, it was interesting that this was only against general practitioners. This ‘representative organization’ did not dare to attack Professor Wodnianski. Finally agreement was reached between the doctors and the disciplinary committee that the general practitioners could not have known that statements

made to me during my research would appear in print. A logical twist that one would not expect of the university-educated. The only point of decisive significance would have been to investigate why Ukrain was effective with some patients, a fact that could be ascertained after the first injections, and why it had no effect on other patients.

The Viennese general practitioner, Dr. Thomas Kroiss, who treated ‘mainly patients in advanced stages of disease where conventional medicine had been unsuccessful’, had already confirmed this phenomenon at the time with half of his patients, but also that remissions were achieved even in such advanced cases. Professor Wodnianski emphasized that a precise investigation would only be possible at the University Clinic.

However, this was a closed door from the beginning.

## Obstacles and ‘Coincidences’ Pile Up

If, initially, certain occurrences could be explained as unpleasant coincidences, as time passed something like a system could be discerned. For instance when, remarkably often, post sent abroad or from foreign scientist colleagues did not arrive or when faxes ‘got lost’ because the connection could not be made no matter how often tried. Nowicky also had the feeling that his telephone was bugged. From then on, he used a telephone box on the *Ringstrasse* for important telephone calls, even though there was a telephone box just opposite his flat. He did not trust that one either. He sent important post from distant post offices. One may have thought that he was suffering from paranoia.

Then something happened which could no longer be explained away as a mere coincidence. At the time, Nowicky was doing further research into the alkaloids of greater celandine at the laboratory at the Technical University under the wing of Professor Gutmann. Gutmann confirmed to me that Nowicky often continued working on his experiments late into the night. He had found twenty-six new substances which he intended to send to the Canadian scientist, Professor Andrejs Liepins, at the Memorial University of Newfoundland. The two had been corresponding for some time and Liepins had recently reported interesting in vitro results for Ukrain.

Nowicky took a sample from each of the twenty-six substances, which were stored in numbered bottles in the laboratory, and sealed these in small glass phials. He sent the package via the DHL parcel delivery company. The containers were packed in full view of an employee of the company into transparent packaging which was then stuck down and the whole was then sealed in a large parcel. A list of contents was appended. Before the package arrived, Liepins was informed that it was damaged – and it was indeed, but in a curious way. The outer packaging had been opened on two sides and six of the glass containers had been cut out from the transparent inner packaging.

Professor Liepins took photographs of the damage and told Nowicky the numbers of the missing phials over the telephone. Nowicky promised to send these substances again. The numbers were not in sequence and seemed to have been removed at random. However, to his great astonishment Nowicky found that exactly the same numbered phials had disappeared from his laboratory. The only result of investigation was that the package must have been damaged on the flight between Brussels and USA.

The missing substances were no great loss when one knew how to reproduce them, and they were also of no greater significance than those that remained. Nowicky saw this as ‘psycho-terror’. ‘That was someone who wanted to show me their power.’

Professor Liepins also warned him not to underestimate the influence wielded by the large pharmaceutical companies – not only on university clinics. He advised Nowicky to approach general practitioners. After all, these large companies had invested millions in the development of cytostatica and would hardly be pleased to have to write off these sums before they were amortised.

Nowicky’s first experience of these powers was in 1984 at the chemotherapy congress on Rhodes, to which the president had invited him personally. He was scheduled to talk about research into Ukrain. However, upon arrival he was told that his talk had been cancelled due to ‘pressure of time’. Nowicky left the congress office disappointed and then by chance met the president, George Daikos, who asked him what time he would be speaking. When he discovered that no time had been set aside for Nowicky, he hurried to the office and insisted that Nowicky be allowed to deliver his talk. Nowicky later discovered that sponsoring pharmaceutical companies had threatened to cut off funding if Nowicky spoke at the congress.

There had previously been a short period when the giants of the industry had courted him. It was quite soon after the first sensational results for Ukrain had been published. Cancer specialists discovered that there was a new drug which was completely non-toxic, which enabled tumours and metastases to be seen due to its fluorescence, which attacked only cancer cells while leaving healthy cells undamaged and which had no side effects such as hair loss or nausea. It was then that a series of large pharmaceutical companies lined up to buy the patent and Nowicky's knowledge, offering what were enormous sums for a lone researcher – up to one hundred million dollars.

The first was the company which produces Thiotepe, a substance required for the production of Ukrain. The lure was 80 million dollars. Later, many others followed, including such large concerns as Hoffmann-La Roche and Bristol Myers. In spite of increasing bids, Nowicky obstinately refused all offers although at that time his own means were very limited. Nowicky was unwilling to sell his invention at any price – incredible as that may seem in view of the temptation of the enormous sums involved. He saw these offers as confirmation of his work. Since then, he has attributed some difficulties which he has met on his way to the long arm of the powers he had sent packing.

It is certainly doubtful whether some incidents were entirely within the law. While writing his thesis and working in the laboratory at the Technical University, where Professor Gutmann confirmed that he worked 'like a man obsessed', there were other unpleasant occurrences apart from the theft of the six phials with samples. One of these was the disappearance of all the alkaloids which he was investigating, not only from the laboratory but also from the safe of the Technical University. Another was the wilful dilution of a solution. He would have had to stand guard at his place in the laboratory day and night. However, as though to compensate for these setbacks, Nowicky was greatly helped when a cleaning lady moved one particular solution to a different place. His subsequent use of it cut short potentially lengthy investigations.

However, as the time came for Nowicky's oral examination for his doctorate, he had to contend with more than small hindrances. In March 1993 Nowicky handed in six copies of his dissertation to the university, as prescribed. From there his work was passed on to be examined by Dr. Thomas Kroyer, a specialist in alkaloids, and Professor Gutmann. Both confirmed to Nowicky that they could only evaluate his work positively. Professor Robert Ebermann from the University of Agriculture, whose opinion Gutmann had asked, agreed. The deanery fixed the examination date for 6 May 1993.

However, as Nowicky arrived on that day he was told that the examination had been cancelled. He had previously received an informal telephone call informing him of this but there was nothing in writing. It could have been a trick to make him miss the exam.

He began to understand better what was going on when he was given a form and asked to name two new experts to evaluate his work.

The examination candidate, who had put on his best suit for nothing, decided not to draw in his horns. He discovered from Gutmann that the deacon, Professor Stachelberger, had instructed the two professors not to hand in written reports. Without a written – positive – expert report candidates are not permitted to take the oral examination.

Nowicky found out that the deacon had told Gutmann that he (Gutmann) was no alkaloid specialist and he could 'embarrass himself'. Since Gutmann was an internationally recognised chemist with several doctorates and was a co-author of specialist publications covering 80% of the topics dealt with in Nowicky's dissertation and was cited as a reference in two others, this was simply incredible.

This was of course all of no use, since professors are bound by the instructions of their deacon and could not help the rather desperate examination candidate who had been brought down at the last hurdle. He now knew that he would lose another semester. In addition

Gutmann was about to receive professor emeritus status which would mean that Nowicky would lose his patron and would have to start from scratch.

But Nowicky did not give up. In his years in Vienna Nowicky had already had to suffer too many infringements of the law. He therefore decided first to investigate if this was not a similar case. As soon as he began to study the laws applying to universities he found the relevant paragraph in which the regulations for examinations are laid down. Here Nowicky discovered that the university teacher, the author of a dissertation has chosen to oversee his work, must also deliver a specialist report. The second report could be made by a specialist of a closely related subject. The exam candidate asked for an appointment with the rector.

However, the matter was also taken up from another side. Dr. Norbert Rozsenich, department head at the Ministry of Science heard about the case, which he also could only categorise as a breach of law, and as a higher authority brought an abrupt end to these delaying tactics.

Because the wheels of academe turn slowly, exam dates are a rarity at the end of term and enthusiasm to compensate for this infringement of the law was not bubbling over, Nowicky had to wait until autumn to take (and pass) the oral examination and finally be awarded his doctorate. His other academic qualification, as an electronics engineer, received from the Polytechnic Academy of Lvov had received nostrification by the Technical University of Vienna in 1975 at the time when Nowicky became an Austrian citizen. Since with the end of his studies Nowicky also lost his laboratory place at the Technical University, he set up his own laboratory and did not even tell good friends its address. He could not shake off the suspicion that his telephone was bugged and that he was being watched. It happened repeatedly that his telephone remained silent for hours and that callers could not get through. There were also calls which when answered, there was nobody there.

One malicious act, which was never cleared up, could even have been fatal. On 10 October 1993 he drove home with a friend, parked his car on his street and briefly went up to his flat before continuing his journey. When he came back to the car he noticed a strange pungent smell which he then traced to the tyres. Acid had been poured over them.

If, as usual, he had remained at home, he would not have noticed the smell next day and at some point the acid would have eaten through the tyres. His sister and Professor Liepins from Canada were witnesses.

Throughout the year Nowicky lived in continual fear of losing his emergency accommodation. In the meantime a third child was born and the two-roomed flat became more cramped. Despite several lawyers he hired in the forlorn hope of attaining justice and thereby compensation, the eviction order was not rescinded. The apartment he had been forced to leave remained empty.

Nowicky realised that he had to buy a flat. He also recalled that a Ukrainian farmer, who was said to be able to see into the future, had prophesied that in 1992 he would become a house owner. It was not a house but a spacious flat which he was finally able to buy after a series of strange occurrences which were never explained.

It was November 1992 and Nowicky was harbouring justified doubts about the farmer's prophesy when he saw a notice on a building in the Margaretenstrasse: '300m<sup>2</sup> for sale'. It was like a twist of fate.

He immediately contacted the agent and was told that other potential buyers were interested in the flat and the owner, who lived in Germany, would be coming to Vienna a few days later to decide to whom to sell the property.

Nowicky went to his bank, a branch of the Länderbank, now Bank Austria, to ask for a loan. He was told that a loan would be possible and he waited impatiently for the owner to arrive. Although the flat had previously been used as a large showroom for hairdresser's equipment and needed considerable adaptation, Nowicky was not put off. With the help of friends and relations he would manage it.

On the day of meeting the owner arrived and Nowicky was in with a good chance. The man from Germany had been in Ukraine and had good memories of the country. More particularly he had been forced to leave his home country, Romania, many years previously and therefore knew of the difficulties faced by emigrants. He agreed to sell to Nowicky. With a solicitor, in the presence of the agent, it was agreed that the purchase price should be paid by 3 December, within a few weeks; otherwise the flat would be sold to someone else.

Nowicky left the agent's office with the owner of the flat he had – at least theoretically – bought. They walked a little way together and talked about various subjects. As they said goodbye the owner told Nowicky that he should not worry about the date of payment. If he had not raised the purchase price by 3 December he would still have an option until the end of the month. There were no witnesses to this conversation. Nowicky was not at all anxious – the bank had officially approved the loan. The day before the purchase was to go through he received a tele phone call from the bank. To his amazement he was told that he could unfortunately not be granted the loan. However, if he had already entered into a binding agreement he was advised to appeal.

In answer to Nowicky's astonished 'Why?', he was given the mysterious information, 'Check your post, there you will find the answer.' In his post he found a letter from the tax office saying that he had to make a back payment of €72,000 tax on property.

With overdue tax payments it was clear that there could be no loan from the bank. But where this tax payment came from remained a complete mystery to him. He would have to own property with a value of €7.2 million to receive such a tax demand – and there was no question of that.

He then went to his accountant who was also mystified. However, a few days later, after 3 December, the purchase date agreed in the presence of witnesses, he received a dryly worded letter from the tax office that the demand had been a mistake.

Whoever had instigated all this, it did not work out. Nowicky was able to point to the verbal agreement which the owner confirmed.

Nowicky now had no desire whatsoever to walk into any more traps and he managed to raise the purchase price with the help of friends and his wife's family. Now he finally had an apartment from which nobody could throw him out. After protracted renovation work the family was able to move in two years later.

He was, of course, not protected from other nasty surprises. One of these was provided by his bank as he wanted to close a deal for Ukrain in Thailand.

A Thai pharmaceutical company wanted to make an agency agreement for Ukrain in Asia following the ever more frequent reports on the drug at international conferences. Nowicky was to send a large amount of Ukrain ampoules to Thailand as soon as the company had transferred payment to his account. He needed confirmation from his bank that there was in fact an account in the name of Nowicky. However, the bank refused to confirm this and thereby ruined a potentially very lucrative deal.

A similar fate met a deal with Kuwait, where clinical studies had been carried out with good results. Nowicky was supposed to deliver a large amount of Ukrain. This time the Ministry of Health objected to the official confirmation that a company registered in the name of Dr. Nowicky actually existed. At this time Nowicky had had approval since June 1988 to enter his firm on the register of companies. However, he had not yet done so. The health authorities were therefore formally within the law. In this case, the kind of advice whose lack the Ministry of Science had so criticised was clearly indicated. The two registration officials at the health authorities who knew Nowicky from many meetings would only have had to phone him to tell him to register the company in order then to confirm its existence.

In this way the deal with Kuwait was successfully obstructed – and thereby also further clinical studies - which could have helped cancer patients.

## The Law's Delay

Before a medicine can be sold in chemists and paid for by Austrian state health insurance, it must be approved by the health authorities. There is a special department at the Ministry of Health which deals with the many regulations for this procedure, which can be quick, bureaucratic or obstructive.

In the case of Nowicky and Ukrain it would have been astonishing if obstacles had not piled up during the registration process. Nowicky was forced into the realisation that the authorities measured with two different yardsticks. Foreign drugs from large pharmaceutical concerns were afforded better treatment and quicker approval, even if they were not registered in their country of origin, than the invention of a local outsider.

In 1986 Nowicky tried his luck for the first time and applied to the registration authorities for the approval of a new pharmaceutical speciality for the treatment of cancer. After a long delay and much red tape, he was informed that his documentation was unsatisfactory and much more information was required. From this point on the same answer, 'unsatisfactory', rang like a chorus through all his attempts to bring about the registration of Ukrain through continuously extending the documentation.

For example, there is the regulation that in order to be registered the company must be named which will be responsible for the production of the drug and the filling of the ampoules. Nowicky informed the ministry of the two companies which had given their written consent, Topoplan and Gerot. Soon afterwards, both companies suddenly pulled out of the agreement. Behind closed doors Nowicky heard that 'pressure had been put' on both firms. Now he had to look for new companies but told the civil servants responsible that he would inform them of the names when the preparation was registered.

Even if it is not surprising that an outsider who has no experience of the registration procedure must expect the authorities to demand additional documentation, the extra information which was demanded went on and on. Not only Nowicky saw it this way. Department head Rozsenich from the research department of the Ministry of Science described the way in which Nowicky was treated by the health authorities as less than helpful. 'What's outrageous is, that they don't advise him,' he said during a conversation on this subject. Rozsenich had been following Nowicky's research work since 1978 and had supported him again and again: for instance with the contract provided via Professor Kuffner for €22,000 for further research into the alkaloids. And also later when the assessor appointed by the Ministry of Health, Dr. Heribert Pittner, in one of his stereotypically negative reports, pointed out a weak point in the analysis which could only be carried out with expensive equipment which the institute of the Technical University did not possess, Rozsenich gave his approval to Professor Gutmann's institute to spend €110,000 on this equipment which had been lacking at the institute for a long time.

Still not unwilling at the beginning, Nowicky, who had received his PhD in 1993 and could no longer be labeled a crazy fantasist, provided more and more documentation for the registration of Ukrain. However, again and again, the information proved unsatisfactory. There were also grotesque scenes which revealed how tricky the procedure was.

The department responsible for registration demanded experiments which Nowicky, to be completely sure, commissioned an assessor for chemistry and a toxicologist to carry out, and also paid them. Later, as assessors for the Ministry of Health, these two pulled apart their own reports, describing them as 'unscientific' and not up to the latest standards. They must have forgotten that it was their own (sloppy?) work.

It is no wonder that all the additional documentation demanded led to a certain amount of confusion in the file, since the original order was brought into considerable chaos due to the extra information.

Expert witness Pittner had already made negative or 'supplementary' reports in January 1989 and in May and June 1990. A certain irritation can be noted in his new, once again negative, statement in April 1991 when he wrote of, 'careful specialist detailed work,' and remarked, 'just as with previous submissions, the files have once again been handed in to the authorities in complete disorder.' (In the report the experimental method for tertiary and quaternary alkaloids from greater celandine was demanded which required the equipment approved by the Ministry of Science.) Nowicky also remembers that documents which he had handed in were rejected several times only to be demanded again later.

In Pittner's report from 1991 it is remarkable that he makes express reference to the screening programme of the National Cancer Institute (NCI) in the USA, that shows 'interesting tumour growth inhibition effects of Ukrain on 60 cell lines (8 types of human cancer).' 'Similar favourable in-vitro results have been reported in individual studies by other authors in the USA, Poland and Japan.'

Despite this, the expert witness once again rejected registration but nevertheless admits in his statement that the 'in vitro studies of the anti-proliferation activity of Ukrain are so interesting that further development of the preparation is justified.'

Pittner also agreed with Nowicky that, 'Currently used cytostatic therapy is very aggressive and drastically reduces patients' quality of life.' It is difficult to understand why the expert witness Pittner still adhered to his negative standpoint and spoke out against the registration of Ukrain. He referred to regulations which he had not been called upon to check, making it easy for the registration authority civil servants to reject the application. On 16 November 1992 he made a statement, 'for the last time about the individual parts of the documentation and their inadequacies'. However, the fact is that from 1996 Pittner suddenly no longer appeared as an expert witness. It was even reported that he had been suspended.

Pittner's negative reports of course fitted in with the plans of civil servants at the Ministry of Health who several times told business people who were interested in Ukrain that no registration of this cancer drug could be reckoned with. Very early on, a potential investor was advised to risk no capital on the product, 'There's no hope.'

In 1997 as an executive from a large Dutch company visited the ministry because they wanted to make an agency agreement for Ukrain to use it against osteoporosis, he was astonished to hear the decisive answer, 'Ukrain will never be registered.' It seemed as if the civil servants were the accomplices of that professor whose remarkable statement had been reported to Nowicky, 'Even if 99% of stage IV patients are healed, I will never register Ukrain.'

In any case, the intention once hit upon for mysterious reasons by the civil servants responsible, never to register Ukrain, scared off potential investors and others interested in the drug. Statements made under oath are available from such interested parties so that these events cannot be pushed into the realm of fairy-tales.

The tactics of obstruction were also aided by a lot of red tape. For example, on 30 December 1993 Nowicky handed in a report of a comparative clinical study to the appropriate department of the ministry. It was only there so that it could be stamped and then passed on to the office next door to be forwarded to the expert witness. The document was then kept for four full weeks before being stamped. It remained in the office next door for another ten days before it finally arrived at the expert witness's institute. This was still Pittner, whose negative report was already complete five days later.

'The methodology is inadequate,' he complained. There was also no study plan: 'The objectives are not stated.' It was not made clear in the study, 'What Ukrain is: a cytostaticum or an immuno-stimulator. The study does not meet the criteria for clinical studies demanded in the West.'

The study had been carried out at the National Ukraine Medical University of Kiev. There was good reason for interest in a new cancer therapy there, as can be seen from some quotes from the report:

‘The urgency of the cancer problem following the effects of Chernobyl,’ was reason enough to carry out, ‘...a scientific clinical study of the application of Ukrain as therapy for colorectal cancer,’ according to the decision of the Ethics Committee of the Institute for General Surgery and the Institute for Oncology of the National Medical University of Kiev. Mention is made that Nowicky provided, ‘around 1,000 ampoules of Ukrain free of charge’.

‘The aim of this study,’ it goes on, ‘was to investigate the application of Ukrain as monotherapy in colorectal cancer with unfavourable anthro-po-genetic factors.’

Expert witness Pittner also remained unmoved by the conclusion of the clinical report, which contained some very remarkable statements:

‘The investigations carried out confirm the results of the good tolerance and atoxicity of Ukrain. Analyses show that, in comparison to complex conventional therapy, Ukrain therapy causes a significant improvement in the general condition (improvement in the quality of life) of patients with advanced colorectal cancer. It enables patients to be brought from an inoperable to an operable condition and thereby to prolong their lives.’

‘An important property of Ukrain is its ability to correct the immune system, which is an especially topical point in oncological treatment ...’

Improvement in the quality of life, correction of the immune system, bringing from an inoperable to an operable condition – all of this made no impression on the expert witness. To justify the renewed rejection, he complained that it was not clear from the study what immuno-stimulators had been administered to the control patients who received normal chemotherapy. There is also no mention of remissions.

The study was carried out with two groups of 15 patients who were past medical care, that is, those who could only expect death. Pittner must have read the study only very superficially because it expressly states that 72.4% of patients treated with Ukrain, apart from the improvement in their general condition, had an average survival time of one and a half years whereas only 43.4% of the control group lived this long and suffered a deterioration in their general condition.

Even if this study was not carried out according to ‘western criteria’, it should certainly have been paid more attention in view of the fact that statistics show that in Austria alone over 2,000 patients per year die from colorectal cancer. It is incomprehensible that not even one cancer institute was prepared to repeat the experiment.

However, whatever Nowicky tried, he could never do the right thing in the eyes of the registration authorities. Everywhere there were barriers, bans, obstacles. It was as if it had been decided from the beginning to give Ukrain no chance. In 1979-80 Professor Spengler had investigated the phenomenon of the accumulation of Ukrain around cancer cells and its fluorescence in the area of cancer. This was a sensational discovery whose importance for diagnosis could not be overlooked. A urine test was also discovered, which, after the administration of Ukrain, produces different results for cancer sufferers and healthy patients.

‘It was very promising,’ Spengler remembered in March 1998. ‘I advised him (Nowicky) to study more cases of the same kind of cancer.’ Such as a group of patients with lung cancer or intestinal cancer, not just individual cases. ‘My hospital is too small to do that.’ He never had enough cases of the same type of cancer over a short period.

At that time Spengler had the impression that Ukrain was indirectly effective via the immune system.

In spring 1985 Dr. Salzer from the University Gynaecological Clinic of Essen declared himself prepared to carry out a clinical study. This was immediately blocked by the Ministry of Health which claimed that the toxicological tests had not been performed in accordance with GLP (good laboratory practice). However, the toxicological harmlessness

had been confirmed a long time previously by the Pharmacological Institute of the University of Vienna.

In 1998 Spängler said that he had prepared a report for the Ministry of Science just a few years previously. At that time there had been the first indication of the possibility of continuous research into Ukrain. Had he been in favour of Ukrain? 'Yes, of course!'

In 1993, as the drugs commission finally gave approval for wide-ranging clinical studies, it became clear that these could not be carried out. The costs were set so high that Nowicky had no chance of meeting them.

It was in exactly this year that the registration regulations were made more strict. As a result, the process had become so expensive that small companies no longer had a chance while large concerns were favoured. 'Nowadays you have to reckon with 500 million dollars, all in all, up to registration,' said the German biologist Harald von Eick, who worked for a pharmaceutical company for ten years and knows the business from the inside. Such high sums can only be raised by big companies. Interestingly, no protests were heard from this direction as costs for registration were increased. 'The only voices raised in protest came from medium-sized and small pharmaceutical companies who now have no chance of bringing their drugs onto the market, no matter how good they are,' said von Eick.

The competition was eliminated.

'This process will intensify still more through the mergers of giant pharmaceutical companies,' says von Eick. 'Small and medium-sized competition has been swept out of the way. The question arises as to whether the pharmaceutical industry and the authorities, who have always had a very close relationship, had not also been working together in this case. Our cartel laws are obviously not good enough to prevent such mergers.'

And coming back to the case of Nowicky, 'Without a distribution organisation it will not work.'

He said that worldwide, 'The clinical picture does not look at all bad. But the authorities can always withhold approval on formal grounds. There are already enough studies available which show that patients treated with Ukrain improved, whereas the condition of the control group was always worse.'

Von Eick says that for this reason alone, 'It is an ethical duty to approve this substance provisionally. If the studies currently in progress do not produce the expected results, approval could be revoked. Then Nowicky would have the chance to finance the approval procedure through the sale of Ukrain.'

In the same year that the registration regulations were made drastically stricter and the Ministry of Health finally gave approval for clinical studies with Ukrain, there was yet another meeting at the ministry which was intended to make clear to Nowicky how pointless his efforts were. Present at this meeting in November 1993 were the registration civil servants Jentsch and Michtner, their head of department Liebeswar and the petitioner without a chance, Nowicky. The subject was: clinical studies.

He was told that it was impossible for an individual researcher. 'Only a large company can have clinical studies carried out.' Nowicky remembers that he was told, almost triumphantly, that the total costs would run to 100 million dollars. Therefore, without a company there was no chance.

'Which company?' Nowicky asked.

'That doesn't matter,' was the answer.

'When is it paid?' he asked.

And again, 'That doesn't matter.'

'If it doesn't matter to you then I'll set up a company myself.'

And Nowicky, who still did not think of giving up, founded Nowicky Pharma.

Of course, subsequently it proved impossible to carry out clinical studies. Nowicky would have had to come up with at least €70,000 per patient. And again when the Ministry of

Science wanted to lend a hand there were 'no patients' in the hospitals which came into consideration for the study. They had already been 'reserved' for other pharmaceutical companies whose products the registration authorities were less fussy about.

For example, in the same year of 1993 the cancer drug Taxol from the US company Bristol Myers (headquarters in Chicago) appeared. For registration it was necessary to provide results from a clinical study carried out on only 17 patients with no restrictions and no control group.

Taxol, developed by the Caribbean branch of Bristol-Myers in Mayaguez, Puerto Rico and distributed by Bristol-Myers Squibb in Vienna, is a highly toxic cancer drug that was registered within five months in Austria as the first country in the world even though the clinical study had not been completed at that time, a randomised study was just being repeated and the drug had not been investigated for possible carcinogenic effects.

Bristol-Myers is one of the biggest pharmaceutical companies in the USA and for such giants the registration process is straightforward, even though, in the case of Taxol, there are extremely negative side-effects. At a cancer congress in Munich in the same year (1993) there had already been urgent warnings of exaggerated expectations for the cancer drug which had been launched on the market with great publicity. In fact, Taxol does not only cause hair loss but also causes the nails to fall off.

It is also expressly stated in the 1993/94 codex for dispensing chemists, 'Since serious over-sensitivity reactions can appear, appropriate equipment must be available for emergencies.' Medical personnel must also take precautionary measures to avoid contact with skin and mucous membrane.

Taxol is administered as an infusion which takes three hours and patients must be pre-treated with cortisone preparations. According to the codex Taxol is for the treatment of metastasing breast or ovarian cancer 'after standard therapy has failed'. Investigation of possible interactions with other cytostatica was also not required for registration. Even the fact that in *in vitro* animal tests Taxol had proved to be mutagenic (leading to genetic changes) could not hinder its triumph.

The American journal 'Science' calculated that Taxol would be extremely expensive because at least three cycles of treatment were necessary just to find out whether the patient would react positively to the drug. Thereafter, the cost of a course of treatment of ten therapy cycles would cost €22,000, plus hospitalisation and other 'overheads'. How the patient would cope with the side-effects was not included in the calculation.

For another cancer drug, which has been registered since 1993 – Cisplatin, a heavy metal complex compound which according to the codex is 'highly toxic' and regarded as a 'potential carcinogenic' – the possible side-effects take up half a page of the codex. Cisplatin is used as palliative therapy, which means that it is a treatment which does not fight the cause of the disease. Because it attacks the kidneys and can cause irreversible damage to kidney function as well as ('rarely') heart rhythm which can go as far as the heart stopping, this drug can in no way be described as harmless. Nausea, vomiting, stomach pains, hearing disorders, loss of hearing and cramp attacks are other 'frequent' side-effects which turn treatment into torture for patients.

At the time that Taxol was registered in suspiciously rushed circumstances by the Ministry of Health, doing without evidence that had been absolutely necessary for Ukraine, there had already been far more than 100 case reports for Ukraine in 1983, 80% of them from Austria and the others from France and Switzerland.

A comparison with the effects of Ukraine, which is neither toxic nor mutagenic and besides slight nausea causes no negative side effects, should have caused Austrian oncologists to have opened their ears, if not the authorities. In any case, there are far more than 100 publications on Ukraine from Austria and abroad (more than 80 in the USA alone) and there have been reports on Ukraine at more than 100 congresses. The point which has been seen as

particularly crucial is that Ukrain is the first and so far the only drug which attacks only cancer cells while leaving healthy cells undamaged, as demonstrated many times *in vitro* (including at the National Cancer Institute, Bethesda, USA).

Numerous scientists are now investigating Ukrain. Professor Liepins demonstrated Ukrain induced growth inhibition of one hundred percent on the same human tumour cell lines investigated at Bethesda and reported his findings at the 17<sup>th</sup> International Chemotherapy Congress in Berlin in June 1991. This was confirmed by EORTC (European Organisation for Research and Treatment of Cancer) in Holland. The Mayo Clinic in the USA confirmed that Ukrain destroyed cancerous melanoma and breast cancer cells as well as other human cancer cells. Similar results were reported from Japan and at the University of Vermont the anti-cancer effect of Ukrain was even demonstrated on cells which had proved resistant to Cisplatin.

It is all the more curious that the pharmacist, Reinhard Fischill from Vienna wrote a letter to the Austrian pharmacists' journal (*Österreichische Apotheker Zeitung*, 20 May 1996) saying, 'As a pharmacist it makes my hair stand on end,' when he reads, 'The alkaloid derivative from greater celandine attacks only tumour cells and leaves normal cells undamaged.' In addition, he pokes fun at the experiments carried out by Dr. Thomas Tritton at the University of Vermont which had shown that Ukrain was also effective where Cisplatin had failed.

Understandably, Nowicky was puzzled about the source from which Fischill drew his knowledge. All the documentation handed to the authorities for the registration process was confidential (as Dr. Jentzsch expressly assured me). The fact that Fischill worked closely with the Ministry of Health as a member of the Austrian Pharmacists' Association and particularly that he is connected to the company Novipharm, which produces the mistletoe preparation Isorel, are far from being reasons to bring him to registration documentation, even those of a competitor. Isorel is used as an alternative cancer treatment; one that was quickly registered.

In reaction to Fischill's allegations in his letter, Jentzsch, who until now has blocked the registration of Ukrain, explained to me on 8 February 1994, 'It is certainly no quack medicine. We are all interested, but if the requirements are not fulfilled, there will be no registration.' Asked whether, in view of the studies available until then from all over the world, the researcher should not be given a grant for further research, Jentzsch replied, 'The ministry (of health) has always demanded that with such important things there should be intensive...' he interrupted and corrected himself, 'intensive is maybe overstated... cooperation with the Ministry of Science.'

At the Ministry of Science, however, there is another viewpoint. From 1984 the Research Department had, as the only government office, greatly promoted Nowicky's work. In addition to the grants already mentioned, in 1992 and 1996 two special editions of the journal *Drugs Under Research* were sponsored in which the most important results of Austrian and foreign researchers were collected. The first special edition of 109 pages was presented at a symposium organised by the Ministry of Science under the then minister, Dr. Erhard Busek on 25 May 1993. Cancer specialists and doctors were invited to hear talks delivered by scientists from Austria and abroad under the title 'New Methods of Cancer Treatment – the Example of Ukrain'. This was not some obscure pamphlet by dubious authors but serious scientific contributions from serious researchers.

Years later, in the Oncological Department of Vienna General Hospital, I found out what clinical circles thought about an initiative like this. After Dr. S. had said in a radio discussion on 7 February 1997 that Ukrain was carcinogenic, I visited him a few weeks later at the hospital because I wanted to know what experimental results had led him to this statement which appears nowhere else in any literature on Ukrain.

However, as soon as we began talking, he threatened me with legal action if I named him in any report of our conversation. This was already disappointing. There had been no

experiments at all investigating 'carcinogenic'. He had only been talking about alternative remedies in general, thereby including Ukrain too. Most of them are carcinogenic. The fact that he could have mentioned in the radio programme that many cancer drugs approved by traditional medicine such as Cisplatin are carcinogenic (as explicitly stated in the codex) went under in a flood of jargon which could only confuse a layman.

The fact remained that Dr. S. knew of no studies which had described Ukrain as carcinogenic, nor had he carried out any such studies himself.

When I referred to the second special edition Update on Ukrain, in which there are reports of not only case studies but summaries of results presented at numerous congresses, the cancer specialist replied that the special edition sponsored by the Ministry of Science was only worth as much as a paid advertisement. I wanted to know what he meant by that. 'The contributions,' he said, 'are of low scientific value.'

'There are gaps in the knowledge of some professors and lecturers at the medical faculty,' railed Department Head Rozsenich from the Ministry of Science, under whose auspices the special edition appeared. 'What I condemn is that there are only very few doctors who are interested in complimentary medicine and research into it. If they don't know internationally renowned journals, there is no excuse for them. Then research comes off badly. What quality can the teaching of such people have?'

In just this special edition there was a detailed paper by Professor Liepins describing how Ukrain causes the death of those cells which, for as yet unknown reasons, are not subject to programmed cell death (apoptosis) and therefore produce proliferating cancer.

## Harassment from All Sides

The year 1993 brought international cancer research trail-blazing new evidence about the cancer process. In studies of cell death and 'programmed cell death' within cells, American and Australian scientists gained a completely new insight into understanding this insidious disease. According to them, cells have an inner clock which tells them when they must die. In cancer this clock does not seem to work, whereby the life of the cells is prolonged and the life of the carrier of these cells is put at risk. The cancer runs its course. It had already been known for a long time that in the development of embryos certain cells are programmed to die at a certain time. The researchers now discovered that this phenomenon was not confined to the development of embryos. In medical terminology this programmed cell death (PCD) is called apoptosis, a Greek expression for leaves falling from a tree or a plant.

In 1993 these new findings were published in the renowned American journal 'Science'. At the time, cancer researchers throughout the world tried to find a substance which would force cancer cells to carry out the 'suicide' order. The first to find one was Professor Liepins at the Memorial University in St. John's, Canada. At the 11<sup>th</sup> Interdisciplinary World Congress in Geneva he reported on his experiments with Ukrain as an agent of cell death at a session dedicated to Ukrain with a total of nine papers delivered. He had demonstrated in laboratory experiments that the alkaloid derivative from greater celandine, Ukrain, caused characteristic programmed cell death.

With the exception of Nowicky, not a single Austrian was represented at the congress as a speaker. Austrian cancer specialists stayed away from this session. The fact that they continued to ignore this drug, which had been developed in Austria, can be explained in no other way.

For years, Ukrain had been discussed at all international cancer congresses (far more than 100). Nowicky had been expressly invited to most of them including the 20<sup>th</sup> International Congress of Chemotherapy from 29 June to 3 July 1997 in Sydney, Australia, where eleven speakers presented their results with Ukrain at a special session. Nowicky reported on a clinical study carried out in Poland in which Ukrain had been used to cause cell death in patients suffering from breast cancer. Even at the low dose of only 50 mg, Ukrain caused cell death in cancer cells. The number of cells which reacted was dependent on the malignancy of the cancer.

In 1993 the connection was made between cancer and programmed cell death. In April 1994 in Geneva, Ukrain was reported to be the trigger to bring about the death of cells which had refused to die. In June 1993 the Austrian Ministry of Health had given approval for clinical studies on the basis of a report from the drugs commission. In June 1994 the same ministry wrote to the regional health insurance authorities in Upper Austria ('Re: Use of Ukrain') referring to a 'general ban on the use of Ukrain due to a decree of the federal ministry of 25 July 1986 - although this ban had not been binding for a long time on purely formal grounds (there was no confirmation).

It went on, 'Until now, no definitive, state-of-the-art evidence of efficacy has been brought forward for the substance Ukrain.' Furthermore, it was also pointed out that the list of publications given to the health insurance authorities included publications which had also been given to the drugs commission for assessment. Why this fact should be detrimental was not explained. 'Therefore,' continued the letter with incestuous logic, 'it is still not scientifically proven that the substance Ukrain can achieve the above-mentioned 'success'.' It also did not fail to refer to the fact that if Ukrain was administered outside the framework of a clinical study, a fine of 'up to €72,000' was threatened.

Whatever was already scientifically demonstrated at that time was simply (in ministerial arrogance?) not paid any attention. The responsible civil servants did not seem to want to do so at all since they even ignored the final report of their own drugs commission of the Federal Ministry of Health, Sport and Consumer Protection, General Health Department. This had already stated in November 1992 that, among other things, no kinds of side effects had been observed in patients with various forms of cancer.

The report went on, 'Clinically, it was reported that these patients showed the following reactions: partial remission, total remission and total remissions which have already lasted for several years (up to ten years).'

The layman is forced to ask what more can be demanded of an anti-cancer drug that is non-toxic, without negative side effects and not carcinogenic. In addition the question could also be asked as to why Ukrain was put before the drugs commission at all because the substance had been tested again and again in Austria since the summer of 1983. 'Since tolerance is obviously very good,' the report finished, 'a clinical study could under certain circumstances be given continued approval.'

A cryptic sentence which neither explains the 'certain circumstances' nor how or since when clinical studies had previously been approved.

However, there could still be no question of real clinical studies, not to mention registration.

The real state of affairs for clinical studies can be seen from a letter from Dr. R. from a Viennese gynecological clinic to the Ministry of Science on 8 May 1995. He had given his support for a clinical study. As is prescribed for such studies, Dr. R. had handed in to the Ethics Commission of the Medical Faculty of the University of Vienna the protocol of his methodology for a study of Ukrain in the treatment of recidivist cervical cancer and received an astounding rebuff for an 'ethics commission'. This insisted on a randomised, placebo-controlled double blind study, which means that one group of patients would be treated with Ukrain while the other group received only a placebo for comparison purposes. Quite correctly Dr. R. pointed out that it would hardly be possible to get the consent of patients suffering from a deadly disease to be treated with a placebo and that for cancer patients in Stage II new chemotherapy drugs had been tested without placebo groups for comparison (as stated in the Codex for Taxol).

The Ethics Commission remained unimpressed with these objections, stating that in contrast to cytotoxic drugs, the mechanism of action of Ukrain was completely unclear. The doctor should present a new protocol.

The Ethics Commission, made up of professors and civil servants, was obviously unaware of the fact that according to the World Health Organisation (WHO) placebo studies are forbidden with cancer patients. No sensible person would think of carrying out a double blind study with cancer, it stated. Since Dr. R. had no desire to follow the wishes of the Ethics Commission, he withdrew his application, but not without informing the Ministry of Science of his failed plan to set up a clinical study.

At this time Ukrain was being used on cancer patients not only in Austria but also in many other countries, especially USA. Many of these patients had gone through normal chemotherapy which undermined their general condition. However, in almost all cases Ukrain therapy led to an improvement in the quality of life, sometimes astonishingly so. In a very few cases, patients who had been through normal forms of therapy and were suffering from extremely advanced cancer with no prospects of a cure even achieved remissions. Others, in any case, experienced a subjective improvement in their general condition. Remarkable remissions were achieved particularly with advanced melanomas with metastases and with small-cell lung cancer, both forms of cancer which could not be dealt with using normal means.

The case previously described which led Professor Wodnianski to write to the Ministry of Science could now be supplemented with many other case studies.

Also in the early 1980's, when Ukrain had hardly been used on patients, a 43 year-old Vienna doctor (Dr. I.R.) underwent Ukrain monotherapy (treatment only with Ukrain, without conventional medicine) at his own request, treated by the internist, Dr. Alexander Schmid and the neurologist Dr. Walter Dekan. The precisely documented medical records show that he had been diagnosed with 'metastases from a malignant melanoma' following a fine needle biopsy on a growth in the armpit area. An operation was carried out to remove the growth on 13 July 1983. The histological examination of two walnut-sized pieces of tissue produced the result, 'lymph node metastases from a malignant melanoma'. On the day after the operation treatment with Ukrain was begun and in addition to the normal laboratory tests, melanin in the urine was also investigated. 'The result was positive,' stated the report, 'so that a stage III cancer must be assumed.'

During the course of six series of injections, which were carried out with pauses of 15 days rising to a maximum of 60 days, the fluorescence of Ukrain was investigated. Wherever there were metastases fluorescence appeared after Ukrain had been injected. At first this was very clear but gradually reduced during treatment until it did not appear at all. While urine tests in July and September 1983 still showed melanin, in March 1984 no more melanin was found, a result that did not change after repeated examinations. The patient remained without complaints and without a recurrence of the disease.

Case studies from the following ten years would fill a thick book on their own. Their findings resulted in a change in Ukrain therapy. Monotherapy proved itself to be not always a panacea. When tumours were too big but an operation was possible, then surgery was needed. It was also discovered that thanks to the accumulation of Ukrain around tumours, even when they had seemed previously inoperable, it now became possible to remove them surgically. In certain cases supplementary radiotherapy was also helpful. Nowicky only excluded chemotherapy, which along with cancer cells also destroys healthy cells and weakens the immune system and thereby the patient. However, Ukrain showed itself to be especially helpful after chemotherapy in rebuilding the body's own defence mechanisms and improving the general condition, mostly in a spectacular way.

However, the health authorities continued to ignore such reports and oncologists who had the opportunity to check the findings refused, at least officially, to use Ukrain experimentally. This meant that it was mostly general practitioners who prescribed Ukrain for their patients under paragraph 12 of Austrian medical law, which allows an unregistered drug to be used when the patient is at great risk and no other medicine can be expected to help.

This paragraph was obviously a thorn in the side of the health authorities since it continuously reminded them of their 'ban' on Ukrain, notwithstanding the fact that this ban was invalid since the decree was in contravention of the law. Despite this, all health authorities throughout Austria received official letters referring to this 'ban'. These offices threatened 150 doctors with sanctions.

Finally exasperated at these circular letters Nowicky, via his lawyer Dr. Michael Graff, telephoned the Austrian Constitutional Court which promptly lifted the decree with the 'ban' as 'unconstitutional' and on 26 February 1996 ordered the Federal State, i.e. the taxpayer, to pay €940 to Nowicky as 'compensation', payable 'within two weeks or goods will be impounded'.

The eight-page document outlining the grounds for the decision of the Constitutional Court reads like an – unintentional – record of the tricks with which registration had continually been prevented. It states that the 'authority being sued' (the Ministry of Health) has answered the statements of the appellant (Nowicky) but 'their explanation is too general and amounts only to assertions with no recognisable basis. It is partly also unclear what the authority being sued wishes to prove with their explanations.' The Ministry of Health is also,

in several cases, missing relevant documents, 'but does not explain what these are or what purpose they serve'.

Michtner, who wanted to prevent the registration of Ukrain by any means, sought to refute the accusations brought by the lawyer Graff on behalf of Nowicky in an eleven-page document addressed to the Constitutional Court and dated 2 October 1995.

In this defence, which was thrown out by the court and which does not reflect favourably on the legal abilities of the civil servant, it is stated that the accusation of prejudice is decisively refuted, on the contrary: Nowicky was 'extremely favourably treated'. The fact that the same law was not applied to Ukrain as to the anti-cancer drug Taxol was explained with the astonishing reasoning that Taxol was only registered for hopeless cases when no other anti-cancer drug helped, leading to the fact that, 'no investigations of a possible carcinogenic effect were necessary and also no comparative studies with other cytotoxica needed to be carried out'.

Finally: 'The Federal Minister for Health and Consumer Protection petitions that the claim should not be recognised and should be dismissed with costs.'

However, the Constitutional Court ruled against the authorities on 26 February 1996. But although Nowicky's case had been upheld this brought no change of attitude on the part of the civil servants from the registration authorities. The more time that elapsed, the more they appeared to be contented. The worldwide patent on Ukrain was due to run out soon.

The fact that the Austrian Medical Association also played its part in this harassment of Nowicky and Ukrain is a further sad chapter in the story of how this cancer drug has been suppressed. On what thin ice the disciplinary council of this doctors' representative organisation walks was demonstrated in the case of a courageous physician. The fact that her name is Gazyna Nowicki made her especially suspicious. The similarity in names is only phonetic. Dr. Gazyna Nowicki is not related to Dr. Jaroslaw Nowicky in any way.

Gazyna Nowicki was treating a child suffering from a bone tumour and wanted to use Ukrain, which in the meantime had been registered in Belarus, since all other means appeared to have failed. She wrote a prescription and, as was usual in such a case, she requested permission to import the drug. Normally the chemist applies for permission to import a medicine and confirms that it is registered in the country from which it comes. This procedure usually takes one week – but not in this case.

The doctor was summoned to appear before the Disciplinary Commission of the Austrian Medical Association. She was told, 'to appear reliably before the undersigned examiner' on 1 March 1996 in the offices of the Austrian Medical Association to answer a breach of discipline: and this breach of discipline was 'use of the medicament Ukrain'. Punctually, at the time stipulated in the summons the doctor appeared accompanied by a lawyer from Dr. Graff's office. After the lawyer had established her credentials the two women were told that the summons was a mistake.

The doctor asked herself how the Medical Association knew about her application to import Ukrain. In fact, it is not difficult to trace the source of this knowledge. The applications of chemists are made via the Ministry of Health and the civil servants there had obviously taken rapid action. The lawyer, Dr. Michael Graff, then wrote to the ministry but unsurprisingly received no answer. After one and a half years (!) came the news that the application had been refused. One and a half years instead of one week! If that is not working according to double standards!

However, with this the 'measures' against Dr. Grazyna Nowicki were in no way at an end. On 24 September 1997 she was summoned to the Health Department of the Vienna City Council. At the time she was working fifteen hours a week as a doctor for the council. She had already heard on the grapevine that she was on the 'hit list' and since her superior Dr. Graf (not to be confused with the lawyer Dr. Graff) had refused to speak to her privately a few

days previously but had insisted on talking to her only in the presence of a 'commission', she asked the lawyer, Renate Palma, to accompany her. She kept a record of the 'discussion':

'On 24.9.1997 at 09.30 Dr. Nowicki and I arrived at Dr. Graf's office. Several members of the commission, as Dr. Nowicki later told me, were already present, including her superior Dr. Christa Locius. After I had introduced myself, I was asked to provide identification. I handed over my document of title and my driving licence. Dr. Nowicki and I were then asked to leave the office and wait in the corridor. After some time we were called back into the office. When I asked for my identification papers back I was told that they were still with Dr. Graf and that he would phone later. Shortly afterwards we were shown into Dr. Graf's private office.'

'There we were given an extremely reserved and cool reception. Dr. Graf appeared to be incensed. His first words were, 'That's the end of the discussion.' In answer to my question why he was behaving like this he only answered that he was not prepared to talk under these circumstances. Only a discussion had been planned and it would not have been necessary to have been represented by a lawyer. I explained that our client, Dr. Nowicki, had no idea what purpose a discussion in the presence of a commission was meant to serve. In addition, my presence would not disturb anyone because I would only listen. Dr. Graf insisted, as he had decided before, on not allowing the discussion to take place. In answer to my question what would happen next, he replied that he would first talk to Dr. Nowicki privately.'

The harassment of Dr. Jaroslaw Wassil Nowicky, who as an outsider had had the audacity to develop an anti-cancer drug now began to take up more and more of the courts' time.

The owner of the Adler pharmacy in Währing, Vienna, via the lawyer Dr. Karl Grigkar, sent a woman with a prescription for Ukrain to Nowicky. She said that a cancer patient urgently needed the drug but that the pharmacy would not issue it and had sent her to him. She expressly referred to paragraph 12 of medical law whereby in life-threatening cases or when serious damage to health is to be expected a drug which has not yet been registered may be prescribed.

Hardly had Nowicky, in all good faith, provided the woman with Ukrain, than an application for an interim injunction to forbid the sale of Ukrain was made to the courts by the company Novipharm GmbH on 28.8.1996. Since Nowicky knew that the company Novipharm produced the alternative cancer drug Isorel and that this application was not completely disinterested, with the help of the lawyers' office of Professor Walter Barfuss, he set about defending himself. Successfully. On 21 April 1997 the case was dropped.

However, that was not the end of the matter. The owner of the Adler pharmacy, who was closely connected with Novipharm, appealed against the decision. The grounds upon which the Commercial Court, Vienna rejected this appeal on 15 May 1997 reveal the questionable methods which could have caused the downfall of Nowicky if the court had not seen through them and denounced them in writing.

The court records that the representative of the appellant who bought the Ukrain leading to this case at the Commercial Court was given the drug after he had, in contravention of the truth, named a non-existent person and declared that it was required urgently. The prescription demanded from the defendant in accordance with paragraph 12 of medical law could not be provided or demanded because the name and address, according to the invoice, proved to be false. The suspicion exists that, at the time of the purchase which is the subject of this case, Frau Fruhmann, an employee of the plaintiff's lawyer (!), falsely presented herself as a cancer patient and had also deceived Dr. Riessberger in order to get a prescription.

The appeal court saw the 'unethical' nature of the whole purchase not only in the behaviour of the purchaser, who had also 'instigated' the case, but also in that of the plaintiff (the Adler pharmacy) which had 'not only refused to dispense Ukrain under the conditions

laid out in paragraph 12 of medical law but also sent an employee of a lawyer friend as a test purchaser to the defendant’.

‘The behaviour of the plaintiff’ it concluded, ‘is in the opinion of the appeal court undoubtedly to be considered unethical and beyond the bounds of forbidden incitement with the use of an agent provocateur to trick a competitor. There is no basis for the accusation contained in the charge that the defendant acted in contravention of the law.’

The administrative court also had to concern itself with Ukrain and paragraph 12 of medical law several times. Dr. Grazyna Nowicki also had to answer to the court in this connection. As an ear, nose and throat specialist, with the required certification, she had received Ukrain from Dr. Nowicky for a patient suffering from a malignant melanoma. Shortly afterwards she was charged with the illegal administration of an unregistered drug. This case was also dropped after an appeal to the independent administration court.

What is astonishing about all this harassment is that it appeared to be of no interest at all what success Ukrain had in fighting cancer. – Despite the fact that this promising anti-cancer drug was repeatedly brought to the attention of the changing ministers at the Ministry of Health by journalists, patients and doctors. Some of them discussed this with their civil servants – they were always the same ones - with the best intentions but, as was to be expected, they were strongly advised against having anything to do with the drug. Almost all cancer specialists reacted in the same way. Medical records for which patients had given their permission to be publically used and whose doctors were also prepared to reveal their part in the treatment met with an irritated lack of interest as if only a swindle could be expected from a local outsider.

This was especially astonishing in the case of a nine year-old girl with Ewing’s sarcoma. This case was documented with Xrays in ‘Drugs Under Research’ in 1992. This malignant growth, which appears particularly at an early age in long tubular bones and all too often leads to the amputation of a leg, had affected the girl’s right calf bone. After both radiotherapy and chemotherapy had proved ineffective and the tumour continued growing, the desperate mother decided to try using Ukrain. This case is not only fully recorded but the X-rays were made at regular intervals at Vienna’s St. Anna’s Children’s Hospital where many children suffering from cancer are treated. The X-ray pictures printed in ‘Drugs Under Research’ are enough for the layman to be able to follow the course of the healing process. After one year with six series of therapy with Ukrain, neither Xrays nor laboratory tests showed any signs of disease.

Whoever believes that at St. Anna’s Children’s Hospital, in the interest of suffering children, special attention might be paid to this case and perhaps even further tests tried in hopeless cases is wrong. Since that time, nothing in this lack of interest has changed.

## Patients Struggle in Vain

It can only be supposed that with great probability Austrian cancer specialists not only are unaware of the medical literature about Ukrain but also that they either do not attend international cancer congresses or that, out of prejudice, they boycott the many short talks or even whole sessions. There is no other way to explain the irritable disapproval which arises as soon as the word Ukrain is mentioned.

The civil servants at the registration authorities have shown the same refusal to pay attention to the results of international research into Ukrain. Their eagerness always to demand new documentation and then to reject it as unsatisfactory is obviously not the same when it comes to the drugs of powerful international companies, as previously seen in the case of Taxol.

If it was only a question of importing a product of merely financial significance, it would be of no importance. However, it is a question of the lives and the quality of life of people who are suffering and whose deaths conventional medicine cannot prevent in so many cases. On ethical grounds, insofar as there is scientific evidence, even the smallest glimmer of hope should be investigated: and specialist publications in renowned medical journals, even if these were sponsored by the (obviously 'opposing') Ministry of Trade, should not be brushed aside as 'paid advertisements'.

The many hundreds of case records of patients who have been able to survive thanks to Ukrain, or at least experienced a great improvement in the quality of their lives, has at any rate resulted in over 160 doctors in Austria having treated their cancer patients with Ukrain, at least as adjuvant therapy. And this, despite the fact that the Ministry of Health has been untiring in reminding them of the 'ban' and has been mysteriously informed about both postal and telephone orders for Ukrain. This was especially noticeable with a doctor who had previously never prescribed or ordered Ukrain. On 17 June 1998 he ordered the drug by telephone for the first time. By post he received the package together with the invoice. Despite the fact that he showed nobody the invoice, on 20 July he received the 'decree' from the Ministry of Health stating that the use of Ukrain was forbidden.

The ministry seems untiring in pursuing this tactic. When doctors ordered Ukrain, they almost automatically received notification of this 'decree' which sometimes even arrived before or at the same time as the ampoules. Since this 'decree' was found only in the letterboxes of doctors who had ordered Ukrain and those of nobody else, Nowicky was puzzled how, in view of the secrecy of the postal service and the ban on tapping telephones, the names of customers could have arrived at the ministry. Coincidence can be ruled out: there have been 258 doctors so far who have been notified of this illegal ban and threatened with consequences.

In contrast to the hospitals, for whom Ukrain appears to be not worth trying or researching, general practitioners in Austria and abroad have long brought the proof for the efficacy of Ukrain which the registration authorities supposedly are panting for. Of course, in accordance with current regulations, even such a large collection of individual cases cannot take the place of a clinical study, which is still being prevented. Patients who live in fear for their lives cannot understand the behaviour of the authorities. It is also a mystery to many general practitioners who have seen the effect of Ukrain in their surgeries. Many of their observations are documented in reports. These include for example, results from a doctor in Burgenland who treated 12 cancer patients with Ukrain. A 'massive improvement in the general condition' was observed in a 61 year-old patient with prostate cancer who was 'in a bad condition and almost unable to walk' after an operation. In the case of a 75 year-old woman with lymphatic leukaemia: 'After Ukrain therapy her disease has regressed, swelling has gone down on all the lymph nodes and can no longer be detected.'

All these cases are too recent for there to be a final report. However, his summary concurs with reports from other doctors. He reports: 'In my observations I concluded that Ukrain is a real help and a positive supplement to other forms of treatment. In addition to the remissions achieved it should be noted that patients feel comfortable during and after treatment and their lives have become more worth living.'

A general practitioner in Vienna who has treated patients with Ukrain for more than twenty years, and as a result of his experience is in favour of low doses, stated, 'Ukrain definitely has a tumour-inhibiting effect.' Even with patients in advanced stages. 'Since in these cases,' he reports, 'there is naturally a very unfavourable prognosis, I find it extremely remarkable that the vast majority of patients have lived far longer than could be expected from the prognosis and at the same time the quality of their lives has been improved. They had far fewer pains and felt stronger and often existing pains noticeably reduced in the course of treatment.'

In conclusion he also comes down in favour of the rapid registration of Ukrain since, 'a considerable improvement in the general prognosis in relation to the length and quality of life is to be expected. This is all the more important because the currently common aftercare for tumours with chemotherapy and radiotherapy has negative effects on the immune systems of patients which in the long run decisively worsens the prognosis.'

It was also emphasised that Ukrain prevents the formation and further growth of metastases.

A general practitioner with many years' experience at a hospital abroad can only confirm these findings. For the last seven years she has mainly been treating patients, 'who have been given up by conventional medicine and desperately look for a last chance of treatment. It should be said in advance that with all these patients an unexpected subjective and objective improvement both in their physical and mental conditions came about after the first injection with Ukrain, which I can in no way define as a placebo effect. Patients improved their eating and sleeping habits and reported that pains had been relieved so that in many cases it was unnecessary to administer strong analgesics. They lost their general malaise and their initially depressed basic mood brightened up. It should be noted that most of the patients reported their better feeling for life on their own initiative.'

In her report the doctor presents some 'remarkable therapeutic successes'. A 66 year-old woman came to her with a malignant melanoma on her lower leg with massive lymphatic oedema (concentration of water) in her leg and multiple metastases in the cerebrum (brain) and in the spinal canal. She had been discharged from hospital as untreatable. After the third series of Ukrain therapy the massive primary tumour and the lymphatic oedema reduced in size. The tumour could now be operatively removed and the metastases in the central nervous system were reduced. After the seventh series of Ukrain treatment no more metastases could be detected. The patient has been free of recidivisms for three years, feels healthy and receives Ukrain at longer and longer intervals.

The doctor also reported the case of a 60 year-old man who was also discharged from hospital as untreatable with lung cancer with metastases. The hospital had not been able to suggest any possible type of therapy. 'Extremely short of breath, can only walk a few metres without having to rest. During treatment with Ukrain the patient experienced an improvement in his condition which was almost a miracle. His difficulty in breathing disappeared almost completely and he can go for hour-long hikes. He died three months later during an examination in hospital shortly after he had been injected with morphine.'

A similar end was met by Frau S. from Waidhofen who had been suffering from stomach cancer and was treated with Ukrain after being discharged from hospital. A letter from her daughter describes what happened: 'She was doing very well until last October. She could eat everything and was not in pain. Then she went to the next examination at the hospital. Gastroscopy was carried out again. The doctor who had carried out the previous two

examinations was not there so another doctor performed the gastroscopy. He took three tissue samples, which was very painful for my mother. After this examination she could no longer keep down her food, she always had to be sick and was in great pain. From Christmas she sometimes couldn't keep down fluid food. In the last months she also brought up blood. In the last three weeks before her death my mother could neither eat nor drink. We think that our mother would still be alive today if computer tomography had been used.'

Among the many case histories, which in most cases are of patients with very advanced cancer, there are naturally many in which Ukrain brought about a subjectively improved general condition but could at best slow the disease but not prevent its fatal outcome. Most remissions were seen in cases which had not gone beyond stage II. There were also cases where Ukrain had no effect at all. The reason for this has not yet been explained. It seems that Ukrain is particularly effective against small-cell lung cancer, colonic cancer and melanomas as well as against forms of cancer producing metastases in the liver and intestines.

I myself observed an astonishingly rapid improvement in two relatives suffering from lung cancer. Both patients were tormented by agonizing coughs and could get through the day only by lying down for most of the time. One of them frequently had to use an oxygen flask. After a few weeks both of them could once again begin to lead normal lives, after two months the coughs had disappeared and their quality of life was returned almost to normal. A beneficial 'side effect' of Ukrain seems to be a favourable, partly curative effect on arthritic and rheumatic complaints.

This sensational aspect is surprisingly overlooked in an expert report by Professor G. Hitzenberger, specialist for internal medicine and expert appointed by the court in Vienna. He was asked by the court in Innsbruck to draw up a specialist report on the case of Gerlind Schöpf from Lienz who had applied to the health insurance authorities for compensation for the costs of Ukrain treatment before and after she was operated on for breast cancer.

The report on the operation speaks of a 'cancer in the right breast in stage T3. Histologically, it is a moderately differentiated invasive ductal carcinoma, malignancy stage II with penetration of the lymph ducts. One year before she was diagnosed with cancer the patient had to apply for early retirement because she could no longer do her job. This was granted due to her rheumatic complaints, degenerative changes in the spine and varicose veins. These complaints had tormented Frau Schöpf since 1989, which was confirmed both by the doctor treating her and a physiotherapist. The latter remembers that she had 'never treated a patient in such a bad condition', which is also noted in the specialist report. However, the report 'with a probability bordering on certainty' refutes a connection between rheumatic complaints and breast cancer (a suspicion which had been expressed by an internist in Lienz Hospital).

In his negative report the internist Hitzenberger comes to the conclusion that it could not be proved that Ukrain had any effect and that the costs should therefore not be refunded. The specialist took no notice of the fact that the patient, the 'plaintiff', expressly stated that her state of health had improved considerably, 'so that many movements which would have been impossible before could now be made without any trouble although I had taken no anti-rheumatica or painkillers'. However, what he himself wrote is clear enough to bring Ukrain into connection with rheumatic complaints which torment so many people who then become unable to work and who place a heavy burden on social insurance funds. He expressly remarked that 'the patient can once again completely stretch her right arm above her head, sitting and driving are no longer a problem, she finds walking easy and she feels really light-footed'.

Among his reasons for rejecting Ukrain the specialist states, 'the patient was already in a bad state of health a long time before breast cancer was diagnosed and grew successively worse. Her complaints were however primarily to do with the spine and were always described as degenerative'. He goes on to say that no metastases appeared: 'It therefore also

cannot be proved that treatment with Ukrain achieved any kind of success since also without this treatment and without any other chemotherapy metastases do not appear inevitably.’ He concludes: ‘Whether or not the improvement in the patient’s general state of health can be attributed to Ukrain is a question which also cannot be answered. After all, Ukrain is not used for the treatment of degenerative spinal disorders or disorders of a degenerative nature in the region of the finger joints. As far as the undersigned specialist knows, registration has not even been applied for as an anti-rheumatica.’

Since, as an internist, Professor Hitzberger is doubtlessly continually confronted with extremely painful rheumatic diseases, it would perhaps have been more to the point if he had concerned himself with Ukrain as a possible anti-rheumatic drug. If what cancer patients with rheumatism or arthritis often report should prove to be true (after several series of Ukrain therapy my sister also reported that she had no more problems with her peri-arthritis) it would in fact be a sensational ‘side effect’ of Ukrain which should, without any connection to cancer, immediately be thoroughly investigated. Instead, the specialist writes as though only through registration can a drug be effective. He sticks to his point that ‘the success of Ukrain treatment cannot be proved’. The fact that the patient was in good health was obviously irrelevant in this context.

It would be interesting to know how the professor explains the disappearance of the widespread rheumatic disorders since none of the drugs used for this purpose were administered and he never talks about ‘spontaneous healing’.

After this report the health insurance authorities certainly did not need to refund the costs for Ukrain, as in many other cases. One of these is currently at the Court of Human Rights in Strasbourg.

The plaintiff, Frau J.H., underwent surgery in July 1988 for colonic cancer (adenocarcinoma of the right colon flexura C1). ‘Colonic cancer in stage Dukes C undoubtedly has an unfavourable prognosis,’ as Professor Dr. Christoph Zielinski from the Oncological Department of the Vienna General Hospital remarked in his (negative) report. ‘which fortunately did not apply to the patient in this case.’

She is convinced that this luck can be attributed to several series of Ukrain therapy, and two doctors confirm this. Between the operation and the Zielinski report, seven years went by. In any case, Frau H. received no chemotherapy, which is why the specialist also suggested that one of the normal forms of chemotherapy could have proved ‘extremely effective’. However, after the operation – a tumour the size of a child’s head had been removed, but not all lymph node metastases – she was in such bad condition that no chemotherapy was carried out and she was discharged with the gloomy prognosis that there was no hope and she had only a few months to live. At least this is what her husband was told. She was therefore in a life-threatening condition in which paragraph 12 of medical law allows an unregistered drug to be used.

However, the Vienna health insurance authority rejected the application to pay the costs for Ukrain treatment on the completely fictitious grounds that, apart from the fact that the medical effect of Ukrain had not been proven, ‘serious side effects’ had to be reckoned with. In answer to Frau H.’s question what these side effects were, she received the reply that according to the Ministry of Health Ukrain ‘is currently undergoing clinical trials’ and it is forbidden to release interim results such as effects and side effects before those trials have been completed. The fact that this hopeless case had already been sent home from hospital seven years previously and was still alive did not appear to be worth a thought for the bureaucrats.

Frau H. appealed against this decision to a local appeal tribunal. Specialist reports were ordered including that of Professor Zielinski who seven years after the event wrote that the unfavourable prognosis in stage C ‘luckily did not apply to the patient in this case’. He endorsed the decision ‘not to refund to the patient the costs for the preparation Ukrain. In

conclusion, in this case there is no indication whatsoever for the anyway questionable effectiveness of the preparation.'

This contradicts the conclusions of a Vienna general practitioner who had used Ukrain for many years and was asked for an opinion:

The patient J.H. was most certainly in danger of her life, both before and after the operation. I have treated a very similar case myself with Ukrain. A 30 year-old woman with colonic cancer and lymph node metastases who had a hemi-colectomy like Frau J.H. and also widespread bone and especially liver metastases. After three months of treatment with Ukrain the liver metastases disappeared. This was demonstrated by computer tomography several times and by MRI and ultrasound.'

'Since I have worked with Ukrain for a long time,' continued the doctor, 'and increasingly see the unbelievably positive effects it can have, both on tumour activity and on the immune system, in this special case of Frau H. I can imagine no other reason for the patient's survival than the effect of Ukrain. I would be pleased to present the numerous, medically proven cases where patients have the efficacy of Ukrain to thank for their survival.'

As may have been expected, nobody was interested in taking up this offer.

Two other doctors who had experience of Ukrain also gave their opinions. Dr. P.K. reminded the tribunal that according to data from the World Health Organisation the five-year survival time for adenocarcinomas of the intestine with lymph node metastases in stage Dukes C1 was only 7 percent. And that according to clinical experience recidivisms could also be expected after this period. Preventing this was he said 'of the greatest importance'. A colleague also confirmed that in this life-threatening case paragraph 12 of medical law should be applied.

'When Professor Zielinski stresses (after seven years) that the patient was luckily not affected by the unfavourable prognosis for colonic cancer Dukes C1, he is taking no account of the fact that this can indeed be attributed to Ukrain. In addition, since according to Professor Zielinski's statement the patient's chances at the time of the operation were so bad, it is even *most probable* that the reason that the unfavourable prognosis did not apply to Frau H. can be attributed to Ukrain.'

Since in the meantime, there was a case in progress at the Constitutional Court about the 'decree' from the Ministry of Health which forbade the use of Ukrain, the proceedings in Frau J.H.'s case were adjourned. Her lawyer, Dr. Michael Graff raised an objection.

On 19 June 1996 the Constitutional Court concluded 'that the improperly announced orders have no basis in law and that these should not have been applied by the courts from the outset, and also without appeal to the Constitutional Court.' Whereby the health insurance authorities could no longer claim in court that there was a 'ban' on the use of Ukrain.

The proceedings in the case of J.H. were now continued with new specialist reports both pro and contra Ukrain. An internist, Dr. Donatus Pokorny stated on 12 August 1996 – eight years after the operation – that there were no metastases in the patient's lymph nodes and that it had not been established that Ukrain was used 'for the treatment of existing tumour manifestations' or against expected recidivisms. He did not go into the fact that the doctors at the hospital had sent the patient home after the operation with no further treatment and had told her husband that they could do no more and she could only be expected to live a few months. Every part of this report was torn to pieces by another report which accused Pokorny of obvious bias and described his argument that, according to statistics, after an operation for colonic cancer and without further treatment the patient had a thirty percent chance of survival and that Ukrain would therefore not have been necessary as 'a scandal in itself'.

Pokorny then countered with an 'interim supplementary report' in which he claimed that in this case Ukrain had been applied 'purely speculatively' and because of this it was unsuitable because after the operation during the regular examinations no recidivism and no

metastases could be found. That Ukrain could possibly have been the cause of this welcome consequence, as the doctors in attendance agreed, was not even taken into consideration.

Pokorny thereby passed a devastating judgement on the doctors at the Vienna General Hospital: nine years previously they should not have discharged the patient, who was obviously not really so ill, as moribund and should not have told her husband that she was close to death.

The proceedings dragged on into the following year. On 30 December 1996 the head of the Medical Department of the Wilhelminen Hospital in Vienna, Dr. Heinz Ludwig, was asked to draw up another report. He began by stating that there were no distant metastases 'so that the stage of the tumour was categorised as Dukes C1'. The cure rate for this is 40 to 50 percent with only surgical treatment. The other patients have recidivisms which 'then leads to the death of the patient'. Since no studies are available which have been carried out with the 'required scientific care' it cannot be assumed that Ukrain is 'a suitable therapeutic instrument for patients in this stage of disease'.

The general practitioner treating the patient J.H., Dr. Thomas Kroiss, was now asked for his opinion. He was the only one who had followed her suffering over a long period of time, he began treating her six weeks after the operation. He confirms that, 'there were clear signs that the disease was still present'. She herself knew nothing of this. The doctors at the hospital had told only her husband that there was no point in trying chemotherapy and that she had only a few months to live. Therefore Kroiss said, he began with 'extensive holistic therapy', a part of which was Ukrain.

On the basis of the negative reports by the specialists Pokorny and Ludwig, on 14 March 1997 the tribunal rejected the claim for the costs of Ukrain treatment to be refunded. Frau J.H. appealed against the decision. On 5 June she wrote to the European Commission for Human Rights.

'I have the impression,' she wrote, 'that the tribunal is trying to draw out the decision for so long that I might die before the proceedings are concluded.' She could no longer pay for the medicine. This is one example among many.

Parallel to this, there were administrative proceedings about the way in which the Ministry of Health had been delaying the registration of Ukrain. After the Constitutional Court lifted the negative 'decree' Nowicky applied for another specialist report to be commissioned.

This was done, but if Nowicky now hoped for an objective specialist report on Ukrain, he was to be sorely disappointed. The commission which, on 1 September 1997, Ministerialrat Jentzsch gave to the director of the Institute for Clinical Pharmacology of the University of Vienna, Professor Hans Jörg Eichler, as expert witness, consisted solely of justifying the previous negative reports.

In his application Nowicky expressly stated that he would bring forward anything which had previously been lacking; he also offered to bring to Vienna the doctors who had carried out studies of Ukrain abroad with interpreters so that they could be questioned. They had consented to come.

None of all this interested the expert witness – he had only been commissioned to justify the negative reports of the highest health authority. It is no wonder then, that Eichler's report is miles away from a neutral, objective viewpoint.

An example: Nowicky offered conclusive proof that Ukrain was well tolerated. This was rejected on the astonishing grounds that it was not relevant. It then appeared in the report as 'unproven'. The report was prepared in just under two months.

On reading the 17 page report it is noticeable that the author is obviously taking care to protect himself in case Ukrain was actually effective, but on the other hand he mainly follows the line of argument of the authorities when he concludes: 'There is not a single document here which according to present standards in science credibly confirms that Ukrain

brings benefits to patients.’ He continues, ‘The good tolerance to Ukrain which is described in almost all reports should be regarded as just as unproven as the efficacy described.’

Then follows the amazing passage: ‘The conclusion of the above-mentioned considerations is that it is impossible to evaluate correctly the benefits and risks of Ukrain. I must expressly state that this negative judgement is not based on the fact that the benefits and the good tolerability claimed for Ukrain are inadequate for the drug to be registered – on the contrary, the benefits claimed for it must be described as spectacular – but that the data provided is dubious.’

## Obstruction Intensifies

Not only medical experts and the courts, but even the secret service became involved with Ukrain. Not however in order to obstruct it, but to deal with the extremely suspicious events taking place in connection with this anti-cancer drug.

One evening, a member of the secret service, Johann Wagner, turned up at Nowicky's flat and told the baffled inventor that it had been reported that the secret service of a Mediterranean country had given the order to liquidate Nowicky. However, the hired assassins had confided in the Austrian authorities.

This occurrence, which took place in 1996, was again brought to mind in spring 1998 when a registered parcel arrived at Nowicky's Ukrainian Anti-Cancer Institute in Margaretenstrasse in Vienna. On the parcel was written that the sender was the headquarters of the tax office for Vienna, Lower Austria and Burgenland in Vienna's third district; although the parcel had been sent from a post office in the ninth district of the city.

At the time, Nowicky was at a medical congress in the USA, so the packet was opened by the vice-president of the institute, Tibor Nemeth, who happened to be present when it arrived. Inside a normal shoe box was the skeleton of a lobster. Nowicky associated this with mafia messages such as the horse's severed head in 'The Godfather'.

Nowicky would have let it rest at that and just filed it under 'terror' if his accountant, Peter Obermayer, had not urgently advised him to report it to the police. Nowicky went to the police with the evidence. The shoe box and its contents were photographed, but no other action was taken. Of course, the tax office had nothing to do with the case in its official capacity.

On the other hand, Nowicky was informed by his accountant not only that the tax office was about to check his books (which in the meantime was carried out and no irregularities found) but that the tax office had demanded two ampoules of his preparation Ukrain so that they themselves could determine the cost of production, which they suspected Nowicky had stated too high. On the basis of what research the civil servants came to the conclusion that it cost €20 per ampoule will remain a secret of the tax office.

As if this harassment was still not enough, foreign customers who had been ordering Ukrain for a long time and paying via bank transfer to the Creditanstalt bank without any difficulty were now suddenly confronted with Austrian antics. For example, instead of a small amount such as \$3000 being credited to Nowicky's account, the money was returned to the sender without explanation. It is all too easy to understand why Nowicky then changed his bank.

At almost the same time very many cheap Ukrain preparations were brought onto the US market, and these also appeared within just one week in England, Canada and Australia. Professor Liepins, who had known Ukrain from the beginning, investigated these cheap products which proved themselves as totally ineffective. The contents of one ampoule also proved not to be sterile. Since then the Food and Drug Administration has warned on the internet that Ukrain is unsterile and even could contain the AIDS virus.

A letter from Nowicky drawing attention to this mistake in which he even named the institute whose products in which the AIDS virus was found remained unanswered. The error on the internet has also not been corrected.

At the same time as all these unpleasant occurrences, tests on the efficacy of Ukrain were being carried out in Ukraine, the country most damaged by the Chernobyl disaster. It was there that the story of Ukrain began and it was there that on 15 October 1998 the registration of Ukrain was unanimously approved.

Austria would be left standing if a miracle did not happen.

For three decades Nowicky had made efforts and put up with all the harassment so that his invention could move onto the world market from Austria; 'out of gratitude' as he says because this country had given him a home. He also knew very well the financial benefits which the country could reap. Each year Austria spends €100 million in the USA on chemotherapeutic drugs alone – minus 'commission', by which 'donations' are also to be understood. And although Ukrain is not yet registered €1.3 million come back to Austria from the sale of Ukrain alone. 'The commercial aspect does not interest us,' said Dr. Johann Jentzsch, Ministerialrat and the Ministry of Health, in a talk with me on 8 February 1994. When I pointed out the danger that Nowicky could go abroad he was almost euphoric; 'He should go to Germany!' he said with joy.

A study carried out in Germany in February 1998 by Harald von Eick, director of business development at an international services company in the field of clinical research (CRO), who specialises in the market sectors 'strategic management for immunology and oncology' shows that the economic aspects of Ukrain are in no way uninteresting for the country in which Ukrain is produced and from which it is distributed. In view of the fact that Ukrain is non-toxic in therapeutic doses and that quality of life is significantly improved – even in the final stages of disease when all else has failed – von Eick sees the market potential of Ukrain as extremely positive.

If one supposes that in the first year in which Ukrain becomes available it will predominantly be used on patients in the final stages of disease who conventional medicine can no longer help, von Eick forecasts that Ukrain could gain a 30 percent market share in Europe in the first three years - which means that 76,500 patients would benefit from it. This is an unusually successful perspective for a new drug in the oncological field, wrote von Eick. Nowicky himself is rather more reserved in such forecasts. 'On the basis of studies carried out so far on efficacy and tolerance, a market share of five to ten percent is realistic for the treatment of solid tumours such as cancers of the breast, colon and rectum, lung, prostate, and bladder as well as melanomas,' according to his application to the trade and industry research grant fund.

Among the forms of cancer listed it is noticeable that three are included against which drugs are to a large extent powerless. These are breast, colon and lung cancer with metastases, as stated in a radio discussion between Austrian cancer specialists on 7 February 1997.

Now icky's current turnover, as stated in his application to the trade and industry research fund is €500,000 in Austria and just over that abroad. The total market volume in the framework of the project was calculated as €100 million in Austria and €20 billion abroad. In the first phase a production and research organisation creating 50 jobs would be set up and this would expand to 200 jobs in the final phase. The cultivation of greater celandine for the extraction of raw materials is estimated to create 500 to 1,000 jobs in agriculture. It is not difficult to imagine what that would mean for farmers who are having a hard time making a living. Finally, the revenue from taxes is a factor which cannot be overlooked.

All these advantages could benefit another country if a miracle does not happen – only because the authorities and various interest groups in Austria have been able to prevent the drug's registration. It is hardly credible that one single civil servant, or more of them, could have set the wheels in motion for this obstruction. The question also arises what interest they could have in doing so. It is rather more probable that large pharmaceutical concerns which themselves have spent billions developing chemotherapeutic drugs would have a few million to spare to obstruct a new anti-cancer drug: N.B. if that drug achieved much better results with extremely negligible side effects. The fact that these concerns were disturbed by the regular reports on Ukrain at national and international congresses is confirmed by the tempting offers which once again arrived from an international concern for the Ukrain patent and the relevant expertise.

Wassil Nowicky is not the first person in this country who has stared failure in the face due to a lack of understanding and good will, if not worse. All because he had the audacity to want nothing other than to promote his invention himself – not least for the good of the patients – and thereby to allow the country to benefit which twenty five years ago gave him a home and enabled him to carry out research – even if with many obstacles.

If he had not been encouraged by many scientists abroad, it is possible that he would have given up long ago, despite his innate stubbornness. In 1998 such encouragement came from the president of the German Oncological Association, Professor Dr. J. Beuth from Cologne University. He had worked out a programme with which ‘all legal conditions for registration would be fulfilled, especially proof of efficacy in the EU,’ as he wrote to Nowicky in a personal letter. Nowicky wanted to raise the comparatively moderate costs of € 80,000 through sponsors. However, this project was also cancelled due to fruitless controversy and troublemaking.

In the meantime Nowicky’s opponents in Vienna had also not been idle. And so that he would not forget that his ‘friends’ at the Ministry of Health were still keeping a careful eye on him, they gave him a reminder at every opportunity – such as in September 1998.

Nowicky read in an Austrian medical journal that Professor Dr. Ernst Kubista from the Gynaecological Clinic of the Vienna General Hospital had developed a test to check the sensitivity of cancer tissue to various chemotherapy drugs. Sterile tumour tissue was removed during an operation and exposed to the various drugs. The medical journal quoted Kubista as saying that the test would show with ninety percent certainty which cancer drug would be effective and which would not.

Nowicky wrote to the professor suggesting that he should also test Ukrain and that he would supply sufficient quantities of the drug at no cost.

The busy professor did not deem the letter worthy of an answer.

However, around three weeks later Nowicky received a letter from the Ministry of Health signed by the civil servant Michtner. In this letter medical legislation was quoted, where according to paragraph 3 it is forbidden, ‘to distribute drugs if it appears uncertain that they have no harmful effect when used normally.’

The absurdity of the whole letter is shown up by the fact, undoubtedly known to the ministry, that the Kubista test was to be carried out on tissue cultures (in vitro) and not on patients. Were they afraid that Ukrain could have demonstrated its effects? – And if so, what would happen then? Or was it simply a question of doing everything possible not to have to reverse the decision that Ukrain ‘will never be registered’?

The refusal of the Ministry of Health to grant an official certificate was part of this ploy. Nowicky had asked for a ‘Certificate of a Pharmaceutical Product’, the only purpose of which was to confirm that a drug by the name of Ukrain actually existed. Since Ukrain had been approved for clinical tests, whereby its existence appeared to be officially recognised, the untiring supplicant Nowicky thought that nothing could stand in the way.

The application was made on 5 November 1998. The enclosed documentation from the company Solvay, including a certificate from the Dutch Ministry of Health confirming that the company produced the drug according to GMP (Good Manufacturing Practice), was returned on the grounds that it was unnecessary. Nowicky was informed that on the following Monday, 9 November, the certificate could be collected from the ministry.

On 9 November the application could at first not be found. Two civil servants, Fleischig and Pfaffinger searched in vain for the document. Fortunately, Nowicky’s courier had brought a copy of the application. On the same day, in response to a telephone inquiry from Herr Pfaffinger, it was explained that Nowicky was the producer of Ukrain and the company Solvay was contracted to fill the ampoules. Everything appeared to be in order and on 12 November a short telephone call from Herr Fleischig informed Nowicky that the document could be picked up that morning.

So once again Nowicky went to the ministry. What then happened is described by Nowicky, who was in the habit of recording his experiences in writing. 'I was handed a document which I had to sign to confirm receipt. I assumed that I would then be given the whole document but I was mistaken. Without further ado it was taken from my hands and I was given only the appended letter – signed on behalf of the Federal Minister. The letter contained a rejection of Nowicky's application on the grounds that the Ministry of Health, 'neither knows whether the company Solvay Pharmaceuticals from The Netherlands has approval to produce cytostatica such as Ukrain, nor is there any proof that the production of the drug is carried out by this company'.

The certification from the Dutch Ministry of Health stating that Solvay was an approved producer of human medicines and that the company actually did this in accordance with GMP regulations had been handed back as unnecessary at the time of the application. – Along with the documentation covering the second point of the rejection.

There was stated: 'The manufacture of Ukrain is said to be contracted out. It should be emphasised that the company Nowicky Pharma has neither a trade licence nor approval in accordance with paragraph 63 for the production of parenteral drugs and can therefore cannot appear as the contractor in relation to such drugs. The existing patents and trade licence cover only the manufacture of the effective substance.'

Apart from the fact that it was intended that Solvay fill the ampoules, Nowicky had a 'concession decree' from 1988 giving him permission for 'the manufacture of substances and preparations for medicinal use.'

His company, Nowicky Pharma, is entered on the register of companies. The height of this absurdity is the fact that in 1994 Nowicky had already received such a 'Certificate of a Pharmaceutical Product' rubber-stamped by the Ministry of Health without any objection.

If so much is 'unknown' to the ministry, it could be due to the fact that so much of the documentation was repeatedly handed back at the time of the application since it was deemed unnecessary.

Nowicky once again experienced how unhelpful information from civil servants at the Ministry of Health was, when in a letter of 25 November 1998, addressed to the Minister of Health, Eleonore Hostasch, he asked for the information: 'What formalities are necessary to set up my own production of Ukrain according to the regulations of Good Manufacturing Practice here in Vienna?' Since his letter was still unanswered in the middle of January 1999, he wrote an urgent letter to the minister on 22 January in which he referred to what he had been told by one of her civil servants. This passage is certainly worth quoting:

'In reply to a brief enquiry to one of your civil servants I received the answer that I should first have the facilities built and then it would be considered whether I would be granted approval for GMP production. Please understand that I cannot spend around € 500,000 if it is possible that I would not receive approval for production in accordance with the regulations.'

After once again referring to the fact that that his anti-cancer drug Ukrain was registered in two countries (Ukraine and Belarus) and that its efficacy had been sufficiently proven, he summarised his frustration in one sentence with an exclamation mark. 'I applied for registration in Austria in 1978 and I am still waiting today!' He continued: 'If the same delaying tactics are used in this matter, i.e. the GMP certification, as in my application for registration, for which I have been waiting for more than twenty years, I will finally be left with no option but to take the production and distribution of Ukrain abroad, where my efforts are supported. I would therefore URGENTLY ask you to give me a clear answer to my question as quickly as possible.'

The answer arrived before four weeks had gone by, dated 19 February 1999 and signed by the civil servant Michtner who was responsible for registration. In just two sentences he managed to avoid the clear answer Nowicky had asked for. 'With reference to

your letter of 22.1.1999 addressed to the Federal Minister, may we point out that on the basis of your first letter of 25.11.1998 regarding this matter, in personal discussions it was requested that the question of the production of the drug Ukrain in Austria should be discussed in connection with the decision on the registration of Ukrain which is soon to be taken.'

The second and concluding sentence: 'We would once again like to ask for your understanding that isolated consideration of questions arising in relation to the possible production of Ukrain in Austria can lead to no conclusive judgement.'

'The decision on the registration of Ukrain which is soon to be taken' went as follows. On 16 April 1999 seven civil servants, three of whom were only present for a short time, gathered in a room on the second floor of the Ministry of Health. Dr. Heribert Pittner also re-emerged to join in. Nowicky and a representative from Dr. Graff's lawyer firm kept records of the conversation.

Initial discussion was once again about the chemical composition, the various stages of production, in short about a 'definition' of the compound. Nowicky pointed out that the ministry had been in possession of descriptions for years and that all this was clearly defined in his patent.

They then turned to his urgent request with regard to the formalities of building his own laboratory in Austria and producing Ukrain there. Nowicky asked them to consider the fact that the production of Ukrain was intended for countries in which the drug was already registered. It was therefore not reasonable that this matter should be connected to registration in Austria. On the one hand he could not build facilities which would then be refused approval, and on the other hand it could mean considerable revenue for the minister of finance and jobs for the country. Logically, he would have to know the regulations before beginning construction.

If the answer had been deftly avoided in the letter from the ministry, this time he was not deemed worthy of any answer at all.

There followed a general discussion about registration, during which the expert Pittner suddenly stated that clinical studies need not necessarily be carried out in Austria but could also be carried out in east European countries. This was sensational in view of the fact that previously such studies had been rejected as irrelevant and not up to western standards, with the undertone 'dubious'.

This was also the fate of a clinical study carried out at the University of Kiev which had been thrown out by Pittner in 1993. However, this time Pittner expressly referred to it, calling it 'very good'. It only had 'methodological inadequacies'. In answer to the hopeful question of how long it would take until registration with a new application, the answer was 'at least eight years'. And as if this dampener was not discouragement enough, Pittner added that the regulations could have changed by the time the new documentation was submitted. Then the whole process would have to be repeated in order to be in line with the latest medical knowledge.

The inventor, who was still not finally discouraged, then raised the question of registration in relation to the significant improvement in the general condition and the quality of life which had been confirmed by every doctor in every study. Here too, there was no chance. There are no objective criteria to prove this.

Once again, nothing gained for the patients.

Finally, Nowicky attempted to bring in the improvement in the immune status, which brings about the improvement in general condition as a logical result.

The objection was raised that there was already a registered drug for correction of the immune system. This was Isorel. Nowicky then wanted to know how it was possible that this drug was registered so quickly and what proof of its efficacy was necessary. They were not authorised to answer these questions.

Still attempting to find a tolerable period of time for registration, Nowicky then asked Pittner how long a clinical study for the indication 'increase in immune defence' would take. Three years at least, he was told. But since a prolongation could not be ruled out, it could easily take three times three, i.e. nine years.

This would mean that Nowicky would have spent thirty years attempting to get his anti-cancer drug registered and that the result would still be uncertain.

This has been a never-ending story of obstruction. The question as to who benefits from this obstruction hangs in the air. Or vice versa: who is damaged by the use of an anti-cancer drug which does not do harm and can also help?

In 1998, 5.8 million people worldwide died of cancer, of these 18,955 in Austria.

Millions are affected by this insidious disease and it will kill many more in years to come.

Should not every avenue be explored?