Aug. 26, 1994

To Perry Chapdelaine
From Wayne Martin

Here are two to the editors of the TLFDS.

One is a dramatic case of recovery of hopeless ovarian cancer on treatment with Coley's Toxine.

The other one is what has been happening in treating liver cancer with urea.

Urea is ever so effective in treating liver cancer if treatment is begun shortly after the cancer is diagnosed.

Don Carrow M.D. in Tampa uses both urea and Coley's Toxins. His phone is 813-832-3220.

Threatment of cancer with Coley's Toxins is a four months project. Dr. Carrow says that he will treat patients with Coley's if the patient will move in close to his office and stay there for 4 months of treatment.

One can treat liver cancer at home by talking urea.

Bio Tech in Fayetteville, AR has urea---5 lbs for about $40.00. They will sell to your foundation. Their 1800 number is 345-1199.

The dose is 15 grams in a quart of water. Devide the quart into seven portions and take 1/7th of the quart every 1.5 hours. If there is nausea, start with only 5 grams a day of urea.

Your case is in a very late stage by now so I would not know.

It was the teaching of Professor Danopoulos that if the liver is not more than 30% involved in cancer, urea is always effective.

Best:

Wayne
Aug. 26, 1994

Editor:

In the Feb. Mar. issue of the TLFDs, I had a letter saying let's bring back Coley's Mixed Toxins. In the Aug. Sept. 1994 issue, I had a letter telling the history of Coley's Toxins and of in my estimation one of the great heroes in medicine, Dr. William Coley.

This is to report on a recent case of dramatic recovery of a very far advanced cancer patient on treatment with Coley's Toxins in the year of Our Lord 1994.

The patient is a woman aged 72 with ovarian cancer. The reporting physician is Donald Mantell M.D. of Evans City, PA. In early 1993 the patient was found to have a small ovarian tumor. By November of 1993 the patient's condition had deteriorated greatly. At that time her CEA was 3,910. She had a metastasis around and displacing the liver and other metastases in the peritoneum and pelvis.

The patient continued in a pattern of deterioration and on 02/15/94 a CT showed liver displacement by a large tumor and extensive peritoneal metastases. The patient was in constant pain and there was visual swelling in the area of the liver. Hope was running very low for this patient. Her CA 125 was 5920.

About 16 months ago I went to Guatemala City where I met and liked a Dr. Rolando Comparini. I took or sent to him what was needed to make Coley's Mixed Toxins and lectured him on the use of it. There is a fine small hospital there in which cancer patients can live while being treated with Coley's Toxins. Dr. Comparini has been treating a few American cancer patients there. The above mentioned cancer patient was one of them. Other parties have taken over what I started in Guatemala and I am not entirely happy with the way things have developed. What has happened is that American cancer patients have been sent to Guatemala for 30 days of treatment only. My state of unhappiness has to do with this 30 days of treatment only.

However what happened to the above ovarian cancer patient in 30 days was little short of a miracle. She had 18 intravenous infusions (ivs) of Coley's Toxins that all produced a severe fever and chills reaction. In a few of them there was increased pain in the pelvic area, but after iv number 14, there was almost complete relief from pain. The visual swelling decreased and the patient began to eat and sleep well and live a near normal life.

Back in the USA she is living a normal life and her CA 125 is 2206. Now we get to my unhappiness over 30 days only of treatment. The CA 125 of 2206 tells of active cancer yet.
Another breast cancer patient I am following who was one of the patients who went to Guatemala for 30 days of treatment only had breast cancer with bone metastases and severe bone pain. She also had dramatic relief from pain that happened by about iv 16 and she returned home nearly free from pain. Now after four months at home she is having a resumption of bone pain.

I think that Coley's Toxins used in a proper manner for a long enough duration will cure well over half of all cancers that are solid malignant tumors.

These two cases may throw some light on why Coley's Toxins did not long survive the death of Dr. Coley in 1936. His daughter Helen Coley Nauts D.Sc. founded Cancer Research Institute in 1953 and it has grown into a fine prestigious institution. She has written and published 18 Cancer Research Institute monographs on Coley's Toxins replete with remarkable and dramatic remission of cancer like the above case. While in the period 1893 to about 1940 there were perhaps over 5,000 cancer patients treated with Coley's Toxins, she has found good records on about 950 cases. Of these there were something over 400 cases of meaningful long time regression, many of life time long cures where the patients lived to old age to die of a cause other than cancer. There were also something over 400 cases listed as failures where after treatment the cancer recurred.

There was a marked difference between the failures and the long time regressions and cures. In nearly all of the failures the duration of treatment was for 60 days or less. In all of the very long time regressions and cures, the duration of treatment was from 4 months to over a year.

In a great many of the failed cases there were early on the dramatic relief from pain, the shrinking of tumors and other signs of regression of cancer as is being seen with the few patients in Guatemala. For many years I have asked myself why were there so many cases, where notwithstanding the good indications, did treatment not continue beyond 60 days.

We see a bit of the answer in the above two cases. Here a doctor, who is no friend of mine, decided on 30 days only treatment and this doctor has shown signs of satisfaction with the results.

In Caracas, Venezuela we are seeing a pattern of 45 days of treatment and no more. In Venezuela the government pays for medical treatment, but not for Coley's Toxins. There we see a pattern of patients being helped by Coley's Toxins but running out of money to pay for more treatment.

In Dr. Coley's day it was pay as you go for everyone and many of the failed cases may have been of short duration because patients ran out of money.
The material cost in making Coley's Toxins is nil, about $10.00 in materials will make enough Coley's Toxins to treat several thousand cancer patients. To make enough Coley's Toxins to treat several thousand cancer patients will tie up about four square feet of counter space in a doctor's laboratory for 21 days. The man hours in making a large lot of Coley's Toxins is not more than 10.

Today many doctors have an iv room in their office. One iv of Coley's Toxins should be not in excess of $100.00 and could be less. These patients in Guatemala had about 18 ivs which are not enough. One hundred ivs of Coley's Toxins may be about what are needed for complete regressions.

I show here a vista where it may be possible for $10,000.00 in medical charges for each to cure a lot of cancer patients with no time in a hospital at all.

With a very expensive health bill before congress and so much attention to medical costs, why not begin to have a new look at Coley's Toxins if for no other reason but to reduce the cost of cancer treatment.

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I spent many hours going through the records of New York Hospital back ten years looking for a clue to a better means of cancer treatment and he found one.

In 1881 there had been a young man with cancer of the head and neck who had had surgery for the forth time with much tumor not removed. Shortly after the surgery, the patient was by accident infected with erysipelas in the wound and face. He suffered the high fever of erysipelas and recovered from it and with the recovery from erysipelas there was also a complete regression from cancer. Dr. Coley found this patient ten years later still free from cancer.

There was a surgeon in New York City then of renown by the name of Bull. Dr. Bull was able to find ten cancer patients who were beyond hope. Dr. Coley tried to infect them all with erysipelas. With seven of them, he could not cause an infection. Three of these patients were infected and two of them died rather quickly, perhaps from the erysipelas. However one of them had a dramatic and long lasting remission from cancer.

Dr. Coley then had made by a friendly doctor a killed vaccine of the streptococcus of erysipelas and the newly discovered bacterium Serratia marcescens. This latter bacterium was thought to be non-pathogenic in humans. This vaccine was cultured in beef broth and contained the endotoxins produced by the two bacteria and the dead bacteria. This was and is Coley's Toxins.

Dr. Coley began treating far advanced and hopeless cancer patients with his new vaccine and in the majority of cases he was seeing wonderous long lasting regressions of cancer.

In 1897 he became a surgeon at Memorial Hospital, now Memorial Sloan-Kettering Cancer Center. He remaind as a surgeon until shortly before his death in 1936. Had he been motivated by greed to form a drug firm to make and sell Coley's Toxins, the acceptance of Coley's Toxins by the medical establishment may have been better, however over the next 40 years, Coley's Toxins was used by many doctors in the USA, Canada, the UK and Belgium. It was almost never used except to treat cancer patients who were so far advanced that the decision was that the patient was about to die so why not try Coley's Toxins.

There were two hallmarks of treatment with Coley's Toxins. One was the fast relief from pain and the other was the life time cures that it produced where patients lived to old age to die of a cause other than cancer.
be back to normal with a normal temperature.

Early on before anything was known about dosage, there were three cases of death from overdosing and then with an understanding of a proper dosage established, there were over 3,000 cancer patients treated with it with no problems.

In general the higher fever produced up to 105 F, the faster the regression of cancer.

Dr Coley had as a friend Professor Buxton at Cornell University who from 1893 until 1906 made a fine potent Coley's Toxins for Dr. Coley's and others to use. From 1906 until her retirement in about 1923, Dr. Martha Tracy, pathologist at Memorial Hospital made a fine potent vaccine. One thing that did harm to Coley's Toxins was that for over fifty years the Parke Davis and Company made and sold a weak and sometimes worthless vaccine.

THREE CASES OF HOPELESS CANCER TREATED WITH COLEY'S TOXINS

Three of these cases were of non-fatal overdosing with Coley's Toxins. They will be given here to give one a concept of its anti-cancer effect.

The first case was in Costa Rica in 1901. The patient was a young woman with rapidly growing cancer of the nasopharynx. She was being treated with increasing doses of the Parke Davis vaccine with no reaction and no benefit. Some very potent Buxton vaccine was had and in desperation, a very big injection of it was done. Clearly it was a great overdose.

The injection was done at 11:AM on May 8, 1901. All tumors at once took on a high purple hue. Fever rose to 105 and the pulse could not be detected. Necrotic material formed and had to be removed with forceps to prevent asphyxia. Eight injections were given of digitalis and caffeine as a stimulant. After 12 hours, the fever subsided and the pulse returned to normal. Then at 3:00 AM the following morning, the swelling in her face was gone and her tumors had reduced in size by half.

By 72 hours after the injection, one tumor the size of an orange was gone and another large tumor was reduced to the size of a small nut.

The next case was in 1912. Again the patient was a young woman of 26 living in Kentville, Nova Scotia. She had renal cell carcinoma with extensive metastases in the peritoneum. She was taken to a hospital in Halifax forty miles away where exploratory surgery was done. The surgeon felt that she was utterly hopeless and he did not think that she would survive
suffering. This big overdose had the effect of causing vast improvement in the patient. The patient then had 18 IM injections in the buttocks and six weeks later was free from all signs of cancer. She was traced forty years later still free from cancer.

The third case may be the most dramatic case of the history of Coley's Toxins. The place was New York City and the patient was an officer on a merchant ship. The time was 1926. The cancer was recticum cell sarcoma of the tibia. Amputation was done. Three months later there was a metastasis above the umbilicus. One month later there was a fist size tumor on the amputated stump. One month later, there was another lemon size tumor on the stump and the entire stump was increasing in size.

By this time in 1926, the only vaccine to be had was the weak Parke Davis vaccine. Very big doses of the Parke Davis vaccine were injected into the patient's stump and the reactions were severe. There were signs of regression but the patient asked for a respite. During the time of the respite his tumors grew at an astounding rate. There were now several tumors under the skin of the abdomen and in many other parts of the body, in the scalp, cranial bones, and vertebrae. The stump enlarged to 31 inches in circumference and the end of the stump had broken down into an ulcerated mass from which there was a foul smelling discharge.

Injections were begun into the stump and caution was thrown to the wind. Doses of over ten times normal were used. The reactions were severe with the patient saying he was being greatly beat up. The injections were done every day. After 28 daily injections, the stump had returned to its proper size and was completely healed. All the other metastases had either vanished or had become greatly reduced in size. Treatment was stopped at this time and sixty days later he showed no sign of cancer. This patient died of a heart attack in 1959.

RECENT HISTORY OF COLEY'S TOXINS

The American Cancer Society was formed in 1925 and has been an implacable enemy of Coley's Toxins and had it on its list of unproven remedies until about 1973. In 1972 Dr. Lloyd Old, then Director of Research at Memorial Sloan-Kettering Cancer Center, while looking into the anti-cancer effect of Coley's Toxins discovered tumor necrosis factor and that in the reaction to Coley's Toxins the body produces both interferon and tumor necrosis factor. Thereafter the American Cancer Society removed Coley's Toxins from its list of unproven remedies but in so doing they never told anyone that they had done so. As a result many older doctors today still are of
Dr. Coley's daughter, Helen Coley Nauts, founded Cancer Research Institute in 1953 and it has grown large and prestigious but she has been unable to overcome the opposition of the American Cancer Society to get Coley's Toxins into widespread use again. Circa 1955 Coley's Toxins were made at Memorial Sloan-Kettering Cancer Center and there was some use of it in parts of the nation in treating cancer. At that time in 1961 one of the most remarkable cases in the history of Coley's Toxins was recorded. The patient was a retired contractor with colon cancer. The place was the Baptist Memorial Hospital in Oklahoma City. The time was February, 1961. He had had surgery followed by a massive recurrence of cancer. He had an enlarged liver, with many metastases in the abdomen with ascites. His family physician had been tapping the abdomen daily obtaining four to eight quarts of bloody fluid. Bloody pleural fluid was aspirated from the lungs every second day about a quart each time. Malignant cells were found in the fluid removed from both the abdomen and the lungs. At this time, the expected survival was less than a week.

On Feb. 22, 1961, intradermal injections of Coley's Toxins were begun and they were given daily for eight days. At the sites of the injections, there was an extensive inflammatory reaction and pain. There was aching and shaking chills with a fever of 102 about three hours after each injection. The plural effusion diminished within 24 hour after the first injection and after the third day there were no further ascites. In all there were eight injections of Coley's Toxins. The patient began to live a normal life and to regain lost weight (30 lbs). He returned home on March 10, and there was every indication of a complete regression of cancer. He was followed and was alive and well in 1970 eleven years later.

Meanwhile the American Cancer Society had been pushing hard for the passage of the Kefauver-Harris Amendment to the Pure Food and Drug Act. It was passed in June of 1962. It had a grandfather clause under which aspirin was made legal. The American Cancer Society saw to it that Coley's Toxins was not grandfathered under this new law. The FDA declared it to be a "New Drug" subject to all the expensive testing associated with getting approval of a new drug. There is no possibility of anyone getting a patent on Coley's Toxins and drug firms show no interest in spending any money on a drug or vaccine on which a patent cannot be obtained.

At the time of the passage of this amendment, there were several cancer patients being treated with Coley's Toxins and showing partial remissions. They were cut off from more treatment and that was the end of treating cancer patients with Coley's Toxins in the USA in a legal way.
Aug. 20, 1994

Editor: This is the story of urea in treating liver cancer revisited. You should take some satisfaction in that your fine pulication has been responsible for the restoration to good health of many patients with liver cancer due to your prior publication on this subject.

I think that I may now be averaging about three phone calls a week from liver cancer patients or relatives of them. For a long time I would get such a call and rush around getting a packet in the mail and then never hear anything back. Now I am telling callers that they are putting me to some trouble and that in return for my effort, I want to hear something back. I am hearing back. In two recent cases the report was that the patient's doctor had persuaded the patients not to take urea and they had been put on a chemotherapeutic pump. Both of these patients died rather quickly.

At the same time I have heard two success stories. Before I tell of them I wish to mention the anticancer effect of urea as stated by Dr. Bernard Ecanow et al of the University of Illinois Medical Center in Chicago (Clinical Oncology 1977. 3, 319-20). Urea breaks the hydrophobic bond that holds a solid malignant tumor together. Break the hydrophobic bond and the tumor falls apart. Then cancer cells cannot feed themselves from the vascular network formed by the tumor by the process of angiogenesis and they starve. Also most such tumors coat themselves with a protective coating of fibrin. As the colony falls apart, cancer cells are exposed to the attack of our cancer cell killing immunocytes.

So I have just had a phone call from a man in Pennsylvania who called me about a month ago. He has a liver metastasis and his doctor had given him a very bad prognosis. The symptoms of liver cancer are swelling in the area of the liver, pain and often nausea. It is the teaching of my old and dear friend the late Professor Evangelos Danopoulos of Athens, Greece that if the liver is not more than 30% involved in cancer, then oral urea is always effective. This man had considerable swelling but no pain or nausea. He tells me that he will write me a letter to go with this letter. He reports that within a week on taking urea, most of the swelling in the area of the liver was gone. He reports that it is now all gone. He is taking the combination of urea and creatine hydrate.

The first report in English by Professor Danopoulos on treating liver cancer, primary or metastasis with urea was in The Lancet in the Jan. 26, 1974 issue. About 6 years ago he added creatine hydrate to urea as a cancer treatment. Oral urea goes to the liver via the portal vein where the concentration is high enough to have a marked anticancer effect in the liver. By the time urea leaves the liver and
reaches other parts of the body, it no longer has an anticancer effect. Professor Danopoulos added creatine hydrate to urea for the treatment of cancer in other parts of the body. He had some success in so doing, in one case, pancreatic cancer. This patient in Pennsylvania is taking the combination of urea and creatine hydrate.

Now I will tell of another recent report. This is a woman breast cancer patient in Eastern Pennsylvania. She had several course of chemotherapy followed by three courses of the "new low cost" toxol, $4,500.00 per course). While this treatment was going on, she developed a liver metastasis with both pain and swelling. She was on oral urea for 8 days and reported that the swelling had subsided as had the pain. Her hemoglobin is 8.8 and she suffers from fatigue, but the threat of a quick death from the liver metastasis now seems more remote.

There is a doctor in the New York City area doing alternate cancer treatment. Two women in his office know that his treatment is not effective in treating liver cancer. For a long time they told many patients sub rosa to call me to learn about urea. Then in time they just told the patients to take urea. They saw this dramatic and quick resolution of the symptoms of liver cancer but they also took note that in two or three years, the patients died of metastases to other parts of the body. It would seem that if these patients had taken the combination of urea and creatine hydrate, they might not have the formation of metastases in other parts of the body.

Doctors fight urea for liver cancer tooth and nail. In Australia the orthodox medical establishment is even more truculent than what we have in the USA. I heard from a man in Hobart, Tasmania. The TLFDS gets around. The son was able to get a supply of urea from his high school chemistry teacher but urea was not permitted in the hospital where the patient was. The patient died with no treatment.

I will tell two more stories. One has to do with a Chinese patient in Singapore. In the summer of 1985 he had surgery for colon cancer. At the time of the surgery the surgeons could see a large liver metastasis. The patient was given a very bad prognosis. He called me by phone and I arranged for an air shipment of urea. He did fine on it and six months later, in the best of health he went back to the surgeons to show them how well he was doing and to tell them about urea for liver cancer. The result was that they flew into a rage. They went to customs in Singapore and got customs to ban shipments of urea from the USA.

I found that Mallinkrodt Chemical has an office and a warehouse in Singapore so he was able to get his urea in downtown Singapore. Last year he sent me one pound of green tea with a note that a CAT scan now shows fibrous tissue
where once his liver metastasis had been. He is no longer taking urea.

He told the story of another liver cancer patient in Singapore. This was a very poor Chinese woman with stomach cancer with a liver metastasis. They do not have the equivalent of our Medicaid in Singapore. This poor woman was being offered no medical treatment. Her liver cancer had her swollen as large as a full term pregnancy. My friend gave her a pound of his urea. On taking it, her swelling subsided in 10 days time and the pain even more quickly. In time she died of the stomach cancer.

I have a doctor friend in a VA hospital. He had a patient with colon cancer with a liver metastasis who was swollen, had pain and nausea. Another doctor there had given a prognosis of death within a few weeks. Before using anything such as urea in treating liver cancer, my friend felt that he should check with the Head there. The Head said in noway would any patient be treated with urea in his hospital. The patient was living at home so my doctor friend wrote out a prescription for urea 15 grams a day and told the wife to take it to any drug store. The druggist called I think Mallinkrodt Chemical Co. and got something like 50 Lbs of urea for about $6.00 a pound via over night air.

The patient took urea daily and quickly all the symptoms of liver cancer vanished. Six months later my friend thought to make a point about urea in treating liver cancer so he brought the patient back in a fine state of health. The Head said to do a liver scan again and the tumor was still there. It often happens that urea will convert a liver metastasis into a kind of non invasive tumor that will permit the patient to live a normal life. In this case the patients needs to keep on taking urea. In this case the Head said that obviously urea had done this patient no good and henceforth my doctor friend was to never again tell a liver cancer patient, in or out of the hospital to take urea. Thereafter my friend told liver cancer patients to call me.

I have one more story of this kind. A retired New York City fireman living in New Jersey called me. His mother had had surgery for breast cancer some nine years before. She had all the symptoms of liver cancer, swelling, pain and nausea. Her doctor had scheduled her to come to the hospital two weeks hence for a needle biopsy. I wonder now what he would have done after the needle biopsy. Her son called me and then ordered in an over night air shipment of urea. He called me one week later asking if urea could be effective in five days time. I told him that it was indeed possible. His mother presented for her biopsy one week later with no symptoms of liver cancer whatever. Her doctor said that he must have been mistaken and did not do a biopsy. He was never told that the patient was taking urea.
The dose of urea is 15 grams a day. The urea is put into a quart of water or fruit juice. The quart is divided into seven portions and one portion drunk every hour and a half during the waking day. Urea acts to cause the loss of potassium. One should eat a banana a day to replace potassium. Dr. Hans Nieper in Germany visits friends at the rocket center in Huntsville, AL. One day he called me from Huntsville telling me how much he liked urea for liver cancer but he said that 15 grams was not the proper dose. He said that the dose should be 17 grams.

The dose of urea and creatine hydrate is 15 grams of urea and 25 grams of creatine hydrate. Both are put in a quart of water. Urea is water soluble. Creatine is not. Put the quart in a half gallon container. Every hour and a half, give the quart a good shake and pour out one seventh of a quart and drink it. In taking this combination for cancer in a part of the body other than the liver, the patient should have his blood urea nitrogen (BUN) checked every 10 days. It is desired that BUN be kept in a range of 35 to 40. It is often the case that on taking this combination, BUN will be about 18. If this is the case, the dose of urea is increased to 20 grams a day. The dose of creatine hydrate never changes. It remains at 25 grams a day. There have been cases where the urea dose must be as high as 30 grams a day to keep BUN in the range of 35 to 40. If BUN gets over 40 then the urea dose is reduced.

In closing I want to tell of one remarkable case that Professor Danopoulos tells of and reported in Clinical Oncology 1983, 9, 89-94. This patient was a 66 year old man. The date was Sept. 1980. The patient had a large mass of tumor in the rectum. He had a permanent urethral catheter in place. On Sept 15, 1980 a computed tomography was done showing large masses of tumor in the pelvis minor and the iliac and para-aortic lymphnodes. The rectum was completely blocked. There was also a metastasis in the liver. A colostomy was done and no further treatment as the patient was considered to be hopeless. He had lost 16 kg of weight and his liver was swollen. On Oct. 18, 1980 he was started on oral urea 15 grams a day divided into 6 doses and he had 20 ml. of 15 % urea introduced into his colostomy tube by means of a urethral Nelaton catheter six times a day.

By Dec. 24 the liver was no longer swollen, the patient was eating well and had regained 13 Kg of weight and he no longer needed an urethral catheter. On Feb. 10 of 1981, some of the infused urea began to leak from an opening in the anus which had been completely obstructed. By March 1981 he was able to pass stools through the anus. On Oct 22, 1981, 13 months after his first presentation, a second computed tomography showed no tumor anywhere. The tumor mass in both liver and rectum was gone. On Jan. 28, 1982 a barium enema showed no sign of tumor. In June of 1982 a rectosigmoidectomy was done and there was no sign of tumor.
The patient was in good health and had gained back all lost weight.

At that time it was suggested that the colostomy be reversed.

The cost of urea alone is about $10.00 a month. The cost of the combination of urea and creatine hydrate is about $100.00 a month.

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Phone and FAX 205-928-0150
Urea for Liver Cancer Only
15 grams of urea per pint of water or fruit juice
Divide into 7 portions. Take 1 every 1-1/2 hours throughout waking day
Sometime must take for life
Letter from Wayne Martin about Coley's Toxins

Editor:

I hope to persuade you to run Helen Nauts' Coley's Toxins - The First Century, written in 1993, one hundred years after Dr. Coley had cured his first hopeless cancer patient with Coley Toxins in 1893. Helen Nauts was Coley's daughter. She founded Cancer Research Institute in 1953.

In 1934 a prominent cancer surgeon from Massachusetts General Hospital, Ernest Codman had for over 20 years been a detractor of Coley Toxins and Coley. In 1934, two years before Coley's death, he did an about-face and had words of praise for Coley and for Coley's Toxins, saying there had been occasional miracles but not infrequent miracles in treating cancer with Coley's Toxins. Coley had many supporters - among them the Mayo brothers - but his detractors were legion including his superior at Memorial Hospital, now Memorial Sloan-Kettering Hospital, Dr. James Ewing.

Read The First Century and you will get the idea that when Coley's Toxins was used over a period of several months producing a fever of 103° to 104°, the cure rate in solid malignant tumors was close to 50%.

Had Coley's Toxins been accepted and used as a standard practice in treating cancer, there might have been a few million cancer patients who died of cancer over the past century who would have gotten well and lived to old age. The American Cancer Society was formed in 1913 and became an enemy of Coley's Toxins.

Coley's Toxins done by intravenous infusion is by far more effective in producing strong fever reactions and Coley knew this to be the case but there was the idea that nothing should be put in the vein. Also there was the fear that an overdose could cause death. Now a rectal suppository of Tylenol can turn off a reaction if it gets too severe.

By combining the precaution of having Tylenol on hand while doing intravenous infusions of Coley's Toxins, it should be possible to get better results in treating cancer than Coley and others had.

If the patient has a vein port put in, treatment with Coley's Toxins can be done at home as self-medication, making possible vast reductions in the cost of treatment.

In 1995 I went to Guatemala and found a bacteriologist and gave him $800 to make 2,000cc of Coley's Toxins. About six months ago I was able to get 600cc of that vaccine and I gave it to my friend, Glen Wilcoxson, MD.

Meanwhile, I found a doctor in Guatemala who owned a small hospital. For $1,000 he would put patients up in his hospital for 30 days and give them 20 IVs of Coley's Toxins. A woman from near Pittsburgh had called me by phone. She had ovarian cancer with a CA 125 of 6,200. She was badly swollen and in great distress. I do not know how she made the trip. On getting 20 IVs of Coley's Toxins over a 30-day period, the swelling was gone and her CA 125 was reduced to 2,100. She felt much better.

At about that time someone told the Minister of Health that the American Cancer Society had Coley's Toxins listed as a quack cancer treatment and treatment of cancer with Coley's Toxins was banned from use in Guatemala.

At the same time, the late Dr. Don Carrow, following my instructions, made a lot of Coley's Toxins. He had a 50-year-old nurse who had non-Hodgkin's lymphoma with a tumor the size of a football under one arm. Dr. Carrow injected his Coley's Toxins into the center of the big tumor. It shrank down to a flabby bag and was excised. That was eight years ago and last year the patient was alive and free from cancer. Dr. Carrow then had problems with the State Board.

Dr. Wilcoxson last year had a patient with a tumor the size of a chicken egg on his neck thought to be a metastasis from a primary in a tonsil. He did IVs and the tumor injections. That tumor is gone now.

Dr. Wilcoxson has a new cancer patient now. The patient is a young man from Tennessee. He has osteogenic sarcoma. He suffered amputation and has two lung metastases. Chemotherapy did no good. He was in Dr. Wilcoxson's office for one day only. He was very sick. He had his first IV of Coley's Toxins. He and a nurse returned home and for 30 days the nurse has been doing IVs of Coley's Toxins every second day. He is getting reactions of 104° F which is very good. After 30 days he is feeling better, is eating better and has gained 4 lbs of weight.

Meanwhile, Richard Masion, MD of Powell, Ohio had made contact with me and had made his first lot of Coley's Toxins and tested it on himself. He is going to give it to Dr. Wilcoxson for use on his sarcoma patient.

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Coley's Toxins – The First Century

by Helen Coley Nauts, DSc
Director, Science and Medical Communications
Cancer Research Institute, Inc.

In January, 1893 W. B. Coley, a young New York surgeon treated his first case of cancer with the mixed bacterial toxins of Streptococcus pyogenes and Bacillus prodigious (now known as Serratia marcescens). This bedridden male, aged 19 had an inoperable sarcoma of the abdominal wall and pelvis (16x13 cm.) involving the bladder with incontinence. Only biopsy had been performed. Injections in or near the tumor caused reactions up to 40°C or more, and complete regression occurred in four months. He remained well until death from a heart attack 2 years later.1

Back in 1939, when we began our analysis of Coley's method the following questions needed to be answered: was there sufficient clinical and experimental evidence to justify the conclusion that the method had therapeutic value? If so, what factors governed success or failure? Why did the method not achieve wider recognition? If the conclusions to these questions warranted further study we asked ourselves what can be done to make the Coley's toxins consistently effective in most types of neoplastic disease.2

Factors that seemed vital to success or failure

1. Variability of preparations used

No comprehensive textbook on the method had been published by Coley, although he was working on one at the time of his death in 1936. He made every effort to obtain unequivocal diagnoses by eminent pathologists from the beginning. However he did not recognize the great importance of obtaining potent, stable preparations of the mixed toxins to avoid variability from different formulae or from one batch to another.2,12 Coley had no bacteriological tests at all and relied on other preparations.

The first decision brought out by our long-term study was that at least 13 different preparations had been used during the first five years, (1892-1936), of which at least are considerably more potent than the old Buxton VI, Trax and Buxton XVI. Unfortunately the first two commercial preparations (Parke, Davis & Co.) IX and XII were very weak and the English preparation (Lister Institute VIII) was even weaker, so very few English surgeons achieved success.1,2 These weaker preparations did not produce adequate febrile reactions.3 (Figure 1)

In 1902 a patient with recurrent inoperable lymphoma of the pectoral region and axilla reported to Coley that it took 8 minims of the Park Davis IX to give the same febrile reaction as 1/4 minims of the Buxton VI.6 Despite such a cut-case, Coley does not seem to have attempted to remedy the situation.

Coley seemed to be unaware of this problem until 1911 when he gave a clinical lecture at Guy's Hospital in London and he discussed it briefly in his response to the vote of thanks, ending with the remark “success depends on the preparation…”

Finally in May 1915, Tuholske of St. Louis wrote him about a case of extensive sarcoma of the pharynx and nasopharynx with almost complete obstruction – a tracheotomy was imminent.1,5 Even massive doses of Parke Davis XII had had no effect at all. Coley then sent him the Trac XI (see below for details relating to technique). This case made him contact Parke Davis and get them to work more closely with Tracy and so Type XIII was made considerably more potent than XII.1,2

2. Technique of administration

Although Coley published 143 papers or monographs on his method between 1893 and 1936,8 they did not give sufficient detail on how to administer the toxins, i.e. site, dosage, frequency and duration, and the optimum febrile reaction to aim for. The Tuholske case illustrates the importance of these factors. First, the danger of stopping the injections too soon, even if complete regression has occurred. Although complete regression occurred in six weeks, the disease recurred on the opposite side in about three months with evidence of brain metastases. Second, the injections for the recurrence were given subcutaneously or intramuscularly in the deltoid or scapular regions with very poor absorption. Not until given in the abdominal wall did good febrile reactions occur, and the recurrence disappeared, but the symptoms of brain metastases persisted. The patient went into coma for 3-1/2 weeks. No further injections were given. With supportive treatment he regained consciousness and made a complete recovery. He remained well until death from coronary occlusion 33 years later.3

a. Duration

Coley himself did not recognize the extreme importance of duration of treatment, especially in the inoperable cases, until 1926 when Christian and Palmer succeeded in curing a reticulum cell sarcoma of the tibia recurrent in the stump after amputation with extensive metastases near the umbilicus and in the left inguinal region. In discussing this case in 1927 Coley stated “I am quite willing to admit that, had the patient been under my care, I would probably have not been alive today. … I am almost certain that I should not have continued the treatment after three months when not only had no improvement been noticed, but marked increase had taken place in the metastatic tumors and especially in the recurrent tumor of the stump (from 17-31 inches). In the second place I am quite sure that I should not have dared to increase the dose to such a large amount (2 cc). However, it was not until these large doses were given that the improvement continued until all the tumors had disappeared. … I feel that many of the past failures might have resulted otherwise had larger doses and more frequent injections been given.”

Our end result studies beginning in 1946 have shown that, if the injections were given for six months, 80% of inoperable sarcoma of soft tissues survived 5-8 years.3

In osteogenic sarcoma when the Coley's toxins were given as an adjuvant to surgery for at least three months, 85% survived and were traced up to 59 years later. Three other cases so treated died 4-13 years later of late recurrence or metastases, i.e. prolonged survival. If given for less than three months 36-43% survived. This was considerably better than the 10-15% survival from amputation alone in that period.4

b. Type of febrile reaction

Coley also did not sufficiently appreciate the benefit of producing febrile reactions averaging 39°-40°C
Coley's Toxins

(102°-104°F) from the beginning of treatment. This did not occur if they used small doses intramuscularly or subcutaneously remote from the tumor, or when the very weak products were used. This factor was more important in treating inoperable cases. For example, in the soft tissue sarcoma 60% of the inoperable cases, whose reactions averaged 102°-104°F with chills, were traced well 5 to 88 years, as compared to only 25% of those having reactions below 102°F and no chills.3

c. Site and dosage injection

The type of reaction elicited depended on two things. The site of injection and the dosage. Injections given intramuscularly or subcutaneously remote from the tumor, required much larger doses to elicit a reaction of 101°F or more than did an injection into the tumor or in a vascular tissue or intravenously. In the early years Coley used intratumoral injections into different parts of the tumors. These elicited not only fever but tumor necrosis factor and an inflammatory reaction – all of which were more effective in causing destruction of the tumor thus imitating an erysipelas infection. (The most dramatic “spontaneous” regressions of cancer occurred during and following acute erysipelas injections which produce a more intensive inflammatory reaction than any other infection).

We found only one case treated by Senecal with intraperitoneal injections – a huge ovarian carcinoma with widespread metastases in the peritoneum and ascites. Very dramatic regression occurred in four weeks. The case became operable and recovered. She remained well for 27 years.1

Intravenous injections were not used by Coley until about 1925 and usually some intramuscular injections were given first. Very much smaller doses were needed, and these caused no inflammatory reactions. They were well-tolerated.

Fowler in 1898 recognized the importance of site of injection. When given subcutaneously the intensity of the general reaction varied with the dosage. With subcutaneous injections a larger dose was required to produce the desired reaction, whereas a few drops were sufficient for the intravenous route. “The vascularity of the tumors explains the ease with which a reaction can be produced by Coley's method of interstitial injections, the latter being quite analogous, if not identical with the intravenous method.”9

X-ray and radium were discovered in 1895, only a year after Coley read his first important paper before the American Surgical Association.4 Coley was one of the very first surgeons in New York to use the x-ray in his practice, and in 1901 he persuaded Memorial Hospital to allow him to procure an X-ray machine there, paid for by one of his wealthy patients. He read his first report on the work before the American Surgical Association in June 1901.11 The growing enthusiasm of the profession and of patients for both X-ray and radium quickly overshadowed Coley's method before it had been properly standardized or its mode of action understood. Coley then became anxious to prove that the toxins had a systemic rather than local action such as X-ray, radium and surgery, so he stopped using intratumoral injections in 1906, and not until a year or two before he died did he come to realize the mistake he had made.

d. Frequency of injections

In the early years Coley and other surgeons gave injections daily or every other day at first, which appeared to be more effective than less frequent injections, especially when treating inoperable cases. One surgeon who routinely used the Coley's toxins in both his operable and inoperable cases, Calkins of Watertown, New York, gave the injections daily for about six months, then twice weekly with occasional intervals of rest for another six months.12 Injections were given as an outpatient after the first two weeks. Calkins achieved 80% five-year survival in using this technique over a 32 year period. Matagle also often gave injections daily (see below).

Many surgeons, such as the Mayo brothers, did not wish to get involved in such long term therapy, so they advised the family physician who had referred the case to the Mayo Clinic to administer the injections after the patient returned home. As a result, a considerable number of Mayo clinic cases were successfully treated.

3. Stage of the disease

In treating operable cases as an adjuvant to surgery very few surgeons began the treatment prior to surgery. This is unfortunate because preliminary toxin therapy, even for only a brief course, can counteract the immunosuppressive effects of anesthesia and surgery, due to stimulation of cytokines such as interferon, interleukins, tumor necrosis factor and others. In cases of amputation, it counteracts the psychic stress of losing a limb, which is also immunosuppressive.

The first physician to recognize that operable cases might benefit was Matagne of Bruxelles, Belgium. He first began using the Coley's toxins in inoperable cancers, having observed a dramatic case cured by contracting an erysipelas infection in 1891 reported by Bidot.7 In 1896 he gave a rather brief incomplete description of his inoperable cases and was soon criticized by a commission charged with examining it.14 This did not deter him from continuing his clinical studies and over the next 57 years he published 12 more papers interrupted by two world wars.

In 1902 he reported on the use of Coley's toxins in operable cases as a means of preventing recurrence, the first physician to do so anywhere.14-16 In 1905 he presented a series of these operable cancers in which he had administered the toxins before operation, usually for four or five weeks, in some cases for three months.17

One extensive recurrent inoperable malignant melanoma of the upper arm in the region of the humeral artery with metastases in the axilla, received injections in the recurrent tumor for seven months in 1902 with rapid but incomplete regression of the recurrent mass, but the axillary metastases did not regress. Shoulder joint disarticulation was then performed. There was no further recurrence and the patient was traced well over 41 years after onset.15-17

Matagne prepared his own Coley's toxins using the effective Buxton VI formula.17 He gave injections daily into the tumor beginning with a dose of 5 cc, gradually increasing by 2.5 cc, each day or every other day until a feeble reaction of 39°-39.5°C, or 40°C was elicited. The reaction usually consisted of a violent chill which began 30 minutes after injection and lasted 30 minutes. Dosage was increased to 10 cc in some cases, in others to 30, 40 or even 50 cc.

The first surgeon to save a limb by using Coley's toxins following surgery was Owens in 1894 in a highly vascular giant cell tumor of the proximal tibia following curettage. This was the first case of giant cell tumor in which the limb was saved.19 In two-thirds of the giant cell tumor cases involving long bones, the limb was saved by the use of curettage and toxin therapy combined, in some cases, with radiation. The remarkable regeneration of bone destroyed by the tumor following toxin therapy was
especially evident in Series A, cases 8, 11, 13, 36 and 40.

Coley himself began using his toxins in operable cases as early as 1895. The first published case was an osteogenic sarcoma of the femur. The patient remained free from recurrence or metastases for 13 years. Other American surgeons soon followed, including Oscher in 1915 and Calkins in 1917, for breast carcinoma and sarcoma and Meyering of the Mayo Clinic for osteogenic sarcoma and Ewing's sarcoma of bone.

4. Early criticism: limiting types of tumors treated

Between 1891 and 1896 Coley published 16 papers describing his method. Editorials began to appear in 1894 with the first negative report entitled "Failure of the Erysipelae Toxins." In 1896 Abee, the President of the New York Surgical Society, suggested that the method be tried in different hospitals, a fair proposal, but no enthusiasm was shown. It is a great pity that such a plan was not carried out, but it is not surprising that a group of surgeons were reluctant to pursue a medical approach to the treatment of cancer.

On October 16, 1896 Coley read a paper before the New York State Medical Association entitled: "The indications for the non-operative treatment of tumors: The value of toxins." This was published in reprint form in 1896. Undoubtedly this report caused more concern among surgeons and a few more negative reports appeared.

Editorials appeared mostly unfavorable, and Coley responded objectively. On December 29, 1894 he wrote: "That a few physicians in a very limited number of cases with indolent preparations of the toxins have failed to obtain good results will not...have great weight in the minds of the scientific portion of the profession in determining failure or success of this method of treatment of sarcoma.

In 1915 Harmer of Boston published a rather comprehensive report on 134 microscopically proven cases treated by Coley's toxins. He concluded that they are of value in certain cases of inoperable sarcoma. He noted that in a small number of cases they produced striking relief of pain. However, his conclusions were rather negative.

In June 1914 his report included two unusual cases, one a recurrent extensive giant cell tumor of the spine who recovered completely under toxins alone and remained well, until death in 1977 from lung cancer, 65 years after onset.

The other was a recurrent malignant melanoma with metastases who under prolonged toxin therapy had complete regression of all the lesions. He then went on a spree for 19 days returning haggard and weak - the disease reactivated and killed him over three years after onset.

Coley's many surgical friends in England and in the United States urged him to limit his use of the toxins to sarcomas since the early experiences with his weaker preparations in advanced carcinomas or melanomas had not proved successful. However, other surgeons had successfully treated metastatic cervical carcinoma, extensive metastatic breast carcinoma, giant cell tumor of vertebrae, recurrent malignant melanoma, ovary, metastatic.

These reports encouraged Coley to use his method on many other neoplasms, testicular cancer, breast

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**Coley's Toxins**

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Coley’s Toxins

...cancer,23 lymphoma and Hodgkin’s disease,24,25 malignant melanoma,26 multiple myeloma,28 Ewing’s sarcoma,29 neuroblastoma,30 colon cancer,31 and renal cancer,32 with a great many remarkable results.33

5. Animal experiments
In 1907 Beebe and Tracy published the results of their studies in which they stated; “The striking results attained [by Coley] in an increasing number of cases have diverted the attention to the possible significance of the Bacillus prodigiosus in the preparation. ...It seemed important to study with some care the effect of inoculation, not only with the Bacillus prodigiosus [now known as Serratia marcescens] but with other bacterial toxins as well with the hope of determining the rationale of this method of treatment, and if possible of placing it on a more scientific basis.” They used B. prodigiosus, Streptococcus pyogenes, Staphylococcus aureus and Bacillus communis (now known as Escherichia coli), also the mixture known as Coley’s toxins. They treated lymphosarcoma grown in dogs transplanted from a spontaneous tumor, with these preparations.

They reported that B. prodigiosus alone and Streptococcus pyogenes alone as well as the mixture of these two (the Coley’s toxins), caused regression of this tumor in the dogs. Staphylococcus aureus given into the tumors caused fever to 105.9°C, but no real regression. One dog received E. coli causing steady regression: all tumors disappeared in five weeks. They used different sites of injection. The intratumoral injections caused much more rapid regression.34

In conclusion they stated that, “though the action is chiefly local, it is at the same time something more than this for it was repeatedly observed that tumors at a distance from the site of injection undergo regression simultaneously while in one dog all the injections were given remote from the tumor.” This paper deserves study.34

6. Radiation and toxin therapy
X-ray and radium therapy, having been introduced and embraced by Coley and other surgeons, were used without any knowledge of how radiation might affect the patient’s ability to respond to toxin therapy, or if there might be an optimum timing for giving these two modalities since no one knew how the toxins exerted their beneficial effects. This was a serious problem. We now know that if toxins were given prior to radiation they potentiated the response of the tumor to the X-ray or radium while protecting the normal tissues from radiation damage (see below).

Ewing became medical director of Memorial Hospital about 1915 and he was an ardent advocate of radium, a large supply of which had been given to the hospital by Dr. Douglas. Ewing had no interest in Coley’s method.

At that time Coley had been appointed chief of the Bone Tumor Service. Ewing insisted that every single ward case should receive radium or X-ray prior to amputation. Despite the fact that Coley believed this to be a dangerous protocol, he had to comply. In 1927 Coley published the end results on 169 cases.35 Not a single patient so treated had survived, while in his private patients to whom he gave the toxins following surgery, 50% had survived. If injections were given for three or more months to these osteogenic sarcomas, 85% survived four-40 years later.36 The Mayo Clinic also achieved 50% five year survival in their toxin-treated cases, while other surgeons here and abroad were curing only 10-15% with amputation alone.

Matagne, as well as Coley, became interested in utilizing radiation in his practice and he acquired some radium at considerable expense which he used especially in epitheliomas. Like many other surgeons he felt constrained to use it to justify the expense incurred. This meant he treated fewer patients with the toxins thereafter.

One of the first cases Coley treated with X-ray therapy was an inoperable lymphosarcoma of the cervical, axillary and mediastinal nodes, with dyspnea and edema of the lower extremities. Marked regression and increased mobility had occurred following toxin therapy alone, but then control was lost and the patient became bedridden, with severe dyspnea. X-ray was then given 4 to 6 times weekly in 1902 causing remarkable regression in three weeks, complete disappearance in six months. No further toxins were given after radiation was begun. The disease then reactivated with hundreds of pea to egg-sized nodules over the entire body. Death occurred in June 1904, 5-1/2 years after onset. Coley believed the radiation had lowered the resistance of this patient to her tumor.

In contrast to this case is the following where too much radiation was not given. An eight year-old boy had had amputation for a fungating Ewing’s sarcoma of the fibula with metastases to the inguinal and iliac lymph nodes. (It was later regarded as a reticulum cell sarcoma). Toxins (Tracy XI) were begun immediately after amputation and given two months with marked reactions. Soon after the injections were stopped a 15 cm mass in the iliac fossa and lung metastases developed. All disappeared after one radium pack to the groin.10 The child remained well and free from disease until death from an emergency appendectomy 15 years later.37 This case suggests that the preliminary two month course of toxins may have potentiated the response of the tumor to the radiation.

Unfortunately such cases did not seem to make Coley recognize the value of beginning the toxin injections prior to radiation, or of giving them for a longer period, especially when metastases were present.

7. Radiation protection
About 1958 a number of investigators began reporting on the protective effect of bacterial endotoxins against radiation injury.38 This occurred if injections were given prior to the radiation, optimally 24 hours before.

Thomson (1962) reported that “bacterial endotoxins prepared from Salmonella typhosa, Escherichia coli, Serratia marcescens and Proteus mirabilis all promoted hematopoietic recovery when given before or after whole body radiation. Post-radiation infection is appreciably reduced, hematopoietic tissues regenerate and survival in enhanced.”

Ainsworth, of the Cellular Biology Branch of the US Naval Radiobiological Defense Laboratory, San Francisco, published several reports, in one of which he noted that low pyrogen doses are known to produce a more rapid rise in resistance to injection than larger doses, i.e. 50 mcg. was not as effective as 2 mcg. of pseudomonas in increasing survival time to lethal radiation.40

At our request in 1962, Ainsworth screened the Coley’s toxins as a potential radioprotectant on X-irradiated mice. In this experiment the smaller dose was more protective. This experiment was not published. He sent us the abstract:

Effect of Coley’s Toxins on Survival of Irradiated Mice
Method: Typhoid-paratyphoid vaccine was used to compare Coley’s Toxins since previous data had shown that TAB is highly effective in reducing the radiation mortality in mice. The mice used were CF1 females, 100 days old, weight 19-24
grams. Total body X-irradiation was delivered from a 250 kv Westinghouse X-ray machine operated at 15 ma and a distance of 40 inches. Added filtration consisted of 0.5 mm Cu and 1 mm Al.

<table>
<thead>
<tr>
<th>Substance</th>
<th>Amount</th>
<th>No. Mice</th>
<th>Picric</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coley's Toxins</td>
<td>0.5 ml</td>
<td>25</td>
<td>on back</td>
</tr>
<tr>
<td>Coley's Toxins</td>
<td>0.1 ml</td>
<td>26</td>
<td>on head</td>
</tr>
<tr>
<td>TAB vaccine</td>
<td>0.1 ml</td>
<td>26</td>
<td>on tail</td>
</tr>
<tr>
<td>0.9% NaCl (saline)</td>
<td>0.1 ml</td>
<td>26</td>
<td>none</td>
</tr>
</tbody>
</table>

The mice received 700 r on the day following inoculation. The mice were then caged 8 to a cage — each cage containing two mice from each group. Death checks were made once a day for 30 days following irradiation.

**Summary of Mortality**

<table>
<thead>
<tr>
<th>Substance</th>
<th>Amount</th>
<th>Injected</th>
<th>Mortality*</th>
<th>% Mortality</th>
</tr>
</thead>
<tbody>
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<td>0</td>
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</tr>
<tr>
<td>Coley's Toxins</td>
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<td>0.1 ml</td>
<td>2/9/6</td>
<td>11.5</td>
<td></td>
</tr>
<tr>
<td>0.9% NaCl (saline)</td>
<td>0.1 ml</td>
<td>24/26</td>
<td>92.3</td>
<td></td>
</tr>
</tbody>
</table>

* No. dead/Total

8. Further inertia, criticism and hostility, and occasional enthusiasm

Although Coley continued to publish his results and by 1909, 66 papers had appeared in the United States and Europe, the majority of surgeons ignored or criticized his work.

In 1909 his most comprehensive report to date was read before the Surgical Section of the Royal College of Medicine in London and in 1911 he gave an excellent clinical lecture at Guy's Hospital in London. In response Dr. Hall White stated: "...you have just heard probably the most interesting lecture that has ever been delivered in this theatre. Therefore I am sure you will agree with me that we ought to pass a very hearty vote of thanks to Dr. Coley for having spared the time to give us such a treat,...The proposition was carried by acclamation amid a scene of great enthusiasm which lasted some time." Dr. Coley stated: "I am greatly obliged to you, gentlemen. What I have heard led me to believe that British audiences were cold, but I have never in my own country received such a hearty reception as you have given me today. Sir Alfred Fripp tells me that you have tried the fluid in the hospital. The trouble has been that a different preparation is sometimes used. Mr. Mansell Moullin of the London Hospital had five successful cases, and has said he got his successes with the fluid obtained from the Cornell Laboratory [Buxton VI]. Middlesex Hospital had had three failures but in the fourth, they used the Buxton VI and the growth regressed to 1/14 in a few weeks...."
Coley’s Toxins

was given in January. Richardson concluded: “The tumor, though as large as a child’s head, disappeared.... If a cure by means other than surgical is, from the very fact of cure, declared sufficient proof of a mistaken diagnosis, there seems little use in presenting evidence... The curative influence of micro-organisms upon malignant growth, whether during the course of an accidental wound infection, or under the influence of deliberate toxin injection is a hopeful indication of far-reaching possibilities for good.”

9. Mode of action

In addition to radiation protection and potentiation of tumor response, the Coley’s toxins produce fever which we know is beneficial; they also stimulate the reticuloendothelial system, activate macrophages, increase hematopoeisis, increase production of prostacynin, endogenous interferon, endorphins, tumor necrosis factor, interleukins and growth factors. Interleukin-1 for example, induces a profound hypothermia which assists the patient in withstanding iron from the cancer cells. Weinberg has summarized some of the numerous papers in regard to this subject including Torrance et al. Certain infections such as erysipelas and the Coley’s toxins also stimulate wound healing and regeneration of bone destroyed by tumor. For example, a case of an extensive giant cell tumor of the proximal femur with complete destruction of 17 cm. including the neck and trochanter with pathologic fracture, recovered under Coley’s toxins in or near the tumor given for 7-1/2 months combined with two radium treatments. The first was given after one week of toxins, the second seven weeks later. Complete regression of the tumor and regeneration of the hip joint occurred, with 14 cm. shortening; well until death 45 years later of coronary occlusion. A second case involved the neck, both trochanters, with complete destruction of the acetabulum and ischium and pathologic fracture. He received one radium treatment (9000 mch) 3 days before toxins were begun. Complete regression occurred. The limb was kept in traction and the hip joint and femur regenerated without shortening.

In another giant cell tumor of the distal radius involving the ulna, the extensive tumor regressed completely under toxins alone and the bone regenerated with perfect function.

10. Overwork and health

From his earliest years in practice Coley had always taken on many burdens and responsibilities. At Memorial Hospital, of which he became an attending surgeon in 1897, he established the Needy Patient Fund with spasmodic donations from some of his wealthy patients. He sometimes paid some of their bills himself and in 1898 handled over 40 of these accounts. Numerous needy patients were referred to Coley from all over the United States and Canada and he never refused to treat them. He actually did up to 80% of the “free” operations between 1908 and 1913.

In 1901 he established the Huntington Cancer Research Fund at Memorial Hospital with a $100,000 gift from his patient Mrs. Collins P. Huntington. In 1901 with funds supplied by Archer Huntington he established the X-ray department and managed it for the first year, the Board having refused to provide the funds.

In 1903, at Coley’s urgent request, a medical record librarian was appointed to index and organize the hospital records. Coley planned which system to use and ordered the cards from the Library Bureau and obtained the funds for the registrar’s salary. “The Medical Board did not think it proper to put the hospital to any expense in this matter.”

In addition to Memorial Hospital, he operated at the Hospital for the Relief of the Ruptured and Crippled (now called the Hospital for Special Surgery, of which he became Surgeon-in-Chief in 1924).

Unwisely he became Chief Surgeon of one of the divisions of the New York Central Railroad and by 1925, this required three secretaries. The time spent could have been devoted to further studies on his method, but he felt he needed the money.

In 1900 Dr. J. Collins Warren appealed to Coley as regards the needs of Harvard Medical School from which he had graduated in 1888. Over the next two years with a good deal of effort, Coley succeeded in getting John D. Rockefeller, Jr. to give one million dollars and Mrs. Collins P. Huntington to give $300,000 towards the new buildings the school so sorely needed. They were dedicated in 1906.

In 1916 Coley began helping one of his Yale classmates to plan a rural hospital in Cambridge, New York (The Mary McCallen Hospital). It was dedicated in 1919 and he became its Surgeon-in-Chief. This required weekly visits on Sunday and Monday for years, which meant he had only Saturday and Sunday mornings for relaxation.

All these years Coley continued to read papers and write reports on his toxin treated cases, both here and abroad, the most comprehensive of which was read at the International Cancer Congress held in Brussels in 1913 and appeared as a monograph in 1914. For this he abstracted 80 cases which he had successfully treated and included a table of 125 cases successfully treated by other surgeons. He also published extensively on his experience with hernia.

His health had always been remarkably good, despite developing acromegaly. The first symptoms, severe periodic headaches, occurred while Yale in 1883. He did not discuss it with any of his friends or colleagues – even Harvey Cushing. Finally in 1913 someone anonymously sent him a book, Acromegaly, a personal experience by an English physician about his own fatal case. This was a cruel shock, for he had not realized he had it. He determined not to discuss it with his wife, or friends, and so faced it alone, determined to work harder than ever.

Hard work did not affect his health so much as the anxiety and stress due to the growing antagonism of Ewing at Memorial Hospital or with the affairs of the Bone Sarcoma Registry which Codman of Boston had organized in 1920 with Ewing and Bloodgood of Johns Hopkins. In July 1920 Codman wrote “You have probably more living cases than any man in the world. That your treatment has a profound systemic effect I have no question, but I am inclined to attribute the successful cases to errors in diagnosis. Yet I must admit you have more to your credit than anyone else.”

Codman had arbitrarily decided that no successful case should be included if the patient had died prior to 1920. He and Ewing continued to write critical letters to Coley. Finally on February 6, 1922, Codman wrote a particularly galling letter accusing Coley of being distrustful of him or “perhaps too fond of golf” to find time to send the data needed to register his cases. This letter hurt Coley deeply for he felt it was so unjust. He replied the day he received it explaining that Ewing’s laboratory had failed to make duplicate slides as he’d asked them to. “As a matter of fact I have played only nine holes of golf since September,...and had to give up several attractive shooting invitations to stay in town and grind, largely on sarcoma of the long bones. I have had nothing but
weekend vacations for the last four years." He added "I cannot see what is to be gained by scrapping all the facts on the subject that have been gathered by many observers up to the present moment at the expense of hard and patient labor, and dating all real knowledge of the subject from the beginning of your Registry."

"I did not like your letter to Dr. Packard about his case. It certainly was not worthy of the high judicial standards that certainly should obtain with such a committee as you have organized. You could at least have omitted your remark that you 'would regard the case as having gotten well in spite of Coley's toxins instead of with the help of them.'"

Codyman replied on February 20, 1911: "I think your rebuke in regard to the Packard case well merited; what I said was not necessary or wise..." but the harm had been done. Financial strains and his son's divorce were added anxieties. Codyman's letter was the final straw that precipitated an ulcer with an almost fatal duodenal hemorrhage about February 12, 1922. He never regained his former vigor in the remaining 14 years of his life, and after further traumatic episodes with Ewing or Codyman, he had other hemorrhages. The scar tissue from these ulcers caused pyloric stenosis requiring gastroenterostomy in April 1931 – done under local.

By 1926 Codyman managed to assemble all the detailed data on the 170 cases of long bone sarcoma and 69 cases of giant cell tumor he had treated from 1906 on and published two excellent reviews in 1926-27.3.5.48 Despite his poor health in those last years he published 25 more papers including one on Hodgkin's disease and lymphosarcoma. (Between 1910 and 1930 Ewing had consistently opposed Codyman's publishing his end result studies with hostile criticism."

He read papers in London in 1923 and in 1928, and these prompted English and French surgeons and radiologists to send him some interesting cases who benefited by his treatment.

In May 1934 Cordman was Chairman of a Bone Sarcoma Symposium held at Memorial Hospital, and summarized Codyman's paper on Ewing's sarcoma of bone stating, "This paper will give great satisfaction to Dr. Codyman's many friends who have admired his courageous, tireless fight to overcome the skepticism of his colleagues.... His six registered cases of five year cures are alone enough to sustain his argument.... Just as it seemed justifiable for the Memorial Hospital during the last decade to test out the value of radiation alone in inoperable cases or in patients opposed to operation, so it seems even more indicated that some great clinic should try out Codyman's toxins during the next decade. Unquestionably they produce a profound constitutional effect. ...It is time for some great hospital to apply its laboratory resources to the wholly justifiable and distinctly hopeful purpose of giving this treatment a fair trial under favorable conditions. Certainly, in cases of Ewing's tumor, one would hardly feel justified in not recommending the use of the toxins. The question of whether also to give radiation is the difficult one. Dr. Codyman quite logically suggests that the combination of the two may be a bad one, for the rapid destruction caused by irradiation may open up channels for further invasion. Radiation in small amounts stimulates lymphocytosis, and its use in this way was advocated in 1918 for the treatment of malignant tumors by Dr. James B. Murphy, of the Rockefeller Institute, after some very convincing experimental work on animals. Large amounts of radiation, on the contrary, destroy the lymphocytes whose formation it at first stimulates. A series of cases treated by the toxins without the concomitant use of radiation, in which the blood reactions are carefully followed, might prove of value. There must have been many, many cases in the past treated by these toxins on the hit or miss principle by the family doctor, without careful study, such as is possible in the modern clinic. Yet, under these disadvantageous circumstances, occasional miracles have occurred and in Codyman's own undiscovered hand these miracles have not been infrequent."""
Consulting bone tumor service, wrote parker davis & company in 1950, telling them to stop making the toxins. At that time a number of patients were receiving them and this was a cruel blow.

For a time Rhoads had the toxins made at Sloan-kettering institute (skliv) and eight reticulum cell sarcomas were successfully treated with this product, combined with x-ray therapy in some cases. In inoperable cases with metastases the limb was saved in all these, one was a mayo clinic case.

In 1939 we began a half century of study on coley's work. We found the factors affecting success were very concrete as outlined above, but they had been largely ignored by coley and most of the other men using the method. Matagne was an exception. He made his own toxins so they did not have to be shipped and lose potency in transit before the days of airmail, and he administered them wisely.

In 1953 we founded cancer research institute, to provide incentive and support for investigators in this field of cancer immunology. The first two investigators we funded were johnston at new york university and hasavas in temple university. Johnston's laboratory prepared the coley's toxins for clinical use and for a special study at new york university. hasavas reported the effects of the toxins on sarcomas in mice.

Between 1954 and 1969 a number of physicians and surgeons became aware of our studies, requested reprints and obtained toxins (johnston sv). We also sent them detailed directions for administration and toxin therapy record sheets to facilitate analysis of results.

Successful results were obtained by several including johnston and rank in texas, breast cancer; fowler, in connecticut, multiple myeloma and colon cancer. hasavas reported the effects of toxins on sarcomas in mice. hasavas also reported the effects of toxins on sarcomas in mice.

Following the tragedy of thalidomide in Europe in 1963, the kefauver bill was passed enabling the food and drug administration (fda) to establish very stringent regulations regarding clinical trials of new drugs. Though the coley's toxins were 70 years old, the fda ruled it was a new drug requiring special permits and endless red tape to use it clinically, hence all those who were using it stopped.

Despite this terrible blow we continued to assemble data and to edit and to publish 12 monographs after 1963. we also read papers at 11 international cancer conferences.

One study was undertaken with an fda protocol at memorial Sloan-kettering Cancer Center in june 1976 by kempen et al. Patients with advanced non-Hodgkin's lymphoma were randomized to receive or not receive one subcutaneous injection of MBV five days before each cycle of chemotherapy. There were 40 nodular poorly differentiated lymphomas, 5 nodular mixed lymphomas, 3 nodular histiocytic lymphomas, stage II, 5 cases, stage III, 23 cases, stage IV, 21 cases. Radiation therapy was given to initial areas of bulky disease or to nodal or extranodal sites responding only partially to chemotherapy. The MBV treated patients had a higher rate of complete remission (73 vs 44%) longer duration of remission (p=0.005) and longer survival (p=0.005).

The product they used was made in Germany by Bayer, and they used only subcutaneous injections at infrequent intervals which caused little or no febrile reactions. Despite these factors the MBV did improve remission and survival, although a few years later the survival curves merged due to late recurrences. Thus the study was not continued, although the authors had reported in 1981 that the study strongly suggested a potential role for MBV therapy in the management of these tumors.

Another physician in Milwaukee, Wisconsin managed a regional burn unit for nine years where he used a mixed bacterial vaccine on 3,000 patients to prevent the virulent infections these patients developed. This made isolation and antibiotics unnecessary. In 1972 he began treating cancer patients with his vaccine and in 1986 he reported on 139 cases. They also received BCG and transfer factor—all were advanced cases that had failed under chemotherapy or refused it. His results indicate that combined immunotherapy was well tolerated, safe and that it had a salutary effect on a number of patients. His best results were in lung cancers and in operable breast cancers given as an adjuvant to surgery: none of the 30 cases so treated has died.

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13. China programs

In 1981 Guo, a pediatric oncology surgeon at Beijing Children's Hospital, became interested in using the method for his patients. He also was impressed by a case of very extensive sarcoma of the thigh that had recovered following a severe staphylococcus infection with complete recovery. He also had read our first monograph which was in the Medical School Library. He wrote us and we provided the end result studies on pediatric malignancies, the directions as to preparing and administering the toxins and kept in close touch. We went to China in October 1983 and brought Guo to New York that fall, so he could visit Memorial Sloan-Kettering Cancer Center's excellent pediatric division. We emphasized the need for more space in the ward, an area for play and more nurses. We also stressed the need to allow the mothers to be with their children as much as possible to reduce stress which is immunosuppressive. We provided the toxins prepared by Havas in Philadelphia for part of the time.

In the past 7-1/2 years he has treated 49 cases in children. Of the inoperable cases receiving 10 or more injections 8 were successful, traced up to eight years after onset. There were 16 inoperable failures, of whom six received 7 to 10 injections – too brief a period.

Of the 22 operable cases, only two have died, one of which was recurrent when toxins were begun; 12 have remained free from disease up to six years after onset; seven more recent cases remain well and one equivocal case is probably cured but awaits a “second look.”

Guo is the first surgeon since Matagne in Belgium to use the toxins before as well as after surgery. His results indicate how successful this technique can be: he used injections intratumorally, intradermally over the tumor site, and intramuscularly. Guo has also treated a considerable number of adults in another hospital, mostly hepatomas, but it is too soon to evaluate the results.

In Shanghai, at our suggestion, Tang, a very well-known liver cancer surgeon, has been using the Coley's toxins provided by Havas of Temple University. From May 1985 to December 1987 patients received hepatic arterial ligation plus cannulation for 30 consecutive days, including 12 cases with second stage resection, and 34 patients with palliative resection. These cases were randomized. The controls did not receive MBV or mixed bacterial toxins (as the Coley's toxins are now called). One group had Cis-platin, one group had MBV and radiation, one group had all three. The patients receiving MBV had 47.8% survival versus 35% for the controls. In the second look resection 9/25 survived versus 3/20 in the controls. Remarkable lymphocyte infiltration was found in the tumor specimen after second look resection in the MBV cases. They concluded that “MBV is an ideal agent which is cheap, has no side effects and can be given as an adjuvant with surgery, chemotherapy and radiotherapy.” They found that “if MBV is given before chemotherapy as a non-specific immune stimulant, it can prevent the immunosuppression.”

14. Conclusions

We believe that the factors outlined in this review indicate why the Coley's toxins never achieved wider recognition.

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Since the mistakes of the past are now clearly understood and can be avoided, there is a real opportunity to organize cooperative studies not only for inoperable cancers but as an immunoadjuvant to potentiate the response to the usual modalities and protect against their immunosuppressive effects. The Chinese studies have already shown that this is possible.

A shorter version was read in Rome, Italy, May 1989 at the meeting of the "International Clinical Hyperthermia Society" and will be published.

References


6. Nauta, H.C., Fowler, G.A.: End results in lymphosarcoma treated by toxin therapy alone or combined with surgery and/or radiation (57 cases) or with concurrent bacterial infection (14 cases). Monograph #6, New York Cancer Research Institute, New York, 1967.


16. Miller, T.N. & Coley, W.B.: J.T.: End results in reticulum cell sarcoma of bone treated by toxin...
Here is how to make Coley's Toxins.

What is needed are some glassware and an incubator.

It is best to use as a broth Difco AOAC -- a product of Difco Laboratories in Detroit -- in Coley’s day they started with a pound of ground beef and if you have an interest I will tell you about doing it that way also.

So start with 1,000 cc of distilled water. Add to it 10 % glucose. Then add 15 grams of Difco AOAC and 10 grams of Bacto peptone -- another Difco product -- and 5 grams of sodium chloride. Stir well. Next get it to a pH of 7.1 to 7.2. This is greatly important. If there is no pH tester at hand, use litmus paper and get just on the alkaline side. It will most likely have a pH of about 6.8 in the beginning. The pH can be adjusted with a few drops of dilute sodium hydroxide.

Now take 100 cc of this in a small neck flask. Seed it with live streptococcus of erysipelas. Stopper it with sterile cotton -- these bacteria need air but not dust. Two labs out of the country make 500 cc at a time.

Put in an incubator at 36°C grow for 10 days.

It is important that the solution gets to be very cloudy.

After 10 days take out of the incubator and get to 24°C to 35°C -- an air-conditioned room -- and seed with live S. marcescens. The reason for 24°C to 25°C is that the S. marcescens will not grow well at a higher temperature. Let the two grow together for 10 days at 24°C to 25°C. The S. marcescens is red and the resulting solution should be pink. It is the S. marcescens that puts the punch in Coley’s, so a pink solution is a good indicator.

Then heat kill by heating to 65°C for two hours. Check to see that the solution is sterile. Add 0.03 cc of benzyl alcohol per cc of solution to prevent the growth of fungus.

Store at 2°C to 4°C. This vaccine will last for months at this temperature.

The cost of materials to make 1000 cc of vaccine is about $30.00 and this is enough to treat several hundred cancer patients.

In Coley’s days, there were some very strong vaccines and some weak ones. In general a weak vaccine was just as good as a strong one. The dose just had to be greater.