SUBMISSION
ACCESS TO CANCER MEDICINES
SENATE INQUIRY

Executive Summary

Mortality from rare and less common cancers accounts for half of all cancer deaths in Australia. Using Incidence to Mortality ratios as a proxy there has been **no significant change in overall survival rates over the past 20 years for patients with these cancers.**

The challenges inherent in treating very small patient groups have conspired to create an environment in which Australian patients, with rare and less common cancers, are completely excluded from the progress achieved through improved research and treatments for those with more common cancer variations. **Action is needed now.**

The combination of large numbers of therapies, high costs of development and small population groups are creating a perfect storm where both government and industry are struggling to make the current system work. Cost-effectiveness has been used effectively over the years to sustain systems like the PBS but its relevance to assessing new innovative treatments that are increasingly focused on small patient populations is under question.

The current deficiencies in the system are so profound that our organisation has been moved to establish a charitable Cancer Medicines Fund under the campaign banner of Sick or Treat. The associated website is listed below. ***That we needed to establish this site says everything we need to say about the current state of cancer medicines in Australia.***

As an organisation we are constantly faced with coming up with new ways of helping patients secure sufficient funding so that they may access the treatments they need. We have, over time, also considered how we might as a country improve access for all Australian patients.

We have made two such recommendations to this Inquiry; firstly the creation of an Interim Access Fund, and secondly a change to our approach for funding cancer medicines, which we've termed "Medicines as a Service".

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If we continue to fail to act on the evidence we have that shows Australian patients, with rare and less common cancers, being denied access to new, innovative and specialist medicines, the next 20 years will go by and we still won't have had an impact on the overall survival rates for these patients.

Treatments are available now, that could help Australian patients with rare and less common cancers now. These patients, who account for 50% of all Australian cancer deaths, deserve better but instead of helping them, Australia has so far left them to fend for themselves, to fund for themselves, in short, we've left them for dead.

Rare Cancers Australia welcomes this opportunity to provide this submission to the Senate Inquiry and would be delighted to provide further evidence as required.

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Introduction

In 2013 Rare Cancers Australia released a report entitled "Just a little more time". The report was launched in Parliament House Canberra by the Leader of the Government in the Senate, Senator Eric Abetz. The report relied on the European RARECARE definition of rare cancers as being an incidence of less than 6 per 100,000 per year and supplemented this with a definition of "less common" cancers as being an incidence of between 6 and 12 (inclusive) per 100,000. In brief the report showed the following:

- Incidence and Mortality increasing at twice the rate of population growth due in large part to the ageing of the Australian population. **Mortality from rare and less common cancers accounts for half of all cancer deaths in Australia**

- Using Incidence to Mortality ratios as a proxy the report showed **no significant change in overall survival rates over the past 20 years for these cancers**

- A disproportionately small spend on medicines for these cancer patients **(less than 15%) through the PBS** when compared to both incidence and mortality

- A similarly small spend on research for these cancers – less than 20% with almost all these funds targeted at less common cancers and a token funding only of rare cancers

In short the challenges inherent in treating very small patient groups have conspired to create the current environment in which these patients are completely excluded from the progress achieved for those with more common cancer variations. **Action is needed now.**

Imagine the following scenario. Two Australians, both aged 55, both employed in the same role for 40 years paying the same amount of tax and both diagnosed with cancer on the same day – one cancer is common and the other is rare.

Both patients consult the same oncologist who determines after consideration that they should both be treated with the same medicine. In the case of the patient with the common cancer his treatment is fully funded through the PBS.

The rare cancer patient, in contrast, must find $7,000 per month to pay for his treatment simply because his disease is rare.

Australia prides itself on the "fair go" for all. There is nothing fair about the above situation and it is happening every day all over the country.

Background to the current system

In 1949 the Australian Government formed the Pharmaceutical Benefits Scheme (PBS) with the objective of providing government-subsidised medicines to the Australian community. The task of assessing those medicines proposed for inclusion on the PBS was given to the Pharmaceutical Benefits Advisory Committee (PBAC).

The PBAC is a collection of health care professionals and health economists and is very focused on cost effectiveness of medicines as the primary determinant. Health Technology Assessment or more specifically Pharmacoeconomics is the tool used.

This system of examining cost effectiveness has been used effectively over the years to sustain systems like the PBS and the UK's NICE but its relevance to assessing new innovative treatments that are increasingly focused on small patient populations is under question.

Nowhere is this more readily seen than in the area of new treatments for rare and less common (RLC) cancers and the "off label" use of common cancer treatments for RLC patients.

See Appendix A for further explanation.

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The Problems

When evaluating a new medicine for funding there are a number of things that need to be considered and the more significant of these are listed below:

- The system relies very heavily on large scale evidence of improved overall survival. This creates problems where new drugs are proving so effective in trials that "cross overs" are deemed ethically necessary to provide optimum patient care. The current evaluation method struggles to accommodate this and "cross overs" are considered to weaken the evidence base for a new medicine.

- The quality of evidence appears to depend very much on the number of clinical trial participants. i.e. the larger the trial numbers, the more compelling the results. With rare cancers it is often difficult, if not impossible to achieve large trials. The link below is to paper where the trial took 3 years to identify 50 patients with the target mutation.

  http://m.jco.ascopubs.org/content/early/2015/02/03/JCO.2014.59.8334.full

- Similarly, the cost to pharmaceutical companies of making submissions can mean that it is impractical and uneconomic for them to bother making a submission where the market is small, cost is high and the evidence is unlikely to have sufficient patient numbers to receive a positive recommendation or realistic price level. For example, a drug that is effective in both a common cancer and a rare cancer may never be approved for the rare cancer because the work required to prepare a submission is not commercially viable given the small patient population (market)

- "Off label" usage of existing medicines is not unusual among oncologists, however there is no mechanism in place whereby an oncologist can present a case to the authorities that there is a "plausible hypothesis" for the funded use of the drug in question. This is currently achieved either by requests for compassionate access to medicines from the pharmaceutical companies, by the patient paying to access the medicines or in extreme cases, the clinician is forced to "misdiagnose" the patient to gain access to the optimal treatment.

- On average, once a medicine is registered with the TGA, it is reportedly taking a further 31 months for it to be approved for listing on the PBS. Time delays are a function of both administrative process and extended

approval chains. Any PBS listing that will incur a liability to the government of more than A$20 Million must be approved by Cabinet. Less than $20 Million can be approved by the Health Minister.

The issues raised above when combined with the rate of development of new cancer therapies means the current mechanisms are under extreme stress and this is causing a breakdown in the established processes. The combination of large numbers of therapies, high costs of development and small population groups are creating a perfect storm where both government and industry are struggling to make the current system work.

The Challenge

The primary challenge is to allow clinicians to prescribe medicines that they assess will be effective for their patients without regard to the financial position of the patient. That is NOT currently the case.

The challenge therefore, is to find a mechanism whereby Australians suffering from rare or less common cancers can receive equitable and fair access to medicines that have reasonable, proven safety and efficacy for those diseases.

To do so, the mechanism would need to cater for the following situations:

1. Drugs that are TGA registered for an indication but have not yet completed the PBS process or been assessed by the PBAC for that indication.

2. Drugs that are registered for one indication but are also considered to be applicable for other indications. As clinicians understand the more and more about the genetic drivers of cancer the science increasingly supports this situation. Technology is outstripping our regulatory process.

3. Drugs that are TGA registered and PBS listed for one or more indications but are also applicable to other indications for which, for whatever reason, no applications have yet been made.

4. Drugs that are registered in the US or Europe but not yet TGA or PBS approved here.

The most common reasons for these types of situations is that the small population groups make it both commercially unprofitable and technically difficult to accumulate trial evidence and fund subsequent submissions.

The Role of Clinicians

It is expected that a patient seeing a clinician will have their treatment determined by that clinician based on his qualifications, knowledge and experience. Where drugs are funded through the PBS this is exactly what happens.

However, where a drug is not funded for the particular indication that afflicts the patient, the clinician is faced with less optimal choices, namely:

- Prescribe a "second choice" medication that is funded through the PBS.
- Seek compassionate or charitable access to the first choice medicine through a compassionate program or clinical trial. This option is not always available.
- Present the facts to the patient and let them decide if they can fund their own treatment.
- Deliberately misdiagnose the patient so that the patient can access the treatment through the PBS for a funded indication. **In these circumstances we are confronting clinicians with the choice of fraud or inadequate care.**

Australians believe their care should be determined by their clinicians – they entrust their lives to their doctor. Clinicians are among the most educated, respected and trusted professionals in our society and cancer physicians, in particular, deal with life and death situations every day. **It is essential that they have a louder, more authoritative voice in the determination of funded patient treatment.**

Case Studies

The current deficiencies in the system are so profound that our organisation has been moved to establish a charitable Cancer Medicines Fund under the campaign banner of Sick or Treat. The associated website is listed below. ***That we needed to establish this site says everything we need to say about the current state of cancer medicines in Australia.***

In Appendix B we have included two powerful examples of why we need to address this issue. They appear similar but represent quite distinct examples of the issues we aim to address. Both these patients benefit from the Cancer Medicines Fund and we refer Senators to www.sickortreat.org.au

The first of these examples, Anita, has been diagnosed with non-small cell lung cancer and has been diagnosed as having an ALK+ genetic mutation as a contributing factor. Her oncologist prescribed a drug called Crizotinib and Anita has responded well for a number of months. Crizotinib has been recommended for listing by the PBAC for Anita's cancer but as the contractual process unfolds, it may yet take some months for it to be listed. In the meantime our Cancer Medicines Fund continues to fund her treatment at $7,400 per month.

Our second patient is Lillian who has also been diagnosed with non-small cell lung cancer but in Lillian's case her much rarer mutation is in the ROS1 gene. Her highly respected oncologist has also prescribed Crizotinib as there is substantial evidence of benefit. Lillian is also responding well but because her cancer or indication is so rare there is currently no application to PBS for re-imbursement.

Hence we face a situation where both Lillian and Anita need to self fund today at a cost of over $7,400 per month yet simply because of the random genetic mutations they have, Lillian will never receive funded medicines through the PBS whilst Anita hopefully will.

Same cancer, same treatment but no fairness.

Note: Only information previously published on www.sickortreat.org.au is included about these patients.

Mechanisms for reform

As an organisation we are constantly faced with coming up with new ways of helping patients secure sufficient funding so that they may access the treatments they need. We have, over time, also considered how we might as a country improve access for all Australian patients. The following two mechanisms described detail just some of Rare Cancers' suggestions.

1) Bridging the Gap - Interim Access Fund (IAF)

There is no doubt that our current system "has a problem with rare". The PBS has served Australia well with its principle of "the greatest good for the greatest number" but we need flexibility and change if we are to expand its reach to include the "greatest number of diseases" be they rare or common.

Working within the existing framework

Whilst there is a pressing need to allow rare cancer patients to access medicines and this may require substantial long term reform, it is possible to have an immediate impact. To do so it is recommended that the Department of Health be empowered to make interim funding approvals for medicines that for whatever reason, have not been listed on the PBS for funding. This would require the creation of an Interim Access Fund (IAF)

How might the process function?

The following mechanisms or similar would be put in place:

1. For a drug to be considered for funding through the IAF, an application will be required to be made by a suitably qualified clinician.

2. The targeted indication will be considered and accepted by the Department as rare or less common. Defining this requires further consideration however one possible example might be that if the indication meets the definition of "rare" and the company declares that it will not be making a submission to the PBAC for that indication. These definitions can be solidified through industry and departmental discussions once there is a commitment to establish the fund.

3. To ensure best practice it is recommended that a panel of clinicians and patient advocates be formed to review applications for the IAF and provide feedback to the department on issues such as safety, efficacy and potential value of the proposed drug.

4. Where a medicine is approved by the panel of experts for use in the nominated indication, the manufacturer will be asked to supply the treatment for the indication on the following basis:

    a. The medicine will be supplied for a period of years (TBC) or until PBAC listing is granted (whichever is sooner) and can be used for the indication as though it was already listed.

    b. In order to protect the company's pricing integrity a price can be agreed between company and Department that will be paid and held in escrow or trust whilst the normal PBAC processes are completed.

    c. Clinicians accessing the medicine must agree to participate in detailed collection of data on patients using the medicine.

    d. Where a drug is ultimately listed by the PBAC, the agreed PBS price will be used to reconcile the amounts held in escrow and the outstanding amounts paid to the company. Any balance will be returned to the government, any shortfall will be provided by the government.

    e. Where the agreed number of years pass and for whatever reason, the drug is not yet listed on the PBS, the PBAC, on the advice of the expert panel and after examining the data collected by prescribing clinicians, will determine an appropriate price for the medicine and adjust payments as in (d) above.

    f. Where a medicine has been previously approved for a different indication, the approved price will be aligned with current price unless exceptional circumstances exist.

Other considerations

In considering an IAF it would be appropriate to consider other possible impacts

1. Industry and Clinicians would need to be satisfied that there was an imperative to insure that the PBAC considers applications in a timely manner. Some form of time limit with penalties would be needed.

2. Consideration will need to be given as to how to regulate the use of medicines in the IAF in respect of:

a. Where in the treatment cycle they can be used
b. In what combinations or sequences they can be used
c. In what dosages they can be used

Funding

The Interim Access Fund will require significant funding and in particular, the creation of a reserves fund for those medicines that are being used through the interim mechanism.

The scale of those funds will be directly related **to the definition of those rare or less common indications** that are eligible for funding and also the level of participation from pharmaceutical companies.

Subject to the above and based on observed overseas experience we would estimate a figure of between $100 Million and $250 Million per year but stress that this is subject to a wide range of variables.

2) Licensing Innovative Oncology Medicines - "Medicines as a Service"

Whilst the Interim Access Fund would provide much needed immediate relief it does not address the fundamental issue that we are facing an avalanche of highly specialized medicines for cancer patients and it is difficult, if not impossible to see how the current PBAC and PBS systems will cope. If this situation is not addressed in the medium term Australians with cancer will be the losers.

We can and must do better.

In Australia today and in many other developed economies a regular process occurs of pharmaceutical companies (sponsors) preparing and lodging submissions to government regulatory bodies such as the PBAC for the re-imbursement of each and every single medicine.

As discussed earlier the system is under severe strain and is characterised by:

- Lengthy delays in making life-saving or life–extending medicines available to citizens in need.

- The imposition of significant cost being borne by both pharmaceutical companies and government in assessing and analysing the cost-effectiveness of each drug

- Restrictions on drug usage that disadvantage patients, hamstring clinicians and impose significant compliance costs on government. These restrictions can dictate when in the path of disease the medicine can be

used and also in what types of disease they can be used

- **The intrusion of economics on the relationship between clinician and patient and as a consequence the clinicians inability to treat the patient in what the clinician believes to be the optimum manner**

This problem is getting worse not better. Since the mapping of the human genome and the ability to better understand the molecular structure of many diseases, when combined with dramatic developments in technology and computer simulations, mean that in cancer today, over 900 new medicines are under development globally.

Many will be targeted treatments with small patient populations. The current model simply doesn't cope. Science is (as is common) developing at a much faster pace than the regulatory environment.

The Question

Are we looking at the provision of innovative medicines the right way in the 21st century?

Today we consider medicine a product and each product is examined separately for re-imbursement based on accepted Health Technology Assessments. But what happens if we, instead, look at treating innovative medicines as intellectual property and apply a "service" model.

Software is perhaps the best example of where society has moved from buying and maintaining a product to viewing it increasingly as a service. Both Government and Corporate communities license software such as Microsoft Office for entire communities rather than purchasing individual versions of the same product.

This methodology contains parallels to the provision on innovative oncology medicines and provides a proven road map for reform.

Similar although not identical, models have been used for the provision of such consumer "services" as software, music and film. In simple terms, we buy a Foxtel, Netflix or Spotify service which allows us access to a range of music or film. We no longer make a decision about whether we want to purchase a particular Album or Film.

None of these examples provide perfect parallels to innovative cancer medicines but they do show that industries and consumers can adapt to the challenges of new technologies and innovations by viewing the outcomes differently from the traditional product view.

The Proposition

The proposition is that, in order to address the failings and delays of the current system and to avoid the future capacity issues that seem likely, we look at the model of "Medicines as a service". In other words instead of pricing and costing each tablet or ampule as a separate exercise we examine the possibility of licensed usage for a medicine.

This may mean licensing an individual product, for example, the government agreeing to $200 per year for the right to supply medicine XYZ to Australians. Regardless of how much is used, when it is used and why it is used the cost is fixed at $200

It may, alternatively, mean that a company might license its entire oncology portfolio for an annual fee with the result that company A receives $100 per year for Australia to have the right to use its portfolio of cancer medicines.

A third option might be a more granular approach whereby health insurance funds are allowed to license medicines in combination with public and private hospitals.

This funding mechanism would remain subject to current TGA approval processes and the evaluation of value would continue to be influenced by proven Health Technology Assessment methodologies.

The Benefits

If such a scheme could be introduced it would provide many advantages to all parties:

Certainty

The scheme would provide budgetary certainty to both government and the pharmaceutical industry. Over prescribing, whilst still an issue, would offer no commercial advantage to the company and hence there would be less reason to over inflate the qualities of the medicine to clinicians

Flexibility

Perhaps most importantly, a geographic licensing system would allow clinicians to use their best judgment when treating a patient. We would return to the point where how a patient was treated was determined by their doctor not an economist or committee in Canberra.

Simplicity

The red tape that surrounds the PBS and clinicians ability to prescribe medicines is substantial. Properly constructed a licensing system would significantly reduce the red tape currently confronting companies, clinicians and government.

Why Australia?

A reasonable question is why a multinational pharmaceutical company would entertain such an idea from a small market such as Australia (approx. 1% of the global pharmaceutical market). The answer is that, not only are we small, which reduces risk but we are also a sophisticated, mature and wealthy market.
In short we are an ideal "pilot site" where outcomes can be closely monitored, risk can be mitigated and outcomes can be easily translated to bigger markets.

The problems we are considering are not unique to Australia and a first step to an innovative solution would be welcomed and watched around the world.

Conclusion

The recommendations made in this submission are just a starting point for a much broader, more complex discussion on improving access to new, innovative and specialist cancer medicines, but we must start somewhere.

If we continue to fail to act on the evidence we have that shows Australian patients, with rare and less common cancers, being denied access to new, innovative and specialist medicines, the next 20 years will go by and we still won't have had an impact on the overall survival rates for these patients.

Treatments are available now, that could help Australian patients with rare and less common cancers now. These patients, who account for 50% of all Australian cancer deaths, deserve better but instead of helping them, Australia has so far left them to fend for themselves, to fund for themselves, in short, we've left them for dead.

Appendix A

The Cancer Challenges

1. Multiple Indications

The rapid development of so many new types of cancer medicines has been accompanied by a much greater and deeper understanding of the myriad diseases that we refer to under the "catch all" banner that is cancer. Cancers or neoplasms are the uncontrolled growth of new cells within the body. These cells avoid control by the body's immune system and are constantly mutating or evolving in a way that assists their survival, even when under attack from cancer medicines or other treatments.

In recent times, scientists have come to understand that their formation and characteristics are not necessarily related to the site of the body in which they form but the genetic profile of both the patient and the cancer cells themselves. This has led to treatments being developed that have widespread application across many cancers as we understand them today but their rapid approval is limited by a regulatory system that sees a medicine for melanoma as different from a medicine for lung cancer. In fact, the same medicine, acting in the same manner, could be highly efficacious for both conditions.

The current approval process doesn't recognise this development in science and its impact is most strongly felt in the lack of utilisation of existing cancer medicines for treatment of rare cancers.

2. Multiple treatments

As discussed above, one of the great challenges with cancers is their capacity to constantly mutate meaning that whilst one treatment may be effective in destroying a large percentage of the diseased cells, a separate portion may have mutated in a way that is resistant to that one treatment. Consequently, the medical profession is increasingly using medicines in combination rather than sequentially.

These combination treatments facilitate the simultaneous destruction of the multiple mutations of the cancer cells in a way that sequential application of medicines cannot.

Hence the challenge for our current processes is to address the fact that cancers, as a group of diseases, attack our health in a unique way and cannot be effectively treated using the same processes that are in use for widespread uniform diseases such as diabetes or heart disease.

One medicine – many cancers, many combinations

To allow our clinicians the flexibility they need to tackle cancer and to allow downstream processes such as the PBAC to operate quickly, there is a need to look at how treatments are related to indications and treatment combinations. For example, there has recently been significant development around new treatments for Melanoma known as PD-1 Inhibitors.

As the system currently stands, their introduction to Australia will be focussed solely on Melanoma. What we already know, however, is that there is strong evidence that these treatments will be efficacious in a range of other cancers, particularly rare types, where the key characteristics are similar.

Similarly, clinicians may wish to use new treatments in combination to enhance the prospects of success

It is necessary that we consider how these developing treatment regimens are addressed within the current regulatory framework.

Appendix B – Patient stories

Anita McGrath

My name is Anita and I'm fighting a tough battle with lung cancer. I am 44 years old, married with two beautiful boys aged 6 and 10. An accountant by profession working 1 day a week, fit healthy and have never been a smoker. I eat well and exercise daily to keep my body and mind in good working order.

I was diagnosed with Non Small Cell Lung Cancer (NSCLC), Adenocarcinoma, stage 3a in January 2014. At the time of diagnosis they found a 4cm tumour on my right lung and cancer in a few lymph nodes. The tumour is inoperable.

It all began with a persistent cough that was treated with several cycles of antibiotics lasting about a year. During that year I had numerous blood tests, x-rays and sputum tests. I also started working as a tutor at a university so my hoarse voice was put down to increased use. Other symptoms I had over the years were attributed to thyroid issues, a hoarse throat and exhaustion. I decided to get off the antibiotics rollercoaster. It was only a minor but persistent cough with very small amounts of phlegm every now and then.

We moved to Brisbane at the beginning of 2013. Same persistent cough, same symptoms, same tests with inconclusive results. It was around this time that I was getting a sharp pain under my right rib. I thought perhaps I had pulled a muscle while coughing at night. The pain subsided over 3 or so weeks. Not long after that I got a few sharp pains in the middle of my chest. I had an ECG and a cardio stress test, results suggested stress.

In November 2013, I started getting very fine streaks of blood in my phlegm. The GP sent me to an ENT specialist, who then sent me for a CT scan. I delayed the CT scan for a whole month because I was too busy and did not think a cough warranted too much stress. Little did I know! I started getting the pain back under my ribs so thought it was time to get CT scan done. That was the week before Christmas. On the 30th of December I was celebrating my sister's birthday when I got a call from the ENT specialist. A 4cm lump in the right side of my chest was detected and blood tests along with a PET scan were required as soon as possible.

The PET scan produced bad news. They then did a bronchoscope, samples came back as stage 3a, non-small cell carcinoma (Adenocarcinoma). I never thought I was a candidate for lung cancer.

Our family have been an active part of Relay for Life (Cancer Council WA) since 2005, before my diagnosis. I was often questioned about my involvement. I guess I truly believed if I helped patients and their families, karma would dictate that this would never happen to me. This year will be our 10th Relay for Life.

My treatment journey started with chemo (Cisplatin and Paclitaxol) for 9 weeks. This was followed by 40 radiation sessions over 8 weeks, combined with chemo (Etoposide and Cisplatin). Unfortunately there was no significant improvement resulting from my treatments.

I had another broncoscopy to get more tissue sample for testing. Good news, I tested positive to Anaplastic Lymphoma Kinase (ALK) fusion gene. It's a rare gene only found in 3-7% of lung cancers. This has opened up options of target therapy treatments for me, in particular Crizotinib. I started taking Crizotinib at a cost to me of $7,500 per month (60 tablets). Crizotinib is not listed on PBS and I have been unsuccessful in accessing the drug on compassionate grounds. Mum and Dad have paid for my first month and friends are fundraising to help me pay for subsequent months. The support I have from family and friends is overwhelming. It's a tough journey but I'm a fighter and believe with access to the most current medication I will live many more years than expected and enjoy watching my 2 boys grow into beautiful young men.

Lillian Leigh

My world shattered just days after my 34th birthday. I was diagnosed with advanced lung cancer. I am not about to let this diagnosis define my whole life. I aim to live with cancer and with love and thankfulness in my heart. You see, I have so much to be thankful for. God has given me a loving husband who is my rock and best friend, an amazing 3-year-old daughter who is our everything, a wonderful extended family that I could not have picked better, beautiful friends and colleagues and a dream job as a social justice lawyer that I am deeply passionate about.

It was easy to miss the signs. I had had a cough for two months prior to my diagnosis, but had dismissed it as a post-viral cough. Any discomfort I had I also took as first trimester morning sickness. We had just started to announce to our family and friends the wonderful news that we were expecting our very much longed for second child. This pregnancy compounded on our situation as we soon faced not only the aftermath of the cancer diagnosis and what that meant, but also an incredibly agonising decision regarding the pregnancy, a decision no parent should ever have to make. We struggled with finding a path forward as doctors advised us that waiting until after pregnancy for treatment is not an option and that terminating the pregnancy would be the best course of action.

As the days went by, further testing showed I had developed a rare form of lung cancer caused by the mutation of the ROS1 gene, a mutation that only 1-2% of non-small cell lung cancer patients have, and one often found in young non-smokers like myself. The target therapy drug Crizotinib (Xalkori) has been found in recent research to be an effective antitumor medicine for this type of mutation and also has minimal side effects compared to other types of chemotherapy.

In a situation where the prognosis is generally dismal, measured in months for advanced stage cancer, Crizotinib has shown potential to extend the prognosis to years. Unfortunately, this medicine is not on the PBS and as there are no current trials available for my mutation type. It will cost us approximately $7,400 a month to access the medication that I need.

I look to this medicine as my hope. I hope to be there to send my daughter off on her first day of school with tears in my eyes, I hope to celebrate many more birthdays with the people I love, and most of all, I hope to share many more years of tears and laughter with my husband, the love of my life, as we navigate this journey together.

Geoff Olsson

I am 46 and I have Gorlins Syndrome. I was born with a number of physical abnormalities. I had an extra half toe on my left foot and an extra part formed finger on my right hand. Both these were removed soon after birth.

My left leg from the shin down was severely turned, facing the right heel. It took over 13 operations to correct. I endured toe to hip plaster for several months. Needless to say, I came into this world facing great hardships. It was a difficult time for my family. With endless surgery related problems, doctors stated that I would be lucky to reach 21. Fortunately they were wrong, I am now 46.

To date, I have had over 176 surgeries. I have since stopped counting. A good year is one that sees me having 3 surgeries, a bad year has been one that includes 11 operations.

Cysts are an ongoing issue with my disease. I have lost count on the numerous teeth and jaw cysts that have been removed. These procedures have resulted in an uneven bite and cracked teeth. My left knee has seen a total of 4 cysts removed.

Scars are a permanent mark on my body. They are a reminder of the physical and emotional pain I have endured in my battle to fight this disease. Growing up was extremely hard. Time off school and the constant bullying was an extra unnecessary burden.

The real burden at the time was the little information and support available to someone like me. There were many questions and very few answers. But I had to live my life and make the most of it. Through IVF and a donor sperm, my wife and I were able to conceive. My son is now 14 years old. At such a young age, he has witnessed the devastating trauma that cancer brings.

I need treatment and I know I will improve with the right drugs but I simply cannot afford the cos

Corey Treleaven

My name is Corey Treleaven. I am 36 years old. I have Stage 4 lung cancer. Three and a half months ago I was given six months to live but I continue to fight, I have a lot to live for…

Five years ago I met my wife Kellie. We have made a wonderful home welcoming two beautiful children, our 3 year old daughter and 11 month old son. We have both gone from single to a family of four and shared our journey being surrounded by close family and friends.
Mid 2014, I turned 36. Shortly thereafter I developed a cough which was diagnosed as pneumonia. I had several courses of antibiotics with no results. The next tests moved very quickly and within days I was sitting across from a doctor, with Kellie by my side and our 7 month old son on her lap, being told I had stage 4 lung cancer and given 6 months to live. The news you fear and never want to receive, was horrible.
Like everyone who receives this devastating news, our lives and the lives of our family and friends were immediately changed. Everyone was in shock. I had never smoked, rarely drank, had a healthy diet and I am a keen cyclist and swimmer. I have never been overweight. I thought I was in great health, but I had just been told that I would be lucky to see my son's first birthday. The next few days were very surreal and we were surrounded by family and friends to help look after the kids, put food on the table, keep the house clean and fill our home with noise to keep the mood light and positive. I met my oncologist who reassured me we would fight this disease together. He gave us hope.

You quickly become an expert on all things cancer and you realise no two lung cancers are the same. I was diagnosed with Non Small Cell Lung Cancer (NSCLC) Adenocarcinoma. It is a cancer that is caused by a gene mutation. It is not hereditary and I will not pass it on to my children. Each day in all of us, these mutations occur and the body normally kills them off and removes them through the lymphatic system. Unfortunately mine kept going. The primary tumour is in my right lung and the cancer had spread to my lymph nodes and to the bones in my spine and pelvis.

In order to work out my treatment plan, my oncologist needed to identify the gene that had mutated, causing my cancer. Unfortunately the first gene test results indicated that my mutation was not common. This meant I was also not a candidate for the more common mutation targeted therapies. Further gene testing was undertaken and my mutation was identified as ALK+ and ROS1+. These occur in only 1-2% of Adenocarcinoma cancers. Luckily, targeted gene mutation therapies was an option for me. These targeted therapies have been developed only recently and have proven to be effective at stopping or

slowing the progression of the cancer – not a cure but time. With two young kids and a beautiful wife, time means everything to me.

The main drug for my mutation is Crizotnib, which currently costs $7,700 per month in Australia as it is not covered by the PBS. Therefore my doctor started me on a course of chemotherapy – 4 treatments in 6 weeks. They were long days, often accompanied with a blood transfusion and because of my veins, I had a port inserted into my chest to administer the chemotherapy. Just prior to Christmas I got my first test results which were better than expected. A reduction in my primary tumour, lymph nodes and bone lesions – the chemotherapy was working.

Early January 2015, I commenced my second course of treatment, once again 4 doses every 6 weeks. I had responded well to chemotherapy, with few side effects but in mid-January, I started to feel nauseous, bloated and had shortness of breath. The change was quite sudden. My doctor rushed my second test results and the news was not good. My original tumours had not grown significantly but new cancers had developed. Fluid had spread to my ankles, stomach, heart and lungs. The doctor said he had not seen such a rapid reversal in test results in many years. The fluid onset and shortness of breath caused me to be rushed to hospital to have Pericardial and Pleural drains inserted into my heart and lungs. I spent 5 days in intensive care having litres of fluid drained from where little or none should be.

My oncologist revised my continuing treatment to begin Crizotinib immediately. As Crizotnib is not listed on the PBS, my friends and family are fundraising to help pay for my treatment…treatment which could turn months into years and allow me more precious time with my family.

Claudio Mongelli

My husband is a hard worker who would take on two jobs at once so that he could care for our family which included Carla 9 and Michael 12. In November 2011, our arduous and emotional journey started. After finishing his night shift at 5am, Claudio came home alarmed as he noticed blood in his urine. We went to emergency and was told that it was a urinary tract infection. Claudio was prescribed a course of antibiotics which cleared the blood. We didn't think anything of it and like every other family, celebrated Christmas surrounded by the ones we loved.

On new year's eve, Claudio told me that there was blood in his urine again. It was the colour of red wine and we knew something was wrong. So instead of celebrating the new year, we went back to the emergency department only to be told that it was the return of the urinary tract infection. Claudio was in excruciating pain, so we went to our local GP who thought that he may have clots in his bladder. We were advised to go back to hospital. A CT scan was ordered. The results were devastating. It hit us hard with a sense of shock and surrealism. My husband, who was rarely sick, had a 15cm tumour on his kidney. The scan also showed that he had a horseshoe shaped kidney.

The week that followed was a blur and it was like we were living somebody else's life. You hear about it but you never think it would happen to you. An uncountable number of doctors were in and out of our room, saying things to both of us that our brains were too shocked to comprehend. Scenarios were given and options were discussed, but it was surreal. The mix of emotions you experience when you discover someone you love has cancer, cannot be easily put to words. We were told that if the cancer was in his kidney, then he would need dialysis for the rest of his life. But all these scenarios couldn't be known for certain until after the surgery. The surgery was probably one of the worse days of my life. Sitting and waiting and not knowing what they have found is even worse than being given the news. Everyone prayed and fortunately, the tumour was removed successfully and 1/4 of his horse shoe kidney was saved so there was no need for dialysis. Our prayers were answered, or so we thought.

As there is no follow on treatment for kidney cancer, the doctors recommended that Claudio go on a clinical trial. It was a 3 year programme but after 12 months we were informed that there was a metastatic tumour in his lungs. He had to stop the trial and needed surgery immediately. His first operation was in May 2013, then in November they found another spot and so he had to have another operation. They were able to remove it.

When you are told that a loved one has cancer, every visit to the doctors sends a fear and sense of anxiety that no one can comprehend. In February 2014 after a scan, we were given news that no one wants to hear. We were told that the cancer had spread to his pelvis and brain. Claudio underwent radiotherapy and tried 2 chemo tablets. This process has a huge financial impact. We had to change roles and I have to take unpaid time off work. Fortunately, the radiotherapy has worked on his brain however both chemo tablets have been unsuccessful.

We were recently informed that there was a new drug that may assist in Claudio's treatment, however it is not yet covered by the government's PBS scheme. The treatment per month is a staggering $6800. We are like a lot of struggling families, we have a mortgage, two small children and daily bills that sometimes we can't meet. To add a monthly cost of $6800 on top is something we can't even begin to contemplate. This is a cost that we cannot afford but desperately need. It will improve the health of my husband and father of my children and it is this outcome that drives us to find this amount somewhere. Another burden to add to the stress and anxiety that we are feeling.

Nick Collings – passed away on 24/1/15

I was diagnosed with Renal Clear Cell Carcinnoma on 8th March 2013 and was admitted to hospital almost immediately for a nephrectomy on my left kidney. There were two tumours 85 x 70 x 60mm in the upper pole and 40 x 25 x 15 mm in the lower pole. Both were Fuhrman grade 2 and they suspected renal sinus invasion in the upper pole block 7 and a loose tumour "plug" in the lumen of the relatively large intra-renal vein.

All this information was like a foreign language to me. I had only made an appointment with the doctor because of an odd feeling in my scrotum and he had sent me to have an ultrasound. Cancer was not the diagnosis I was expecting and it was like being hit between the eyes with a sledge hammer and it continues to be this way every single day 20 months later.

After the removal of my kidney on 10th March 2013 and a few days of recovery in hospital, I returned home and made the scheduled appointment with my urologist to find out the results. The urologist was hopeful that it was Stage II Renal Cell Carcinoma and was happy that all the tumours had been removed successfully, but just to be certain referred me to an oncologist to get a further CT scan on my lungs. We went home and celebrated a lucky escape.

29th May 2013 rolled around quickly, unfortunately the oncologist and the results were both terrible and it appeared that the cancer had already metastasized to my lungs and there were multiple tumours of varying sizes present and the oncologist cruelly explained that this was a terminal disease with very little hope for treatment or longevity.

I commenced oral chemotherapy using a drug called Zotrient which immediately turned my hair white, gave me mouth ulcers and nearly killed me with transient hepatitis. All the time the tumours were growing and multiplying every day. I was admitted to hospital and was lucky enough to find a new and fantastic oncologist who has stayed with me through this insidious disease and delivered good and bad news in a caring and compassionate way.

I stopped taking chemo for 6 week sat the end of July 2013 and we took a short holiday in our campervan up the east coast of NSW. I lay in the sun, played in the surf and tried to get that zest for life back in my bones. It worked and I came back fresh and ready to fight again.

In September 2013, I commenced a new drug Sutent and it too presented its own set of side effects and I could literally tick all of the boxes for each and everyone but fortunately this time my liver remained unaffected so I was able to continue the treatment but was so happy when the 4 weeks were up and I had my 7 days of being chemo free. This treatment worked

well and every CT scan presented shrinkage of tumours to the point in late January 2014 only 3 lung tumours remained and they were quite small. The oncologist was so happy with the results that my monthly visits were scaled back and my next appointment was May 2014.

There were trips to ED due to pain, and dehydration during this period but no hospital admissions. In May the CT scans showed that the cancer had once again become aggressive and the tumours were growing but not significantly.

But in June I started to develop headaches that would stop me in my tracks out of the blue and I was losing the ability to hold or grip things with my hands. A CT of the brain proved my worst fears, the cancer had now metastasized to my brain and there were in fact 2 tumours. The oncologist called my partner and asked her to bring me to the hospital immediately.

It took a week to map my brain and find the exact location of the tumours in that time my co-ordination deteriorated quite rapidly and we waited patiently for the neurosurgeon to deliver the verdict on whether or not he was able to operate to remove the tumours.

We laughed so hard and were so excited when given the news that I was going to have brain surgery, cancer makes you celebrate the craziest victories, who would have thought I would ever be cheering to have my skull cut open in two places and tumours scooped out of my brain and then 2 metal plates screwed in to keep what was left intact.

The operation was a success but not without its agonising recovery process. All fine motor skills were retained and no nerve damage to report, it was such a relief but those 2 big rows of train track staples up the back and across the top of my head were not pretty. Follow up treatment was Whole Brain Radiotherapy and then another new chemo.

Radiotherapy proved to be the biggest challenge yet. Although no pain is involved, picture having a plastic mesh mask made to the exact dimensions of your head with holes only for your eyes and then having that bolted to a table so that you are not only unable to move, but unable to swallow and for 5 minutes that seems like an eternity. Knowing that I had to do this 10 times caused me more anxiety than I had ever previously experienced. I completed the 10 sessions in August 2014 but it was pure fear and I hope to never have to do that again.

In the meantime CT scans revealed that the lung tumours were multiplying quickly and increasing in size due to not receiving any chemo while recovering from surgery and commencing WBR. So it was decided to immediately commence chemo using Afinator in conjunction with WBR even though this isn't usually recommended. The next CT scan in September 2014 once again showed wide spread disease in the lungs and 4 new tumours in the brain.

I was crushed, defeated and was finding it hard to gather the energy to continue the fight that I seemed to be losing at a rapid rate. I had gone from a fit healthy man that swam 20 laps every day, surfed, worked hard in the construction industry, walked 7kms 3 times a week, to someone who could barely make it up the stairs in the short space of 18 months.

I became depressed and went to bed and stayed there every day a little bit longer and every day I ate a little less, drank a little less until after about 4 weeks I was a shadow of my former self and had to be admitted to Palliative Care. I felt like I was days away from death as this horrible disease consumed my entire being and took my will to live with it.

Luckily for me in the week preceding my admission to Palliative Care my oncologist had given me the option to no longer receive treatment or give it one last shot with a drug that isn't on the PBS although it is a very expensive drug it was my only option and after much debate with myself I finally agreed to commence treatment.

Palliative Care and the chemo have given me a new lease on life, although the road has been tough .The pain at times is unbearable but it will get better and I now am on a reduced dosage to control the cavitation and the ulcers to the mouth and throat.

This drug should be made readily available to not just me but everyone that has RCC, it is cruel to have a drug that can potentially give quality and longevity of life to RCC sufferers but then attach a price tag that makes it impossible to obtain.