William R. Savage

Personal Statement

Background

I am 61 years old and married with no children. I enjoyed good health until June 2006 when I developed a tumour on my left kidney which was removed following a successful laparascopic operation. I have made a full recovery and my current treatment status is "watchful waiting" which involves regular monitoring CT scans but no other therapeutic intervention.

Personal Ethos

I believe in high technology medicine based on double blind randomised placebo testing. I also have a commitment to the NHS and a view that the NHS should meet the highest standards of care and service.

I investigated Kidney Cancer from genetic origins to the latest trials and treatments using the internet as my primary tool. I told my oncologist of my views and volunteered for any trials available in my adjuvant condition. I was offered the HYDRA trial (a combination therapy of interferon, interleukin and fluoracil 5). I researched this therapy and found evidence the technique was not producing measurable benefits in survival rates and was extremely toxic. We declined the trial. No further trials have been offered to date.

In May 2007 my CT scan seemed to show enlargement in my mediastinal glands. This was diagnosed as possible metastatic spread. I decided to research 2 second opinions with leading kidney cancer oncologists which confirmed my treatment options as being limited to the new cancer drugs. A follow-up CT scan revealed no spread cancer and I have been moved to a 6 month regime of CT scans which have continued to be clear of metastatic or other disease.

The NHS and Anti-Cancer Drugs

Our research led us to the emerging treatments for kidney cancer- Sutent, Nexavar, Toricel and Avastin among many options. We researched the evidence using ASCO as our primary source of reference and came to the obvious conclusion that these drugs offered the best opportunities for life extension if not a complete cure. The latest abstracts from the ASCO April 2008 General Meeting confirm the efficacy of all the treatments being reviewed and cost effectiveness of Sutent in particular. By contrast the existing first-line treatment offered by the NHS of interferon or interleukin are much less effective and toxic.

I was greatly alarmed to discover that these drugs were not provided by the NHS on cost-effectiveness grounds despite being licensed for use, prescribed by clinical specialists and with full trials evidence of efficacy being available from the U.S. and European sources. I was further horrified to learn of the NHS blanket ban on co-payment which would have allowed me to buy drugs prescribed by my oncology specialist. It is immoral and inhuman to deny patients the chance of extended life by forcing them to pay for ancillary treatments if they have the temerity to dare to buy effective drug treatments on the open market.

I have spent much time investigating "exceptionality" as a route via the PCT to acquiring the necessary drugs and conclude the policy is a cruel paper chase designed to deny desperate patients the treatments they need at a time of their maximum vulnerability. The system is fatally flawed, non-transparent and unfair and must be reformed as a matter of urgency.

Improving the System

I have joined many organisations (a list is available in Appendix 1) to try to improve the patient experience and treatment. I have been active in 3 main areas :

- **Local cancer service improvements via the Bucks Cancer Patient Forum and the Thames Valley Cancer Network**
- **Clinical policy issues including drug availability via the Tumour Site Specific Group (Urology)**
- **Political policy issues including presenting at the All – Parliamentary Group on Cancer**

NICE and Kidney Cancer

The first –line treatments for kidney cancer provided by the NHS are interleukin and interferon. My research has confirmed that these are dated therapies with limited effectiveness and high toxicity. Kidney Cancer does not respond well to conventional chemotherapies which means there are no options for patients except the drugs which are under review today. My concerns about the NICE process are :

- **Lack of urgency. This review started in 2007 and will not report until 2009. This is far too long.**
- **Lack of transparency. At the heart of the drug availabilty decision is the arbitrary QALY figure of £30000 which will be used to determine cost –effectiveness. The algorithm and its component parts must be open to review and challenge.**
- **Lack of impartiality. NICE is a rationing tool to limit the availability of expensive drugs and thus control the overall NHS drug bill. In the mind of the public this limits the independence of NICE.**

Clinical Effectiveness

Kidney Cancer affects 6000 people a year. The cancer does not respond to standard chemotherapies and the 5 year survival rates are only just over 50%. The current first line treatments are ineffective and very toxic. The first line treatments in the US and Europe are the drugs under review today. It is shocking to me that we kidney cancer patients are still having to debate the efficacy and cost effectiveness of drugs which can extend our lives if not effect a complete cure.

I have investigated the efficacy of these drugs with my clinical consultant and using ASCO as our primary reference point concluded that whereas the drugs concerned are not cures they are effective on prolonging life. I am fully aware of the side-effects of all these treatments. I attach the references for drug performance sourced from ASCO in Appendix II.

Appendix 1

NHS Organisations

- **The Bucks Cancer Patients Partnership**
- **The Thames Valley Cancer Network**
- **The Tumour Site Specific Group—Urology**
- **The Thames Valley Cancer Drugs Therapeutic Committee**

NHS Projects

- **Oxford Cancer Information Unit – Steering Group**
- **Primary Cancer Care –Research Project**
- **Patient Information Prescription project**

Support Groups

- **Kidney Cancer UK**
- **Friends of Renal Cancer oncology –Oxford Churchill**

Charities and Campaign Groups

- **Rarer Cancer Forum**

Appendix II

Bevacizumab/Avastin (VEGF Inhibitor) in combination with IFNalpha

	BEV + IFN	IFN alone
PFS (Progression free survival)	10 months	5 months

'significantly improved progression free survival in patients with mRCC'. B J Esudier et al ASCO2008.
J Clin Oncol 26: 2008 (May 20 suppl; abstr 5025)

(The trial AVOREN is ongoing with more results due this autumn.)

Sorafenib/Nexavar (TKI)

	Sorafenib	Placebo
OR (Objective Response) (Phase II)	25%	5%
PFS (Progression free survival)	24 weeks	12 weeks

'Overall survival analysis showed an estimated 30% improvement in overall survival for sorafenib vs placebo. Crossover patients confounded overall results.' R M Bulowski ASCO 2007.
J Clin Oncol 2007 ASCO Annual Meeting Proceedings Part 1. Vol 25, No 18S (June 20 Suppl), 2007: 5023

Sunitinib/Sutent (TKI)

	Sunitinib	IFN
ORR (Overall Response Rate)	47%	12%
PFS (Progression free survival)	11 months	5 months

'Sutent remains a reference standard for first line treatment of mRCC with significantly superior efficacy over IFN-alpha. Final survival analysis will be presented at the meeting'. R A Figlin et al ASCO 2008.
J Clin Oncol 26: 2008 (May 20 suppl; abstr 5024)

The full survival results presented by Dr. Figlin were:-

- Of 193 patients who did not receive any treatment except sunitinib, median survival was 28 months.
- Of 162 patients who did not receive any treatment except IFN-alpha, median survival was 14 months.

This is the true picture. The less impressive statistically insignificant 26.4 months vs 21.8 months is confounded by crossover.

Appendix II(con)

Temsirolimus/Torisel blocks a key protein function (mTOR)

	TEM	IFN
Median overall survival (for poor prognosis patients)	11 months	7 months

Temsirolimus plus interferon didn't improve survival.
G Hudes et al ASCO 2006
J Clin Oncol, 2006 ASCO meeting proceedings Part 1. Vol 24, NO 18S (June 20 suppl), 2006:LBA4

Economic evaluation using the Markov model

'Sunitinib is a cost effective alternative to Sorafenib, Temsirolimus and Bevacizumab/IFN as a first line therapy in mRCC. Cost efficiency ratios were within the established threshold that society is willing to pay for health benefits (USD 50,000 – 100,000 per LY or QLY).
A Benedict ASCO 2008
J Clin Oncol: 2008 (May 20 suppl; abstr 5048)