

# Kidney Cancer Association

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## Written Testimony for the Food and Drug Administration Public Meeting on the Prescription Drug User Fee Act Submitted by the Kidney Cancer Association September 15, 2000

Thank you for allowing me to talk to you today. I am Carl Dixon, the President and Executive Director of the Kidney Cancer Association ("KCA" or "Association") a voluntary, patient organization, which for over a decade has been dedicated to helping kidney cancer patients and their families deal with the physical, emotional and social impact of kidney cancer. I hold a JD from the University of Chicago's Law School and an MA from the Fletcher School.

As the only national kidney cancer patient organization, directed by patients for patients, the Association realizes the importance of a national policy that encourages the efficient development of new drugs and therapies. The Association commends the Food and Drug Administration ("FDA" or "Agency") for holding this important meeting of the public stakeholders prior to the development of new legislation relating to Prescription Drug User Fees ("PDUFA-3"). The Association believes that it is important the voices of the patients and their advocates be heard at the beginning of this process.

Kidney cancer is an uncured disease. There are approximately 200,000 Americans who have kidney cancer. About 30,000 new cases are diagnosed each year. And each year about 12,000 Americans die from kidney cancer. The incidence of kidney cancer in the nation is *increasing at an annual rate of about 3%*. It is one of only three types of cancer with an increasing incidence. The average age of a kidney cancer patient at the time of diagnosis is 62.5 years.

The KCA appreciates the opportunity to provide written and oral testimony to the FDA on PDUFA-3. The Association is available to assist the Agency with needed information as it continues to develop PDUFA-3. The Association commends the FDA for assessing and reviewing the complex subject of user fees and their relationship to the improved development and review of human drug and biological products.

An important part of the Association's mission is encouraging research, so that kidney cancer ceases to be an uncured disease. Private sector research and development provides the best hope for finding new cures for cancer. At the same time, research

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and development is the riskiest form of investment, offering at best a very long term payback.

**Prior User Fee Statutes.** The two earlier user fee statutes ("PDUFA -1 and PDUFA -2") have provided badly needed funding to the FDA. The Association was concerned that funding Agency activities through PDUFA fees might diminish Congressional willingness to appropriate the funds that FDA needs to fulfill its obligations. To address this concern, the present legislation mandates more than 50% of the Agency's budget <sup>for 1 ND</sup> must come from appropriations **other than PDUFA**.

While this requirement has served to protect the Agency's Congressional funding, it appears at times the FDA has had to juggle programs and timing of its activities to comply. Such actions are a waste of valuable time and effort by the Agency. Congress should not abdicate its responsibility to provide adequate funding because of PDUFA.

The Association believes that PDUFA serves as a blueprint for public/private partnerships. KCA is interested in seeing the performance metrics provided for by PDUFA -2, which are not yet available. The Association has heard anecdotally, however, that the FDA has improved circulation and timing of minutes of various meetings, for example. This suggests that the performance metrics will be favorable when they are available.

The Association believes that it is important to maintain a balance on funding the Agency's activities. Looking at nations where a much larger share of the regulator's budget comes from user fees, such as Canada, the UK and Australia, suggests to the Association that increasing reliance on user fees to fund the Agency would be stepping backwards.

Rather, the Association supports the idea of patient advocates working with the FDA to secure adequate funding from Congress. This would, of course, require that the Agency have a more transparent budgeting process.

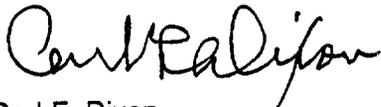
**PDUFA - 3 Issues.** The KCA believes that some revisions to the PDUFA blueprint should be considered in connection with PDUFA - 3. The Association is concerned that adequate funding be provided to the FDA to conduct appropriate advertising review. Nor is it clear that it has the funds needed to appropriately follow up on adverse incident reports. PDUFA - 3 funds should **not** be used for these purposes. Congress needs to provide the funding required.

PDUFA -2 and the related FDA Modernization Act ("FDAMA") created a national listing of clinical trails in a public access data base. This data base was a replacement for the PDQ system. The legislation was passed with an unfunded mandate. This data base needs the full support of the Agency to make sure that patients and their advocates are fully aware of the experimental treatments for serious or life-threatening diseases and conditions. Making the public aware of these trials will also assist the research pharmaceutical industry by making patient accrual to trials more expeditious. Under Section 113 of FDAMA the sponsor of each FDA clinical trail is to submit "such information...not later than 21 days after the approval [by the FDA] of the protocol." The Agency must have the responsibility for making sure that this information is submitted as required.

Therefore, the Association believes that PDUFA –3 should provide for such things as the following:

- The Agency should implement the recommendations of the Armitage Report and create a Center for Cancer Drug Development. At present its cancer activities are spread among several different Centers and Offices. These should be combined into one so that all of the personnel working in the area of cancer are located together.
- Specific line item funding, that can be used for nothing else and represents new funding to the FDA budget, is necessary to make sure that the wonderful public access data base mandated by FADMA is fully complied with by the research pharmaceutical companies.
- The pediatric exclusivity provision contained in PDUFA – 2 should be continued in PDUFA – 3. The benefits of this approach are just now beginning to be seen. This is a useful concept that should be continued.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Carl F. Dixon". The signature is written in a cursive, flowing style.

Carl F. Dixon  
President and Executive Director