North American Pediatric Renal Trials and Collaborative Studies

NAPRTCS

2008 Annual Report

Renal Transplantation

Dialysis

Chronic Renal Insufficiency

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North American Pediatric Renal Trials and Collaborative Studies

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I. INTRODUCTION

INTRODUCTION

The North American Pediatric Renal Trials and Collaborative Studies (NAPRTCS) is a research effort organized in 1987. At its initiation, the project was known as the North American Pediatric Renal Transplant Cooperative Study, but the name was changed with the expansion of its mission. At the outset of the study, the operational objective of this group was to obtain the voluntary participation of all renal transplant centers in the United States and Canada in which multiple (>4) pediatric patients received renal allografts annually. Scientific objectives included capture of information about current practice and trends in immunosuppressive therapy with an ultimate goal of improving care of pediatric renal allograft recipients in North America. In 1992, the study was expanded to include pediatric patients who receive maintenance hemodialysis or peritoneal dialysis therapy. In 1994, data collection began on patients with chronic kidney disease (CKD), defined as a Schwartz calculated creatinine clearance $\leq$75 mL/min/1.73 m^2. Now, not only do we hope to register and follow greater than 80% of the children receiving renal allografts in the United States and Canada, but to study the clinical course and natural history of patients with renal dysfunction and to continue following these patients as they move among the end-stage renal disease (ESRD) therapeutic modalities, thus allowing the NAPRTCS to become a complete ESRD patient data system.

The NAPRTCS has three functioning organizational bodies: the Clinical Coordinating Center, the Data Coordinating Center, and the participating Clinical Centers. Appendix A details the participating Clinical Centers.

This report summarizes data received at the Data Coordinating Center through January 3, 2008. We continue to be particularly pleased and grateful for the enthusiastic response of the volunteer clinical centers, without which this project could not be successful.

At the outset of NAPRTCS, "children" were defined as patients who had not yet attained their 18th birthday at the time of their index transplant. The *index transplant* is defined as the first transplant reported to NAPRTCS during the study period. When the study expanded in 1992 to include maintenance dialysis patients, the age criterion was expanded to include patients who had not yet attained their 21st birthday at the time of index transplant or at the time of index initiation of dialysis, whichever came first. The expanded age criterion was adopted for CKD patients.

Data submission for the study is organized to enable analysis of both patient and event characteristics. Among transplant patients, for example, we are interested in graft survival, morbidity, and the relationships that these endpoints have to patient characteristics such as race/ethnicity, sex, and primary renal disease, and to transplant (i.e., event) characteristics such as age at transplantation, donor source, immunosuppressive treatment, and HLA antigen mismatches. Analogous patient and event characteristics are defined in both the CKD and dialysis populations. As data have matured, it has been our intent to design special studies that focus on issues such as quality of life, rehabilitation, physical and mental development, and other questions of interest for particular patient subgroups. In this manner, the study has served — and continues to serve — as a resource to investigators whose research activities are consistent with the goals and objectives of the program. Appendix B is the NAPRTCS Bibliography and a list of special studies and analyses is shown in Appendix C.

Transplantation follow-up status forms are submitted 6 months following transplant and every 6 months thereafter. For dialysis, follow-up status forms are submitted 30 days after initiation, 6 months after initiation, and every 6 months thereafter. CKD follow-up status forms are submitted at 6-month intervals following the initial reported clinic visit.

As of database closure for this report, 16,874 (535 more than in last year's report) patients had been registered in NAPRTCS, as shown in the following table. Of these patients, data have been reported to all three registries (CKD, dialysis, and transplantation) for 858. These data do not necessarily represent a complete accounting of a patient’s clinical course: a patient may have received care for his CKD at a NAPRTCS center, received maintenance dialysis at a non-NAPRTCS center, and rejoined the study when transplantation was performed at a NAPRTCS center. NAPRTCS registrations are summarized below.

SUMMARY OF NAPRTCS PATIENT REGISTRATIONS		
	N	%
All Patients	16874	100.0
CKD only	4586	27.2
Dialysis only	1828	10.8
Transplant only	4810	28.5
CKD and Dialysis	606	3.6
CKD and Transplant	987	5.8
Dialysis and Transplant	3199	19.0
CKD, Dialysis and Transplant	858	5.1
Total Index Transplant Patients	9854	58.4
Total Index Dialysis Patients	6491	38.5
Total CKD Patients	7037	41.7

Forms have been submitted for 10,762 renal transplants: 9,854 are for index transplants (i.e., first transplant reported to registry) while 908 represent additional reported transplants in the same patient since the study's start on January 1, 1987. The 9,854 index transplants are comprised of 5,451 cases where transplantation was the initial registry and 4,403 cases where transplantation occurred subsequent to an initial report of patient registration in the dialysis (n=2,558) or CKD (n=1,043) or both (n=802) registries.

Modality initiation forms have been submitted for 8,451 independent courses of dialysis. An independent course of dialysis therapy is defined to have occurred when a patient is maintained on a hemodialysis or peritoneal dialysis course for 30 or more days. Of these, 6,491 represent index initiations and 1,960 are for initiations subsequent to the index course. The 6,491 index dialysis courses are comprised of 4,386 cases where dialysis is the initial NAPRTCS registration and 2,105 cases of dialysis initiation subsequent to graft failure (n=641) or termination of CKD status (n=1,408) or both (n=56).

Initial CKD status forms have been submitted for 7,037 patients. In NAPRTCS, patients are eligible for the chronic renal insufficiency component if, at the first reported clinic visit, the

Schwartz calculated creatinine clearance is 75 mL/min/1.73 m^2 or lower. In total, we have received a CKD Termination Form for 3,236 of the 7,037 CKD patients.

This report summarizes both patient-level and therapy-level data. In general, descriptive information will focus on the transplant or dialytic modality as the unit of observation. Variables pertinent to the patient (e.g., sex, race, primary diagnosis) will use the number of patients as the denominator. Formal analysis of failure times — patient and graft survival and rejection-free intervals — include only the first transplant during the study period (the index transplant) for each patient. Occasional missing information on individual characteristics results in the analysis of slightly different subgroups. Continued capture of this information is part of the ongoing data collection process.

In addition to the registry components, NAPRTCS initiated its first randomized prospective clinical trial (Protocol IN01) in 1995, the first ever controlled clinical trial of OKT3 induction therapy in children and adolescents. Nested within the primary random assignment to the OKT3 or No OKT3 groups, patients were randomized to receive either Sandimmune or Neoral maintenance cyclosporine therapy. Randomized prospective trials of growth hormone have been performed: one was designed to evaluate the post transplant use of recombinant human growth hormone (rhGH) therapy and the second was a study of rhGH therapy in pediatric dialysis patients. In the transplant study, patients were randomized to standard dose (0.05/mg/kg/day) therapy or a delayed treatment control group. After the initial no treatment period of 12 months, control group patients received rhGH therapy for the duration of the study. In the dialysis study, all patients receive standard dose rhGH therapy during the first 12 months, after which patients are randomized either to continue on standard dose therapy or to receive a double dose (0.10/mg/kg/day). Patients continued on their "randomized" dose for an additional 12 months.

Through the Collaborative Clinical Trials in Pediatric Transplantation effort sponsored by the NIAID, NAPRTCS sites have enrolled patients into large, randomized trials to evaluate the potential to limit steroid therapy in transplant patients. Other research programs are ongoing.

Currently, several NAPRTCS centers have begun a clinical trial investigating the conversion from calcineurin inhibitors to sirolimus at 6 months post-transplant in select patients. This is a limited center study that has begun to accrue patients in 2008. Target enrollment is 50 patients.

II. TRANSPLANTATION

SECTION 1: TRANSPLANT PATIENT CHARACTERISTICS

Patient and transplant characteristics are summarized in Exhibit 1.1 for the entire history of the cooperative study. Because of reporting lags, annual accrual totals are still likely to increase, particularly for the later years. As of database closure for this report, 10,762 renal transplants had been reported for 9,854 pediatric patients. This represents 363 new transplants and 348 patients with their first registry transplant since the last report.

The percentage of males in the registry, about 60%, has been relatively constant over time (from 55% - 63%). White patients comprise 60% of the cohort, black patients 17%, and Hispanic patients 16%. The percentage of white patients in a given year has decreased from a high of 72% in 1987 to under 50% in 2007. There had been a fairly steady increase in the percent of living donors from 1987 (43%) through 2002 (62%). However, the percentage has been decreasing the last 5 years to under 50% currently. Fifty-one percent of all allografts have come from a living donor. The percentage of young recipients (<6 years old) has remained constant over time at about 20%, while young deceased donors (<10 years old) has decreased from 35% in 1987, to 19% in 1991, to 14% in 2000 and is currently <10%.

Recipient history is further characterized in Exhibit 1.2. The most common primary diagnoses remain aplastic/hypoplastic/dysplastic kidneys (in 15.9% of the children) and obstructive uropathy (in 15.6%). Focal segmental glomerulosclerosis (FSGS) is the third most common (11.7%) and continues to be the most prevalent acquired renal disease. The five most frequent diagnoses, excluding unknown and “other” diagnoses, total 52% of the cases, while the remaining diagnoses are each present in no more than 3% of patients. A diagnosis was established for 94% of patients, while biopsy or nephrectomy confirmation of diagnosis is known not to have occurred in 44% of patients. The distributions of the five most prevalent diagnoses vary between black and white patients. For blacks, FSGS is most prevalent (23.1%), followed by obstructive uropathy (15.0%), aplasia/hypoplasia/dysplasia (13.5%), chronic glomerulonephritis (GN) (3.7%), and SLE nephritis (3.6%). The prevalence of cystinosis, reflux nephropathy, and hemolytic uremic syndrome were under 2% among black transplant patients. Among whites, however, the order of the five most prevalent diagnoses is obstructive uropathy (17.0%), aplasia/hypoplasia/dysplasia (16.9%), FSGS (9.0%), reflux nephropathy (6.2%), and medullary cystic disease (3.7%). The relative order of these prevalent primary diagnoses among Hispanics is similar to that for white patients, except chronic GN is present in 5.4% of the

Hispanics (2.5% of the white patients) and medullary cystic disease is present in only 1.2% of Hispanics.

At the time of their index transplant (first NAPRTCS transplant), 13% (1,241/9,854) of patients were receiving their second (or greater) transplant. Twenty-five percent of primary transplants were preemptive, as these patients had never received maintenance dialysis (Exhibit 1.3). The rate of preemptive transplantation differs significantly ($p<0.001$) between recipients of living (34%) and deceased donor (13%) source organs; between males (28%) and females (20%); among age groups, with rates of 19%, 24%, 28%, 23%, and 21% for recipients 0-1, 2-5, 6-12, 13-17, and 18-20 years old; and across races with whites, blacks, Hispanics, and "other" races having preemptive transplantation rates of 31%, 14%, 16%, and 18%, respectively. Immediately prior to the primary transplant, the percentages of patients maintained exclusively on hemodialysis and peritoneal dialysis were 28% and 39%; 6% received both. At the time of primary transplant few spleens had been removed (<1%) and all native renal tissue had been removed in 22% of patients; transplanted grafts have been removed in 44% of the repeat transplants (Exhibit 1.3).

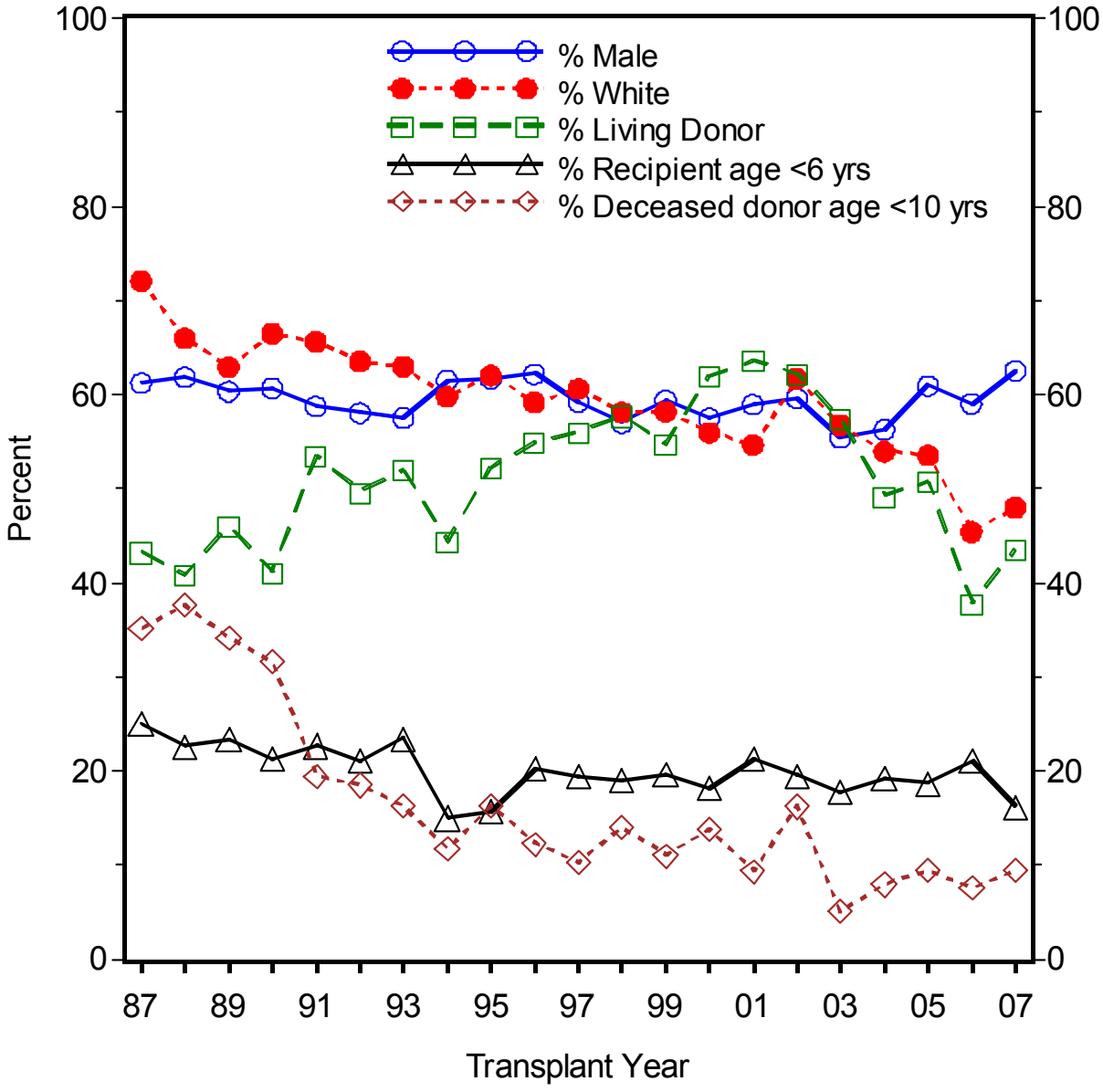
Exhibit 1.4 details recipient age at transplant. Of the 94 transplants occurring in children younger than 12 months old, there were 7, 22, and 63 transplants, respectively, within the 3-5, 6-8 and 9-11 months age categories, and two were less than 3 months. Only 17 infant transplants have been performed since 2000, one in 2000, four in 2001, six in 2002, two in 2004, three in 2005, and one in 2006 — although these numbers may increase as enrollment reports increase. In Exhibit 1.5, it is observed that the sex distribution is most unbalanced in the youngest age groups where 69% of 0-1 and 66% of 2-5 year old patients are male; the distribution is more even among adolescents (56% males). This is due to the fact that males comprise the majority of the aplasia/hypoplasia/dysplasia (62%) and obstructive uropathy (85%) diagnoses (see Exhibit 1.6) and the relative incidence of these diagnoses decreases with age. Thirty-nine percent of male patients fall into these two diagnostic categories, compared to 21% of females. The contrast is particularly steep in the obstructive uropathy group, a diagnosis shared by 22% of the males, but only 6% of females.

Exhibit 1.6 provides for each primary diagnosis the percentages of patients who are male, white race, and known not to have had a biopsy or nephrectomy confirmation of diagnosis. Of transplant registrants with FSGS, 48% are white. Systemic lupus erythematosis is predominantly a disease of females (83%) with a female-specific race distribution given by

24% white, 38% black, 26% Hispanic and 11% other. The percentages of patients *without* a histologically confirmed tissue diagnosis are 70%, 70%, and 64% in aplastic/hypoplastic/dysplastic, obstructive uropathy, and reflux nephropathy patients, respectively. The comparable rates for FSGS, hemolytic uremic syndrome, and lupus nephritis are 6%, 48%, and 5%.

Exhibit 1.7 categorizes primary diagnoses as either FSGS, GN, structural or other and demonstrates how these distributions differ according to age at transplant. GN is comprised of the following primary diagnoses: chronic glomerulonephritis, idiopathic crescentic glomerulonephritis, mebranoproliferative glomerulonephritis – Type I and Type II, SLE nephritis, Henoch-Schonlein nephritis, Berger's (IgA) nephritis, Wegener's granulomatosis, and membranous nephropathy. "Structural" diagnoses (prune belly, reflux nephropathy and aplasia/hypoplasia/displasias) account for the largest proportion of primary diagnoses among children ages 5 and under; whereas, GN and FSGS diagnoses are more prevalent with increasing age.

EXHIBIT 1.1
PATIENT REGISTRATIONS, TRANSPLANTS, AND SELECTED CHARACTERISTICS



# of	Year of Transplant																					Total
	87	88	89	90	91	92	93	94	95	96	97	98	99	00	01	02	03	04	05	06	07	
Pts	531	502	463	498	500	548	574	550	626	551	556	499	517	428	473	441	397	399	340	292	169	9854
Txs	542	530	505	550	565	604	622	627	688	630	597	559	570	466	512	476	440	428	364	308	179	10762

EXHIBIT 1.2
INDEX TRANSPLANTS

Recipient and Transplant Characteristics	N	%
Total	9854	100.0
Sex		
Male	5853	59.4
Female	4001	40.6
Race		
White	5893	59.8
Black	1666	16.9
Hispanic	1646	16.7
Other	649	6.6
Primary Diagnosis		
Aplasia/hypoplasia/dysplasia kidney	1564	15.9
Obstructive uropathy	1538	15.6
Focal segmental glomerulosclerosis	1154	11.7
Reflux nephropathy	515	5.2
Chronic glomerulonephritis	328	3.3
Polycystic disease	287	2.9
Medullary cystic disease	271	2.8
Hemolytic uremic syndrome	260	2.6
Prune Belly	254	2.6
Congenital nephrotic syndrome	254	2.6
Familial nephritis	225	2.3
Cystinosis	201	2.0
Pyelo/interstitial nephritis	173	1.8
Membranoproliferative glomerulonephritis - Type I	171	1.7
Idiopathic crescentic glomerulonephritis	171	1.7
SLE nephritis	150	1.5
Renal infarct	136	1.4
Berger's (IgA) nephritis	127	1.3
Henoch-Schonlein nephritis	110	1.1
Membranoproliferative glomerulonephritis - Type II	81	0.8
Wegener's granulomatosis	55	0.6
Wilms tumor	52	0.5
Drash syndrome	52	0.5
Oxalosis	52	0.5
Membranous nephropathy	44	0.4
Other systemic immunologic disease	32	0.3
Sickle cell nephropathy	16	0.2
Diabetic glomerulonephritis	11	0.1
Other	962	9.8
Unknown	608	6.2

EXHIBIT 1.3
TRANSPLANT CHARACTERISTICS

Transplant Type	N	%
Total Transplants	10762	100.0
Index Transplants	9854	91.6
Primary Transplants	8613	80.0
Index Non-primary Transplants	1241	11.5
Non-Index transplants	908	8.4
Repeat Transplants	2149	20.0

Primary Transplant	N	%
Total Primary Transplants	8613	100.0
Preemptive	2116	24.6
Splenectomy	53	0.6
Native Tissue Removed	1897	22.0
Maintenance Hemodialysis	2444	28.4
Maintenance Peritoneal Dialysis	3387	39.3
Both Maintenance Hemo & Peritoneal Dialysis	497	5.8

Repeat Transplants	N	%
Total Repeat Transplants	2149	100.0
Prior Transplants Removed	941	43.8

EXHIBIT 1.4
AGE AT TRANSPLANTATION

Age at Transplantation (years)	N	%
Total	10762	100.0
0	94	0.9
1	478	4.4
2	481	4.5
3	368	3.4
4	349	3.2
5	395	3.7
6	379	3.5
7	427	4.0
8	458	4.3
9	492	4.6
10	602	5.6
11	572	5.3
12	629	5.8
13	767	7.1
14	784	7.3
15	893	8.3
16	922	8.6
17	833	7.7
≥18	839	7.8

Age Groupings (years)	N	%
0-1	572	5.3
2-5	1593	14.8
6-12	3559	33.1
13-17	4199	39.0
≥18	839	7.8

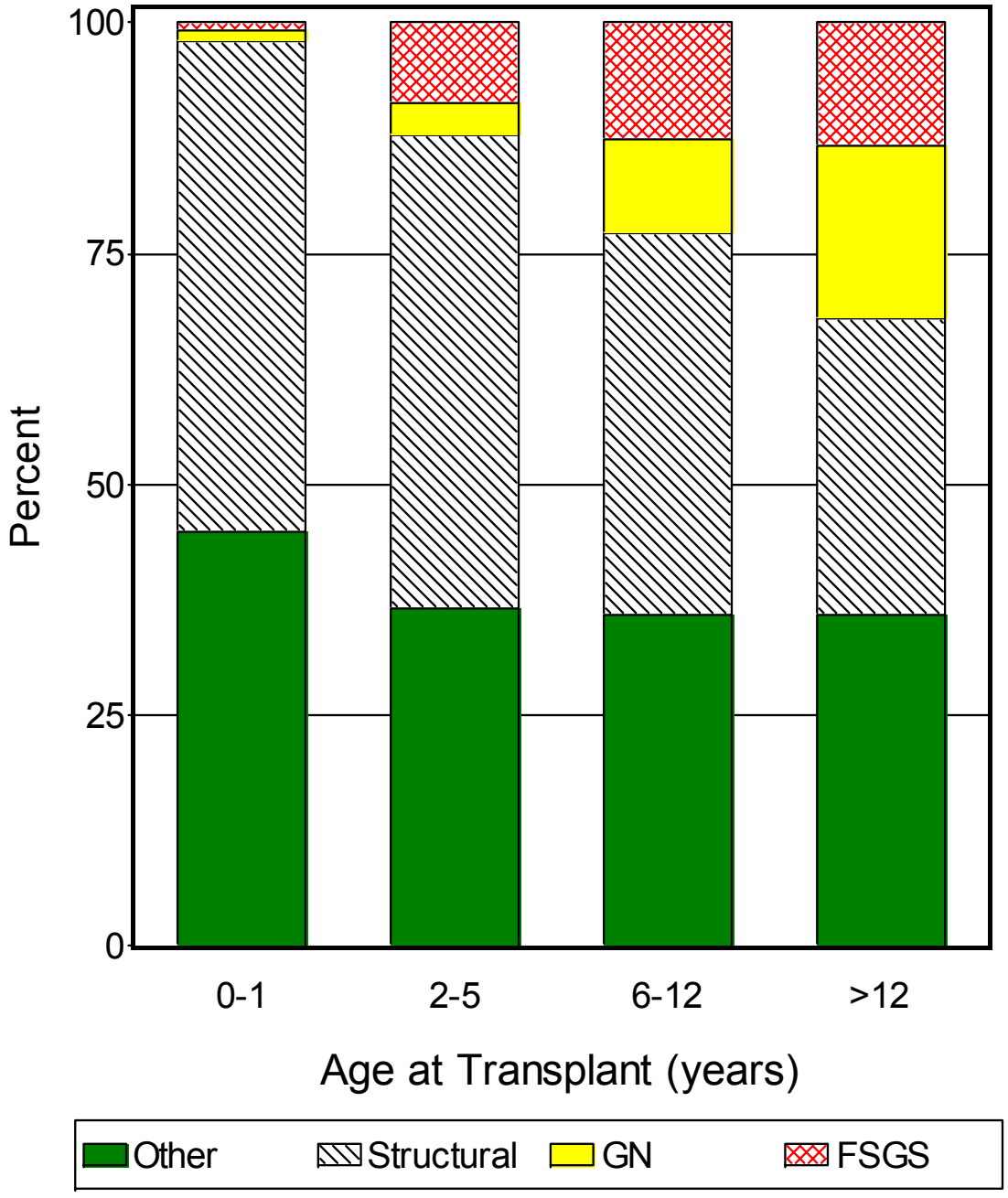
EXHIBIT 1.5
AGE AT INDEX TRANSPLANT
BY SEX, RACE, AND PRIMARY DIAGNOSIS

	Age at Transplantation				
	0-1 years (percent)	2-5 years (percent)	6-12 years (percent)	13-17 years (percent)	≥18 years (percent)
Gender					
Male	68.8	66.3	58.9	56.4	55.6
Female	31.2	33.7	41.1	43.6	44.4
Race					
White	74.5	63.4	60.7	56.6	53.2
Black	8.1	14.5	14.6	19.8	24.2
Hispanic	11.0	15.6	18.0	17.2	14.8
Other	6.4	6.5	6.7	6.4	7.8
Primary Diagnosis					
Renal plasias	29.6	23.7	16.5	11.3	10.0
Obstructive uropathy	18.1	21.2	16.1	13.6	10.1
Other	51.5	46.4	54.7	62.2	63.6
FSGS	0.9	8.7	12.6	12.9	16.3

EXHIBIT 1.6
SEX, RACE, AND BIOPSY DISTRIBUTIONS BY PRIMARY RENAL DIAGNOSIS

Primary Renal Diagnosis	N	% Male	% White	% Not Biopsied
Total	9854	59.4	64.0	44.0
Aplasia/hypoplasia/dysplasia	1564	61.8	67.4	70.1
Obstructive uropathy	1538	85.2	67.9	69.6
Focal segmental glomerulosclerosis	1154	57.8	48.4	6.4
Reflux nephropathy	515	43.3	78.5	64.5
Chronic glomerulonephritis	328	43.0	49.5	25.3
Polycystic disease	287	52.3	77.2	48.1
Medullary cystic disease	271	49.8	87.6	33.6
Hemolytic uremic syndrome	260	56.2	81.2	48.1
Prune Belly	254	97.6	63.0	61.8
Congenital nephrotic syndrome	254	53.1	69.9	13.0
Familial nephritis	225	80.0	62.0	27.6
Cystinosis	201	54.2	90.4	55.2
Pyelo/interstitial nephritis	173	48.0	78.1	23.7
Membranoproliferative glomerulonephritis - Type I	171	44.4	59.6	2.9
Idiopathic crescentic glomerulonephritis	171	33.9	57.1	4.7
SLE nephritis	150	16.7	26.9	4.7
Renal infarct	136	47.8	80.9	63.2
Berger's (IgA) nephritis	127	53.5	70.5	6.3
Henoch-Schonlein nephritis	110	40.9	75.0	14.5
Membranoproliferative glomerulonephritis - Type II	81	50.6	80.3	3.7
Wegener's granulomatosis	55	45.5	78.0	7.3
Wilms tumor	52	57.7	68.1	7.7
Drash syndrome	52	57.7	78.8	7.7
Oxalosis	52	53.8	91.1	25.0
Membranous nephropathy	44	61.4	53.7	6.8
Other systemic immunologic disease	32	12.5	61.5	6.3
Sickle cell nephropathy	16	56.3	0.0	25.0
Diabetic glomerulonephritis	11	36.4	36.4	36.4
Other	962	51.9	63.7	35.9
Unknown	608	53.3	33.2	66.4

EXHIBIT 1.7
PRIMARY DIAGNOSIS BY AGE



SECTION 2: DONOR HISTORY AND ANTIGEN MISMATCHES

As described in Exhibit 2.1, 48.6% of all transplants have involved a deceased donor source, 41.2% came from a parent, with the remaining 10.2% coming from other living donors. Parents comprise 80.0% of living donors: a cross-classification of parent and child sexes (n=4,092 pairs with complete data) reveals that mothers comprise the majority of parent-donors (55.6%), fathers donate to sons 63.3% of the time, while mothers make 59.3% of their donation to sons (p=0.009). There have been 382 transplants between siblings, and 182 (3.3%) live-donor grafts have been from donors under the age of 21. Fifteen living donors were under 18 years of age: 13 were transplants between siblings, 1 was a transplant from parent to child and one was unrelated. For these young sibling donors, the numbers of 3-, 4-, 5-, and 6-antigen matches were 1, 2, 3, and 7, respectively. The number of unrelated living donors has increased from an average of 3 per year in 1987-1995 to 16 per year since then.

Among deceased donor source transplants, 70 (1.3%) have come from donors less than 24 months old and 1058 (20.3%) from donors who were between 2 and 12 years of age; the use of deceased donors <10 years old has declined since the study's start (see Exhibit 1.1). Prior to 1992, infant donors comprised 2.9% (42/1,466) of deceased donor sources, compared to 0.8% (28/3,385) in transplants between 1992 and 2007. Of deceased donor source allografts, 12.6% were preserved by machine perfusion and 71.8% had cold ischemia times of 24 hours or less, with 17 (0.3%) exceeding 48 hours. The median cold time was 20.0 hours; the maximum was 64.5 hours.

Donor-specific transfusions with or without IS coverage were performed in 6.2% of living donor grafts but this procedure has been used only occasionally since 1995. The total number of random transfusions given to recipients differed by donor type: 50.8% of living donor graft recipients and 37.3% of deceased donor graft recipients had zero previous transfusions, while 12.4% and 25.8%, respectively, had more than five transfusions (p<0.001). The percent of patients without prior random transfusions has increased from 17.0% in 1987 (26.5% living and 9.6% deceased donor recipients) to 72.2% in 2007 (72.9% living and 71.6% deceased donor recipients). Time trends in the utilization of donor-specific and random transfusions are provided in Exhibit 2.2.

To date, there have been 54 (0.5%) confirmed transplants across ABO blood group compatibility barriers out of 9,812 transplants with complete blood group data. For O recipients, there have been 32 A donors, 7 B donors, and 2 AB donors; for A recipients, there have been 2 B donors and 2 AB donors; and for B recipients, there have been 6 A donors and 3 AB donors. A special analysis of an early cohort of these patients concluded that pediatric kidney transplantation across ABO compatibility barriers is an uncommon practice, but suggested — based on preliminary experience — that such transplants involving recipients whose anti-A titer history is low (1:4) are associated with satisfactory graft outcome and are deserving of further study. Overall, 87.5% (8,587/9,812) of donor and recipient blood types were identical. Whereas blood group O is present in 56.3% of donors and 47.2% of recipients, blood group AB is present in 1.4% of donors and 3.9% of recipients.

Histocompatibility antigen data are shown in Exhibit 2.3. We count an allele as matching only if identical known alleles are reported for both donor and recipient. Among the living donor transplants, 71.6% had at least one match at each of the A, B, and DR loci, and there were mismatches at all 6 A, B, and DR loci for 15.1% of cases. No matches in either the B or DR loci occurred in 38.9% of the transplants from deceased donor sources; at least one locus match (of B or DR) occurred in 25.1%. Known matches of all 6 A, B and DR alleles occurred in 2.3% of deceased donor source transplants and in 3.4% of living donor source transplants.

Exhibit 2.4 compares donor sources with varying ages at transplant. Children under 5 years of age are more likely to receive a transplant from a living donor rather than a deceased donor, while children ≥ 13 years of age are more likely to receive a deceased donor transplant.

EXHIBIT 2.1
DONOR INFORMATION

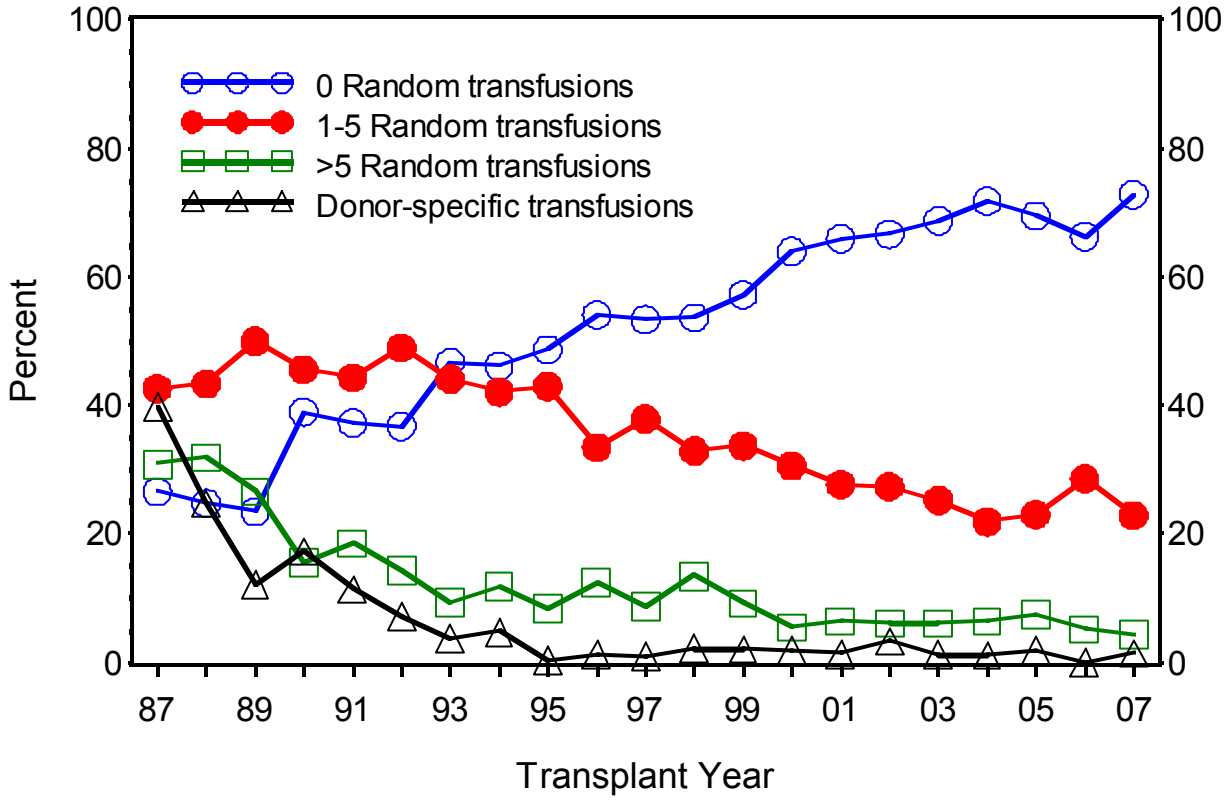
Donor Source	N	%
Live donor/parent	4410	41.2
Live donor/sibling	382	3.6
Live donor/other related	487	4.5
Live donor/unrelated	232	2.2
Deceased Donor	5202	48.6
Missing Donor Type	(49)	

	Living Donor		Deceased Donor	
Donor Age (years)	N	%	N	%
0-1	--	--	70	1.4
2-5	--	--	436	9.0
6-12	--	--	632	13.0
13-17	15	0.3	739	15.2
18-20	167	3.2	556	11.5
21-30	1147	21.7	872	18.0
31-40	2376	45.0	715	14.7
41-50	1369	25.9	558	11.5
> 50	206	3.9	273	5.6
Missing Donor Age	(231)		(351)	

Deceased Donor Source Transplants	N	%
Machine Perfusion Used	560	12.6
Cold Ischemia Time $\leq$ 24 hours	3322	71.8
Cold Ischemia Time > 24 hours	1307	28.2

EXHIBIT 2.2
BLOOD TRANSFUSION USE BY YEAR OF TRANSPLANT

Living Donor



Deceased Donor

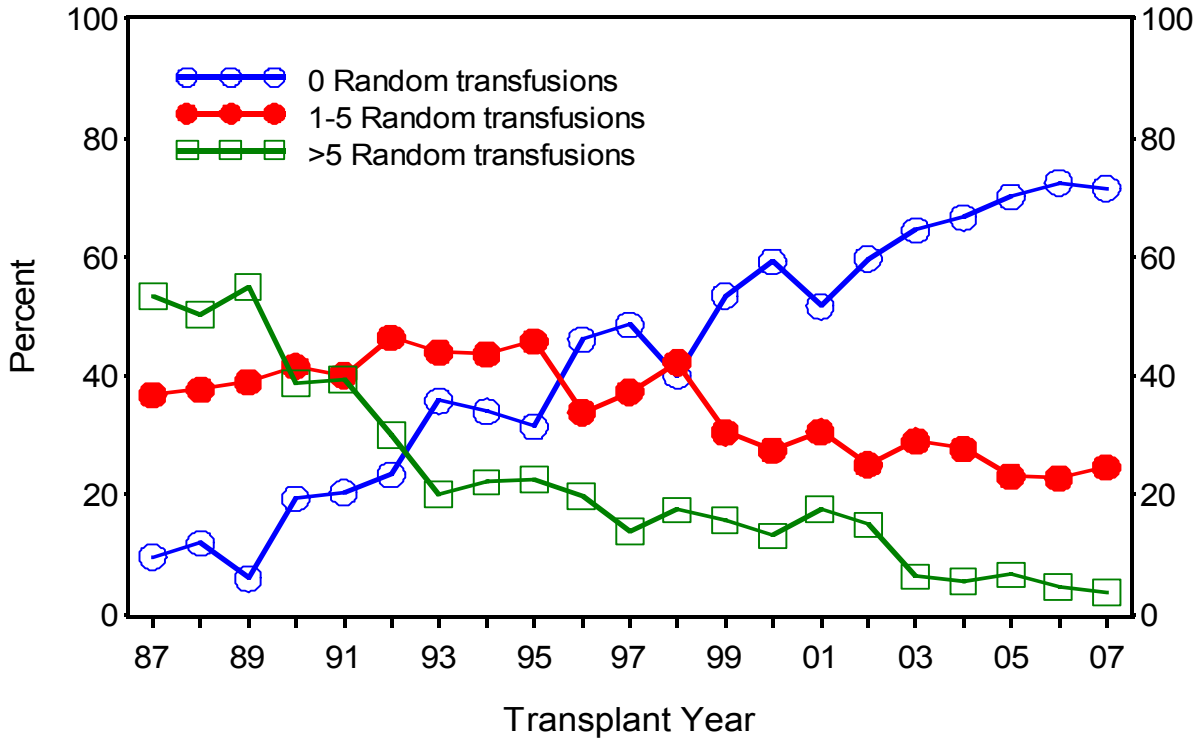
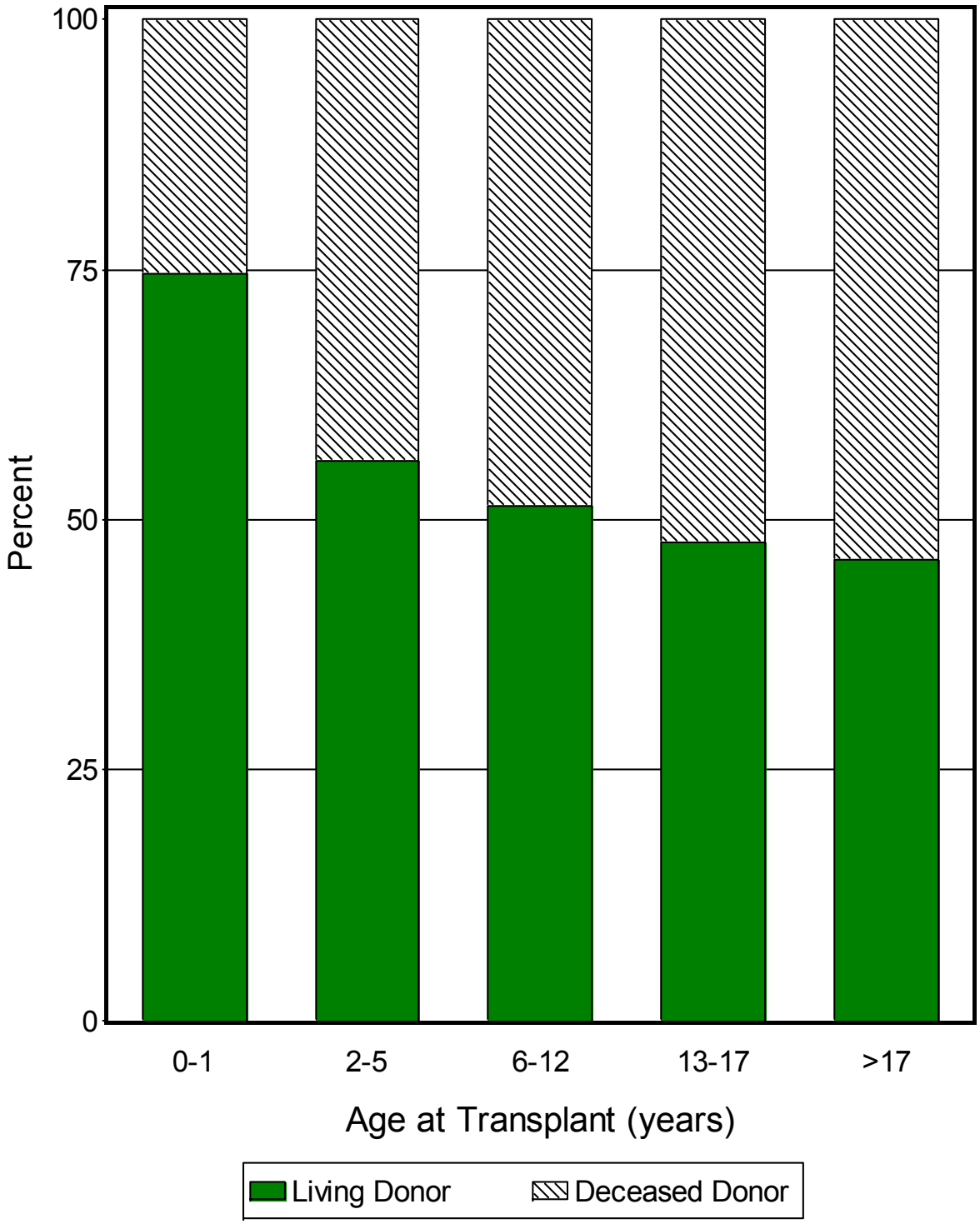


EXHIBIT 2.3
HLA MISMATCHES

	Living Donor		Deceased Donor	
	N	%	N	%
Total	5511	100.0	5202	100.0
HLA-A				
0	776	14.1	410	7.9
1	3738	67.8	1923	37.0
2	997	18.1	2869	55.2
HLA-B				
0	595	10.8	401	7.7
1	3799	68.9	1570	30.2
2	1117	20.3	3231	62.1
HLA-DR				
0	752	13.6	486	9.3
1	3454	62.7	2028	39.0
2	1305	23.7	2688	51.7
HLA-B and -DR				
0	280	5.1	174	3.3
1	732	13.3	302	5.8
2	3054	55.4	1069	20.5
3	523	9.5	1632	31.4
4	922	16.7	2025	38.9
HLA-A, -B, and -DR				
0	186	3.4	121	2.3
1	253	4.6	119	2.3
2	927	16.8	255	4.9
3	2689	48.8	663	12.7
4	459	8.3	1233	23.7
5	163	3.0	1319	25.4
6	834	15.1	1492	28.7

EXHIBIT 2.4
DONOR SOURCE BY AGE AT TRANSPLANT



SECTION 3: THERAPY

The NAPRTCS collects information on post-transplant immunosuppressive medications and dosages at Day 30, Month 6, and every six months thereafter. In addition, a record of the initial day and dose of immunosuppressive medication used during the first post-transplant month is collected. Because of the changes in therapy over the years, this section is restricted to all transplants reported in more recent times starting in 1996. This encompasses 5529 transplants of which 92% are index transplants, 79% are primary transplants, 55% are from living donors and 45% are from deceased donors. Three percent (182) of the grafts failed by 30 days.

Detailed description of pre-operative immunosuppressive therapy is not collected, but it was employed in 43% of living donor transplants. The frequency of use of pre-operative immunotherapy among living donor transplant recipients has remained steady over the last 5 years at about 42%. Among deceased donor transplants, the use of pre-operative immunotherapy has increased from 9% in 1996 to 25% in 2006, but was being used in only 14% of the 2007 cases.

Immunosuppression during the First 30 Days

Exhibit 3.1 details immunosuppressive medication data for the first 30 days post-transplant. Polyclonal antibody ATG/ALG was used in 14% of living donor transplants, decreasing from 28% in 1996 to 5% in 2000, and increasing to 16% in 2006/2007. ATG/ALG was used in 20% of deceased donor transplants, with a similar decrease from 36% in 1996, to 11% in 2000, with a 16% utilization rate in 2006/2007. The median ATG/ALG course was 6 days. The use of monoclonal antibodies has increased from 21% in 1996 to 51% in 2006/2007 for living donor transplants and from 30% in 1996 to 50% in 2006/2007 for deceased donors. The type of monoclonal antibodies has also changed over the years from predominantly OKT3 in 1996 to balsiliximab or daclizumab in 2007. The median length of an OKT3 course was 9 days; for basiliximab patients, it was 2 days; and for daclizumab recipients, the median course was 5 days. Most therapy with monoclonal antibodies is initiated at transplant or Day 1 post transplant. These cases are considered to have induction antibody therapy. However, 164 cases have monoclonal antibody initiated after Day 1 (median day 4 range day 2-28). These cases are not considered induction and are not included in the induction antibody exhibits. The rate of induction antibody use at transplant or one day post transplant, by transplantation year is shown graphically in Exhibit 3.2 and is as follows:

PERCENT INDUCTION ANTIBODY (Initiated at transplant or day 1 post transplant)												
	1996 n=630	1997 n=597	1998 n=559	1999 n=570	2000 n=466	2001 n=512	2002 n=476	2003 n=440	2004 n=428	2005 n=364	2006 n=308	2007 n=179
None	50.5	52.4	44.0	43.9	46.8	45.7	41.0	44.8	48.1	41.5	35.1	46.4
OKT3	21.8	14.6	9.7	4.7	0.4	1.0	0.8	0.5	0.0	0.0	1.0	0.0
Basiliximab	0.0	0.7	4.7	15.1	21.2	29.9	31.3	24.8	24.3	22.8	21.8	24.0
Daclizumab	0.0	4.9	18.1	25.1	19.7	15.0	15.3	13.2	12.4	14.8	19.2	9.5
Other	0.0	0.2	0.9	0.7	6.0	2.9	4.4	5.7	5.8	5.8	9.1	6.2
ATG/ALG	27.8	27.3	22.7	10.5	5.8	5.5	7.1	11.1	9.4	15.1	14.0	14.0

Exhibit 3.3 shows the percentage of week 1 calcineurin inhibitor use by type of induction antibody. OKT3 and ATG/ALG are combined most often with cyclosporine and basiliximab is combined most often with tacrolimus. Cyclosporine and tacrolimus regimens use daclizumab at about the same frequency.

Sirolimus therapy first appeared in 1998 (<1% of the cases), peaked in 2002 with 26% of the cases receiving sirolimus and has tapered off to 3% in 2007. The median day of initiation is 1 day post-transplant with a median initial dose of 3.1 mg/m^2.

Cyclosporine was used for 48% of transplants (see Exhibit 3.1), decreasing from 82% in 1996 to 8% in 2006/2007. Cyclosporine began on the day of transplant for 23%, on day 1 for 27%, days 2-6 for 39% and after day 6 for 10% of the transplants. The median dose of cyclosporine increased during the first month by 1.4 mg/kg and the most common formulation used is Neoral (83%). Tacrolimus was used in 43% of the transplants increasing from 6% in 1996 to 74% in 2006/2007. Tacrolimus was started the day before transplant (2%) or the day of transplant in 19%, on day 1 for 39%, day 2-6 for 31% and after day 6 for 8% of the transplants. The median dose of tacrolimus increased by 0.06 mg/kg during the first month. Prednisone was used in 95% of the cases in 1996. From about the year 2000 prednisone utilization has been decreasing and currently 61% of the cases are treated with prednisone at day 30. Although early graft failures decrease the number of patients still available for immunosuppressive therapy by Day 30, the percentages being treated with prednisone is relatively stable during the first month (84.7% initially and 84.9% at day 30 in patients with functioning graft). Over the month, the median dose of prednisone decreased to approximately 1/3 of the initial amount.

Exhibit 3.4 shows the marked changes in day 30 post transplant dosing strategies (in patients with functioning grafts) that have been observed in the past years. These are substantially caused by the introduction of new drugs such as mycophenolate mofetil and tacrolimus. Use at Day 30 of combination cyclosporine, prednisone, and azathioprine has declined since 1996-1997, from 38% of living donor and 40% of deceased donor organ recipients, to <1 in each group in 2005-2007. The regimen of prednisone, tacrolimus, and mycophenolate mofetil has become more popular. It is used in 60% of living donor and 65% of deceased donor organ transplant in 2005-2007, compared to about 4% of all transplants in 1996-1997.

PERCENT DRUG UTILIZATION - DAY 30 POST TRANSPLANT
(Patients with functioning grafts)

	1996 n=596	1997 n=574	1998 n=533	1999 n=547	2000 n=448	2001 n=496	2002 n=466	2003 n=431	2004 n=422	2005 n=355	2006 n=303	2007 n=176
Prednisone	95.1	97.0	95.1	93.4	92.0	88.5	85.6	73.6	69.0	67.9	62.7	60.8
Cyclosporine	82.4	80.0	72.2	68.6	57.6	46.8	26.2	16.0	9.0	10.4	5.3	10.8
Tacrolimus	3.7	15.0	22.3	24.7	34.6	42.3	58.8	60.6	71.3	69.0	71.6	65.3
MMF	9.1	45.5	66.8	67.3	64.3	54.8	58.2	58.7	64.7	71.8	69.3	66.5
Azathioprine	49.5	34.8	19.9	16.3	13.8	13.1	2.6	3.9	3.3	1.1	1.7	3.4
Sirolimus	0.0	0.0	0.2	0.4	7.6	21.8	25.8	18.8	11.6	5.9	6.3	3.4

This table above mirrors the data in Exhibit 3.4, showing substantial increases in tacrolimus and mycophenolate mofetil, along with a significant decrease in cyclosporine and azathioprine usage. Azathioprine usage has decreased sharply from 50% in 1996 to 3% by 2002, where it remains. Cyclosporine was used in 82% of the 1996 transplants at Day 30, and it continues to show a decline in utilization to 11% in 2007. Prednisone use has slowly been decreasing in recent years from 95% in 1996 to 61% in 2007.

Immunosupppression during Follow-up

Exhibit 3.5 presents immunosuppressive therapy dosages for patients with functioning grafts for selected drug combinations during follow-up. Median daily prednisone doses decrease over the first 2 years after transplantation, while the percentage of transplanted patients receiving alternate day therapy increases from 7% at Month 6 to 16%, 28%, and 36% at years 1, 2 and 4, respectively. Living and deceased donor recipients show similar rates of alternate day prednisone therapy. Tacrolimus recipients receive lower steroid and MMF doses than those on cyclosporine.

Combination therapy at 30 days post transplant and during follow-up for patients with functioning grafts is as follows:

PERCENT DRUG UTILIZATION - POST TRANSPLANT (Patients with functioning grafts)							
	30 days	6 month	1 year	2 years	3 years	4 years	5 years
Prednisone/CsA/MMF	26.5	28.3	28.0	26.9	26.4	24.1	22.6
Prednisone/CsA/Aza	14.9	12.5	11.6	11.6	11.0	10.0	8.5
Prednisone/Csa	8.6	5.0	4.1	4.0	3.8	5.2	5.2
Prednisone /TAC/MMF	29.0	32.7	31.1	29.2	29.5	30.1	30.6
Prednisone /TAC/Aza	2.1	3.5	4.0	4.8	5.8	6.7	7.0
Prednisone /TAC	7.7	9.0	9.4	11.1	10.9	11.1	11.4
TAC/MMF	3.3	2.8	3.4	3.4	2.9	2.7	2.6
Other combinations	8.0	6.3	8.6	9.0	9.7	10.1	12.2

Type of therapy during follow-up remains relatively stable, with slight decreases in cyclosporine based regimens and slight increases in tacrolimus based regimens reflecting the change in immunosuppressive therapies over time.

Exhibit 3.6 displays the percentage of patients at selected follow-up time points who were receiving the eight most common maintenance regiments, by graft donor source. Through 3 years, about 27% of the patients received combination immunosuppressives with prednisone, cyclosporine, and MMF, compared to approximately 12% of patients with prednisone, cyclosporine and azathioprine. About 30% received therapy with prednisone, tacrolimus and MMF and about 10% received prednisone and tacrolimus. Note that therapy strategies appear similar for deceased donor recipients and live donor recipients.

Because of the differential graft survival in black and non-black patients, calcineurin inhibitor blood levels have been examined. At 1 year post transplant, black patients median cyclosporine level was 181 ng/mL (versus 177 ng/mL for non-blacks); and median tacrolimus level was 6.1 ng/mL (versus 6.0 ng/mL for non-blacks). Blood levels by measurement methods are presented below. No deficit in either dose prescribed or blood levels is noted.

IMMUNOSUPPRESSION DOSE AND BLOOD LEVELS (ng/mL) AT 12 MONTHS								
	BLACK				NON-BLACK			
	N	Median	Mean	SE	N	Median	Mean	SE
Cyclosporine Dose (mg/kg/D)	245	6.2	6.7	0.2	1537	6.0	6.8	0.1
CsA Blood Level Method - HPLC	36	161.5	169.4	14.9	318	137	149.4	3.9
CsA Blood Level Method - TDx	138	199	234.2	15.8	770	204	234.9	5.9
CsA Blood Level Monoclonal RIA-specific	40	146	174.7	16.6	263	167	188.1	5.7
Tacrolimus Dose (mg/kg/D)	421	0.17	0.20	0.01	1621	0.12	0.14	0.00
TAC Blood Level Method - HPLC	28	6.1	6.4	0.5	169	6.2	8.3	1.1
TAC Blood Level Method - IMx	139	6.2	6.6	0.3	364	5.7	6.3	0.2

Concomitant Medications

The percentage of patients receiving concomitant anti-hypertensive, prophylactic antibiotic, and anticonvulsant medications, by donor source, are displayed in Exhibit 3.7. A substantial percentage of transplanted children receive antihypertensive medications and antibiotics throughout the follow-up period. The use of antihypertensive medication is 84% for deceased donor and 79% for live donor recipients at transplant. This rate decreases similarly in both groups to 73% in deceased donor and 65% in live donor recipients at 2 years. At 5 years post transplant, the rates are 70% vs. 60% for deceased and live donor recipients. The use of prophylactic antibiotics is similar for deceased and live donors: 80% at transplant falling to 48% at 18 months, where it remains constant to 5 years (45%). At one year, prophylactic antibiotics are used in 48% of those with focal segmental glomerulosclerosis, 56% of those with renal dyplasia, 65% of patients diagnosed with reflux nephropathy and 69% with obstructive uropathy. An anticonvulsant medication was given initially to 5% of the transplant recipients, with no difference observed among recipients of deceased donor organs versus living donor organ recipients. This rate remains constant over the follow-up period.

EXHIBIT 3.1
MEDICATION DATA – FIRST 30 DAYS

Therapy	Percent treated Initially	Median Day of Initiation	Median Initial Dose (mg/kg/D)	Percent treated Day 30*	Median Day 30* Dose (mg/kg/D)
Prednisone	84.7	3	1.51	84.9	0.51
Methylprednisolone	75.6	0	9.55	--	--
Cyclosporine	48.3	1	8.39	46.8	9.81
Tacrolimus	42.6	1	0.15	40.0	0.21
Azathioprine	25.3	0	2.07	16.4	2.02
Mycophenolate Mofetil	61.3	1	27.78	55.7	28.85
ATG/ALG	16.6	0	10.30	--	--
Monoclonal Antibody	42.5	0	--	--	--
OKT3	6.8	0	0.11	--	--
Basiliximab	18.2	0	0.41	--	--
Daclizumab	14.0	0	1.02	--	--
Other	3.4	0	1.04		
Sirolimus	8.1	1	0.11	--	--

For Mycophenolate Mofetil: median initial dose in mg per body surface area is 873.41 and day 30 daily dose is 902.43 mg/m^2/day.

For Sirolomus: median initial dose in mg per body surface area was 3.15 mg/m^2/day.

For ATG/ALG: median dose has decreased from 15.03 mg/kg/D in 1996 to 1.63 mg/kg/D in 2000. In 2007 the median dose is 1.50 mg/kg/D.

* Day 30 results includes only patients with functioning grafts

EXHIBIT 3.2
INDUCTION ANTIBODY USE BY YEAR OF TRANSPLANT

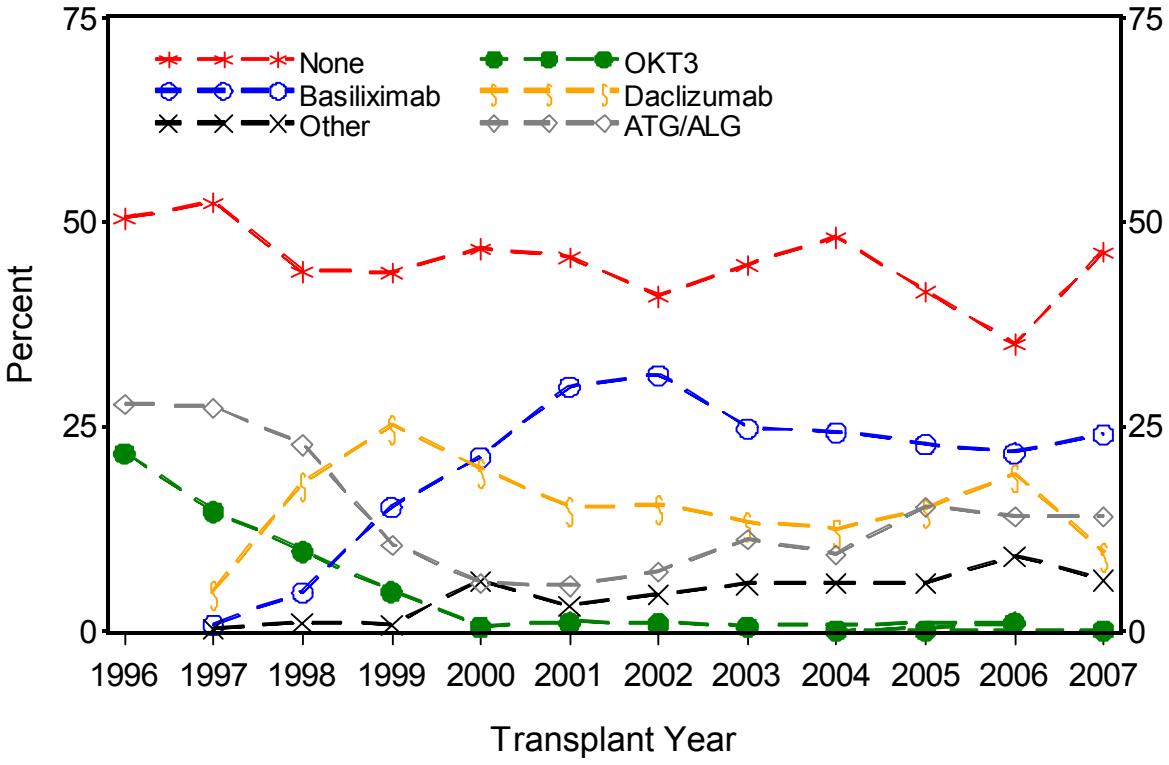


EXHIBIT 3.3
INDUCTION ANTIBODY USE BY WEEK 1 CALCINEURIN INHIBITOR

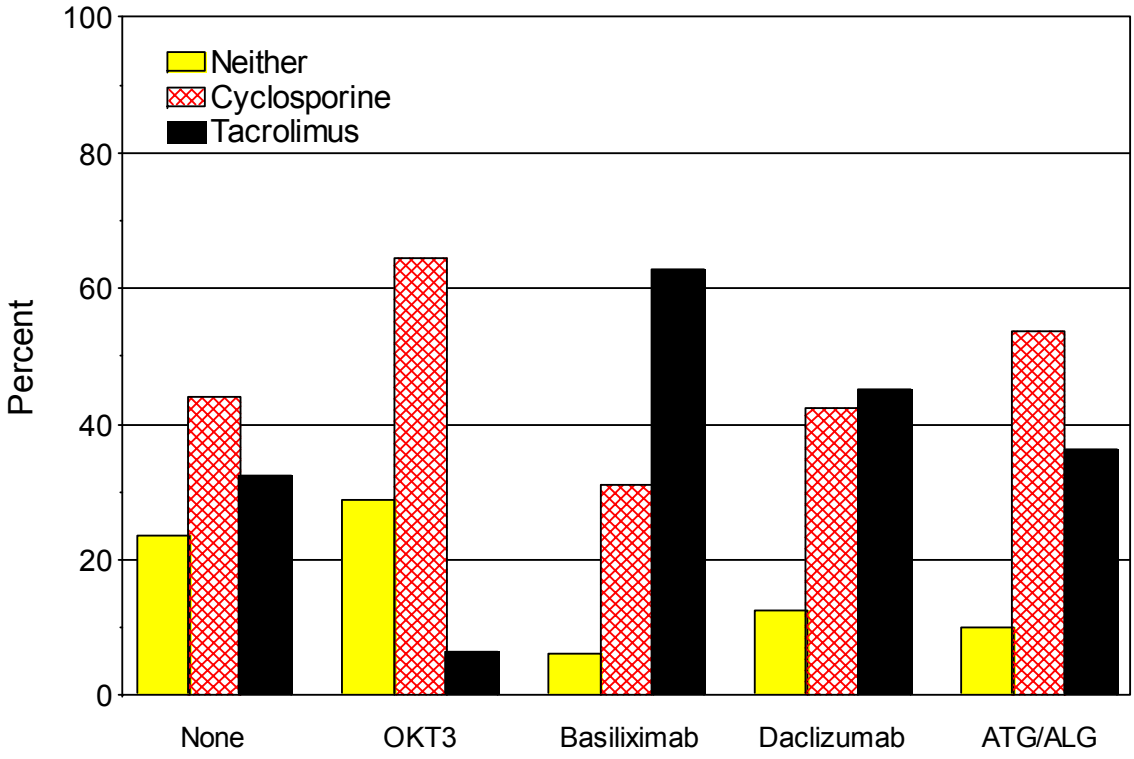
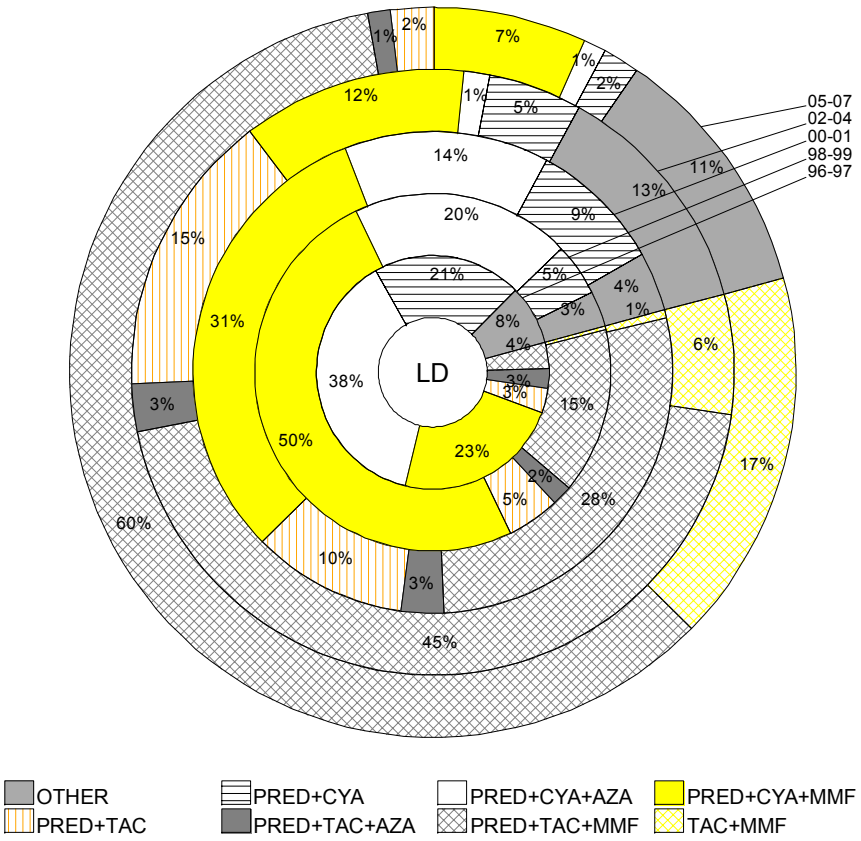


EXHIBIT 3.4
IMMUNOSUPPRESSIVE MEDICATION 30 DAYS POST TRANSPLANT
(patients with a functioning graft)



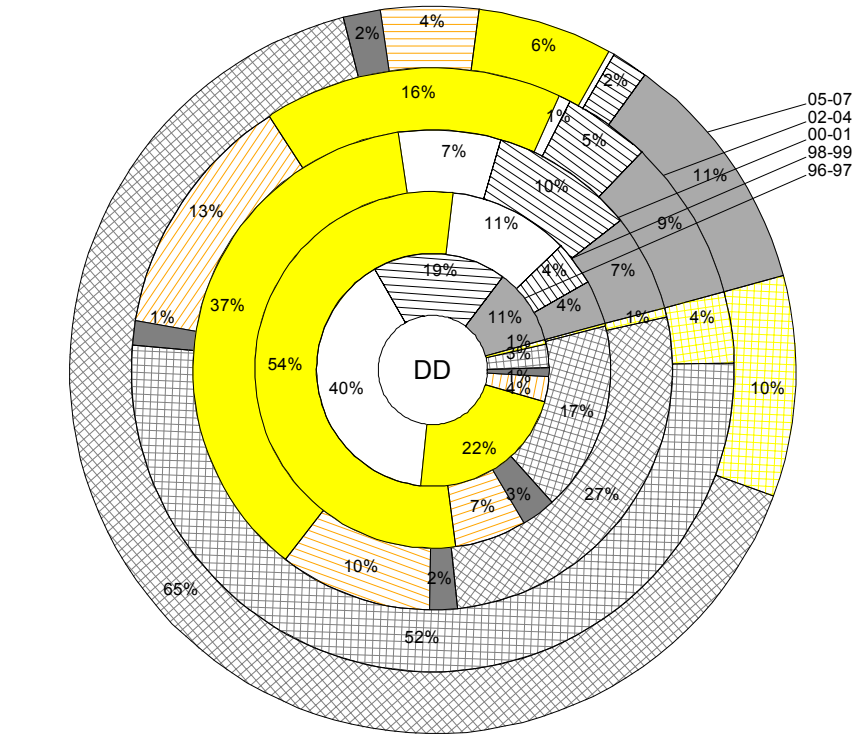


EXHIBIT 3.5
MEAN (±SE) DAILY DRUG DOSAGES BY FOLLOW-UP TIME

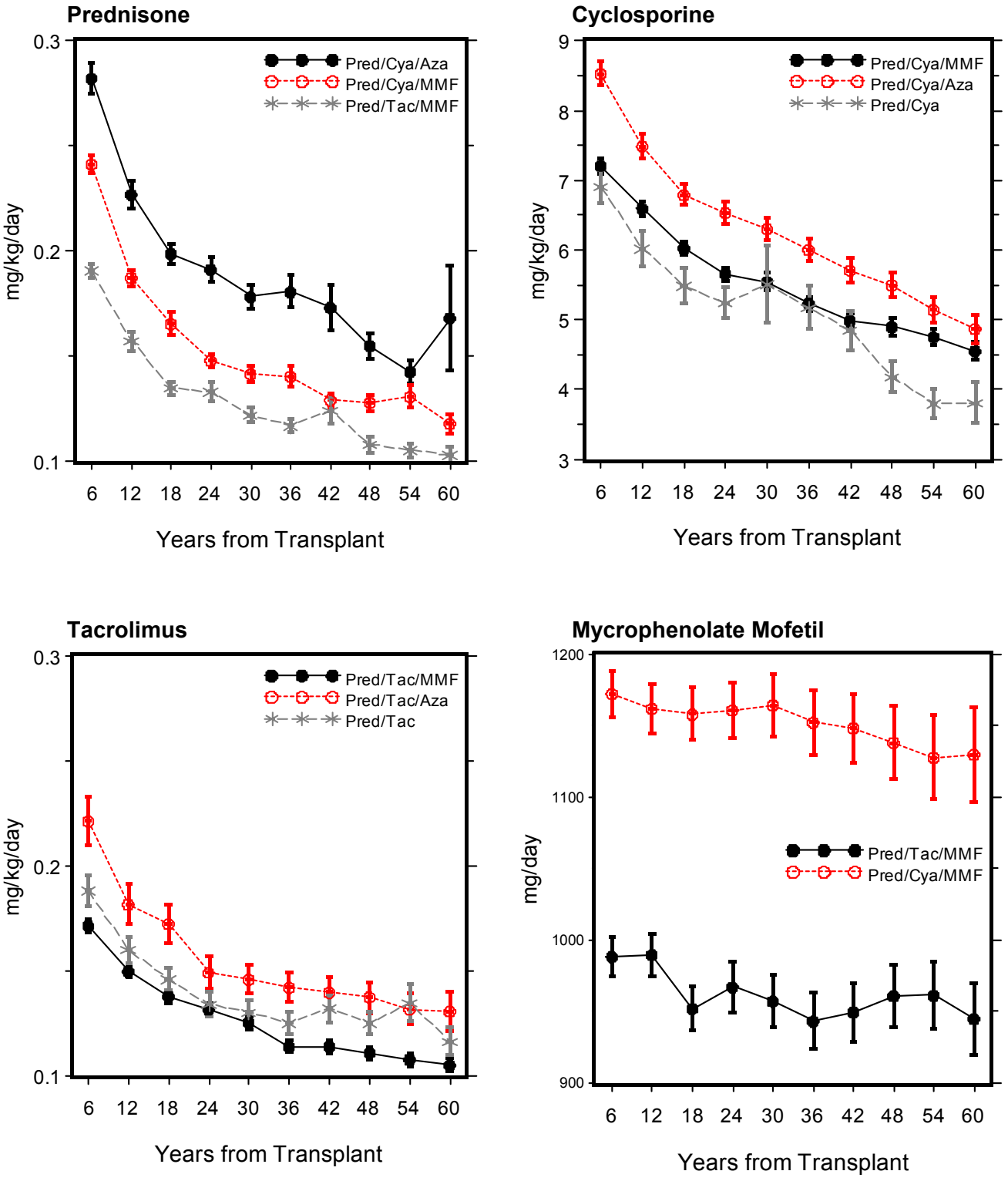
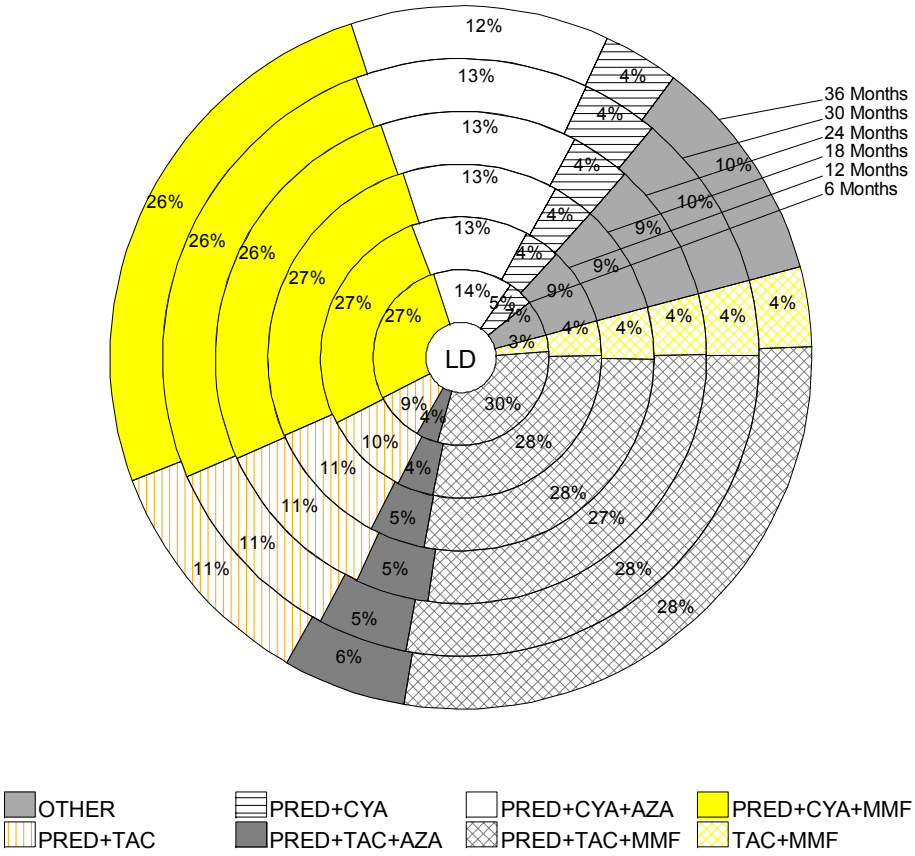


EXHIBIT 3.6
MAINTENANCE IMMUNOSUPPRESSION MEDICATION BY FOLLOW-UP TIME
(patients with a functioning graft)



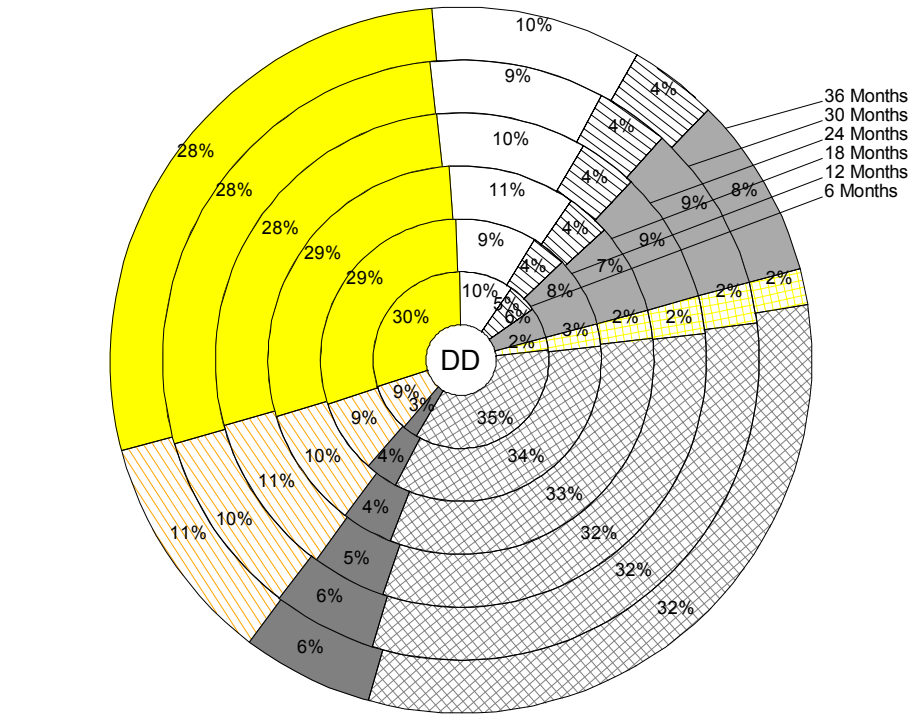
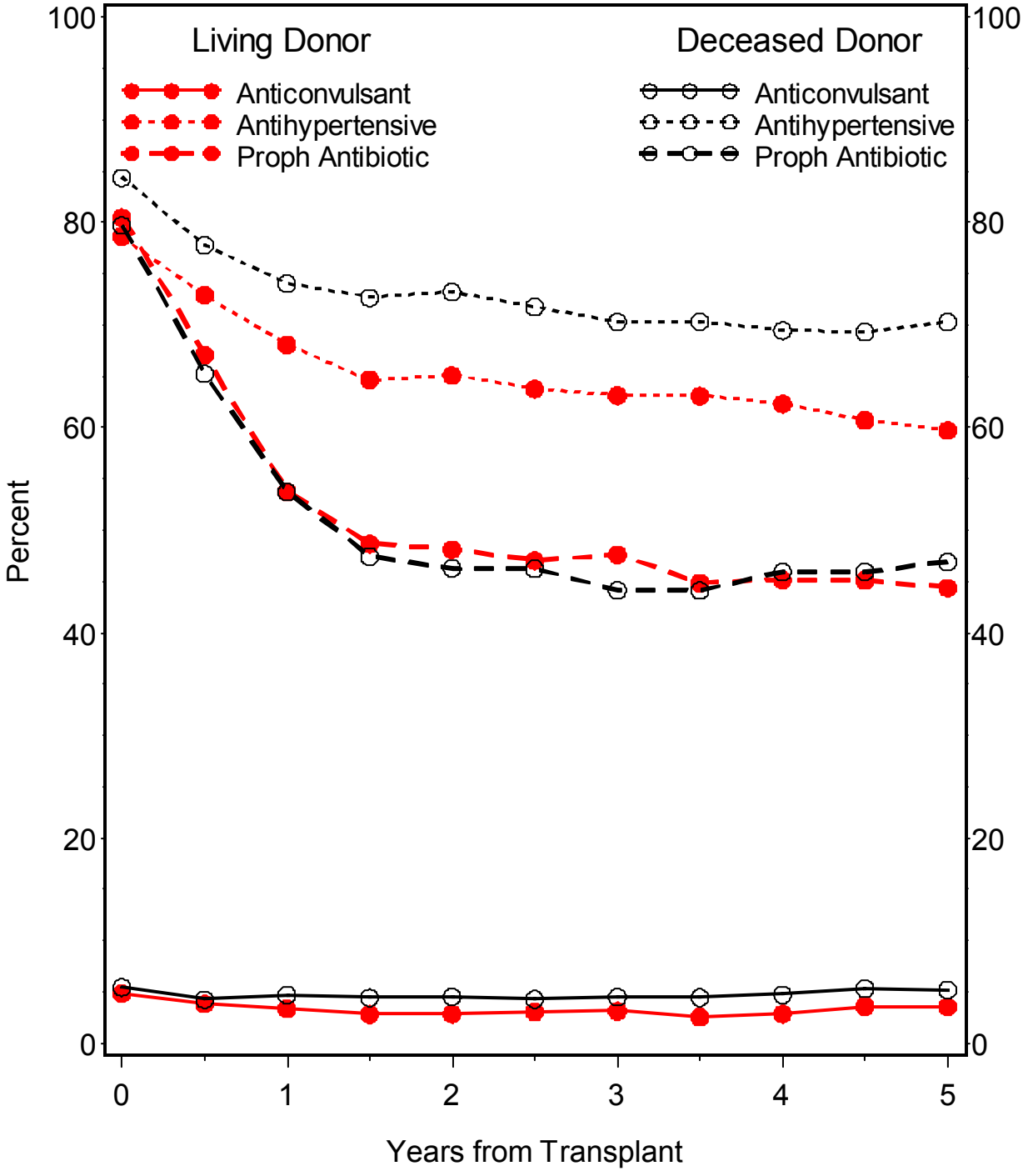


EXHIBIT 3.7
CONCOMITANT MEDICATIONS



SECTION 4: REJECTION

In NAPRTCS, a rejection episode is defined by the physician's decision to initiate specific anti-rejection therapy. For time to event analyses, a rejection episode is also considered to have occurred if rejection is the reported cause of graft failure even in the absence of an acute rejection report and 71 episodes were included as such. As a result, a total of 9,982 episodes of rejection in the 10,762 transplants were available for analysis, as described below.

There were 9,979 acute rejection reports submitted for 10,713 transplants with known donor source. Acute rejection reversal outcome had not been established for 46 of the 9,979 acute rejection reports at the time of database closure.

The frequency of reported acute rejections is presented in Exhibit 4.1A, indicating that of the 10,713 transplants, no acute rejections were reported for 5,687, exactly one rejection was reported for 2,588, two rejections for 1,197, three rejections for 632, and four or more rejections were reported for 609 transplants. 46.9% of the transplants had at least one rejection episode (42% in live donors and 53% in deceased donors). The number of rejections per transplant ranged from 0 to 12. Acute rejection ratios (number of rejections/number of transplants) are shown in Exhibit 4.1B for transplant era 1987 – 1995 and Exhibit 4.1C for 1996 – 2007. On average, 0.78 acute rejections were reported for each living donor transplant, a ratio of 1.19 for 1987 – 1995 and 0.45 for 1996 – 2007 transplants. On average there were 1.09 rejections for each deceased donor transplant, 1.50 in the early years and 0.63 in recent years. Age-specific ratios vary with the lowest rates in the 0-1 year olds in all groups and the highest rates in the 6-12 year olds in 1987 – 1995 group and >12 years in the 1996 – 2007 group for both living and deceased donor recipients. The biopsy rates of reported acute rejections over time are shown in Exhibit 4.1D. Rates of biopsy have increased from 46% in 1987 to 96% in 2007.

Exhibit 4.2 displays the cumulative distribution of times to first rejection by allograft source and transplant year for index transplants. Improvements in rejection experience have occurred over the life of the registry. These changes have been substantial throughout the life of the project. The table below presents 12-month probabilities of acute rejection by transplant year for all transplants. While historically over half of deceased organ recipients experienced a rejection in the first post transplant weeks, the majority of patients now experience an acute rejection free course.

PROBABILITY OF FIRST REJECTION AT 12 MONTHS				
	Living Donor		Deceased Donor	
Transplant Year	%	SE	%	SE
1987-1990	54.1	1.7	68.7	1.5
1991-1994	44.9	1.5	60.3	1.6
1995-1998	33.1	1.4	40.5	1.7
1999-2002	22.3	1.3	27.2	1.8
2003-2007	8.7	1.3	17.7	1.5

Donor source-specific analyses were performed to assess the influence of selected patient and transplant characteristics on the occurrence of first rejection episodes. These analyses were restricted to index transplants. Relative hazards (RH) of first rejection episode by cohort era are presented in Exhibits 4.3A and 4.3B. For living donor transplantation in the early cohort, the incidence of first rejection was increased for black patients, for older children, for patients with one or two HLA-DR mismatches, and for patients who did not receive antibody prophylaxis on post transplant days 0 or 1. Because of its importance the analysis was adjusted with a linear term for transplant year. No significant effects were observed for transfusion history, donor-specific transfusions or the use of pre-operative immunotherapy. There was an approximate 6% reduction in the hazard of rejection with each increasing transplantation year ($p<0.001$).

For living donor transplants in the later cohort, the relative hazard was significantly lower (RH=0.48) for children < 24 months. There was an approximate 10% reduction in the hazard of rejection with each increasing transplantation year ($p<0.001$). In addition, in the later cohort of living donor transplant recipients, the previously identified race effect was not observed. The hazard rate was increased for children with 1 HLA-DR mismatch but not for children with 2 HLA-DR mismatches. The importance of acute tubular necrosis (ATN) on subsequent acute rejection was evaluated by restricting the analysis to cases with more than 7 days of graft function. Patients with first week dialysis, the operational definition of ATN, were at a significantly increased risk of subsequent acute rejection in both the early and late cohort eras (RH=1.90, $p<0.001$ and RH=1.84, $p<0.001$, respectively).

For deceased donor transplantation in the early cohort, black patients had 26% higher hazard of first acute rejection (RH=1.26, $p<0.001$) than non-black patients. Additional risk factors include two HLA-DR mismatches compared to no mismatches (RH=1.32, $p=0.002$) and no induction

therapy (RH=1.22, p<0.001). The effect of transfusion history and cold storage time are not significant when adjusted for the other predictors in the model. The effect of transplant year for the deceased donor model is similar to that for living donor transplantation. For deceased donor recipients in the later cohort era, black race was associated with a higher relative hazard of first rejection (RH=1.43, p<0.001) and there was an 9% reduction in the relative hazard of rejection with each increasing transplantation year (p<0.001).

Cumulative rejection distribution estimates are shown in Exhibit 4.4 for selected patient transplant characteristics. For living donors, significant differences are seen for age, HLA-DR mismatches and ATN (log-rank p<0.001 for each). For deceased donor recipients, significant differences in time to first rejection are seen in age (p<0.001), race (p<0.001) use of induction antibody (p=0.001), and ATN (p=0.003).

Exhibit 4.5A presents the complete (i.e., return to baseline serum creatinine) and partial (i.e., graft function without return to baseline creatinine) reversal rates for each of the treated rejections, by donor source. Among living donor (LD) graft recipients, 52% had a complete reversal of rejection, 43% had a partial reversal, and 5% ended in graft failure or patient death. A poorer prognosis is observed for deceased donor (DD) graft recipients, where 46% of rejection episodes were completely reversed, 48% partially reversed, and 7% ended with graft failure or patient death. The percentage of complete recoveries from acute rejection decreases substantially with increasing number of episodes, averaging 60% and 54%, respectively, for LD and DD sources following the first acute rejection, but only about 43% and 34%, respectively, following the third episode. When stratified by age, the young (infant) transplant recipients of both LD and DD sources are observed to have more severe outcomes from acute rejection, particularly among deceased donor transplants: 12% of acute rejections of DD sources result in graft failure or death and 7% of infants from LD sources. In addition, among living donor transplant recipients, infants have high rates of complete reversal (65%). When restricted to the *first* episode of acute rejection (Exhibit 4.5B), the outcome for infants was particularly poor: 9% of LD and 17% of DD rejections resulted in graft failure or death. Non-biopsied rejections had slightly higher reversal rates than biopsied rejections, suggesting an association between the severity of the rejection episode and the decision to biopsy. Treatment with induction antibody at the time of transplant did not by itself appear to negatively influence the probability of completely reversing later rejections.

Exhibit 4.6 provides information on rejection reversal rates, by transplant year. Despite the decreasing rejection frequency, reversal rates appear to be unchanging. In living-donors, complete reversal rates are 52% in 1987 and 55% in 2006. Please note that there was only 1 living-donor patient transplanted in 2007 who had an acute injection. That case had a complete reversal. Graft failure/death rates in living donors are 4% in 1987 and have remained fairly constant over the years. However there have been no graft failures/deaths from rejection cases transplanted in 2006 and 2007. Deceased donors fluctuate more with 46% complete reversal in 1987, a drop to around 38% from 1998 – 2004 (with a corresponding rise in partial reversals), and an increase in later years.

Rejection history was examined for patients who were rejection-free for a minimum of 365 days post-transplantation and for whom 12-month follow-up data were available. Of the 5019 patients satisfying these criteria, 1004 (20%) subsequently experienced an acute rejection episode (defined here as a ***late*** first rejection). Exhibit 4.7 presents rejection rates by selected characteristics for this group. There were 396 (39%) complete reversals, 539 (54%) partial reversals, and 59 (6%) graft failures/ deaths as a result of the rejection episodes.

EXHIBIT 4.1A
FREQUENCY OF ACUTE REJECTIONS
1987-2007

	Total		Living Donor		Deceased Donor	
	N	%	N	%	N	%
All transplants	10713	100.0	5511	100.0	5202	100.0
Transplants with at Least 1 Rejection	5026	46.9	2289	41.5	2737	52.6
Number of Acute Rejections						
0	5687	100.0	3222	58.5	2465	47.4
1	2588	100.0	1229	22.3	1359	26.1
2	1197	100.0	575	10.4	622	12.0
3	632	100.0	254	4.6	378	7.3
≥4	609	100.0	231	4.2	378	7.3
Transplant Era						
1987-1995	5230	100.0	2468	44.8	2762	53.1
1996-2000	2815	100.0	1599	29.0	1216	23.4
2001-2007	2668	100.0	1444	26.2	1224	23.5

EXHIBIT 4.1B
ACUTE REJECTION RATIOS
1987-1995

	Living Donor			Deceased Donor		
	No. of Transplants	No. of Rejections	Rejection Ratio	No. of Transplants	No. of Rejections	Rejection Ratio
Total	2468	2932	1.19	2762	4143	1.50
Recipient age						
0-1 years	193	141	0.73	87	87	1.00
2-5 years	414	456	1.10	398	599	1.51
6-12 years	870	1176	1.35	963	1519	1.58
> 12 years	991	1159	1.17	1314	1938	1.47

EXHIBIT 4.1C
ACUTE REJECTION RATIOS
1996-2007

	Living Donor			Deceased Donor		
	No. of Transplants	No. of Rejections	Rejection Ratio	No. of Transplants	No. of Rejections	Rejection Ratio
Total	3043	1374	0.45	2440	1530	0.63
Recipient age						
0-1 years	231	42	0.18	57	21	0.37
2-5 years	473	181	0.38	302	149	0.49
6-12 years	949	435	0.46	762	484	0.64
> 12 years	1390	716	0.52	1319	876	0.66

EXHIBIT 4.1D
BIOPSY RATE OF REPORTED ACUTE REJECTIONS

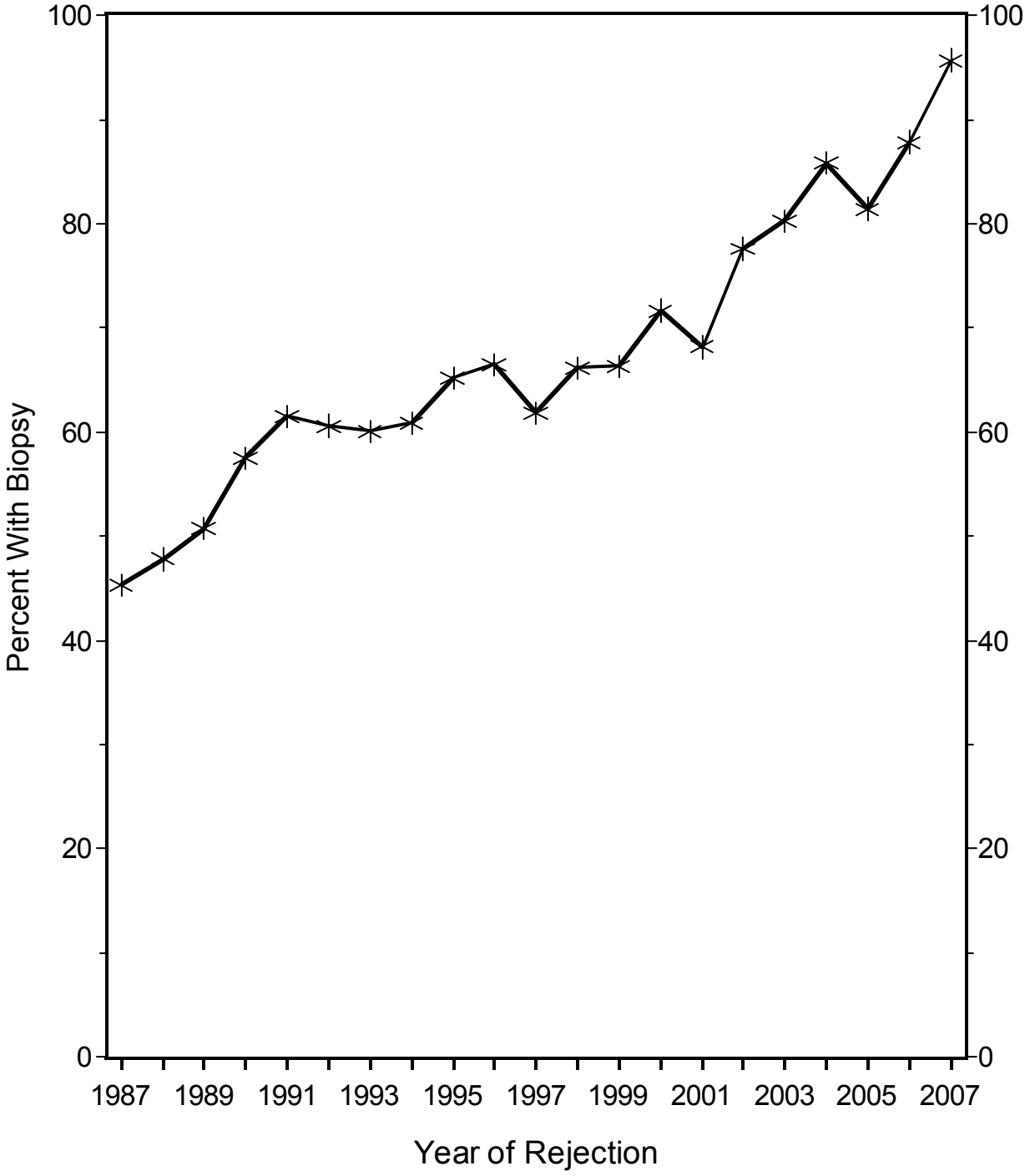
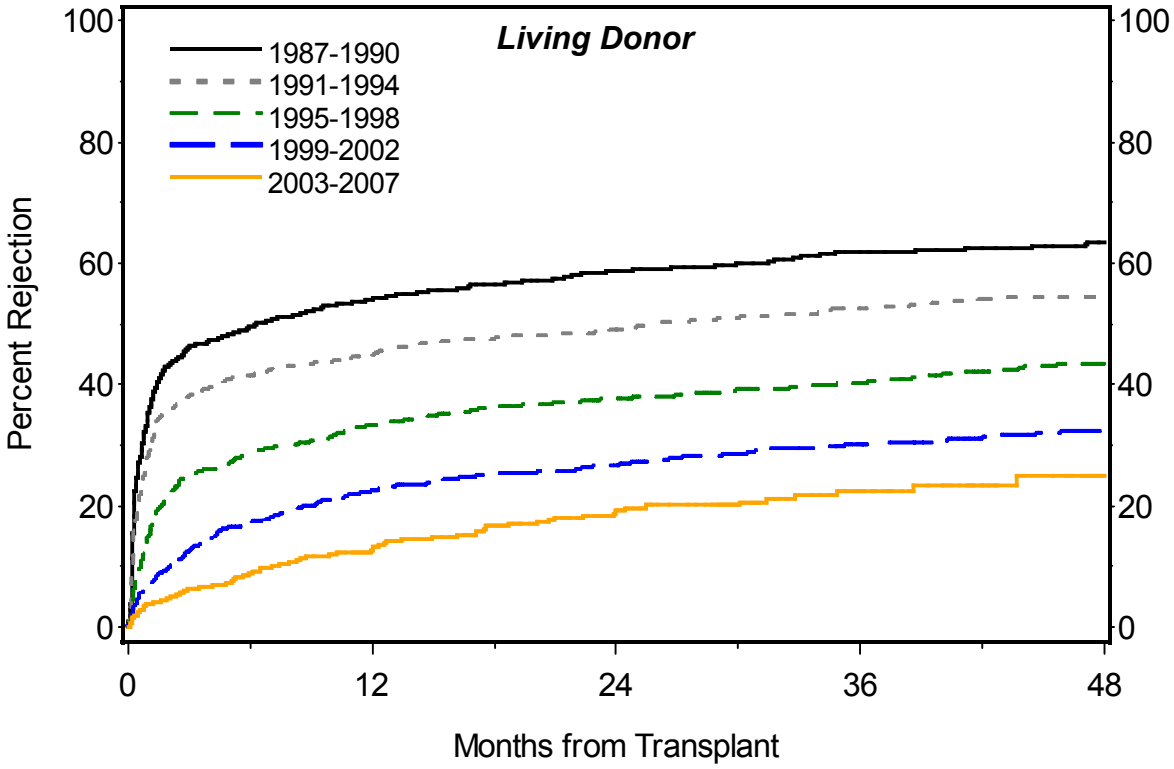


EXHIBIT 4.2
TIME TO FIRST REJECTION FOR INDEX TRANSPLANTS



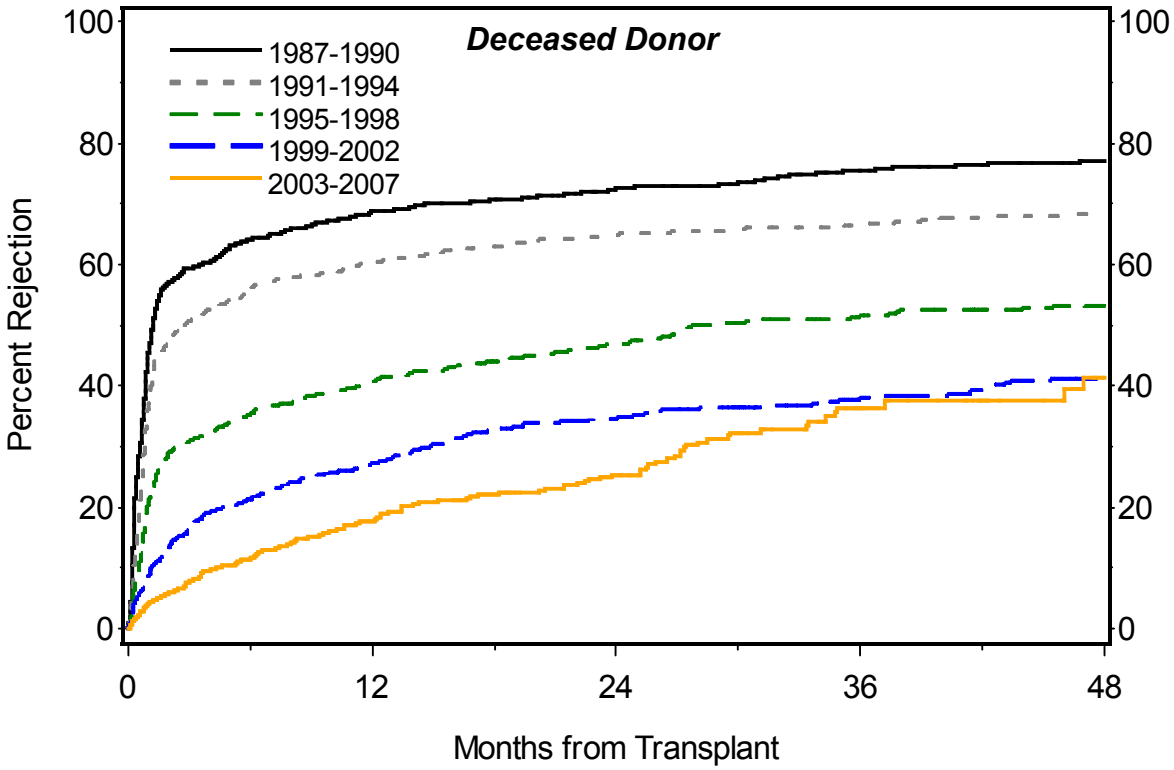


EXHIBIT 4.3A
RELATIVE HAZARD (HR) OF FIRST REJECTION EPISODE
INDEX TRANSPLANTS 1987-1995

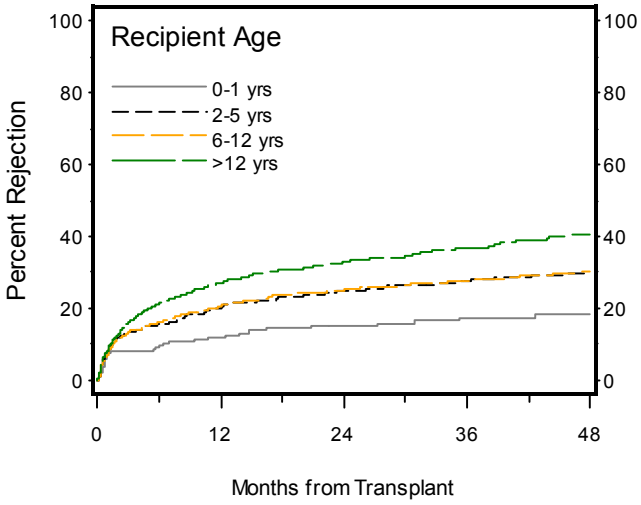
Characteristic	Comparison Group	Reference Group	Living Donor		Deceased Donor	
			RH	p-value	RH	p-value
Recipient Race	Black	Non-black	1.33	<0.001	1.26	<0.001
Recipient Age	<24 months	≥24 months	0.74	0.010	1.12	0.468
HLA-DR Mismatch	1 mismatch 2 mismatches	None	1.62 1.45	<0.001 <0.001	1.13 1.32	0.177 0.002
Induction therapy	No	Yes	1.25	<0.001	1.22	<0.001
Prior random transfusions	1-5 >5	None	0.92 1.08	0.199 0.339	0.93 0.99	0.321 0.927
Donor specific transfusions	Yes	No	0.89	0.204	--	--
Pre-op Immunotherapy	Yes	No	0.96	0.497	--	--
Cold storage time	>24 hours	≤24 hours	--	--	0.99	0.804
Transplant year	1987-1995		0.94	<0.001	0.93	<0.001

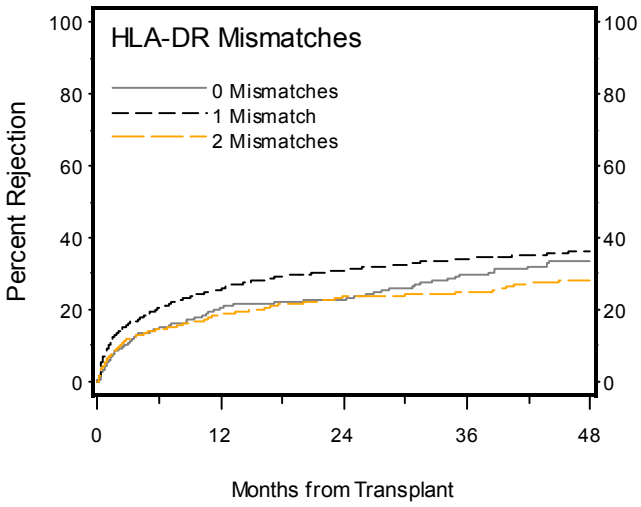
EXHIBIT 4.3B
RELATIVE HAZARD (HR) OF FIRST REJECTION EPISODE
INDEX TRANSPLANTS 1996-2007

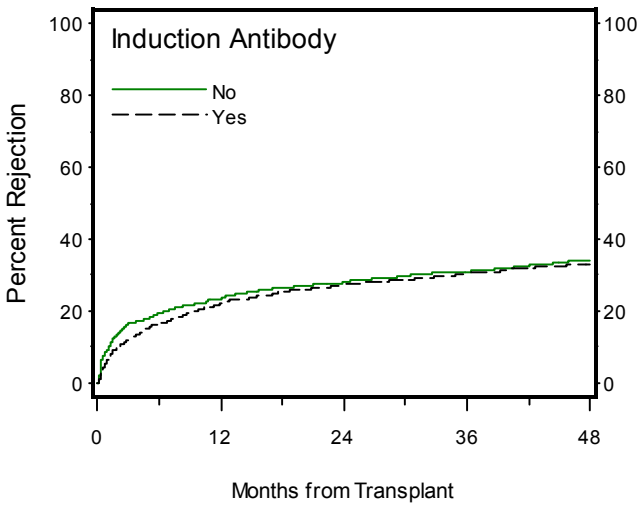
Characteristic	Comparison Group	Reference Group	Living Donor		Deceased Donor	
			RH	p-value	RH	p-value
Recipient Race	Black	Non-black	0.97	0.819	1.43	<0.001
Recipient Age	<24 months	≥24 months	0.48	<0.001	0.55	0.147
HLA-DR Mismatch	1 mismatch 2 mismatches	None	1.30 1.00	0.028 0.984	1.20 1.12	0.271 0.494
Induction therapy	No	Yes	1.14	0.095	0.86	0.127
Prior random transfusions	1-5 >5	None	1.06 1.06	0.457 0.701	1.00 0.96	0.991 0.797
Donor specific transfusions	Yes	No	0.49	0.061	--	--
Pre-op Immunotherapy	Yes	No	1.02	0.753	--	--
Cold storage time	>24 hours	≤24 hours	--	--	1.18	0.183
Transplant year	1996-2007		0.90	<0.001	0.91	<0.001

EXHIBIT 4.4
TIME TO FIRST REJECTION FOR INDEX TRANSPLANTS 1996-2007

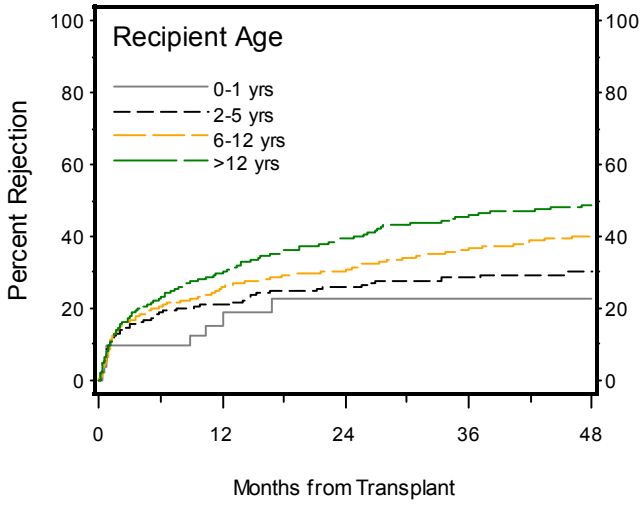
Living Donor

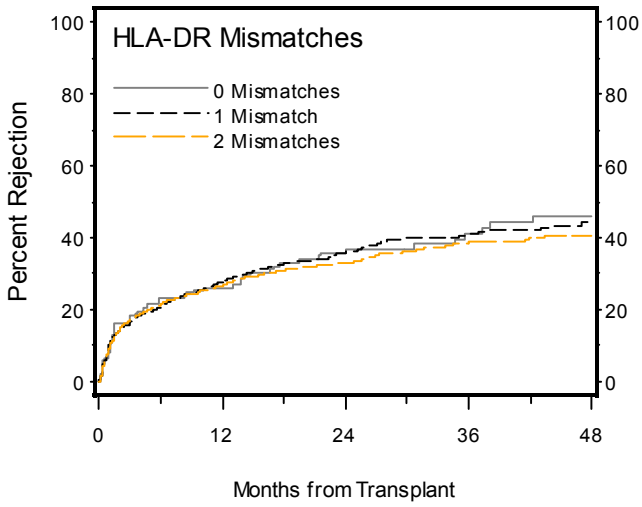






Deceased Donor





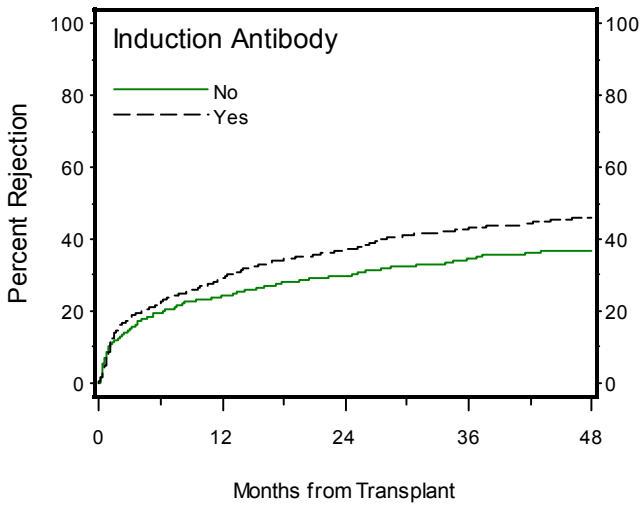
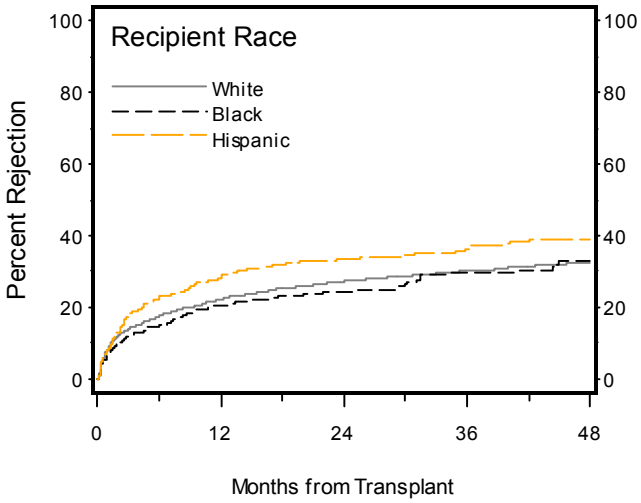
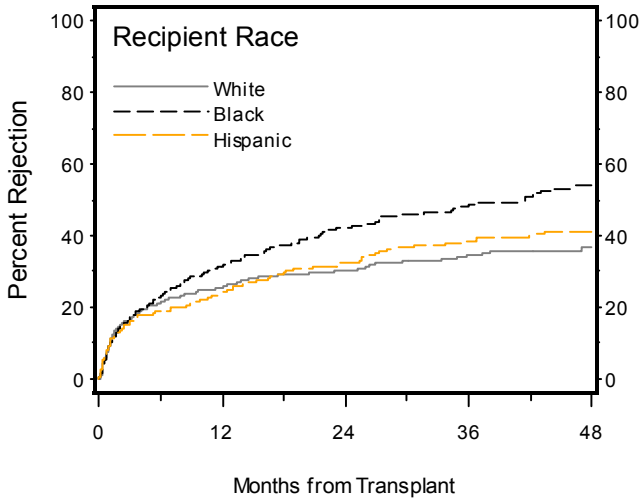
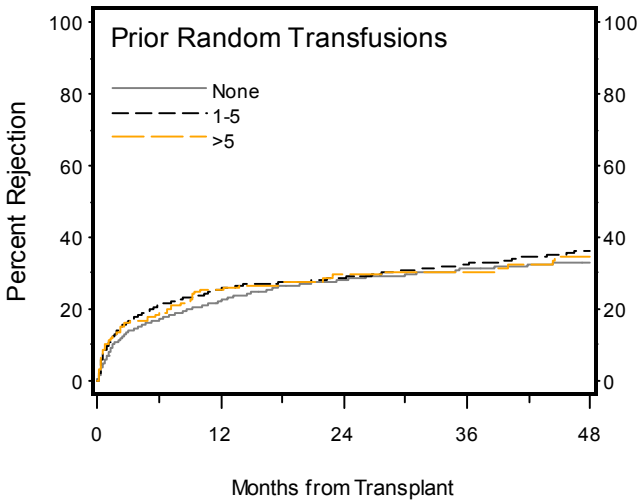


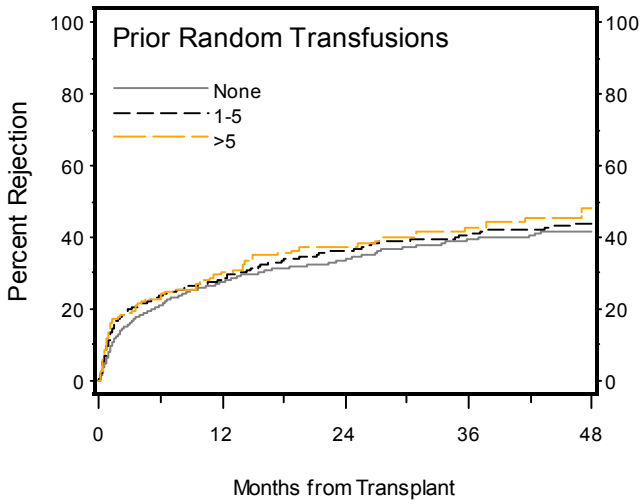
EXHIBIT 4.4 (continued)
TIME TO FIRST REJECTION FOR INDEX TRANSPLANTS 1996-2007

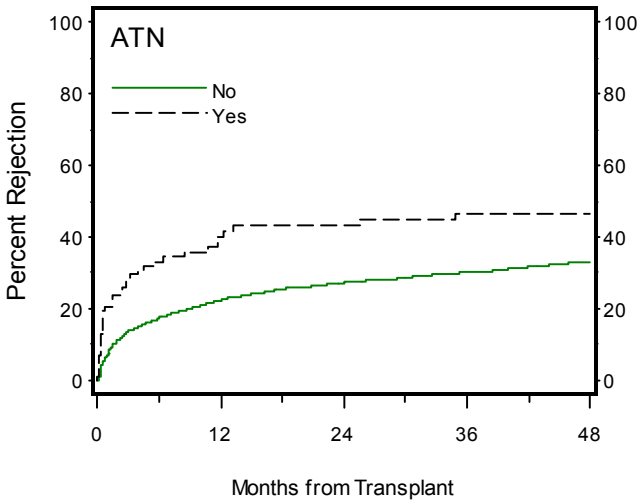
Living Donor | ***Deceased Donor***

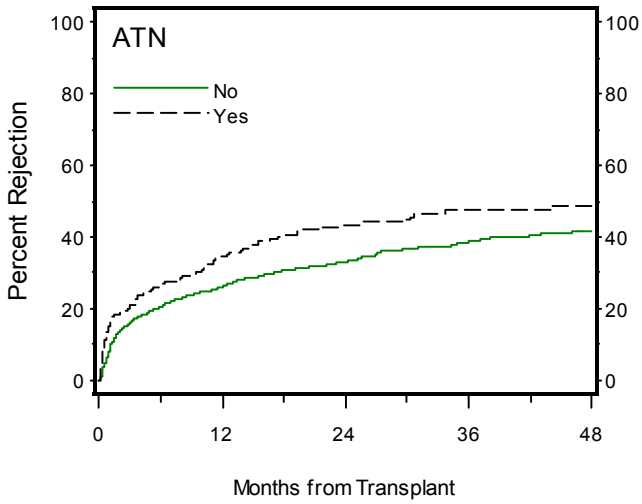












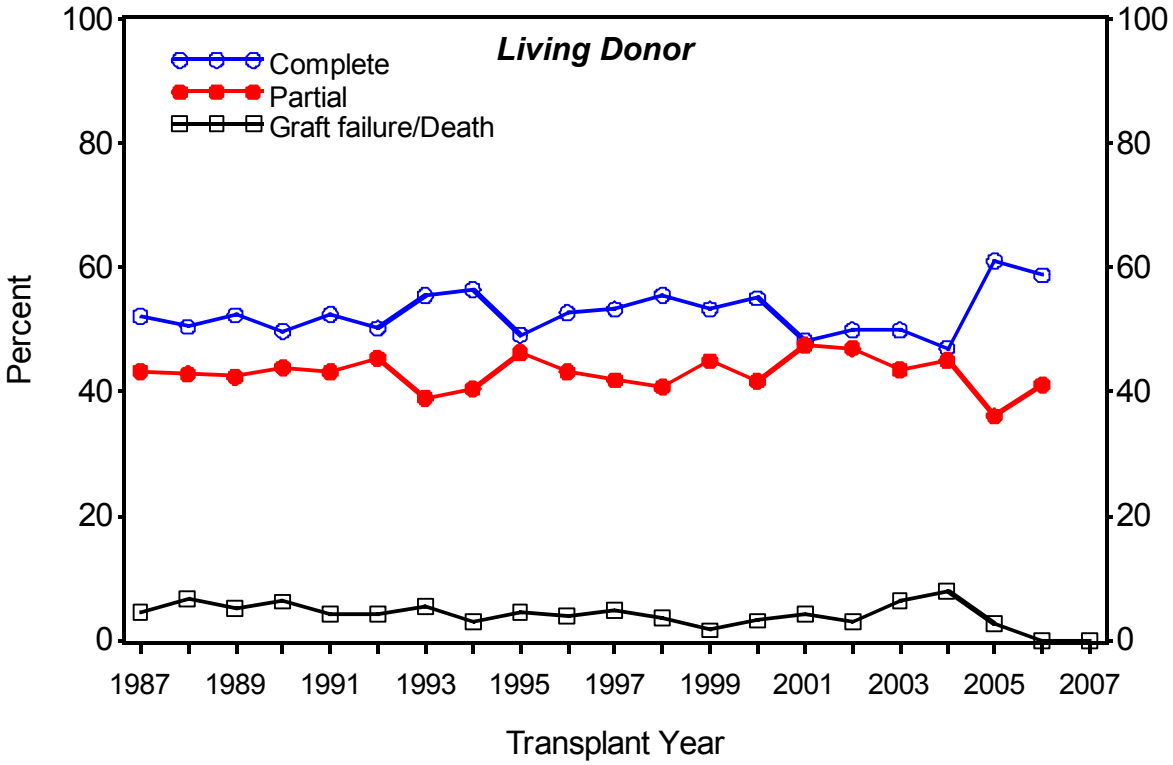
EXIHIBIT 4.5A
REJECTION REVERSAL OUTCOME BY PATIENT CHARACTERISTICS

	Living Donor				Deceased Donor			
	N of rejections	% Complete Reversal	% Partial Reversal	% Graft failure /Death	N of rejections	% Complete Reversal	% Partial Reversal	% Graft failure /Death
Total Rejection Episodes	4296	52.3	43.2	4.5	5637	45.7	47.5	6.8
Rejection Number								
1	2284	60.2	35.1	4.6	2723	54.4	37.2	8.4
2	1059	45.8	49.3	4.9	1369	45.6	49.0	5.4
3	482	42.7	53.9	3.3	750	33.9	60.8	5.3
≤ 4	471	38.2	57.5	4.2	795	27.2	67.9	4.9
Recipient Age								
0-1 years	182	64.8	28.6	6.6	108	55.6	32.4	12.0
2-5 years	635	58.3	37.3	4.4	745	55.2	38.1	6.7
6-12 years	1610	52.0	44.3	3.7	1991	46.1	47.0	6.9
> 12 years	1869	49.3	45.6	5.1	2793	42.5	51.0	6.5
Biopsy								
No	1488	58.5	38.1	3.4	2160	48.1	47.0	4.9
Yes-needle	1323	49.4	46.9	3.7	1425	42.5	51.2	6.3
Yes-tissue	1460	49.5	45.6	4.9	1994	46.5	46.7	6.8
D-R Antigen								
0 mismatch	517	52.6	43.1	4.3	593	47.2	46.9	5.9
1 mismatch	3023	53.4	42.2	4.3	2363	44.7	49.1	6.2
2 mismatch	756	47.6	47.0	5.4	2681	46.3	46.3	7.5
Induction Antibodies								
No	2480	52.6	42.3	5.1	2244	46.0	46.8	7.2
Yes	1816	51.9	44.4	3.7	3393	45.5	48.0	6.5
Transplant Era								
1987-1995	2930	52.1	43.1	4.8	4139	46.8	46.2	7.1
1996-2000	938	53.8	42.6	3.5	1028	43.4	50.9	5.7
2001-2007	428	50.5	45.1	4.4	470	41.5	52.1	6.4

EXHIBIT 4.5B
REJECTION REVERSAL OUTCOME BY PATIENT CHARACTERISTICS
FIRST ACUTE REJECTION EPISODE

	Living Donor				Deceased Donor			
	N of rejections	% Complete Reversal	% Partial Reversal	% Graft failure /Death	N of rejections	% Complete Reversal	% Partial Reversal	% Graft failure /Death
Total Rejection Episodes	2284	60.2	35.1	4.6	2723	54.4	37.2	8.4
Rejection Number								
1	2284	60.2	35.1	4.6	2723	54.4	37.2	8.4
Recipient Age								
0-1 years	119	67.2	23.5	9.2	66	62.1	21.2	16.7
2-5 years	348	67.0	27.6	5.5	346	63.0	26.6	10.4
6-12 years	815	60.5	35.0	4.5	959	53.9	36.9	9.2
> 12 years	1002	56.9	39.2	3.9	1352	52.2	40.8	7.0
Biopsy								
No	776	70.0	27.4	2.6	958	60.4	33.7	5.8
Yes-needle	723	57.1	39.4	3.5	731	49.5	43.9	6.6
Yes-tissue	761	55.1	39.9	5.0	979	55.1	37.5	7.5
D-R Antigen								
0 mismatch	280	58.9	37.1	3.9	268	58.6	33.6	7.8
1 mismatch	1588	61.6	33.9	4.5	1113	54.8	38.3	6.9
2 mismatch	416	55.8	38.5	5.8	1342	53.3	37.0	9.8
Induction Antibodies								
No	1298	60.7	33.8	5.5	1086	56.4	34.6	9.0
Yes	986	59.6	36.8	3.5	1637	53.1	38.9	8.0
Transplant Era								
1987-1995	1441	60.5	33.9	5.6	1893	56.0	34.7	9.2
1996-2000	562	60.0	36.8	3.2	533	51.6	41.8	6.6
2001-2007	281	59.4	38.1	2.5	297	49.2	44.4	6.4

EXHIBIT 4.6
REJECTION REVERSAL OUTCOME



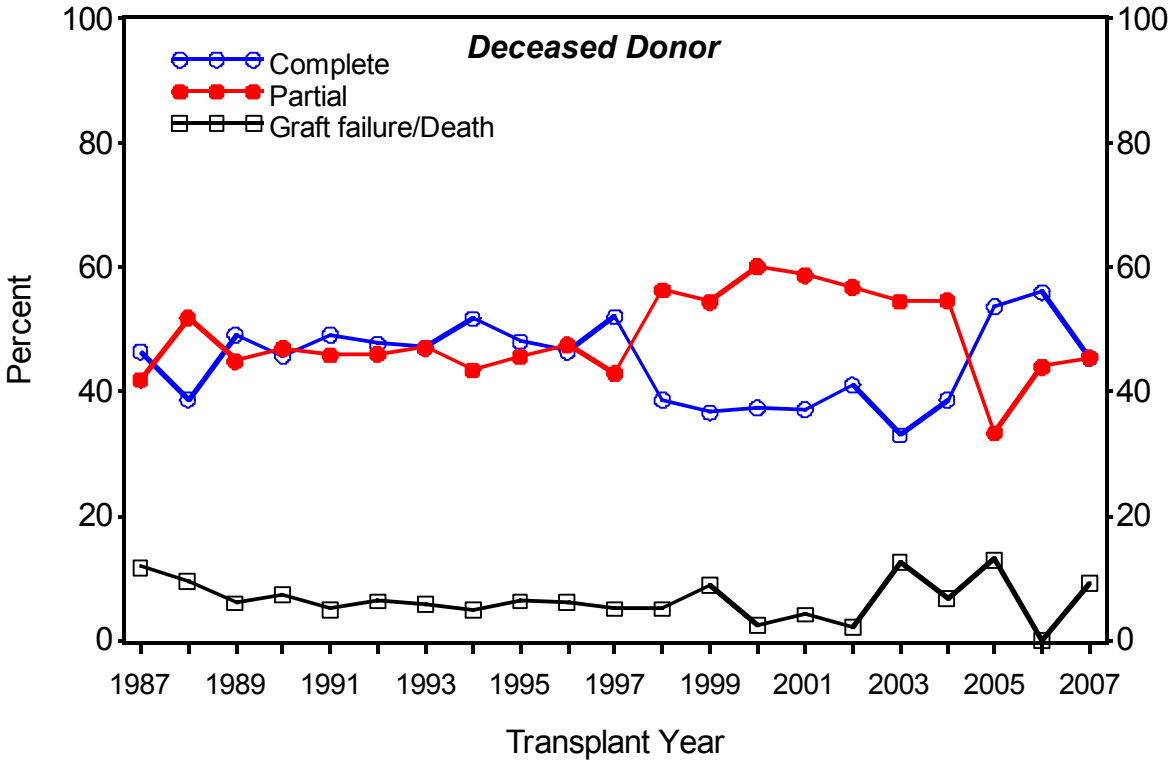


EXHIBIT 4.7
LATE FIRST REJECTIONS BY SELECTED CHARACTERISTICS

	No. of Transplants	No. of Rejections	Percent Rejection
Total	4753	948	19.9
Rejection outcome			
Unknown	1004	10	1.0
Complete	1004	396	39.4
Partial	1004	539	53.7
Graft failure/Death	1004	59	5.9
Donor source			
Living Donor	2902	514	17.7
Deceased Donor	2097	490	23.4
Age			
0-1 years	297	32	10.8
2-5 years	783	137	17.5
6-12 years	1734	401	23.1
> 12 years	2205	434	19.7
Sex			
Male	2965	577	19.5
Female	2054	427	20.8
Race			
White	3123	569	18.2
Nonwhite	1552	364	23.5

SECTION 5: GRAFT FUNCTION

A total of 2,747 graft failures among 10,762 (25.5%) transplants have occurred. This includes 320 patients who have lost 2 or more grafts since the study's start, of which 28 subjects had 3 graft failures and 3 had 4 graft failures. Of index transplants, 2,427 of 9,854 (24.6%) transplants have failed, while 320 of 908 (35.2%) subsequent transplants have failed. Of these 2,747 failures, 249 (9.1%) were deaths with functioning graft. In the remaining failures (with known determination), graft failure was determined by a return to dialysis in 91.9% and a retransplant in 8.1%. Exhibit 5.1 provides the distribution of graft failure causes. Note that tissue confirmation of cause was obtained in 1,522 (55.4%) failures. Of the index graft failures occurring since January 1, 2000, chronic rejection accounted for 40.4% (299/741) while 70 (9.4%) were acute rejection graft failures, (plus 1 hyper acute and 3 accelerated acute rejection), 46 (6.2%) cases discontinued medication, 58 (7.8%) failed from graft thrombosis, 56 (7.6%) had disease recurrences, and 62 (8.4%) were deaths with a functioning graft. With increased length of follow-up of the study cohort, chronic rejection continues to be the most common cause of graft failure. Overall, 50.4% of all graft failures are caused by rejection, with chronic rejection accounting for 35.1% and acute rejection accounting for 13.1% of the failures. Recurrence of original disease as a cause of graft failure has been observed 187 times as follows: focal segmental glomerulosclerosis (83), membranoproliferative glomerulonephritis Type II (17), hemolytic uremic syndrome (17), oxalosis (10), chronic glomerulonephritis (7), others (53). Vascular thrombosis remains a major cause of failure; 376 graft failures are attributed to primary non-function, vascular thrombosis, or miscellaneous technical causes, suggesting that such problems will occur in 3.5% of pediatric transplants. Renal artery stenosis as a cause of graft failure is observed in 1 living donor versus 14 deceased source transplants. Chronic rejection causes graft failure in 7.0% of living donor versus 10.5% of deceased source transplants and respective failure rates due to primary non-function are 0.4% versus 0.9% while those for thrombosis are 1.8% versus 3.2%.

Because of the clinical and statistical significance of donor source, graft failure distributions are presented separately for living and deceased donor transplants. Survival distribution estimates for the index transplants are presented in Exhibit 5.2 by donor source and transplant era. Overall, the mean and median follow-up for subjects with functioning grafts is 4.4 and 3.5 years. Estimated graft survival probabilities are 93.3%, 87.8%, 82.2% and 75.5% at Years 1, 3, 5 and 7 post-transplant, respectively, for recipients of living donor organs. Corresponding estimates for

recipients of deceased donor source organs are 86.4%, 76.3%, 68.5% and 60.7%. Notice from Exhibit 5.2, that more recent deceased donor source transplants have a graft survival experience very similar to that of living donor transplant from the earlier (1987-1994) era. In fact, the graft survival in 1996-2007 is significantly better than in prior years for both deceased donor source ($p<0.001$) and living donor grafts ($p<0.001$). Exhibit 5.3 displays graft failure information by transplant source and selected transplant characteristics (the percentage of grafts in the subgroup, the percentage of failures, the product limit estimate of 5-year graft survival probability and associated standard error are provided). Exhibits 5.4-5.8 provide graft survival distributions for selected donor and recipient characteristics.

The table below shows the relative hazard (RH) of individual prognostic factors in the presence of other factors in multivariate proportional hazards models.

MULTIVARIATE PROPORTIONAL HAZARDS REGRESSION MODEL						
	Comparison Group	Reference Group	Living Donor		Deceased Donor	
Characteristic			RH	p-value	RH	p-value
Recipient Age	≥ 24 months	<24 months	1.16	0.2117	0.62	0.0008
Transplant History	Prior transplants	No prior tx's	1.43	0.0002	1.47	<0.0001
Induction Therapy	Induction	No induction	0.83	0.0034	0.90	0.0807
Transfusion History	>5	≤ 5	1.24	0.0122	1.28	0.0002
HLA-B Mismatch	0 mismatches	1-2 mismatches	1.39	0.0056	1.16	0.0133
HLA-DR Mismatch	0 mismatches	1-2 mismatches	0.84	0.1112	1.12	0.0603
Recipient Race	Black	Non-black	1.99	<0.0001	1.54	<0.0001
Dialysis History	Prior dialysis	No prior dialysis	1.16	0.0444	1.21	0.0520
Cold Storage Time	>24 hours	≤ 24 hours	--	--	1.15	0.0251
Native Nephrectomy	Not removed	Tissue removed	0.85	0.0172	0.96	0.5072
Gender	Male	Female	0.86	0.0204	0.86	0.0064
Transplant Year	1987-2007		0.95	<0.0001	0.94	<0.0001

For recipients of living donor grafts, the most influential prognostic variables (of index transplant graft survival) are race (black vs. non-black; RH=2.0, $p<0.001$), prior transplant (RH=1.4, $p=0.001$), induction antibody therapy (RH=0.83, $p=0.003$) and HLA-B mismatches (RH=1.4, $p=0.006$). A linear trend in improvement in graft retention with later year of entry is also observed (RH=0.95 per year $p<0.001$).

For recipients of deceased donor source organs, review of Exhibit 5.3 indicates multiple variables that are important prognostic factors of graft survival. Exhibit 5.5 shows the graft survival distribution estimates for some of these variables. These include race (black versus non-black; RH=1.5, p<0.001), prior transplant (RH=1.5, p<0.001), age ≥ 24 months (RH=0.62, p<0.001), transfusion history (RH=1.3, p<0.001) and male gender (RH=0.85, p=0.006). The model includes a linear term for year of transplant, whose estimated relative risk increase implies a decreasing hazard (RH=0.94 per year p<0.001). Note that interpretation of the use of induction antibody therapy is hampered by selection factors that motivate its usage; the size and direction of these biases cannot be quantified and the evaluation of this factor cannot be considered definitive.

Plots of graft survival distributions for temporal cohort groups are included in Exhibit 5.6. Marked improvement in deceased donor source graft survival is observed over time. The following table displays graft survival percentages for the various cohorts. (Standard errors range from 0.6% to 1.0% at 1 year and 1.2% to 1.5% at 5 years for living donor, and from 0.9% to 1.3% at 1 year and 1.6 to 1.9% at 5 years for deceased donor source grafts.) These results may be related to temporal trends in immunosuppressive drugs and dosages, decreased transfusion requirements, and decreased use of young deceased donors.

GRAFT SURVIVAL RATES						
	Living Donor			Deceased Donor		
Cohort Group	1yr	3yr	5yr	1yr	3yr	5yr
1987-1990	89.4	81.2	74.6	75.2	63.5	54.8
1991-1994	91.8	85.4	80.4	85.2	76.4	69.5
1995-1998	94.0	90.5	85.3	90.6	81.8	73.9
1999-2002	95.9	91.2	85.9	92.7	83.9	79.5
2003-2007	96.1	90.6	--	94.4	81.1	--

Exhibit 5.7 shows graft survival for HLA-A, HLA-B and HLA-DR mismatches for living and deceased donors. Living donors show a slight graft survival advantage for patients with no HLA-DR mismatches and deceased donors show an advantage for patients with no HLA-B mismatches.

Graft survival for the eight most common categories of primary diagnosis is shown in Exhibit 5.8 for living and deceased donors. In living donors, patients with FSGS have a 5 year graft

survival rate of 71% and patients with GN have a 5 year rate of 77%. All other shown categories of primary diagnoses for living donors have a 5 year graft survival rate above 83%. In the deceased donor group, 5 year graft survival rates are below 64% for GN, FSGS, and CNS and are above 70% for congenital structural, renal infarct, and cystinosis. HUS and familiar nephritis diagnoses have 5-year graft survival rates around 66%.

Acute Tubular Necrosis

Acute tubular necrosis (ATN) is defined by the cooperative study as the use of dialysis in the first transplant week. This delay in graft function is reported for 5.1% of index living donor transplants which is significantly less than the ATN rate reported for deceased donor source transplants (16.4%).

Among the living donor transplants, increased rates of ATN are noted with >5 prior transfusions (11.3%), prior transplants (8.6%), infants <24 months (8.4%), black race (8.1%), children with a native nephrectomy (7.4%) and children receiving prior dialysis (6.9%). These factors continue to be significant in a multivariate logistic regression model with prior dialysis (OR=4.0) and >5 transfusions (OR=2.1) highly significant at $p<0.0001$.

For transplants with deceased donor source organs, the ATN rate increases significantly with several factors: >5 transfusions (27.8%), prior transplant (24.4%), cold ischemia times >24 hours (24.4%), native nephrectomy (22.8%), and black recipients (22.1%). Donor (Age <2 years, 24.6%), donor age ($\geq$50 years, 28.4%) and prior dialysis (18.6%) also had higher rates of ATN. The ATN rate differs for Collins iced electrolyte solution (21.6%) versus Wisconsin solution (16.2%), but not with use of machine perfusion (16.0%). In a multivariate logistic regression analysis, the following variables were significantly predictive of ATN risk in deceased donor graft recipients: prior dialysis (OR=15.1, $p<0.001$), older donor age (OR=2.0, $p<0.001$), cold time ≥ 24 hours (OR=1.9, $p<0.001$), number of prior transfusions (OR=1.9, $p<0.001$), black race (OR=1.8, $p<0.001$), prior transplant (OR=1.5, $p<0.001$) and native nephrectomy (OR=1.3, $p=0.021$).

Graft survival after the first week is displayed in Exhibit 5.9, and is significantly worse in the presence of acute tubular necrosis in both donor source groups. In the living donor group, 5 year graft survival rates are 84.8% for grafts without ATN and 64.6% for grafts with ATN (log-rank $p<0.001$). ATN is significant in the multivariate analysis (RH=2.25, $p<0.001$) along with

race, recipient age, transplant history, and transplant year. Induction therapy, HLA-B matches and nephrectomy are of borderline significance. Among functioning deceased donor grafts at 1 week, 73.4% of subjects without first week dialysis are estimated to be functioning at 5 years as opposed to 55.9% of those with ATN (log-rank $p<0.001$). For deceased donor grafts, after one week, the variates that maintain predictive capability of graft failure include the following: ATN (RH=1.64, $p<0.001$), race, transplant history, recipient age, transfusion history, HLA-B matches, gender, and transplant year. Cold storage time is not predictive ($p=0.625$) after adjustment for first week results.

Serum Creatinine and Creatinine Clearance

Exhibits 5.10 and 5.11 display the means and standard errors of serial serum creatinine and creatinine clearance measurements. At each time point only individuals with functioning grafts are included.

Creatinine clearance (mL/min/1.73 m^2) values were calculated using the Schwartz formula and available morphologic data, with length replacing height in younger recipients, as follows:

SCHWARTZ FORMULA FOR CREATININE CLEARANCE	
Patient's weight (kg)	Creatinine clearance (mL/min/1.73m2)
<10 kg	$\frac{0.45 \times \text{height (cm)}}{\text{serum creatinine (mL)}}$
10kg to 70 kg	$\frac{0.55 \times \text{height (cm)}}{\text{serum creatinine (mL)}}$
>70 kg	$\frac{1.55 \times \text{age(years)} + 0.5 \times \text{height (cm)}}{\text{serum creatinine (mL)}}$

From Exhibit 5.10, decreases in creatinine clearance are observed in living donor recipients over the first 4 years post transplantation. Younger recipients begin with higher calculated clearances that are subject to greater absolute declines, while the oldest subjects behave similarly to adult populations. Likewise, baseline creatinine clearance appears lower in deceased donor organ recipients, but clearance values for both organ source groups approach equivalence in the later years. Serum creatinine rises throughout the course of the study with

older patients and black race patients maintaining a higher mean value over time. (See Exhibit 5.11.)

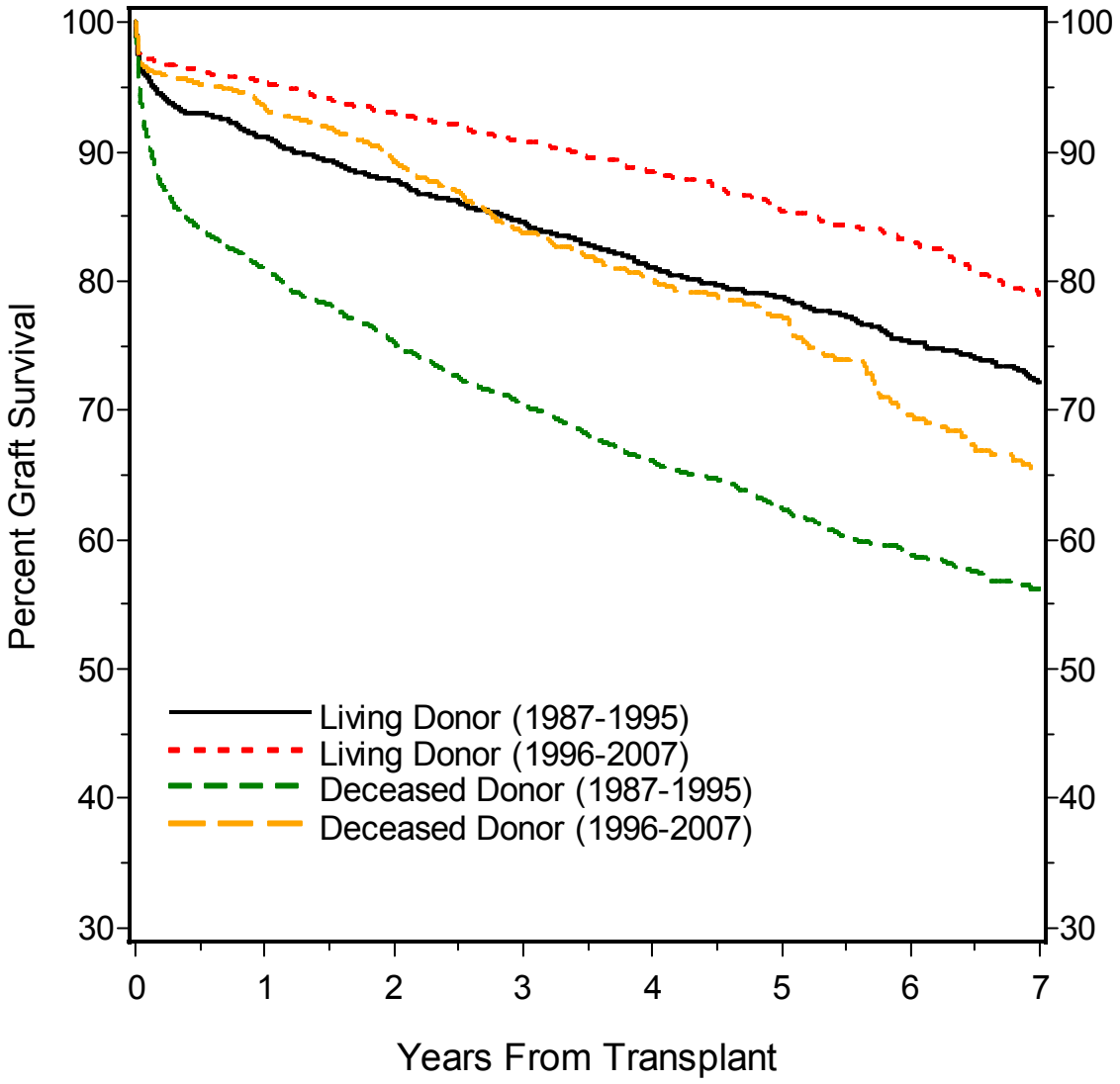
In Exhibits 5.12 - 5.14, graft survival percentage and mean calculated clearance values for subjects with functional grafts are plotted at each annual follow-up visit for various groups, including donor source, transplant year, race and induction antibody therapy use. Continued decreases in both graft survival and graft function are seen through the first five post-transplant years.

The impact of race on calculated clearance and graft survival is observed in Exhibit 5.14. Despite the relatively greater number of graft failures in black recipients, there is no trend towards convergence in serum creatinine values and black recipients have both lower graft survival and clearance values throughout.

EXHIBIT 5.1
CAUSES OF GRAFT FAILURE

	Index Graft Failures		Subsequent Graft Failures		All Graft Failures	
	N	%	N	%	N	%
Total patients with graft failure	2427	100.0	320	100.0	2747	100.0
Cause of Graft Failure						
Death with functioning graft	226	9.3	23	7.2	249	9.1
Primary non-function	60	2.5	2	0.6	62	2.3
Vascular thrombosis	243	10.0	38	11.9	281	10.2
Other technical	29	1.2	4	1.3	33	1.2
Hyper-acute rejection	14	0.6	4	1.3	18	0.7
Accelerated acute rejection	33	1.4	8	2.5	41	1.5
Acute rejection	318	13.1	42	13.1	360	13.1
Chronic rejection	847	34.9	118	36.9	965	35.1
Recurrence of original kidney disease	156	6.4	31	9.7	187	6.8
Renal artery stenosis	15	0.6	0	0.0	15	0.6
Bacterial/viral infection	45	1.9	5	1.6	50	1.8
Cyclosporine toxicity	11	0.5	0	0.0	11	0.4
De novo kidney disease	8	0.3	2	0.6	10	0.4
Patient discontinued medication	113	4.7	8	2.5	121	4.4
Malignancy	32	1.32	2	0.6	34	1.2
Other/Unknown	277	11.4	33	10.3	310	11.3

EXHIBIT 5.2
GRAFT SURVIVAL BY ALLOGRAFT SOURCE AND TRANSPLANT YEAR



	Years Post Transplant							
	Year 1		Year 3		Year 5		Year7	
	%	SE	%	SE	%	SE	%	SE
Living Donor 1987 - 1995	91.2	0.59	84.6	0.76	78.9	0.89	72.2	1.05
Living Donor 1996 - 2007	95.3	0.41	90.9	0.62	85.4	0.91	78.9	1.40
Deceased Donor 1987 - 1995	80.7	0.81	70.5	0.96	62.4	1.06	56.2	1.16
Deceased Donor 1996 - 2007	93.4	0.57	83.8	0.99	77.3	1.31	65.3	2.05

EXHIBIT 5.3
GRAFT FAILURE SUMMARY BY SELECTED TRANSPLANT CHARACTERISTICS

	LIVING DONOR (N=5267)				DECEASED DONOR (N=4540)			
	% of Total	% Failing	5 year Graft Survival	5 year rate SE	% of Total	% Failing	5 year Graft Survival	5 year rate SE
Total	100.0	19.7	82.2	0.6	100.0	30.6	68.5	0.8
Sex								
Male	60.6	18.8	83.2	0.8	58.0	29.7	70.0	1.1
Female	39.4	21.0	80.5	1.0	42.0	31.8	66.5	1.3
Race								
White	68.7	19.2	83.7	0.7	49.7	30.0	72.3	1.1
Black	11.4	30.5	71.2	2.2	23.3	36.4	57.5	1.9
Hispanic	15.7	15.0	83.4	1.6	17.7	28.0	67.0	2.2
Other	4.2	15.3	81.9	3.5	9.3	24.1	74.6	2.6
Transplant History								
No prior transplant	90.5	18.9	82.5	0.7	83.9	28.6	70.4	0.9
Prior transplant	9.5	26.8	78.8	2.3	16.1	41.0	58.7	2.2
Dialysis History								
No prior dialysis	32.6	16.2	86.0	1.0	12.8	23.3	77.2	2.1
Prior dialysis	67.4	21.4	80.3	0.8	87.2	31.6	67.2	0.9
Recipient Age								
0-1 years	8.0	20.6	83.4	2.0	3.0	42.8	57.4	4.9
2-5 years	16.3	23.2	84.6	1.4	13.8	34.6	73.0	2.0
6-12 years	33.2	21.4	84.3	1.0	33.4	33.8	71.3	1.3
>12 years	42.5	16.8	78.3	1.2	49.8	26.6	64.6	1.4
Donor Age								
<2 years	--	--	--	--	1.5	56.9	48.9	6.6
2-17 years	--	--	--	--	37.7	34.4	66.3	1.4
18-49					54.4	27.8	70.7	1.2
≥ 50 years	--	--	--	--	6.4	40.6	57.0	3.8
Cold Ischemia Time								
<24 hours	--	--	--	--	72.4	29.0	69.3	1.0
>24 hours	--	--	--	--	27.6	41.0	62.2	1.6

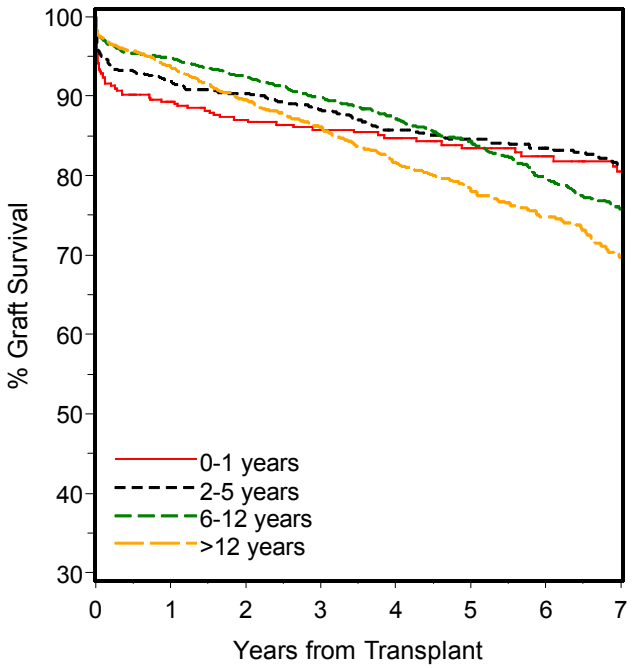
EXHIBIT 5.3 (continued)
GRAFT FAILURE SUMMARY BY SELECTED TRANSPLANT CHARACTERISTICS

	LIVING DONOR (N=5267)				DECEASED DONOR (N=4540)			
	% of Total	% Failing	5 year Graft Survival	5 year rate SE	% of Total	% Failing	5 year Graft Survival	5 year rate SE
Machine Perfusion								
No	--	--	--	--	76.9	31.6	68.5	0.9
Yes	--	--	--	--	11.4	40.4	58.6	2.7
Unknown	--	--	--	--	11.7	19.8	77.1	2.4
HLA-A Mismatches								
0	14.1	20.0	82.5	1.7	7.3	30.5	70.9	2.9
1	67.9	21.2	81.6	0.8	35.8	33.4	67.5	1.3
2/missing	18.0	13.8	84.2	1.5	56.9	28.8	68.7	1.1
HLA-B Mismatches								
0	10.8	17.8	84.8	1.8	7.0	26.3	75.6	2.7
1	69.2	21.2	81.6	0.7	29.0	34.0	68.0	1.5
2/missing	20.1	15.3	82.6	1.5	63.9	29.5	67.9	1.1
HLA-DR Mismatches								
0	13.9	18.1	86.4	1.5	9.3	30.5	70.0	2.6
1	63.0	21.4	80.6	0.8	38.8	32.4	67.5	1.3
2/missing	23.1	15.8	83.8	1.3	52.0	29.2	69.2	1.2
Pre-operative immunosuppression								
No	50.5	18.0	83.0	0.9	--	--	--	--
Yes	49.5	22.0	80.9	0.9	--	--	--	--
Native Nephrectomy								
No	73.6	18.1	82.9	0.7	80.3	29.4	69.2	0.9
Yes	26.5	24.4	80.0	1.2	19.7	37.6	64.6	1.9
Lifetime Transfusion								
0	52.0	15.8	83.7	0.9	40.5	22.3	73.8	1.4
1-5	36.5	21.6	83.2	1.0	37.5	31.2	70.6	1.3
>5	11.5	32.8	72.2	2.0	22.0	48.0	56.3	1.8
Induction Antibody								
No	53.2	21.6	80.2	0.9	42.1	31.6	66.1	1.3
Yes	46.8	17.5	84.5	0.9	58.0	29.8	70.2	1.1

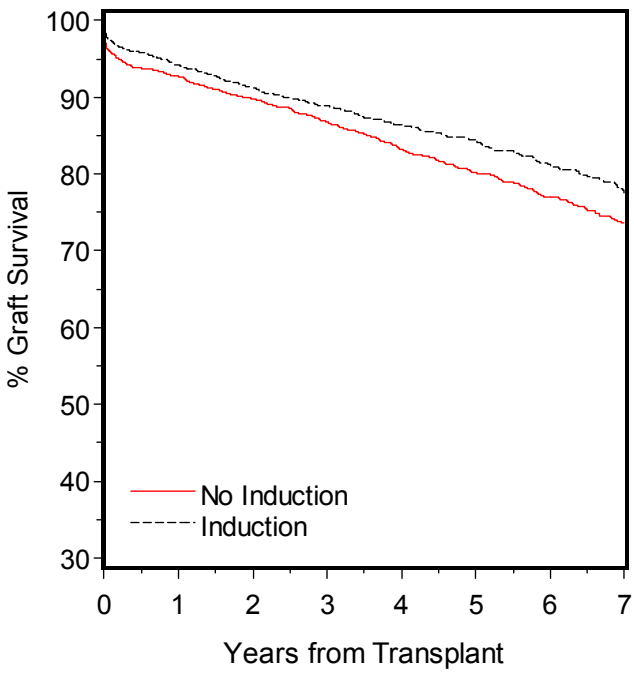
EXHIBIT 5.4
GRAFT SURVIVAL BY SELECTED CHARACTERISTICS

Living Donor

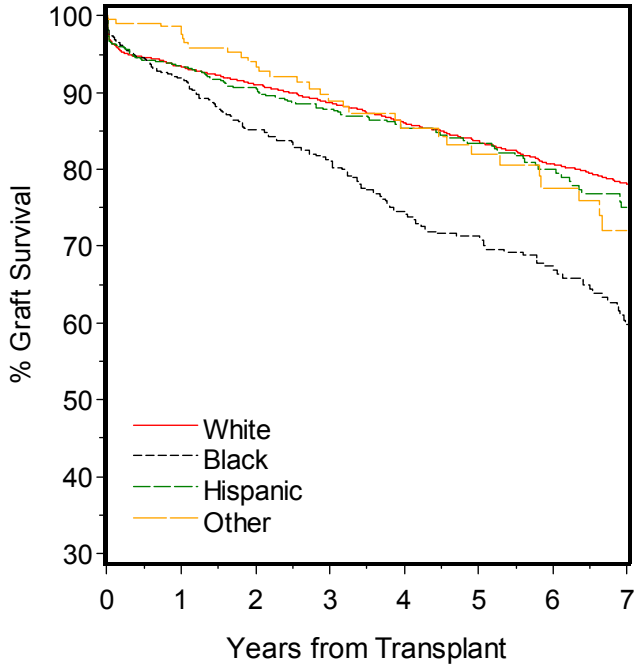
Receipient Age



Induction Antibody



Recipient Race



Transfusion History

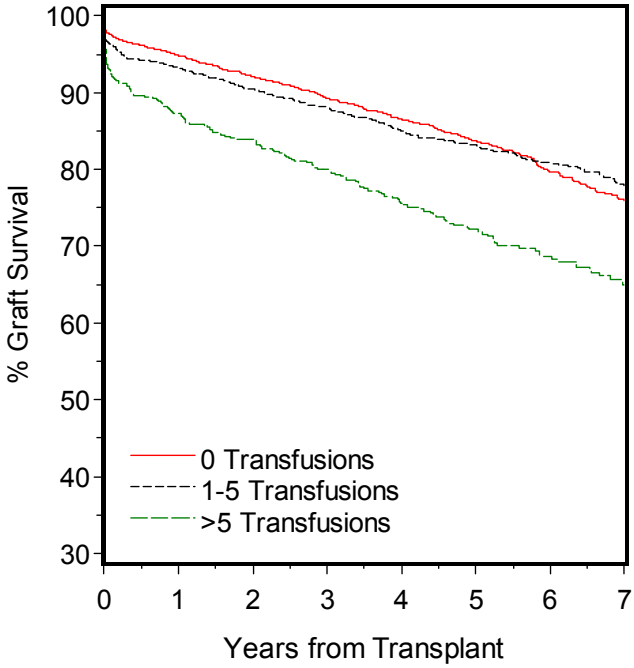
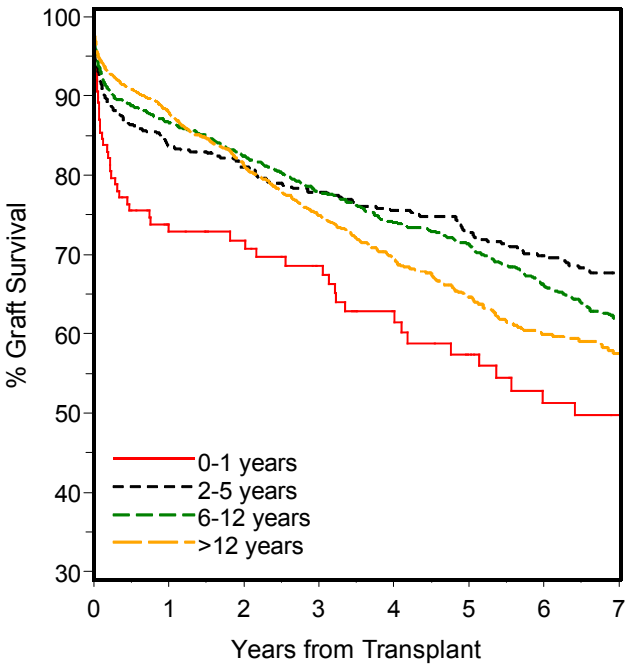


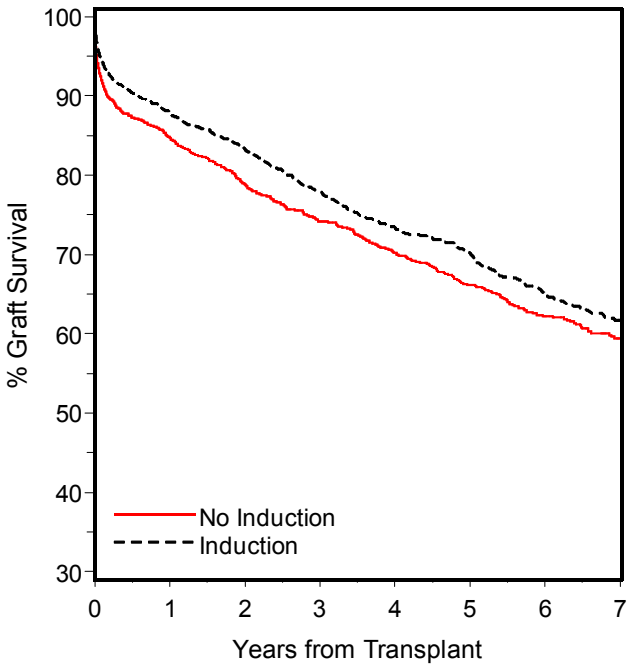
EXHIBIT 5.5
GRAFT SURVIVAL BE SELECTED CHARACTERISTICS

Deceased Donor

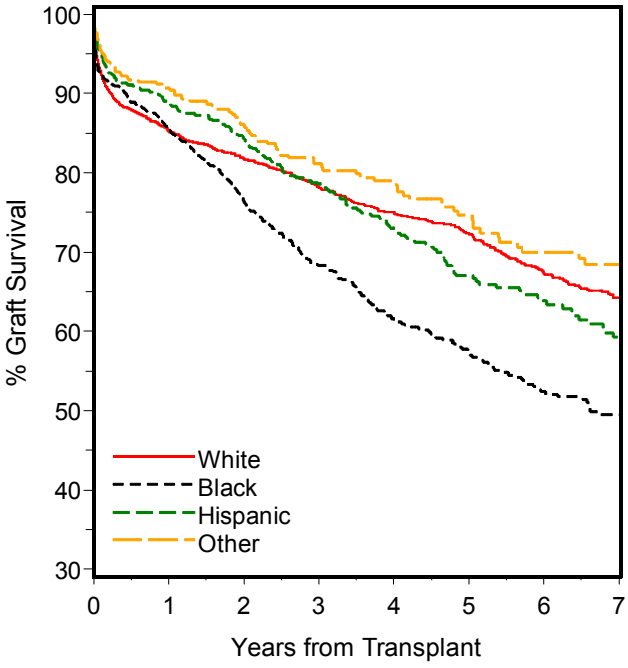
Recipient Age



Induction Antibody



Recipient Race



Transfusion History

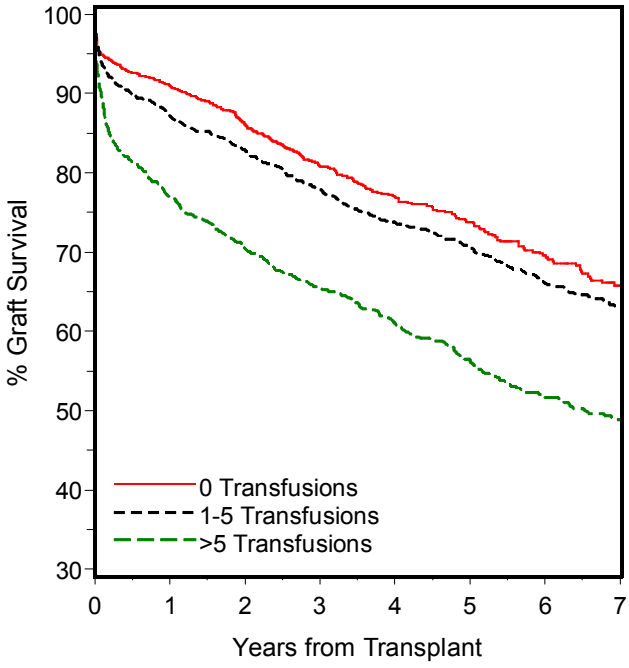
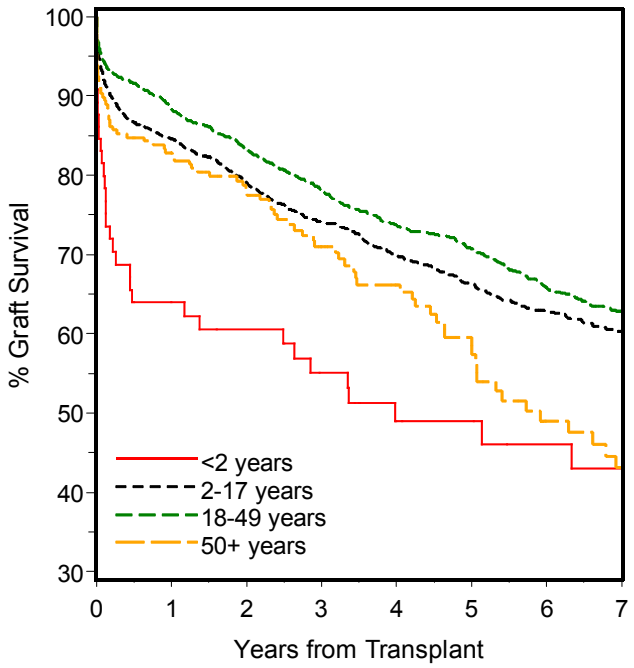


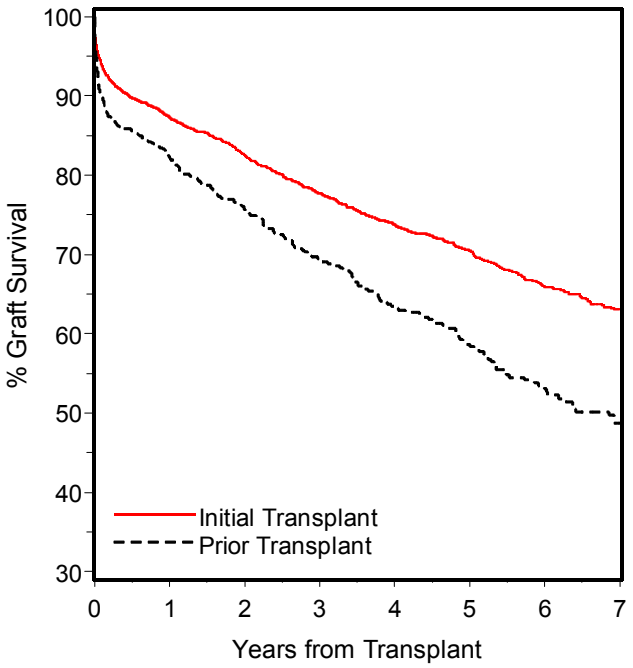
EXHIBIT 5.5 (continued)
GRAFT SURVIVAL BY SELECTED CHARACTERISTICS

Deceased Donor

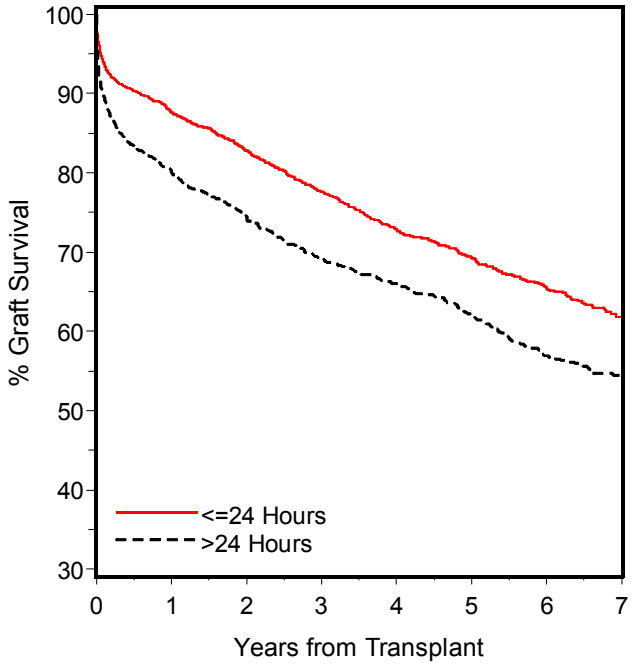
Donor Age



Transplant History



Cold Ischemia Time



Dialysis History

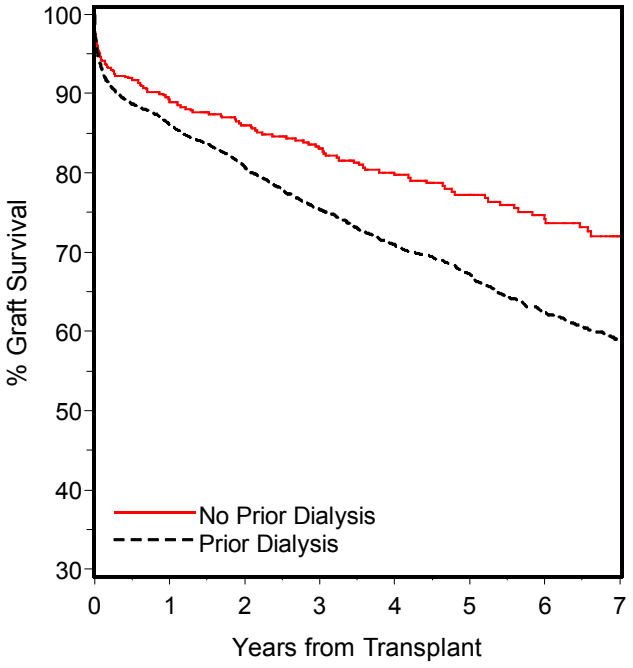
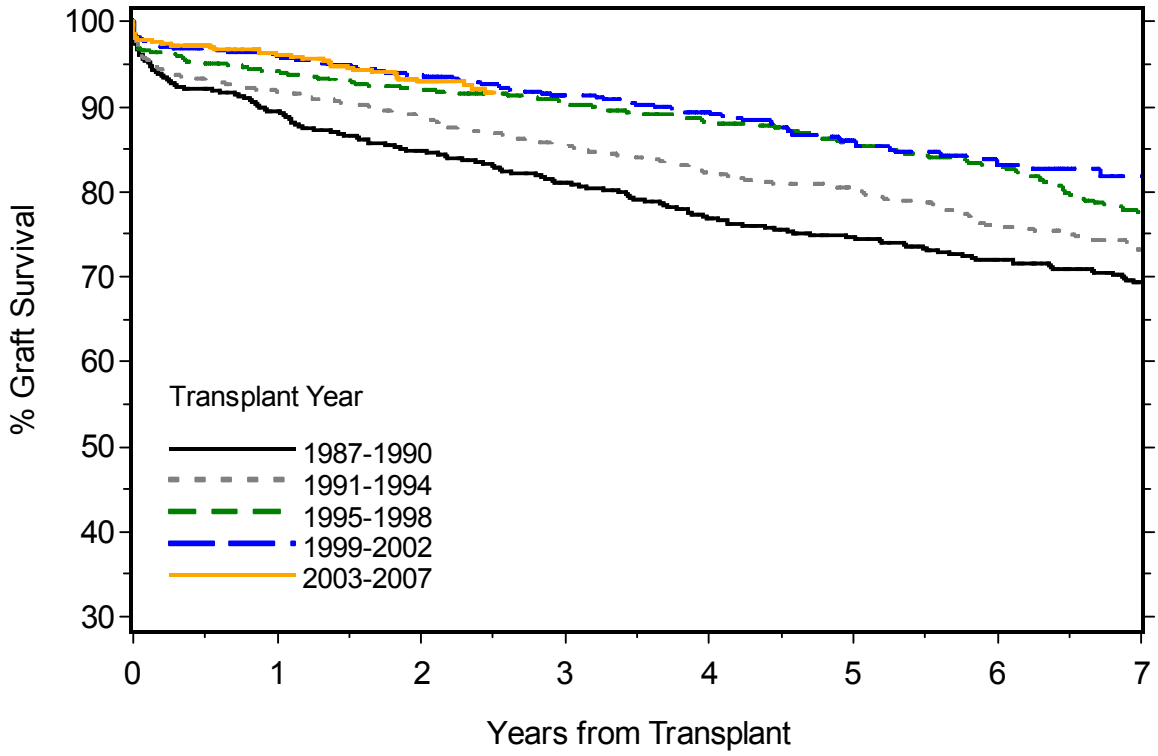


EXHIBIT 5-6
GRAFT SURVIVAL BY TRANSPLANT YEAR

Living Donor



Deceased Donor

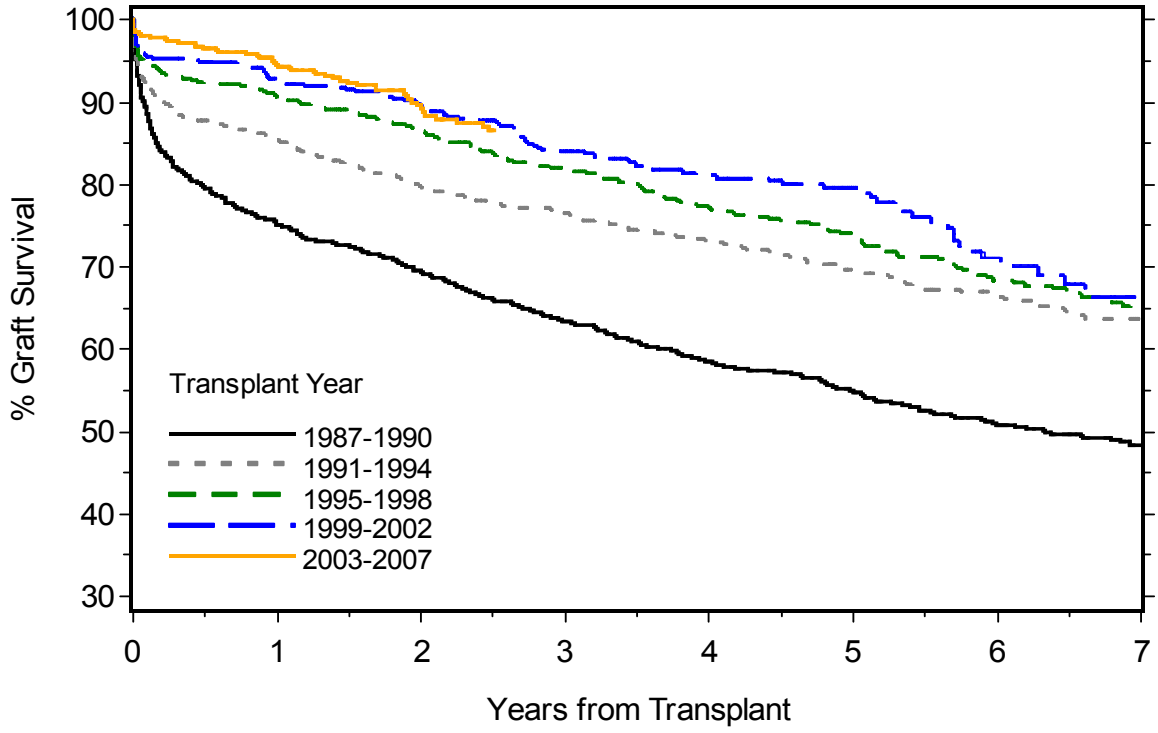
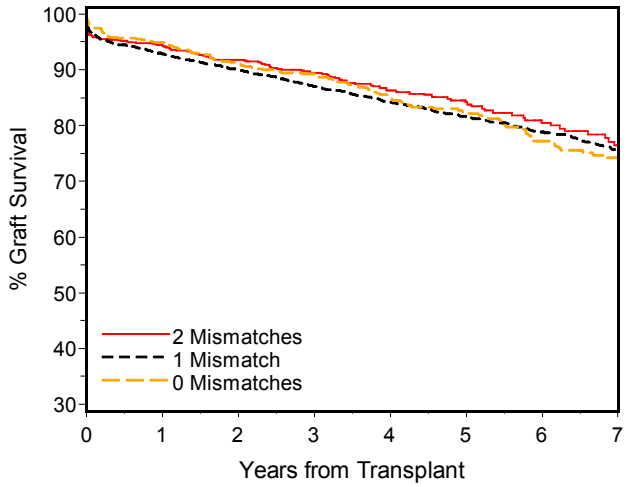
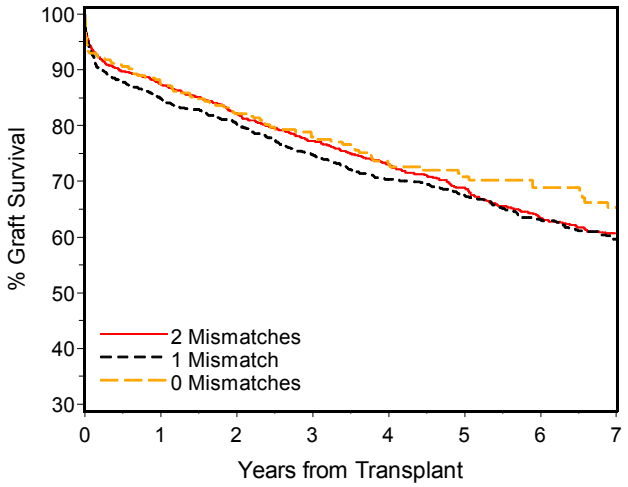


EXHIBIT 5.7
HISTOCOMPATIBILITY DATA

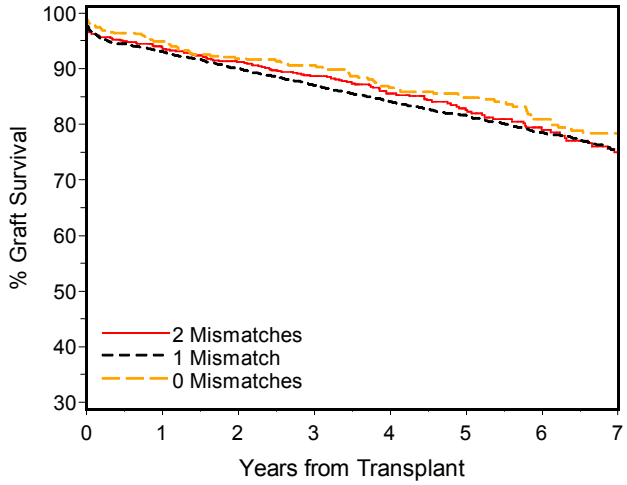
Living Donor | ***Deceased Donor***

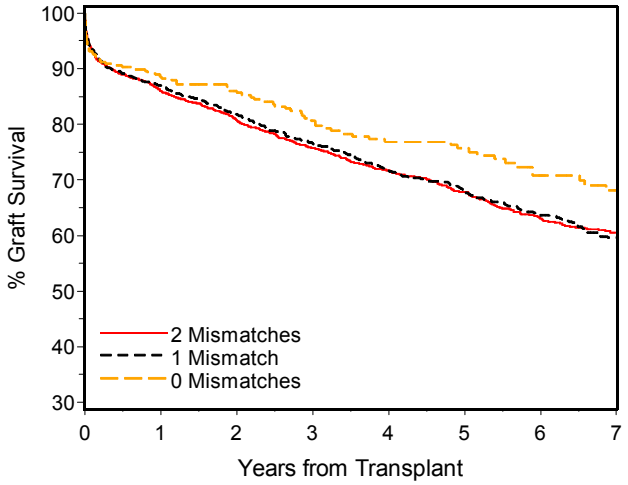
HLA-A



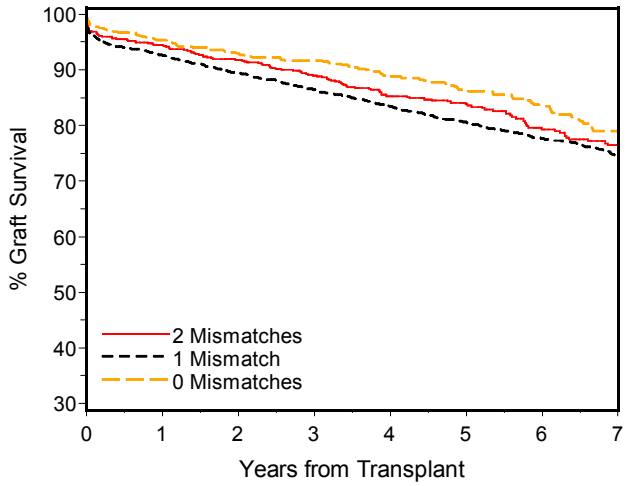


HLA-B





HLA-DR



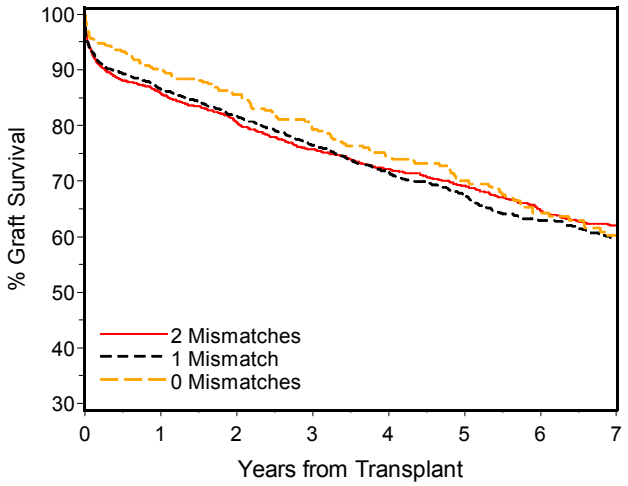
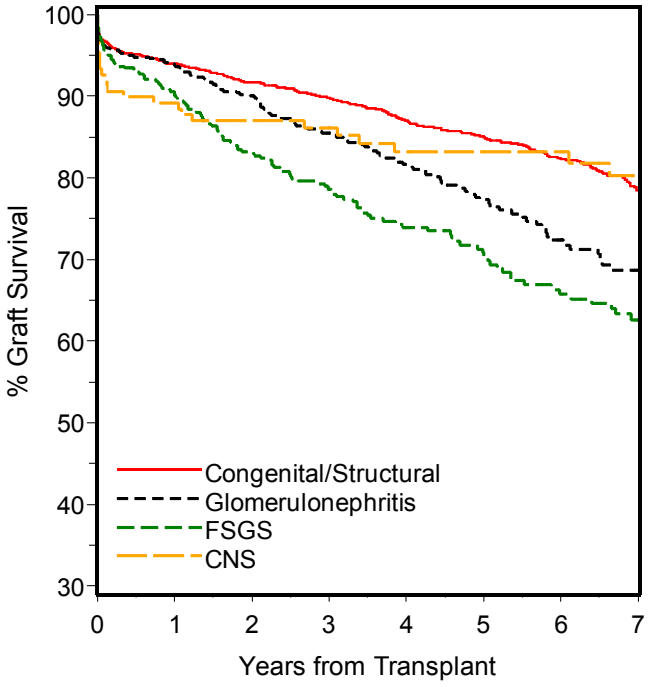
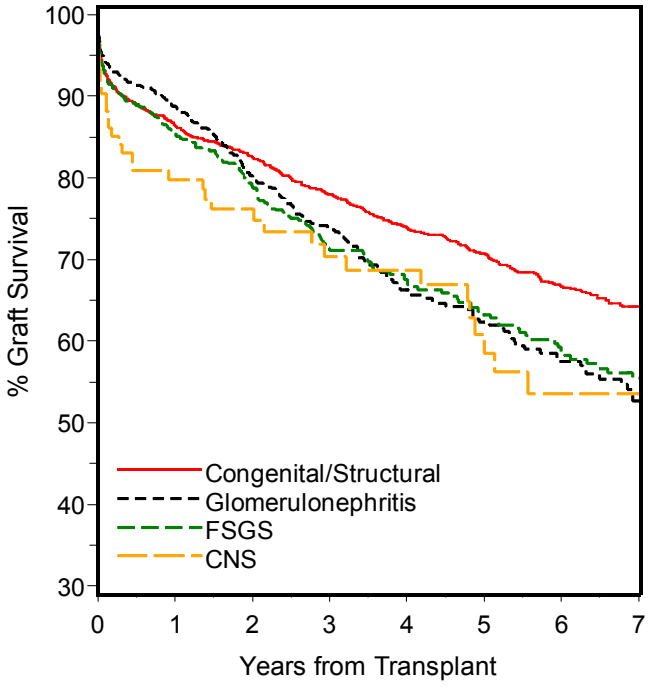


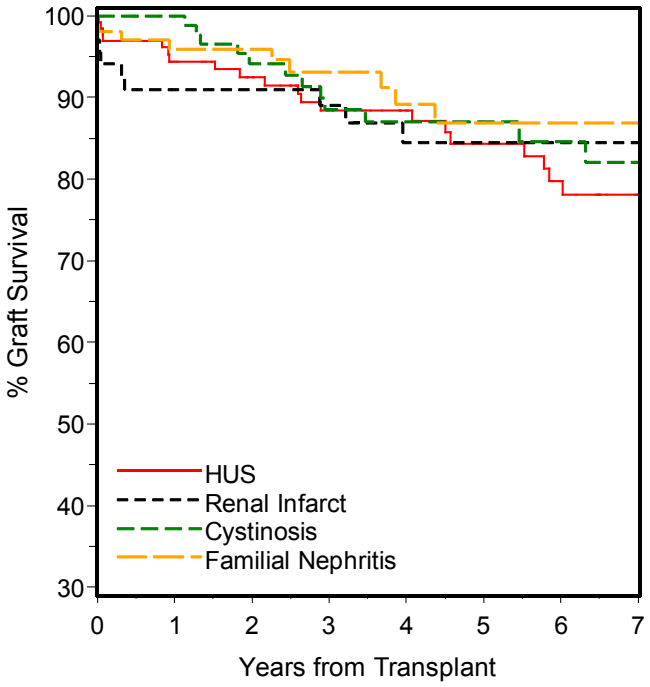
EXHIBIT 5.8
GRAFT SURVIVAL BY PRIMARY DIAGNOSIS

Living Donor



Deceased Donor





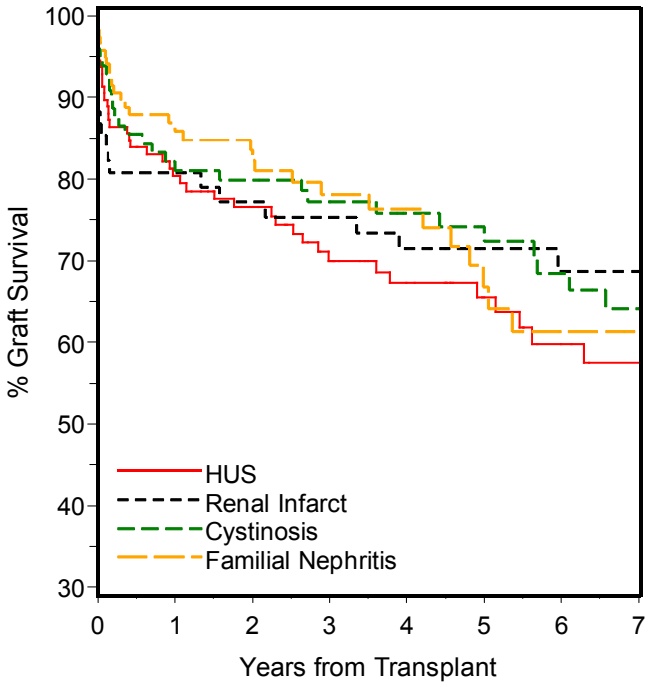
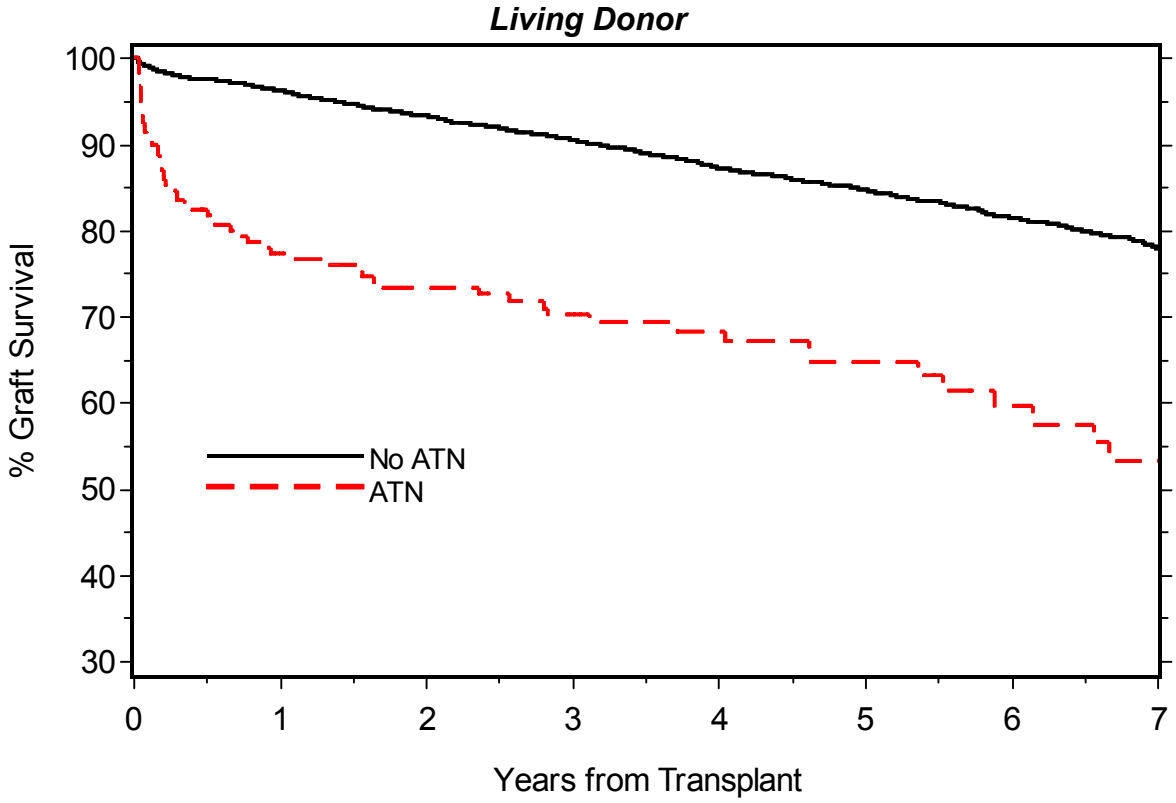


EXHIBIT 5.9
GRAFT SURVIVAL BY ACUTE TUBULAR NECROSIS STATUS
Grafts Surviving beyond 7 days



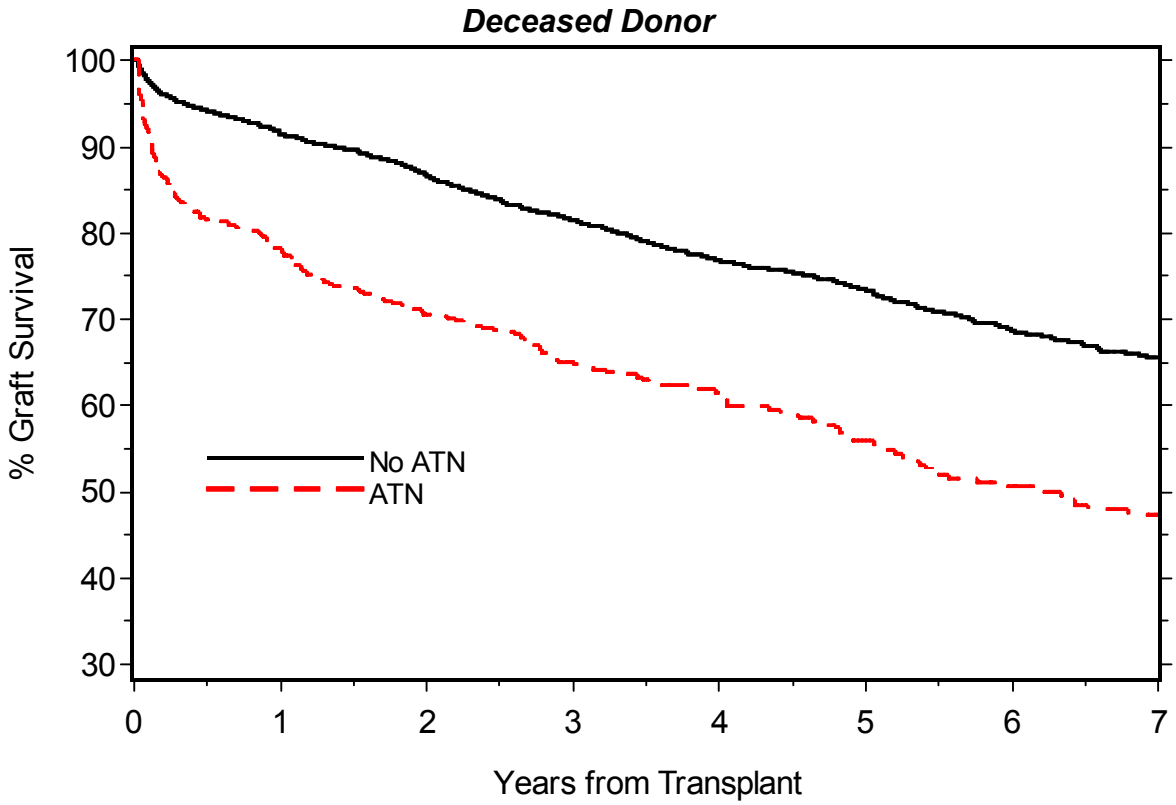
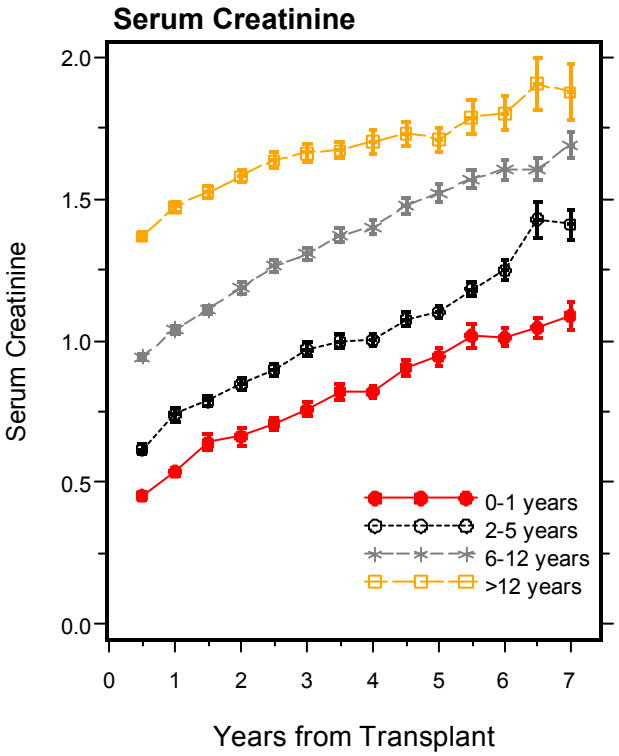
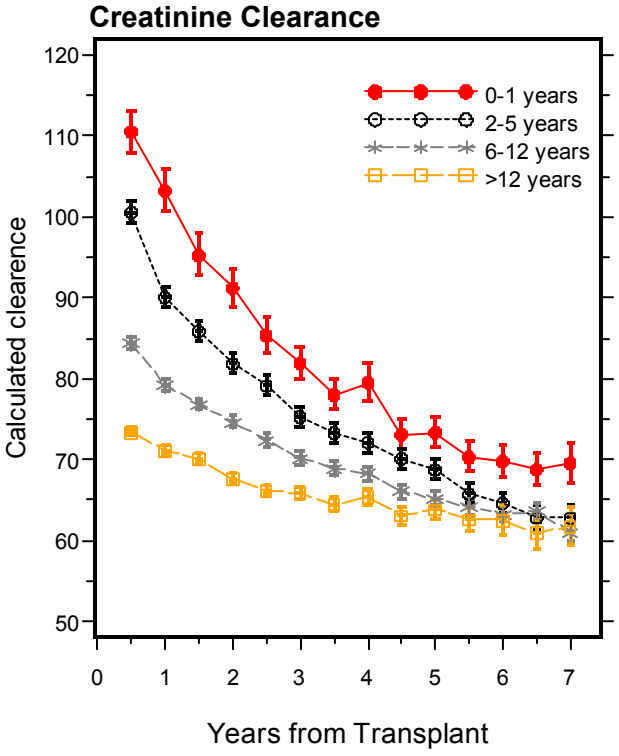


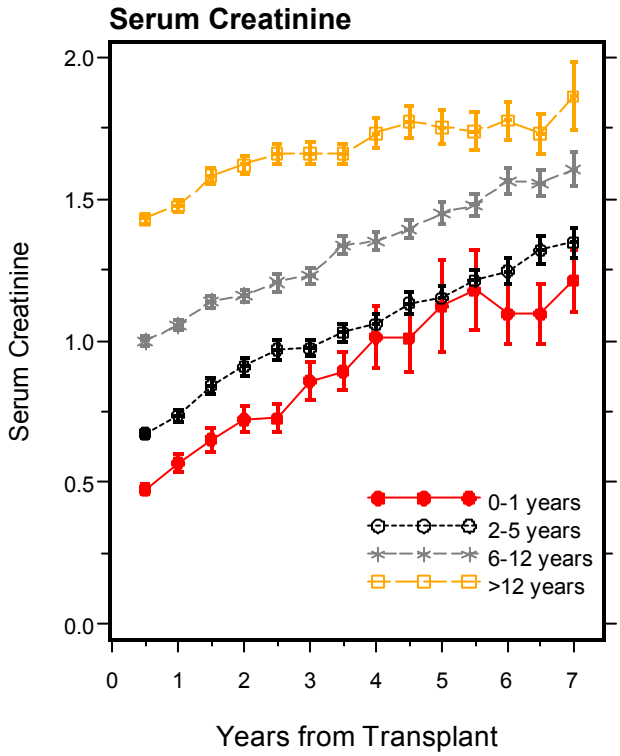
EXHIBIT 5.10
SERUM CREATININE AND CREATININE CLEARANCE (MEAN ± SE) BY AGE
(Index Transplants with Functioning Grafts)

Living Donor





Deceased Donor



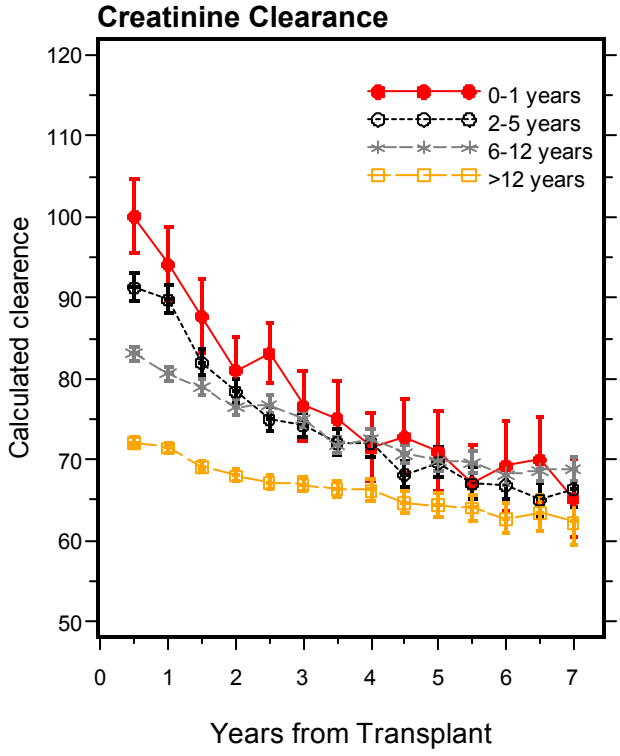


EXHIBIT 5.11
SERUM CREATININE (MEAN ± SE) BY RACE AND INDUCTION ANTIBODY
(Index Transplants with Functioning Grafts)

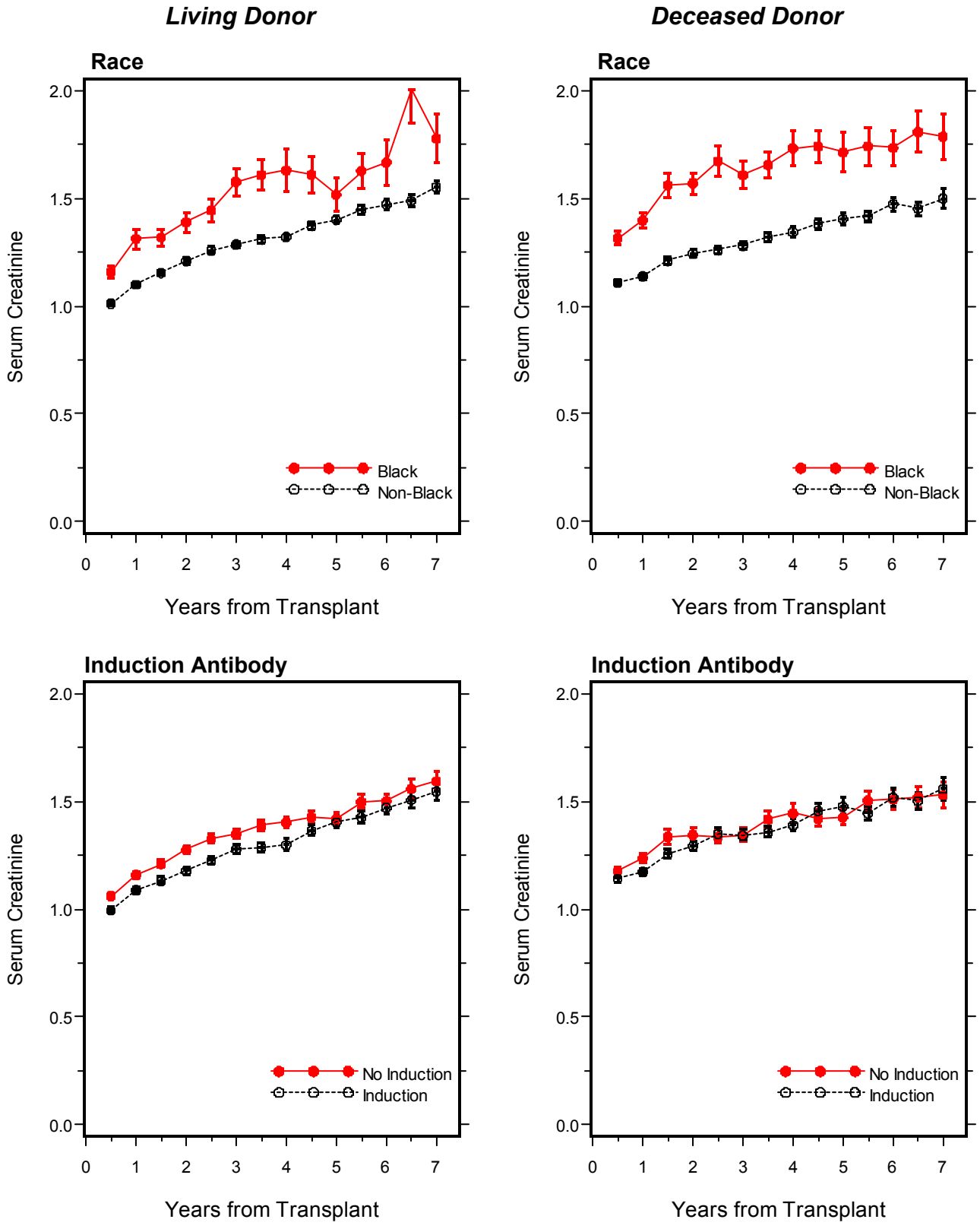
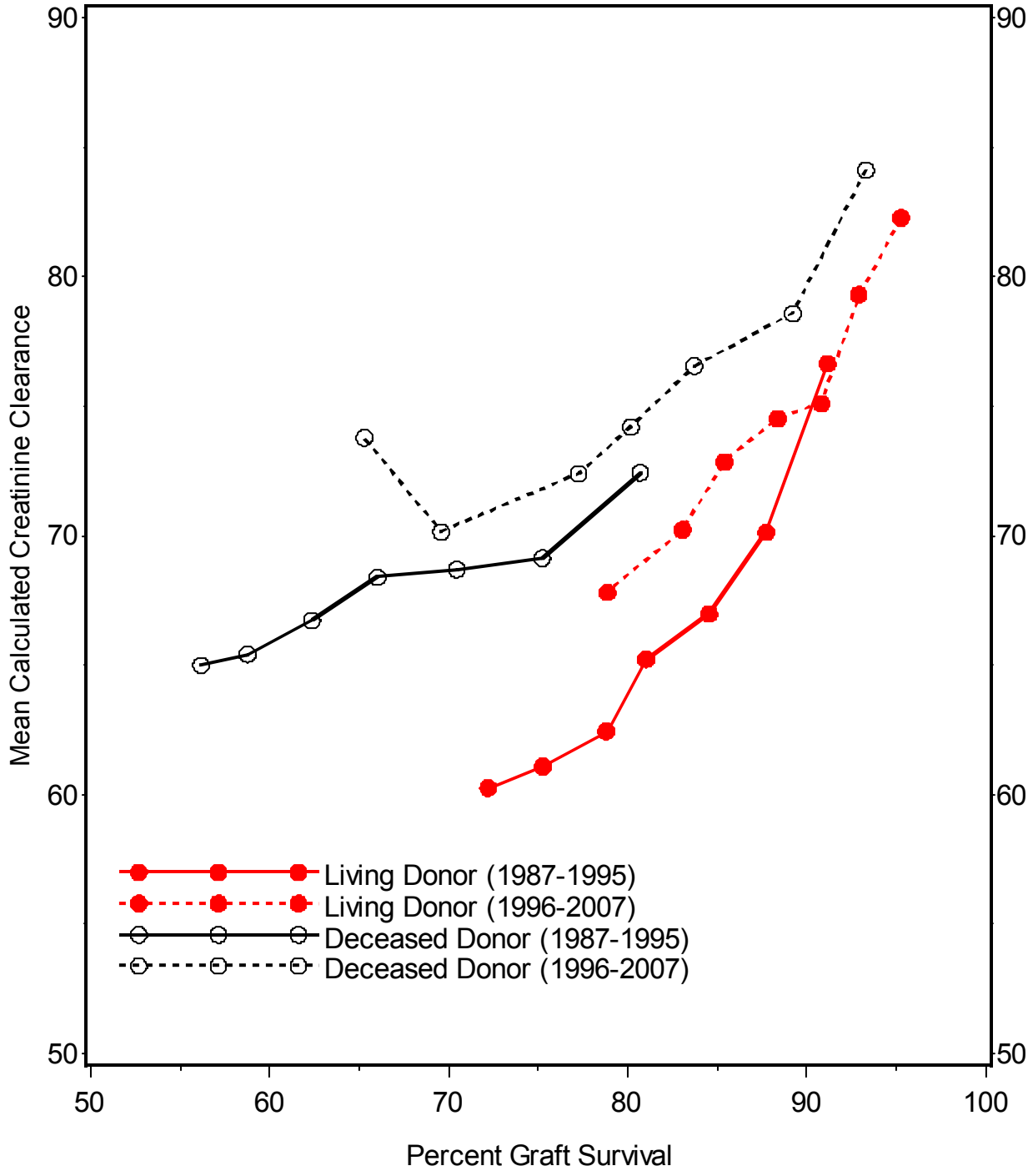


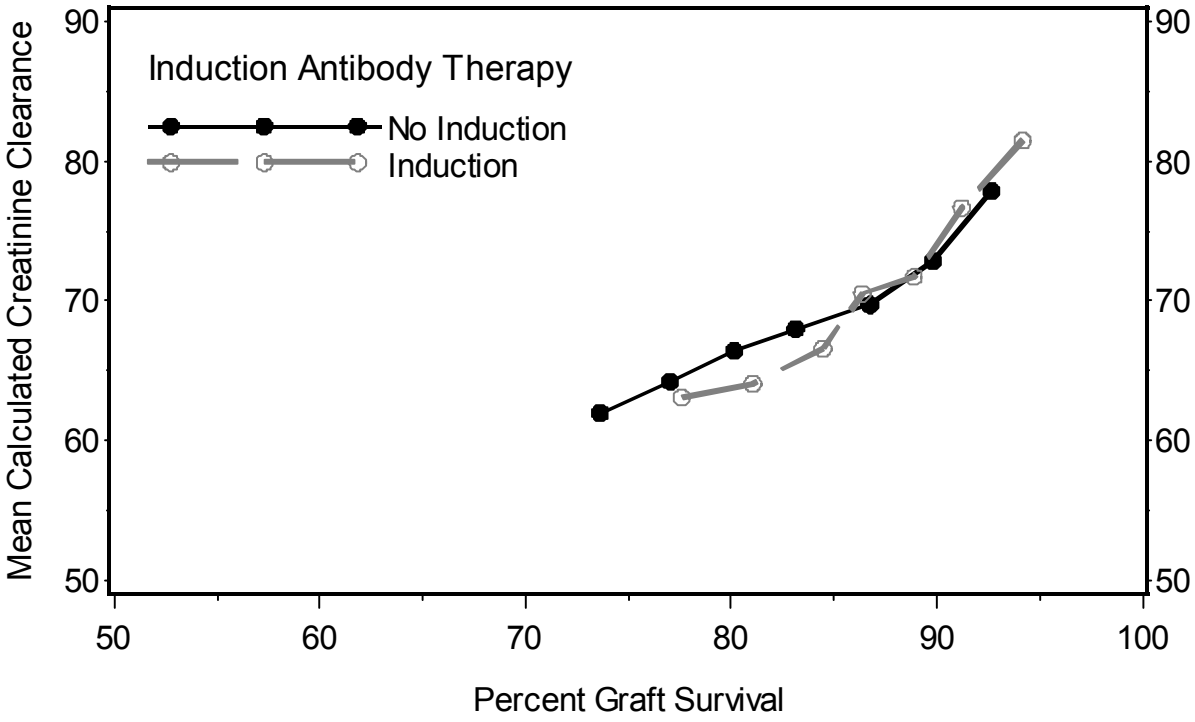
EXHIBIT 5.12
GRAFT FUNCTION
Graft Survival and Mean Calculated Clearance at Annual Follow-up



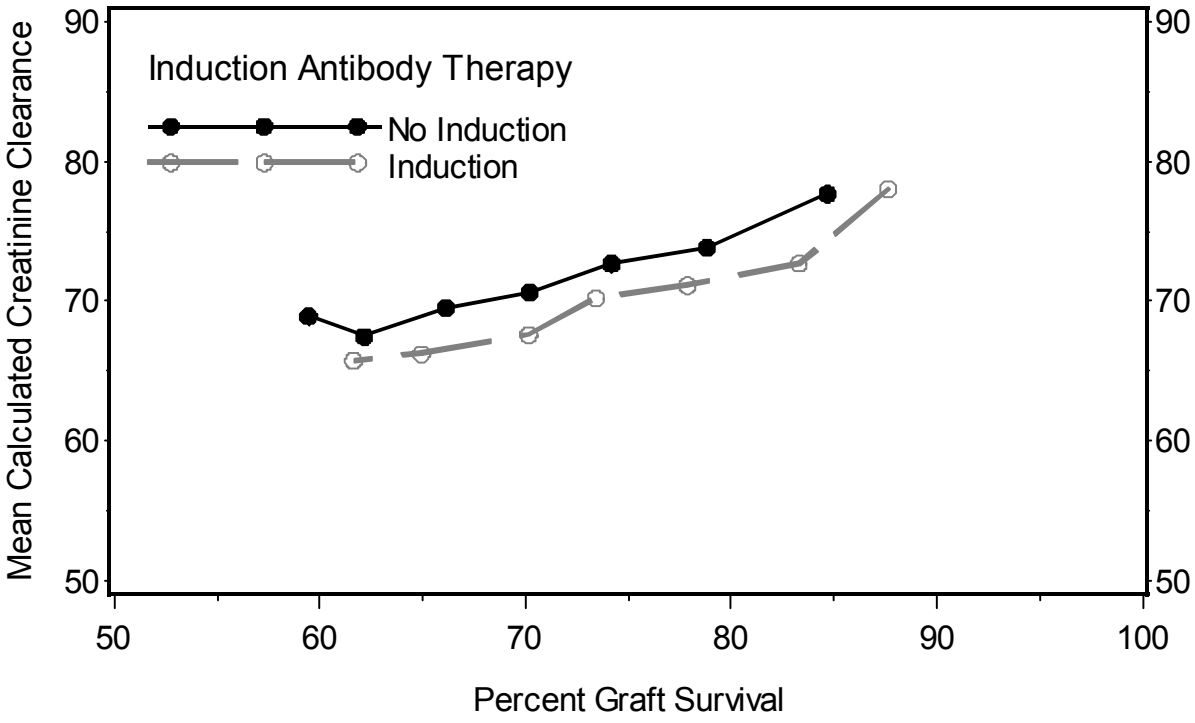
Note: Symbols represent annual follow-up. Year 1 is farthest right and year 7 is farthest left.

EXHIBIT 5.13
GRAFT FUNCTION
Graft Survival and Mean Calculated Clearance at Annual Follow-up

Living Donor



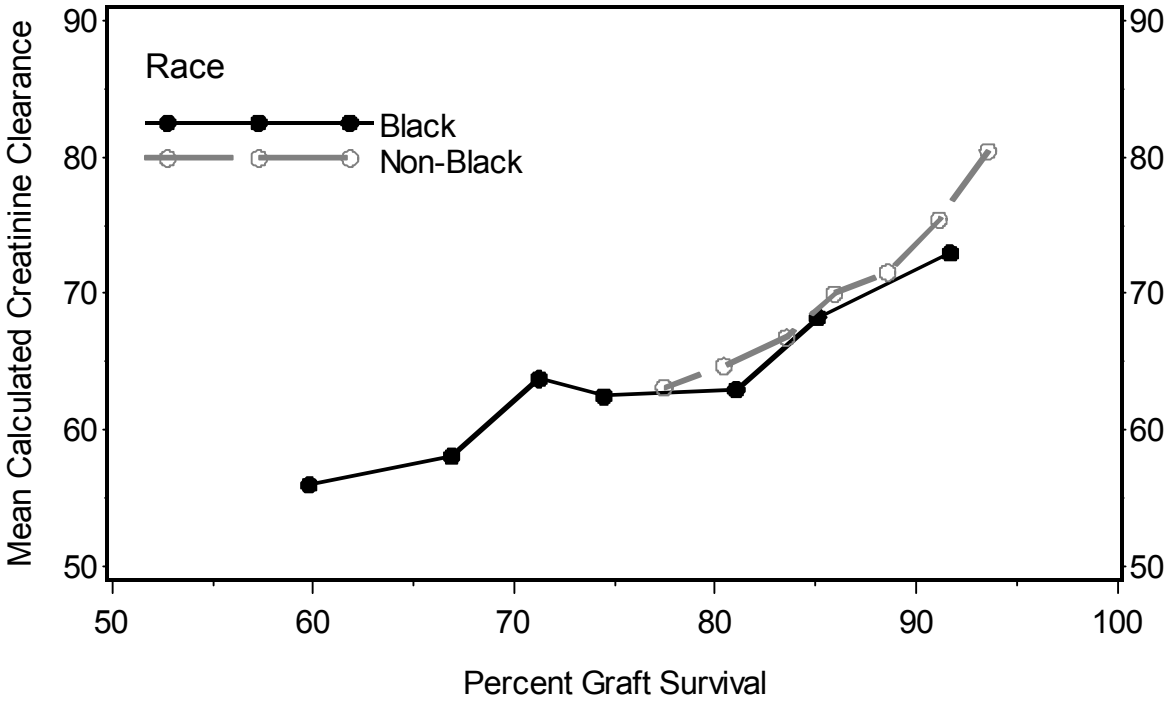
Deceased Donor



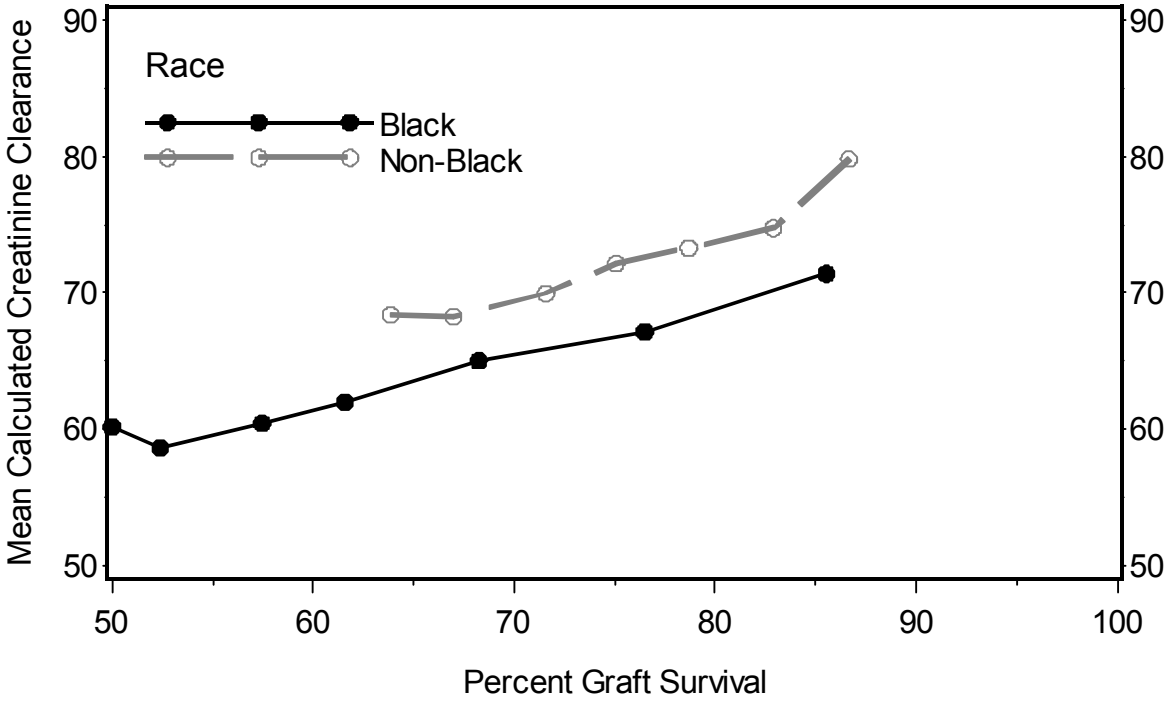
Note: Symbols represent annual follow-up. Year 1 is farthest right and year 7 is farthest left.

EXHIBIT 5.14
GRAFT FUNCTION
Graft Survival and Mean Calculated Clearance at Annual Follow-up

Living Donor



Deceased Donor



Note: Symbols represent annual follow-up. Year 1 is farthest right and year 7 is farthest left.

SECTION 6: GROWTH

At each six-month follow-up, the cooperative study requests the submission of height and weight information on all transplanted patients. Standardized Z-scores are computed following an age- and sex-specific formula based on the NHANES III 2000 growth chart data set. NHANES III is a study sponsored by the National Center for Health Statistics/CDC which provides values at monthly intervals for each sex until the age of 21 years. This is a change in the standardized height and weight calculation from early reports, thus direct comparisons to reports prior to the 2004 annual report should not be made. This section reports on index transplants with functioning grafts.

Exhibit 6.1 presents standardized height and weight Z-scores for patients at entry and at 2, 4 and 6 year follow-up visits for selected characteristics. At transplantation, the mean height deficits for all patients is -1.78; that is, the average patient is nearly 1.8 standard deviations below the appropriate age- and sex-adjusted height level or is shorter than the fourth percentile of their peers. This deficit is greater for males (-1.82) than females (-1.72). Younger subjects (between 2 and 5) and those with prior transplants have greater height deficits at the time of transplantation. Overall, mean height scores remain relatively constant over the available follow-up period. However, growth patterns differ by age at transplant, with younger subjects (less than 6 years of age) experiencing improvement in mean growth deficit. This is further characterized in Exhibit 6.2, where mean Z-scores and Exhibit 6.3 where mean changes from baseline Z-scores are presented graphically. For the youngest age group, an immediate increase in height of 0.23 standard deviations is observed in the first six months post-transplant, which increases to 0.49 by 12 months and 0.66 by 2 years post transplant. Subjects with functioning grafts who were age 2-5 at transplant appear to achieve similar acceleration in linear growth for a couple of years and have a mean increase in Z-score of 0.55 at 2 years. For subjects aged 6-12, linear growth appears to be stable, at about 2 standard deviation below the normal population, and the older subjects have no mean increase in Z-scores.

With respect to weight scores, a rapid increase in standardized weight scores is observed for all age groups in the first 6 months after transplant. Patients gain an average of 0.87 standard deviations in weight in the first year following transplantation, with relative stability in average standardized weight scores over the next 5 years.

Note that as the study has matured, some transplant patients have reached their adult height. The mean Z-score of these subjects, at least 19 years of age (N=2,059), is -1.46. Twenty-five percent of these patients have a Z-score of -2.31 or worse, and 10% are over 3.30 standard deviations below the population average. Significant improvement in terminal height has been observed with the 1987 - 1991 cohort having an average terminal height of -1.93 versus –1.08 for the 1997-2001 cohort.

Exhibit 6.4 demonstrates the improvement in height and weight deficit at the time of initial transplant that has occurred over time. In 1987, patients receiving their initial transplant were an average of 2.43 standard deviations below average in height and 1.91 standard deviations below average in weight. This has improved over the years to -1.33 for height and -0.54 for weight in the 2007 cohort. This increase is shown for age groups in Exhibit 6.5.

Besides age, donor source and use of antihypertensive medication are predictive of 2-year standardized height changes. Recipients of living donor organs had an average increase of 0.23 standard deviations and deceased donors increased by 0.12 standard deviations at 2 years. Subjects not receiving anti-hypertensive therapy during the first post-transplant month have better growth in the first two post-transplant years, an increase of 0.38 standard deviations versus 0.13 for those using antihypertensive medication ($p<0.001$), a difference which is maintained at 3 years.

EXHIBIT 6.1
STANDARDIZED SCORES (MEAN ± SE)
BY SELECTED CHARACTERISTICS AND FOLLOW-UP TIMES

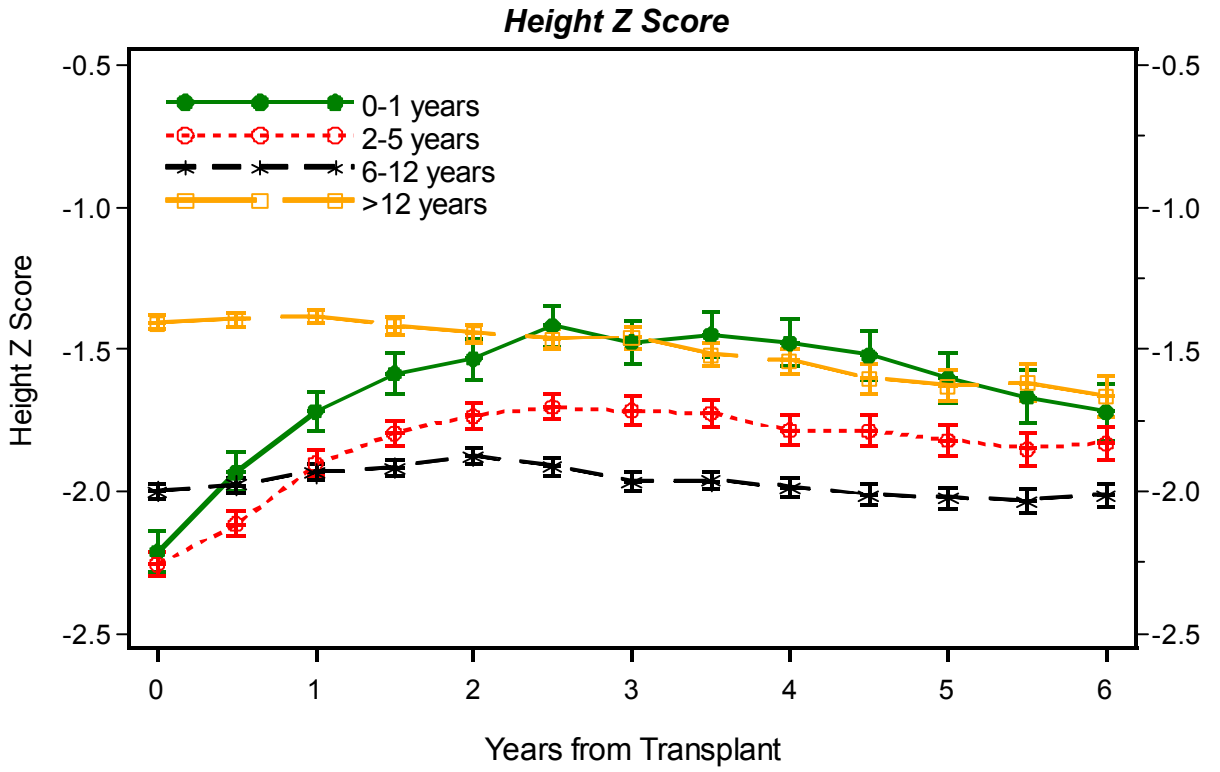
Height Z Score

	Baseline (N=9426)		**2 Years** (N=5659)		**4 Years** (N=3574)		**6 years** (N=2086)	
	Mean	SE	Mean	SE	Mean	SE	Mean	SE
Total	-1.78	0.02	-1.66	0.02	-1.78	0.02	-1.88	0.03
Sex								
Male	-1.82	0.02	-1.68	0.02	-1.82	0.03	-1.91	0.04
Female	-1.72	0.03	-1.63	0.03	-1.72	0.04	-1.84	0.05
Age								
0-1 years	-2.21	0.07	-1.53	0.07	-1.48	0.08	-1.72	0.10
2-5 years	-2.26	0.04	-1.74	0.04	-1.78	0.05	-1.83	0.06
6-12 years	-2.00	0.03	-1.88	0.03	-1.99	0.03	-2.01	0.04
>12 years	-1.41	0.02	-1.44	0.03	-1.54	0.04	-1.67	0.07
Prior Transplant								
No	-1.71	0.02	-1.60	0.02	-1.72	0.02	-1.82	0.03
Yes	-2.24	0.05	-2.09	0.06	-2.31	0.08	-2.42	0.10

Weight Z Score

	Baseline (N=9521)		**24 Months** (N=5720)		**48 Months** (N=3384)		**72 Months** (N=1916)	
	Mean	SE	Mean	SE	Mean	SE	Mean	SE
Total	-1.13	0.02	-0.30	0.02	-0.34	0.03	-0.38	0.04
Sex								
Male	-1.13	0.02	-0.34	0.03	-0.37	0.04	-0.42	0.05
Female	-1.14	0.03	-0.23	0.03	-0.30	0.04	-0.31	0.06
Age								
0-1 years	-1.57	0.07	-0.53	0.07	-0.48	0.09	-0.46	0.09
2-5 years	-1.22	0.04	-0.34	0.05	-0.13	0.06	-0.14	0.06
6-12 years	-1.27	0.03	-0.21	0.03	-0.33	0.04	-0.46	0.05
>12 years	-0.94	0.03	-0.32	0.04	-0.53	0.06	-0.55	0.15
Prior Transplant								
No	-1.10	0.02	-0.27	0.02	-0.31	0.03	-0.33	0.04
Yes	-1.35	0.05	-0.49	0.07	-0.65	0.09	-0.84	0.12

EXHIBIT 6.2
STANDARDIZED SCORE (MEAN ± SE) BY AGE AT TRANSPLANT
(Index transplants with functioning graft)



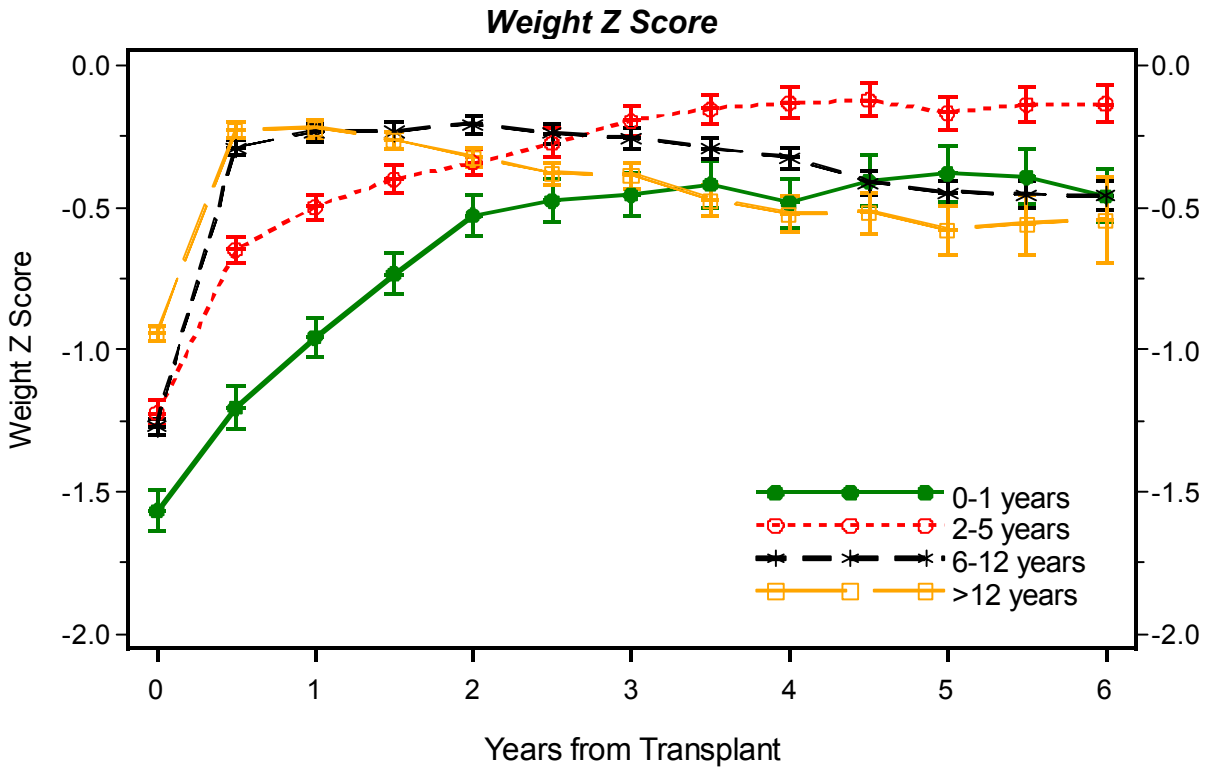
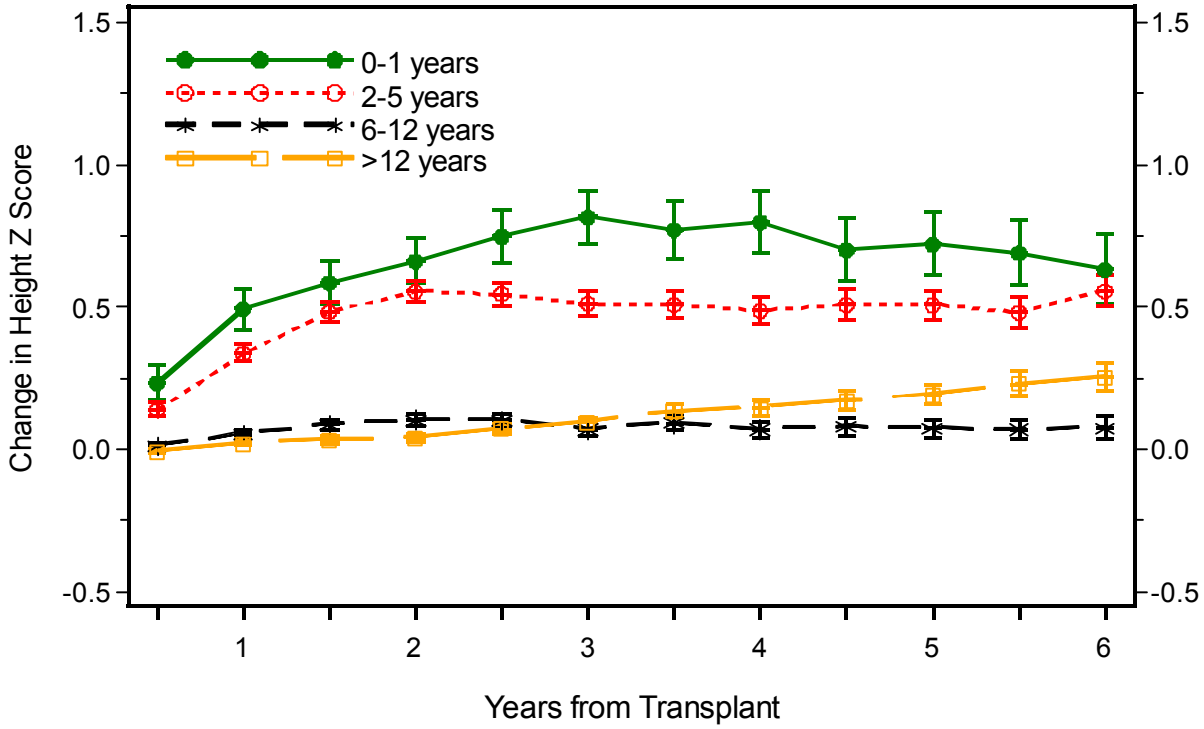


EXHIBIT 6.3
CHANGE FROM BASELINE IN STANDARDIZED SCORE (MEAN ± SE)
BY AGE AT TRANSPLANT
(Index transplants with functioning graft)

Change in Height Z Score



Change in Weight Z Score

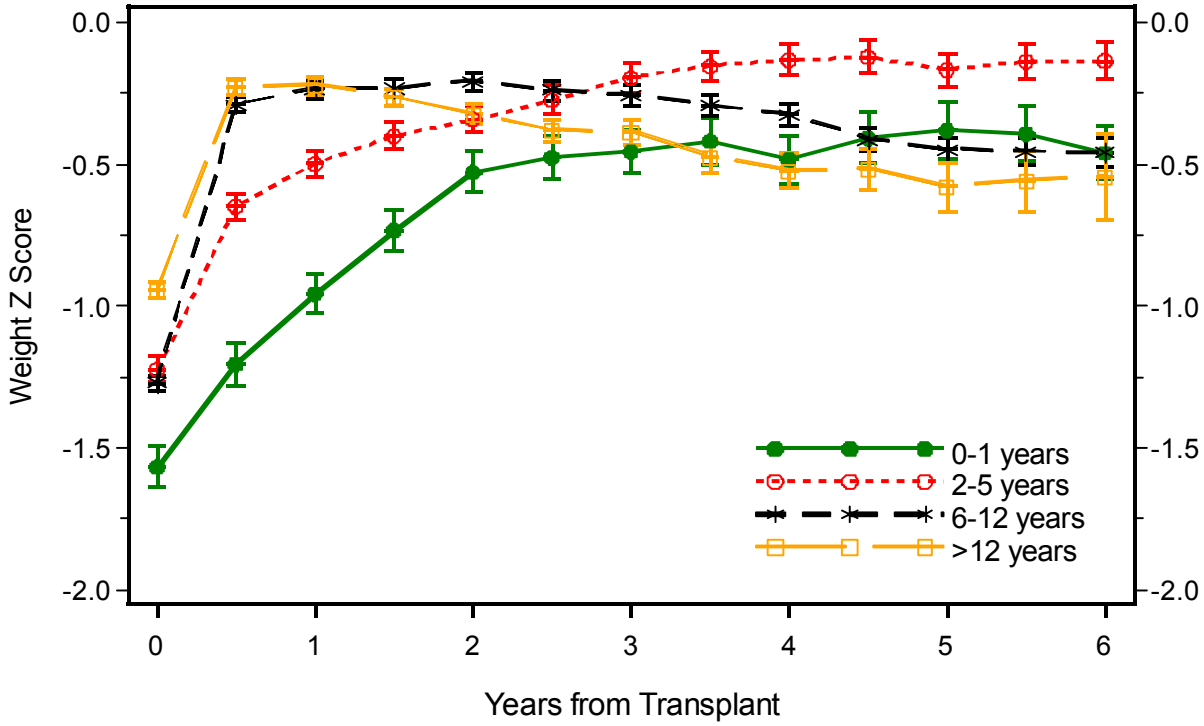


EXHIBIT 6.4
STANDARDIZED SCORES (MEAN ± SE) AT TRANSPLANT
BY YEAR OF TRANSPLANT
(Index transplants)

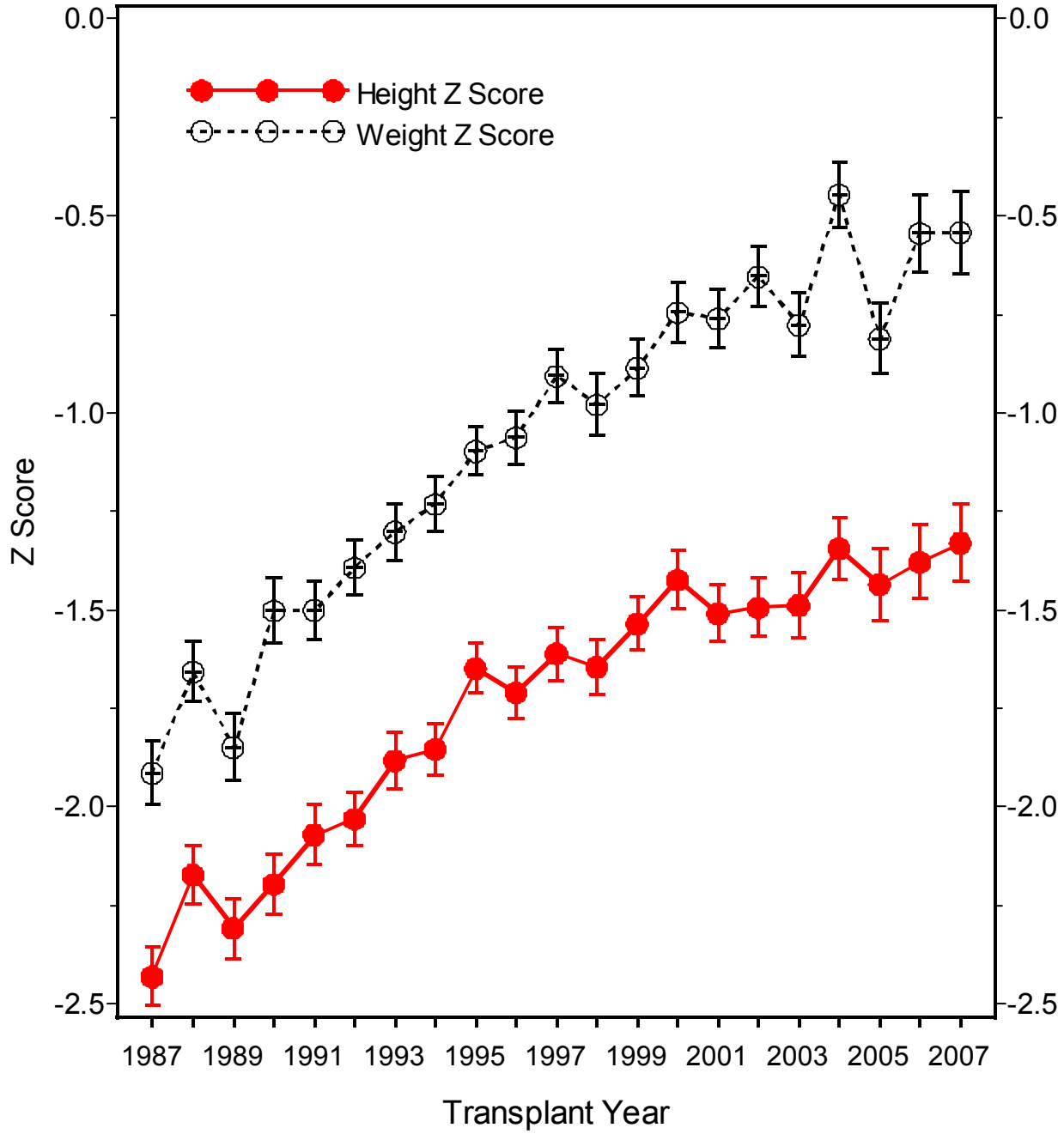
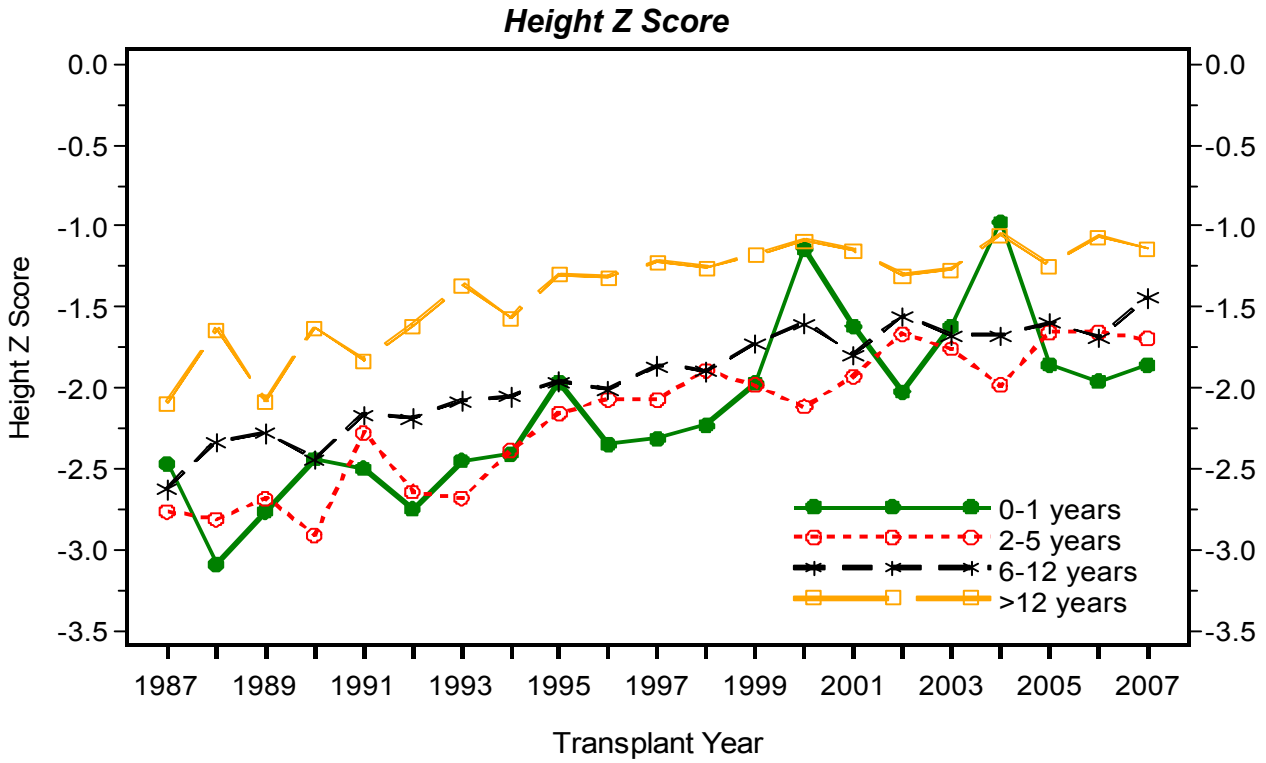
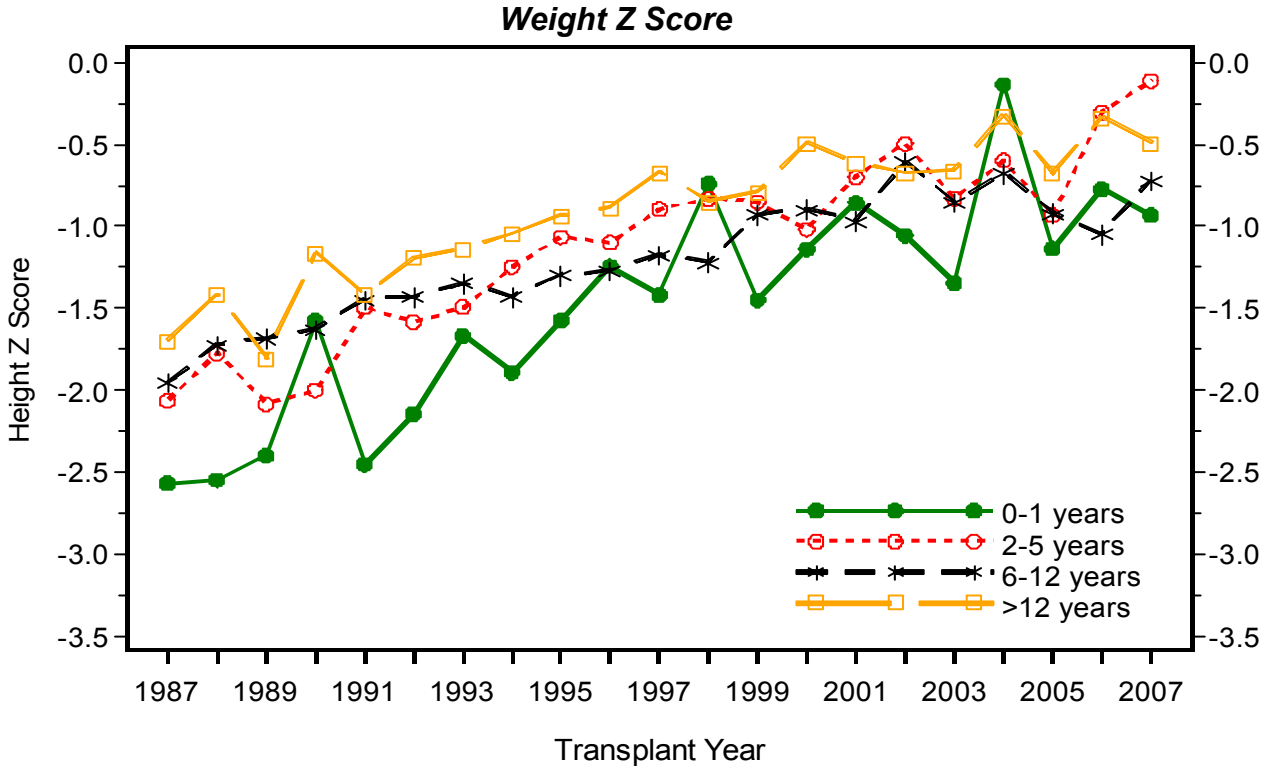


EXHIBIT 6.5
STANDARDIZED SCORES (MEAN ± SE) AT TRANSPLANT
BY AGE AT TRANSPLANT AND YEAR OF TRANSPLANT





SECTION 7: MORBIDITY, MALIGNANCY, AND MORTALITY

Morbidity

In this report, we measure morbidity by the number of hospitalization days. The median duration (to initial discharge) of hospitalization at the time of transplant is 12 days, with lower and upper quartiles of 8 and 18 days. Due to re-hospitalization, patients were hospitalized for a median duration of 13 days during the transplant month with lower and upper quantities of 8 and 20 days. Transplant month hospitalization times are negatively correlated with patient age such that the median hospital stays are 19, 16, 14 and 11 days for patients aged 0-1, 2-5, 6-12, and >12 years, respectively during the transplant month. The median number of hospitalization days in the transplant month for recipients of deceased donor source allografts (15 days) is 3 days longer than for those who received grafts from a living donor. Donor-specific mean (± SE) hospitalization during for the first post transplant month are presented in Exhibit 7.1. In 1987, living donor (LD) transplant recipients, on average, were hospitalized for 18.1 days during the first post transplant month, compared to 21.6 days for deceased donor (DD) transplant recipients. In 1996, mean hospital stays during this initial post transplant period were 12.3 days for LD recipients and 14.7 days for DD transplant recipients. By 2007, mean hospital stays decreased to 8.9 days for LD recipients and 10.7 days for DD recipients.

Exhibit 7.2A, 7.2B, and 7.2C present transplant month hospitalization data for selected patient and transplant characteristics (of all, LD, and DD transplants). In regression analyses that consider transplant era (1987-1995 vs. 1996-2007) and the characteristics shown in Exhibit 7.2A, each characteristic, with the exception of prior transplant, was statistically significant at less than the 0.001 level of significance — in the overall and living donor recipient groups. However, among deceased donor recipients, all characteristics were statistically significant at less than 0.001 level with the exception of prior transplant and prior dialysis. Overall, the transplant month mean hospitalization stays have been six days shorter in the recent era (1996-2007) compared to the earlier era (1987-1995).

Exhibit 7.3 details length of hospital stays during follow-up and reasons for hospitalization for those patients surviving the interval with a functioning graft. Results are provided separately for living and deceased donor sources. During months 1-5, 46.2% of living donor graft recipients were re-hospitalized compared to 53.2% of deceased donor graft recipients. The most common

reason for hospitalization in this interval was treatment of rejection, which occurred in 25.3% and 17.6% of DD and LD patients, respectively. Viral (14.7% versus 12.6%) and bacterial (13.1% versus 11.8%) infections and treatment of hypertension (5.5% versus 3.4%) were other major causes of hospitalization. Hospital stays decrease in both frequency and length by month 6 and beyond. In recent years (2000 - 2007), both the frequency and length of hospitalization in first five months after transplant has decreased. Hospitalization for rejection has decreased to 9.2% in live donor recipients and 11.2% in deceased donor recipients in the first five months of follow-up and continues to be lower at each follow-up visit.

Malignancy

To date, 261 malignancies have been reported of which 255 have confirmed diagnoses — 215 lymphoproliferative (LPD) and 40 non-lymphoproliferative (non-LPD). Exhibit 7.4 shows selected transplant characteristics for the cohort with malignancy. 2.4% of transplants are associated with development of malignancy during the follow-up period. The median time from transplant to malignancy for those with a confirmed diagnosis of LPD was 12.7 months (range 0.9-161.8) and 17.0 months (range 0.9 – 161.8) for all malignancies. One- and three-year product limit estimates of the malignancy rates by era of entry are as follows:

POST TRANSPLANT MALIGNANCY RATE By Transplant Era				
	1 Year		3 Year	
	%	SE	%	SE
1987 – 1990	0.68	0.19	1.05	0.25
1991 – 1994	1.03	0.22	1.40	0.26
1995 – 1998	1.75	0.28	2.93	0.38
1999 – 2003	1.96	0.30	3.00	0.40
2004 - 2007	0.50	0.24	--	--

While substantial temporal improvements have been observed in graft failure, rejection and other endpoints, similar trends for malignancy rates are not observed.

Mortality

To assess post transplant patient survival, we considered 9,807 index transplants (5,267 LD and 4,540 DD). We have not adjusted the analysis for patient deaths that occurred subsequent to graft failure while the patient was receiving maintenance dialysis. Percent patient survival estimates (with standard errors) for all patients at 1, 2, 5 and 7 years post transplant are 97.8±0.2, 97.0±0.2, 94.5±0.3 and 92.4±0.4, respectively. Exhibit 7.5A depicts patient survival by allograft source. Percent patient survival estimates for recipients of index living donor kidneys are 98.3±0.2, 97.6±0.2, 95.8±0.3 and 93.8±0.5 percent, at 1, 2, 5 and 7 years post transplant, respectively. Comparable values for recipients of deceased donor allografts are 97.2±0.3, 96.3±0.4, 92.9±0.5 and 90.7±0.6 percent (log-rank $p<0.001$). Exhibit 7.5B compares patient survival for transplants in 1987-1995 (early era) versus 1996 – 2007 (recent era), by primary allograft source. Patient survival has significantly improved for DD patients in the recent era ($p<0.001$). Their 5-year post transplant survival in the early era was 90.9±0.7, compared to 96.1±0.7 for the recent era. LD patients have also shown some improvement in survival rates with 5-year survival rate of 95.1±0.5 in the early era and 96.4±0.5 in the recent era (Log Rank $p=0.012$).

Patient survival for transplants in 1996-2007, by recipient age at transplant, is shown below and in Exhibits 7.6A and 7.6B for living and deceased donor source transplants. Post transplant survival is markedly lower for infants (<24 months old at transplant) receiving a deceased donor graft, however this group is small, 6 deaths in 55 patients. The following table shows percent survival at 36 months post transplant, by age at transplantation for patients transplanted between 1996 and 2007. Although infants' post transplant survival is lower compared to the other age groups, the situation has been significantly improved in the later cohort. The 3-year patient survival of infants receiving deceased donor source grafts has increased from 78.5% (SE=4.6%) between 1987 and 1995 to 90.7% (SE=4.5%) in 1996 and later. For infants receiving living donor grafts, their 3-year survival also improved from 89.8% (SE=2.2%) in 1987-1995 to 95.7% (SE=1.5%) in 1996 and beyond.

PATIENT SURVIVAL BY AGE AT 3 YEARS POST TRANSPLANT Transplant Era 1996 – 2007				
	Living Donor		Deceased Donor	
	%	SE	%	SE
All Patients	97.6	0.3	97.8	0.4
Age 0-1 years	95.7	1.5	90.7	4.5
Age 2-5 years	97.1	0.9	96.2	1.4
Age 6-12 years	98.1	0.5	98.8	0.5
Age >12 years	97.8	0.5	97.8	0.6

In total, death reports have been received for 546 of the 9,807 patients (5.6%). Crude donor source-specific mortality rates are 4.6% (242/5,267) for recipients of living donor index transplants and 6.7% (304/4,540) for recipient of deceased donor index transplants. Reasons for patient death are shown in Exhibit 7.7. Infection was the cause of death in 156 patients (28.6% of deaths). Other reported causes include cancer/malignancy (n=58, 10.6%), cardiopulmonary (n=84, 15.4%), and dialysis-related complications (n=16, 2.9%). Of the expired patients, 256 (46.9%) died with a functioning graft.

EXHIBIT 7.1
HOSPITALIZATION DAYS (MEAN ± SE)
DURING THE FIRST POST-TRANSPLANT MONTH

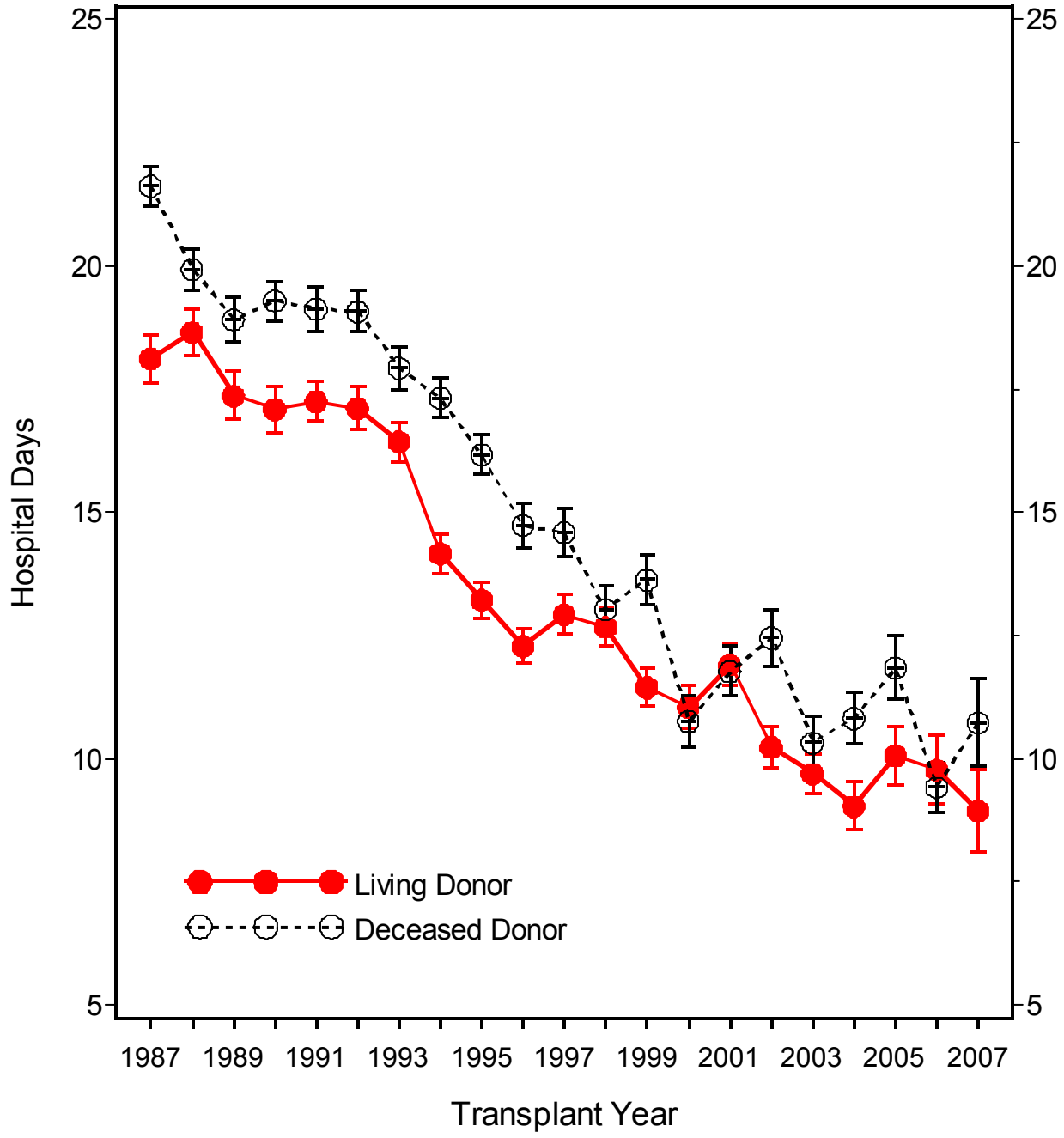


EXHIBIT 7.2A
HOSPITALIZATION DAYS DURING THE FIRST POST- TRANSPLANT MONTH

	Total (N=10456)			Living Donor (N=5371)			Deceased Donor (N=5085)		
	Mean	SE	Median	Mean	SE	Median	Mean	SE	Median
All transplants	14.7	0.08	13.0	13.6	0.10	12.0	15.8	0.12	15.0
Age at transplant									
0-1 years	19.1	0.37	19.0	18.6	0.40	18.0	20.8	0.84	25.0
2-5 years	17.3	0.21	16.0	16.4	0.28	15.5	18.5	0.33	18.0
6-12 years	14.9	0.13	14.0	13.7	0.17	12.0	16.2	0.20	15.0
>12 years	13.2	0.11	11.0	11.6	0.14	10.0	14.6	0.15	13.0
Transplant History									
No prior transplant	14.5	0.09	13.0	13.6	0.11	12.0	15.6	0.13	14.0
Prior transplant	15.4	0.19	14.0	13.7	0.31	12.0	16.3	0.23	15.0
ATN									
No	14.1	0.08	12.0	13.3	0.10	12.0	15.0	0.12	14.0
Yes	19.6	0.24	19.0	19.7	0.51	20.0	19.6	0.28	19.0
Rejection (during 1st month)									
No	13.0	0.08	11.0	12.2	0.10	11.0	13.8	0.12	13.0
Yes	20.7	0.15	21.0	19.7	0.24	19.0	21.5	0.20	22.0
Native Nephrectomy									
Tissue removed	14.1	0.09	12.0	12.8	0.12	11.0	15.4	0.13	14.0
No tissue removed	16.6	0.16	15.0	15.8	0.20	15.0	17.6	0.25	17.0
Dialysis History									
No prior dialysis	12.9	0.16	11.0	12.3	0.17	11.0	14.8	0.35	14.0
Prior dialysis	15.2	0.09	14.0	14.2	0.13	13.0	16.0	0.12	15.0

EXHIBIT 7.2B
HOSPITALIZATION DAYS DURING THE FIRST POST- TRANSPLANT MONTH
TRANSPLANT YEARS 1987 - 1995

	Total (N=5192)			**Living Donor** (N=2449)			**Deceased Donor** (N=2743)		
	Mean	SE	Median	Mean	SE	Median	Mean	SE	Median
All transplants	17.7	0.10	17.0	16.4	0.15	15.0	18.8	0.14	18.0
Age at transplant									
0-1 years	22.2	0.44	23.5	21.1	0.52	21.0	24.7	0.79	28.0
2-5 years	20.2	0.27	20.0	19.5	0.36	19.5	21.0	0.40	21.0
6-12 years	18.0	0.17	17.0	16.5	0.24	15.0	19.3	0.23	18.0
>12 years	16.0	0.15	15.0	14.1	0.21	13.0	17.4	0.20	16.0
Transplant History									
No prior transplant	17.3	0.11	16.0	16.2	0.15	15.0	18.4	0.17	18.0
Prior transplant	19.4	0.24	19.0	18.4	0.47	17.0	19.7	0.28	19.0
ATN									
No	17.2	0.11	16.0	16.2	0.15	15.0	18.3	0.16	17.0
Yes	21.1	0.31	22.0	21.1	0.70	22.5	21.1	0.34	21.0
Rejection (during 1st month)									
No	15.6	0.12	14.0	14.5	0.16	14.0	16.7	0.17	16.0
Yes	21.5	0.16	22.0	20.6	0.26	20.0	22.1	0.21	23.0
Native Nephrectomy									
Tissue removed	17.2	0.12	16.0	15.8	0.17	14.0	18.4	0.16	18.0
No tissue removed	19.0	0.20	18.0	18.0	0.27	17.0	20.2	0.29	19.5
Dialysis History									
No prior dialysis	16.5	0.22	15.0	15.4	0.25	14.0	19.1	0.43	18.0
Prior dialysis	18.0	0.12	17.0	16.8	0.18	16.0	18.7	0.15	18.0

EXHIBIT 7.2C
HOSPITALIZATION DAYS DURING THE FIRST POST- TRANSPLANT MONTH
TRANSPLANT YEARS 1996 - 2007

	Total (N=5264)			**Living Donor** (N=2922)			**Deceased Donor** (N=2342)		
	Mean	SE	Median	Mean	SE	Median	Mean	SE	Median
All transplants	11.7	0.10	10.0	11.2	0.13	9.0	12.3	0.16	11.0
Age at transplant									
0-1	16.0	0.52	15.0	16.4	0.56	16.0	14.0	1.40	14.0
2-5	14.1	0.30	13.0	13.6	0.36	12.0	15.0	0.50	14.0
6-12	11.6	0.17	10.0	11.0	0.22	10.0	12.2	0.28	11.0
>12	10.7	0.13	9.0	9.7	0.17	8.0	11.7	0.20	10.0
Transplant History									
No prior transplant	11.7	0.11	10.0	11.3	0.14	9.0	12.4	0.18	11.0
Prior transplant	11.7	0.24	10.0	11.0	0.36	9.0	12.2	0.32	11.0
ATN									
No	11.1	0.10	9.0	10.8	0.13	9.0	11.4	0.16	10.0
Yes	17.7	0.37	16.0	18.5	0.71	17.5	17.4	0.44	16.0
Rejection (during 1st month)									
No	11.1	0.10	9.0	10.7	0.13	9.0	11.6	0.16	10.0
Yes	17.8	0.36	17.0	17.1	0.49	16.0	18.6	0.51	18.5
Native Nephrectomy									
Tissue removed	11.1	0.11	9.0	10.5	0.14	9.0	11.9	0.18	10.0
No tissue removed	13.9	0.22	12.0	13.6	0.28	12.0	14.3	0.36	13.0
Dialysis History									
No prior dialysis	9.8	0.18	8.0	9.6	0.20	8.0	10.2	0.40	9.0
Prior dialysis	12.3	0.12	10.0	12.0	0.17	10.0	12.6	0.17	11.0

EXHIBIT 7.3
HOSPITALIZATION RESULTS DURING FOLLOW-UP
(Transplants with Functioning Graft)

Living Donor

	Months 1-5	Months 6-11	Months 12-17	Months 18-23	Months 30-35	Months 42-47	Months 54-59
Total Transplants	4704	4336	3954	3622	2998	2409	1870
Median days hospitalized	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Mean days hospitalized	5.7	2.6	2.0	1.4	1.2	1.0	1.0
Hospitalized Transplants							
Median days hospitalized	7.5	5.0	5.0	4.0	4.0	4.0	4.0
Mean days hospitalized	12.1	9.0	8.7	6.9	6.6	6.0	6.4
% Hospitalized	46.2	28.6	23.0	19.9	17.8	16.1	15.5
% Hospitalized for:							
Bacterial infection	11.8	7.6	6.8	5.8	4.6	4.6	4.9
Fungal infection	0.8	0.2	0.3	0.2	0.2	0.2	0.2
Viral infection	12.6	7.8	5.5	5.3	4.1	3.7	3.9
Rejection	17.6	8.1	5.8	4.9	4.2	2.9	3.2
Hypertension	3.4	1.6	1.4	1.0	0.6	0.8	0.6

Deceased Donor

	Months 1-5	Months 6-11	Months 12-17	Months 18-23	Months 30-35	Months 42-47	Months 54-59
Total Transplants	4173	3776	3359	2961	2333	1806	1393
Median days hospitalized	2.0	0.0	0.0	0.0	0.0	0.0	0.0
Mean days hospitalized	7.9	3.4	2.5	1.9	1.6	1.4	1.3
Hospitalized Transplants							
Median days hospitalized	10.0	7.0	6.0	5.0	4.0	4.0	4.0
Mean days hospitalized	14.6	10.7	9.6	8.0	7.3	7.6	7.2
% Hospitalized	53.2	31.3	26.1	23.9	21.6	18.6	17.8
% Hospitalized for:							
Bacterial infection	13.1	9.1	6.7	5.2	5.3	5.2	4.1
Fungal infection	1.0	0.5	0.3	0.1	0.2	0.2	0.1
Viral infection	14.7	7.7	5.9	5.8	4.7	3.9	4.0
Rejection	25.3	11.1	8.4	7.6	6.1	4.7	3.9
Hypertension	5.5	2.7	1.9	2.1	2.0	1.7	1.0

EXHIBIT 7.4
MALIGNANCY RATES BY SELECTED CHARACTERISTICS

	Malignancies	
	N	%
All patients	261	2.43
Donor Source		
Living Donor	134	2.43
Deceased Donor	126	2.42
Age at Transplant		
0-1 years	15	2.62
2-5 years	67	4.21
6-12 years	87	2.44
>12 years	92	1.83
Sex		
Male	156	2.43
Female	105	2.41
Race		
White	189	2.91
Black	29	1.60
Hispanic	31	1.77
Other	12	1.74
Transplant Year		
1987-1990	44	2.07
1991-1994	63	2.61
1995-1999	81	3.27
2000-2003	68	2.76
2004-2007	5	0.39

EXHIBIT 7.5A
PATIENT SURVIVAL BY ALLOGRAFT SOURCE

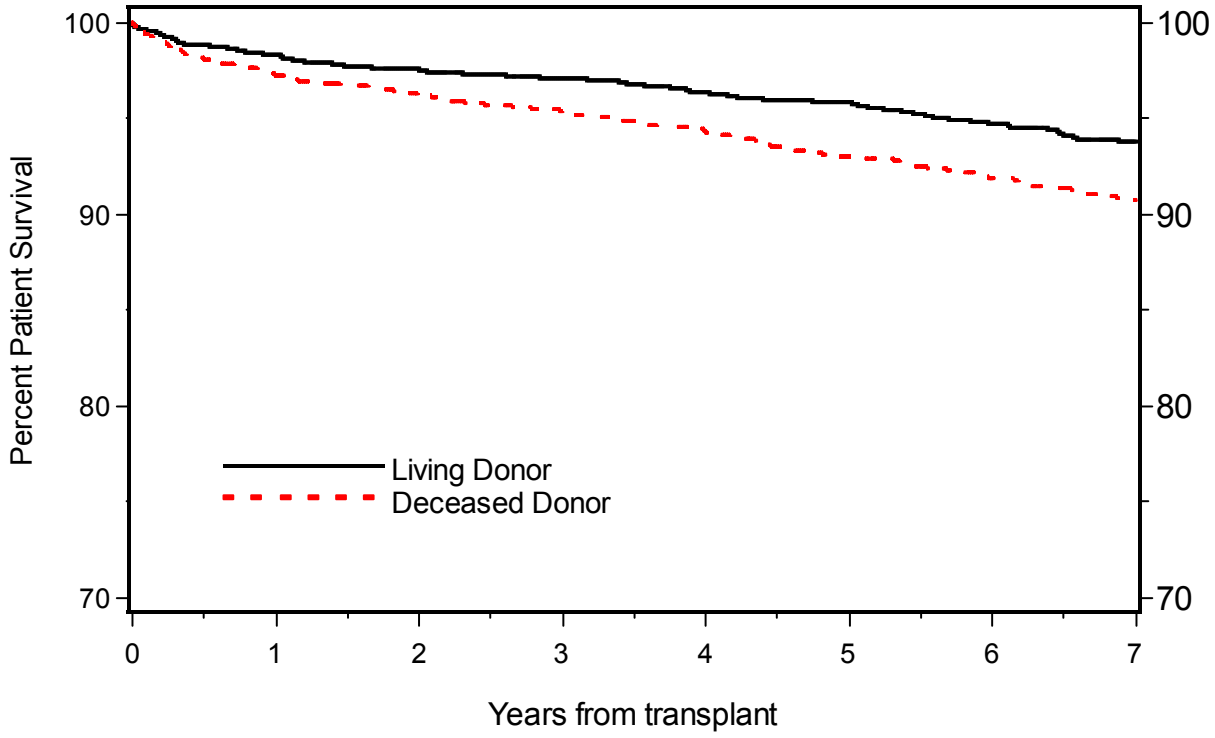


EXHIBIT 7.5B
PATIENT SURVIVAL BY TRANSPLANT ERA AND ALLOGRAFT SOURCE

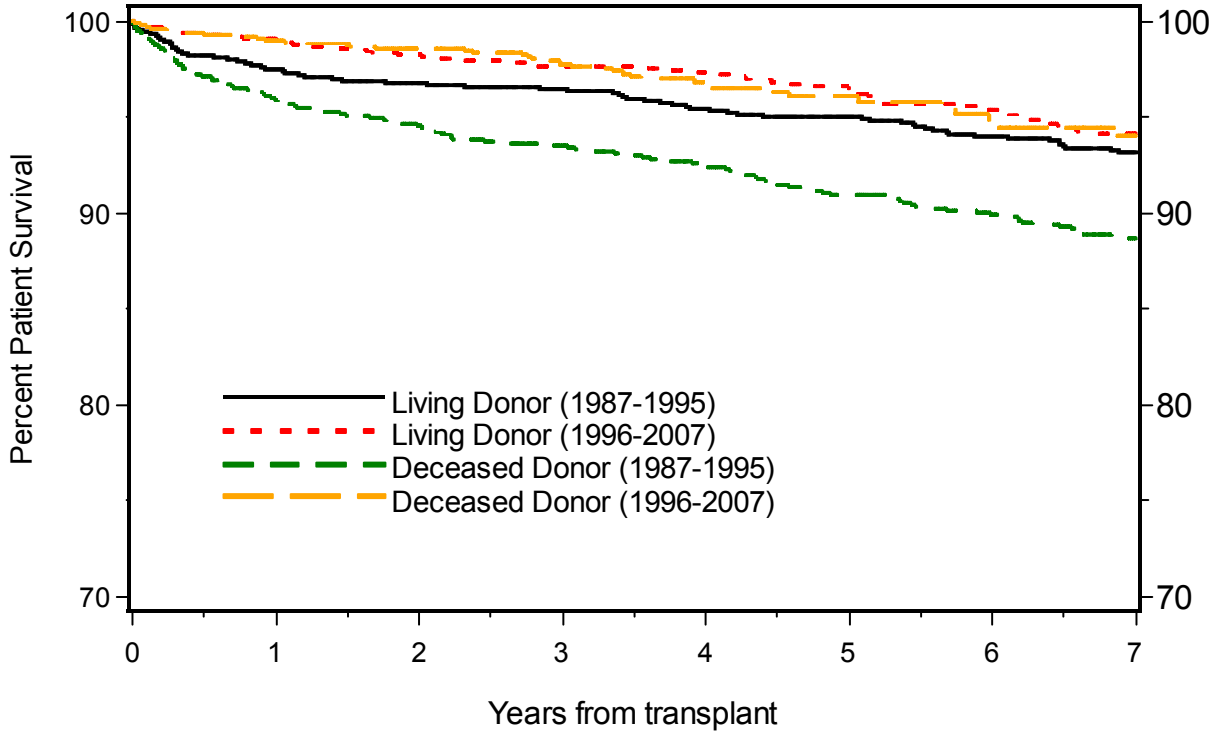
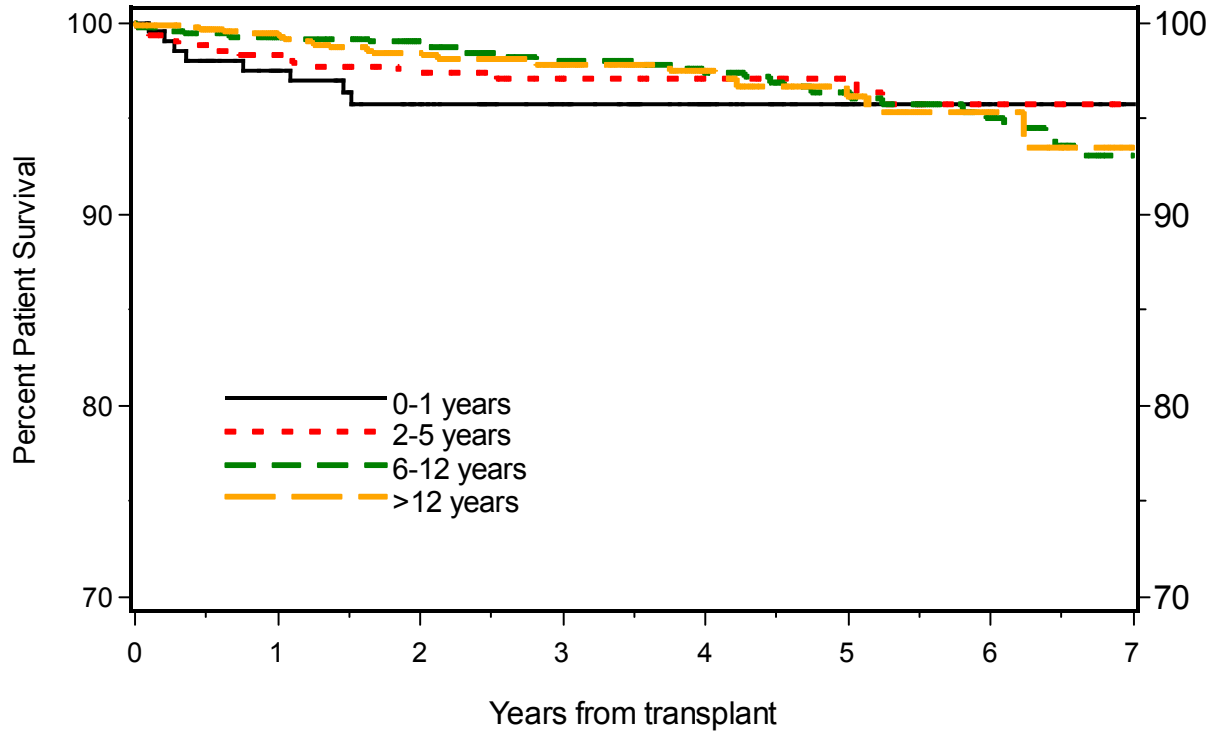


EXHIBIT 7.6
PATIENT SURVIVAL BY AGE AT TRANSPLANT
TRANSPLANT ERA 1996-2006

Living Donor



Deceased Donor

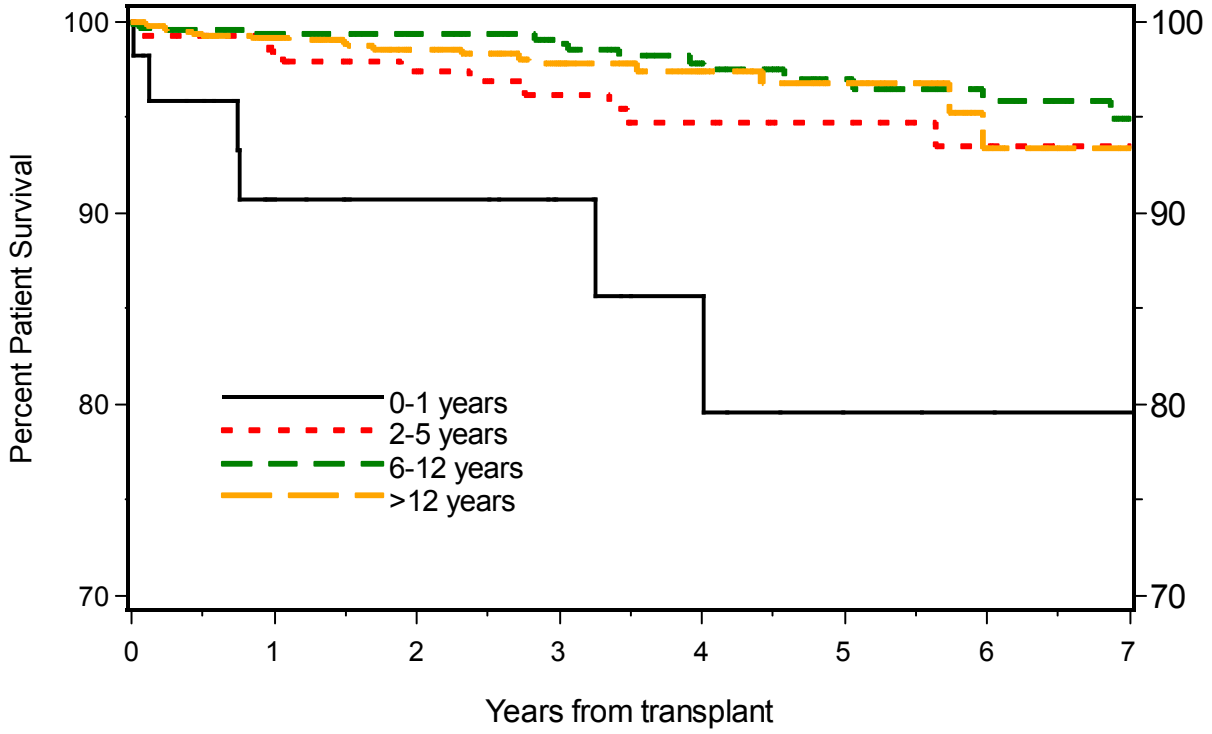


EXHIBIT 7.7
CAUSES OF DEATH FOLLOWING INDEX RENAL TRANSPLANTATION

	Total			Living Donor			Deceased Donor		
	N	%	Func graft	N	%	Func graft	N	%	Func graft
All deceased patients	546	100.0	256	242	100.0	119	304	100.0	137
Cause of Death									
Infection, Viral	44	8.1	23	24	9.9	13	20	6.6	10
Infection, Bacterial	69	12.6	34	33	13.6	15	36	11.8	19
Infection, Not Specified	43	7.9	14	22	9.1	7	21	6.9	7
Cancer/malignancy	58	10.6	40	32	13.2	23	26	8.6	17
Cardiopulmonary	84	15.4	39	30	12.4	15	54	17.8	24
Hemorrhage	33	6.0	12	9	3.7	2	24	7.9	10
Recurrence	10	1.8	1	4	1.7	1	6	2.0	0
Dialysis-related Complications	16	2.9	0	8	3.3	0	8	2.6	0
Other	136	24.9	67	61	25.2	33	75	24.7	34
Unknown	53	9.7	26	19	7.9	10	34	11.2	16

III. DIALYSIS

SECTION 8: DIALYSIS PATIENT CHARACTERISTICS

Maintenance dialysis initiation data have been submitted for 6,491 patients; selected characteristics of these patients are presented in Exhibit 8.1. The percentages of white, black, and Hispanic patients reported to the dialysis registry are 49%, 24%, and 20%, respectively, compared to 60%, 17%, and 17% reported to the transplant registry. 12.7% of patients were less than 2 years old at initiation of the first registered (i.e., index) course of dialysis, compared to 5.3% who were less than 2 years old at index transplantation. (The index dialysis initiation or index transplant is defined as the first of each event reported since the start of the respective study component.) Patients 2-5, 6-12, 13-17, and ≥ 18 years of age at index initiation comprise 10.3%, 30.6%, 38.9%, and 7.4%, respectively, of the cohort. Whereas patients with focal segmental glomerulosclerosis (FSGS) comprise 11.7% of the transplant cohort (the 3rd most common primary renal disease), they comprise 14.4% of dialysis patients, the most prevalent group in the dialysis registry. FSGS cases comprise 23.6% of all black dialysis patients and 30.1% of black patients ≥ 13 years old. The next most prevalent diagnoses among all blacks are obstructive uropathy and renal dysplasia (both 11.7%), and among black patients ≥ 13 years old it is SLE nephritis (9.9%). FSGS accounts for 11.5% of all white dialysis patients, as well as 11.8% of white adolescents. Renal dysplasia (15.5%) remains most common for all whites, but obstructive uropathy (14.1%) is most prevalent among white patients ≥ 13 years old.

Also shown are distributions of selected characteristics, by cohort year. A total of 739 patients (11.4%) were already receiving maintenance dialysis as of the January 1, 1992 (start date for data collection); an additional 476 (7.4%) patients initiated dialysis that year. The distributions of age, race, gender, and dialysis modality have remained fairly stable over the years of data collection.

Race and age distributions, by dialysis modality, are shown in Exhibit 8.2 for all index courses of PD and HD. Among white patients, 42.3% are older than 12 years of age (35.0% of PD ≥ 13 years old, 58.8% of HD ≥13 years old), compared to 57.0% of blacks (46.9% PD, 68.3% HD). This phenomenon may, in part, be explained by the prevalence of FSGS among black adolescents already described.

Current concomitant drug therapy is described in Exhibits 8.3 for the 1-, 12-, 24- and 36-month follow-up visits of dialysis courses. Notable trends include the decreased use over time of anti-hypertensive medication among both HD and PD patients (68% and 63% at 1 month versus 51% and 48% at 36 months respectively) and calcium carbonate (58% and 61% at 1 month versus 36% and 44% at 36 months respectively). Sevelamer HCL increases in both HD and PD patients from 30% and 19% at 1 month to 48% and 34% at 36 months.

At baseline (30 days following index initiation), 3.7% of patients had completed their high school education and 24.9% were not of school age. Available education data for the remaining dialysis patients are presented in Exhibits 8.4 through 8.7. Among school-age patients maintained on peritoneal dialysis, 78% were attending school full-time and 9% part-time, compared to 54% and 27% of children on hemodialysis (Exhibit 8.4). Seven percent of HD patients were not attending school even though they were medically capable, compared to 5% of PD patients.

Education status is also shown according to race (Exhibit 8.5) and age (Exhibit 8.6). Patterns of school attendance are similar between black and white PD patients. Hispanic children have less full-time school attendance (64%) than black (84%) or white (82%) patients. The percentage of children not receiving any schooling is 8% (PD) and 9% (HD) for patients aged 6-12; 7% (PD) and 13% (HD) for patients older than 12. Full-time school attendance — through three years of maintenance dialysis therapy — is depicted in Exhibit 8.7, by dialysis modality, race, and age. Exhibit 8.7 shows that the percentage of Hispanic patients on PD who attend school full-time is less than that of black, white, or other patients at 6 and 12 months. There are 168 Mexican and Costa Rican Hispanics of school age. Full-time school attendance at entry is 69% in North American Hispanics versus 19% in "South of the Border" Hispanics.

To assess dialysis patient survival, we considered 2,867 patients on dialysis whose first reported course of dialysis appears to be the first ever with no history of prior renal transplantation (320 under 1 year-olds, 107 1 year-olds, 306 2-5 year-olds, 860 6-12 year-olds, and 1274 >12 year-olds). The descending age groups have significantly worse survival experience relative to the >12 year old group (6-12 RH= 1.16 (95% CI= 0.84-1.61); 2-5 RH= 1.87 (95% CI= 1.26-2.78); 0-1 RH= 3.96 (95% CI= 2.94-5.32)).

Patient survival estimates at 12, 24, and 36 months following dialysis initiation are provided in the table below.

PATIENT SURVIVAL FOR FIRST DIALYSIS, NO HISTORY OF TRANSPLANT							
Age at dialysis initiation	N	12 Months		24 Months		36 Months	
		% survival	SE	% survival	SE	% survival	SE
< 1 year	320	81.9	2.3	73.2	2.9	65.4	3.6
1 year	107	93.1	2.8	76.1	6.4	69.1	7.5
2-5 years	306	92.2	1.8	87.4	2.6	82.5	3.4
6-12 years	860	96.3	0.8	93.3	1.1	90.5	1.5
> 12 years	1274	97.6	0.5	93.1	1.0	89.0	1.5

Exhibit 8.8 lists the causes of death according to age at time of first dialysis (for all dialysis patients). Of the causes of death specified, cardiopulmonary was the reason cited most (21.3%), both overall and for each of the individual age groups. For those deaths from malignancy with a reported diagnosis, 64% were lymphoproliferative disorders.

Exhibit 8.9 shows patient survival for all index dialysis patients by age at dialysis initiation. Patient survival is measured from the time of dialysis initiation to death, with censoring for transplantation or lost to follow-up visit. Younger patients have significantly worse survival. Survival rates by year of entry for all dialysis patients from time of first dialysis initiation are shown below. Year of entry has had an impact on patient survival HR=0.97, p=0.009 after adjusting for patient's age in years.

PATIENT SURVIVAL BY ERA							
Year of dialysis initiation	N	12 Months		24 Months		36 Months	
		% survival	SE	% survival	SE	% survival	SE
1992 - 1994	1405	95.3	0.6	90.6	1.0	86.7	1.2
1995 - 1997	1444	95.0	0.7	90.8	1.0	86.1	1.4
1998 - 2000	1175	95.6	0.7	93.2	0.9	89.6	1.4
2001 - 2003	892	98.0	0.5	95.3	0.9	90.5	1.8
2004 – 2007	836	97.4	0.7	92.7	1.6	--	--

EXHIBIT 8.1
DIALYSIS PATIENT DEMOGRAPHICS

	All Patients	
	N	%
Total	6491	100.0
Gender		
Male	3619	55.8
Female	2871	44.2
Missing	1	0.0
Race /Ethnicity		
White	3168	48.8
Black	1580	24.3
Hispanic	1310	20.2
Other	433	6.7
Year of Initiation		
Before 1992	739	11.4
1992	476	7.3
1993	462	7.1
1994	467	7.2
1995	510	7.9
1996	468	7.2
1997	466	7.2
1998	400	6.2
1999	410	6.3
2000	365	5.6
2001	342	5.3
2002	291	4.5
2003	259	4.0
2004	281	4.3
2005	282	4.3
2006	166	2.6
2007	107	1.6

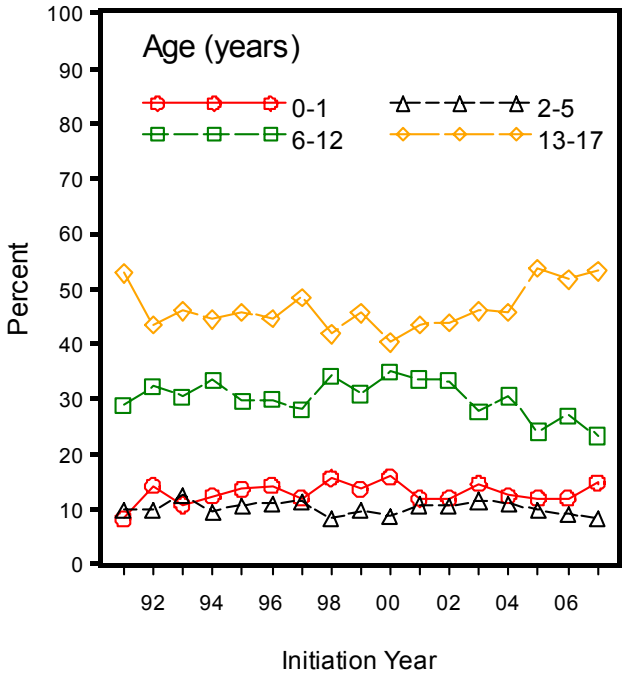
EXHIBIT 8.1 (continued)
DIALYSIS PATIENT DEMOGRAPHICS

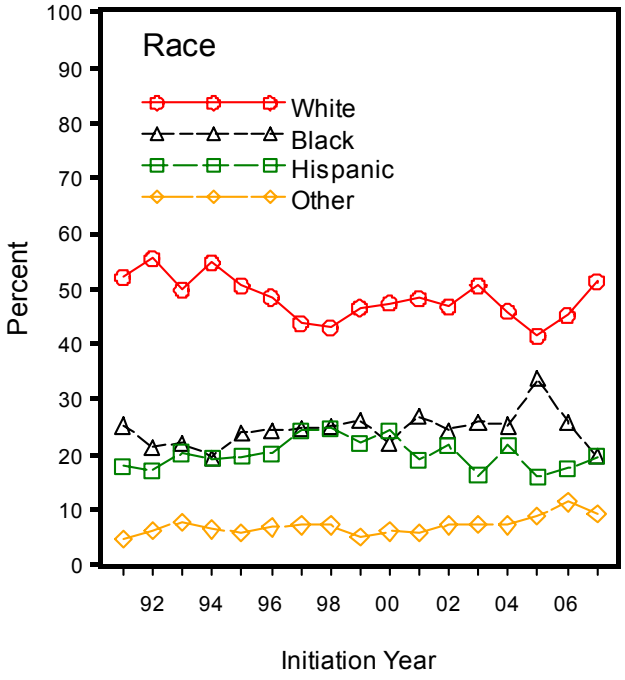
	All Patients	
	N	%
Total	6491	100.0
Primary Diagnosis		
FSGS	933	14.4
A/hypo/dysplastic kidney	910	14.0
Obstructive uropathy	835	12.9
Reflux nephropathy	229	3.5
SLE nephritis	211	3.3
Chronic GN	201	3.1
HUS	197	3.0
Polycystic disease	190	2.9
Congenital nephrotic syndrome	167	2.6
Medullary cystic disease	136	2.1
Prune Belly	133	2.0
Idiopathic crescentic GN	125	1.9
Familial nephritis	121	1.9
MPGN - Type I	111	1.7
Pyelo/interstitial nephritis	97	1.5
Cystinosis	93	1.4
Renal infarct	85	1.3
Berger's (IgA) nephritis	79	1.2
Henoch-Schonlein nephritis	67	1.0
MPGN - Type II	63	1.0
Wilms tumor	49	0.8
Wegener's granulomatosis	45	0.7
Other systemic immunologic	37	0.6
Drash syndrome	37	0.6
Oxalosis	30	0.5
Membranous nephropathy	27	0.4
Sickle cell nephropathy	21	0.3
Diabetic GN	7	0.1
Other	769	11.8
Unknown	486	7.5

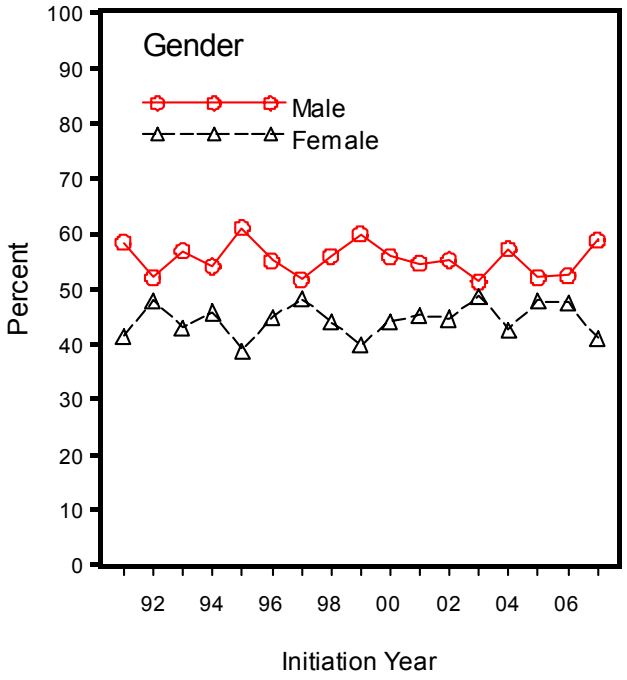
EXHIBIT 8.1 (continued)
DIALYSIS PATIENT DEMOGRAPHICS

	All Patients	
	N	%
Total	6491	100.0
Age at Index Initiation		
<1 year	584	9.0
1 year	241	3.7
2 years	182	2.8
3 years	127	2.0
4 years	178	2.7
5 years	182	2.8
6 years	163	2.5
7 years	217	3.3
8 years	250	3.9
9 years	257	4.0
10 years	339	5.2
11 years	366	5.6
12 years	395	6.1
13 years	499	7.7
14 years	536	8.3
15 years	574	8.8
16 years	516	7.9
17 years	402	6.2
≥ 18 years	482	7.4
Missing	1	0.0
Age Grouping		
0-1 years	825	12.7
2-5 years	669	10.3
6-12 years	1987	30.6
13-17 years	2527	38.9
≥ 18 years	482	7.4
Missing	1	0.0

EXHIBIT 8.1 (continued)
DIALYSIS PATIENT DEMOGRAPHICS







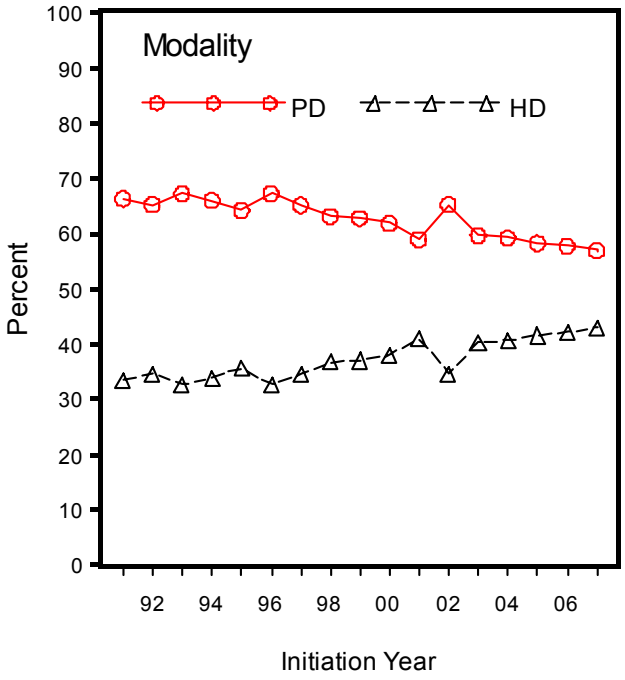


EXHIBIT 8.2
DIALYSIS MODALITY BY AGE AND RACE

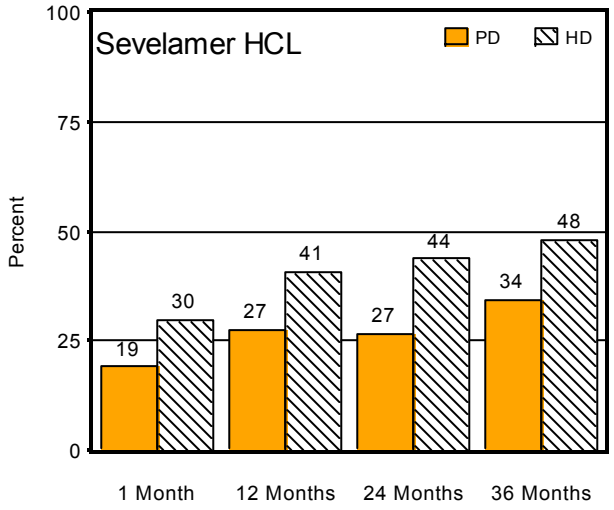
Peritoneal Dialysis

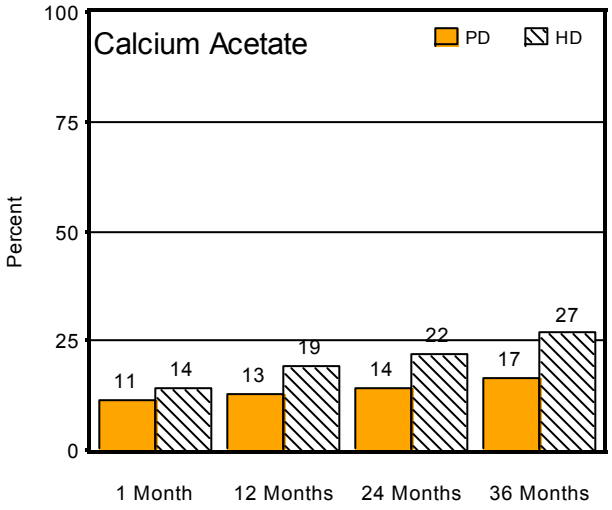
		Age at Index Dialysis Initiation							
		0-1 years		2-5 years		6-12 years		≥ 13 years	
	Total	N	%	N	%	N	%	N	%
All Races	4137	765	18.5	510	12.3	1294	31.3	1568	37.9
White	2198	484	22.0	289	13.1	656	29.8	769	35.0
Black	830	119	14.3	73	8.8	249	30.0	389	46.9
Hispanic	847	119	14.0	106	12.5	318	37.5	304	35.9
Other	262	43	16.4	42	16.0	71	27.1	106	40.5

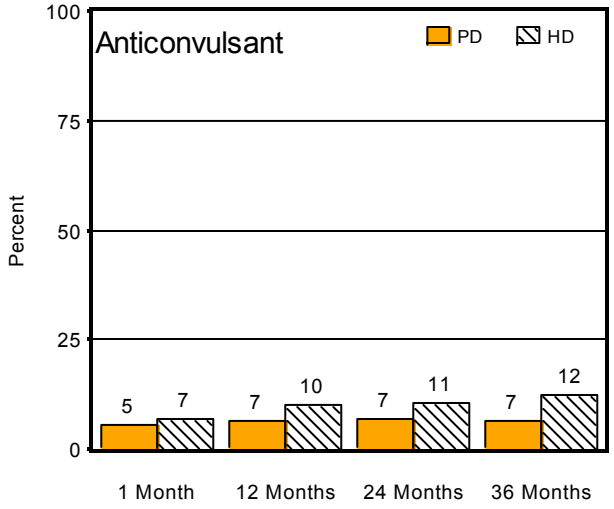
Hemodialysis

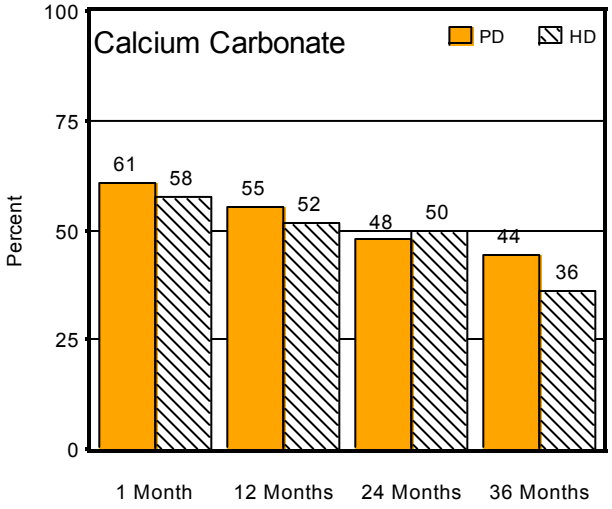
		Age at Index Dialysis Initiation							
		0-1 years		2-5 years		6-12 years		≥ 13 years	
	Total	N	%	N	%	N	%	N	%
All Races	2349	60	2.6	159	6.8	690	29.4	1440	61.3
White	969	32	3.3	80	8.3	287	29.6	570	58.8
Black	748	11	1.5	35	4.7	191	25.5	511	68.3
Hispanic	463	13	2.8	29	6.3	154	33.3	267	57.7
Other	169	4	2.4	15	8.9	58	34.3	92	54.4

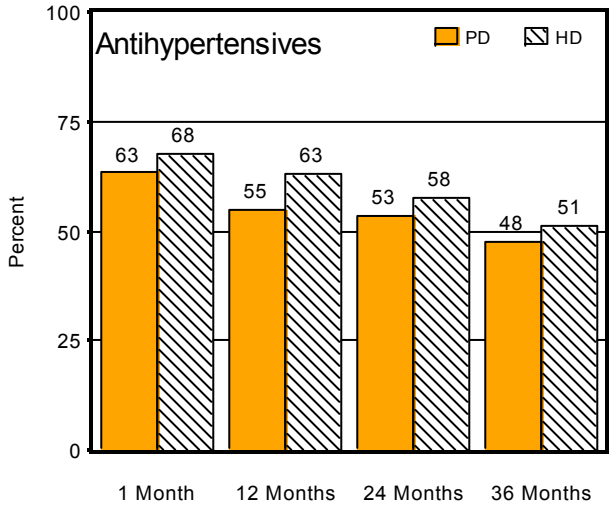
EXHIBIT 8.3
CONCOMITANT DRUG THERAPY
Dialysis Initiation 2000 – 2007











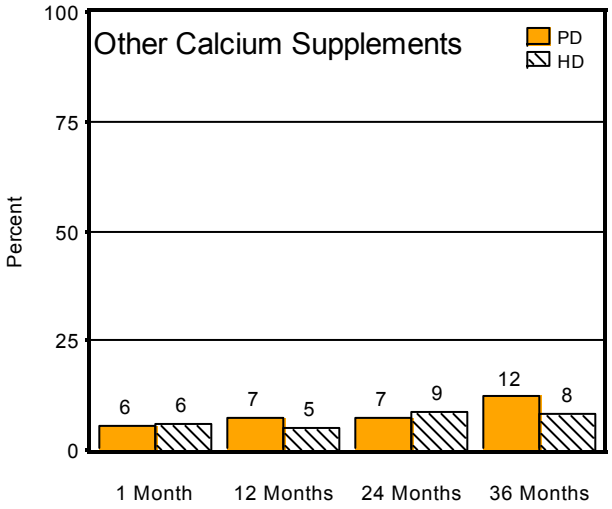
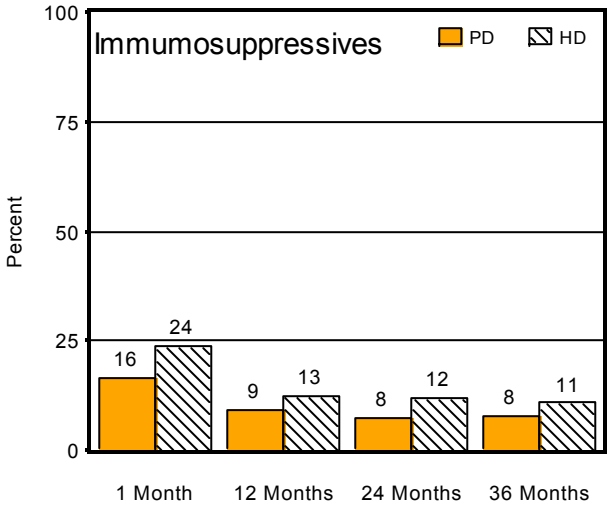
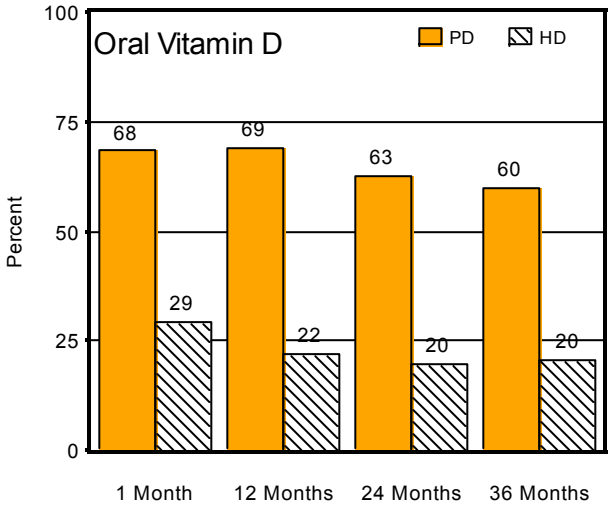
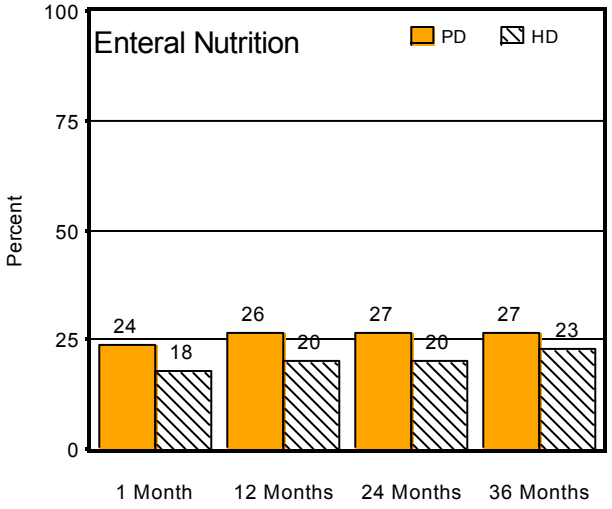
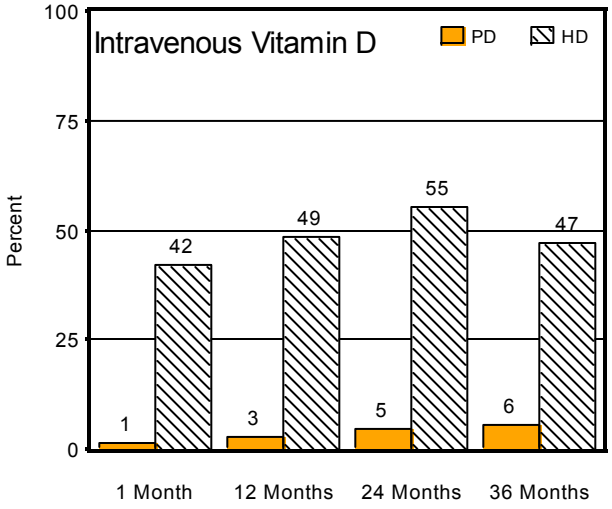


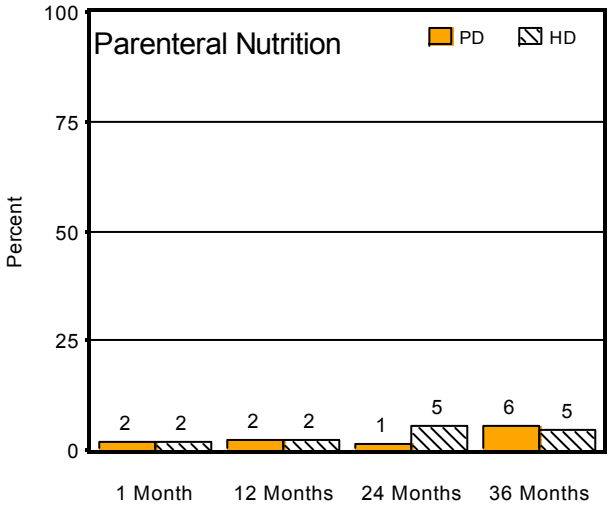
EXHIBIT 8.3 (continued)
CONCOMITANT DRUG THERAPY
Dialysis Initiation 2000 - 2007











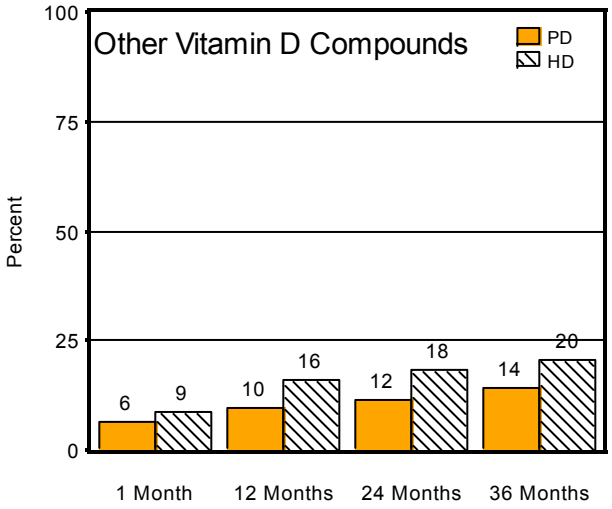
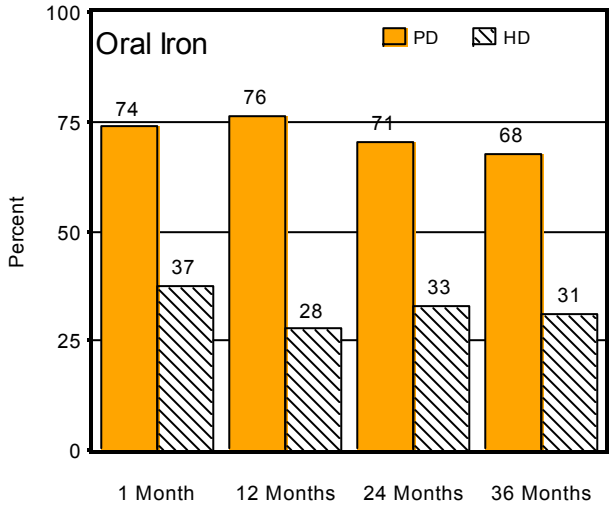
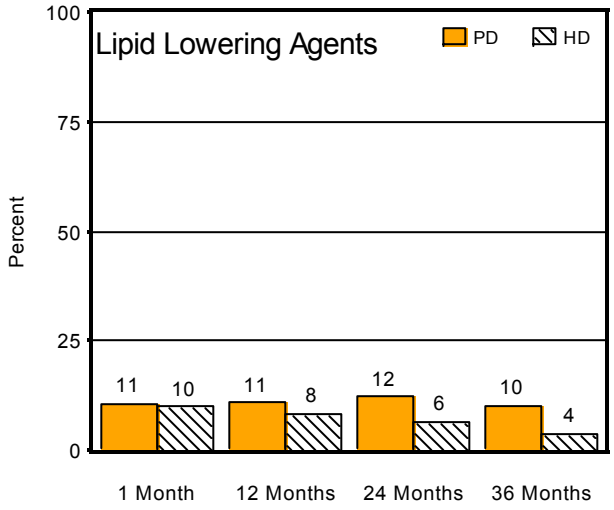
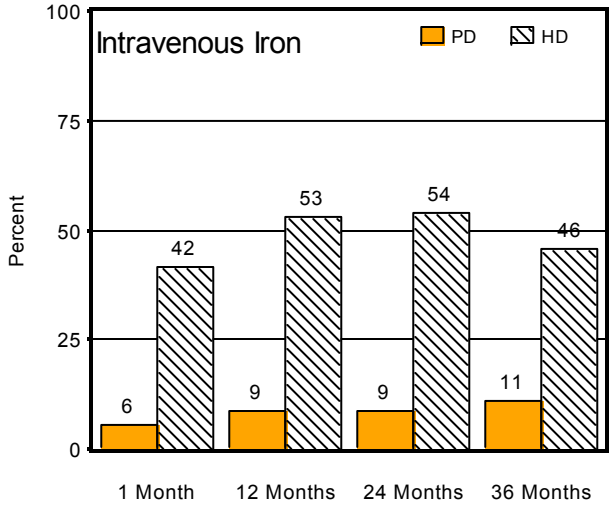
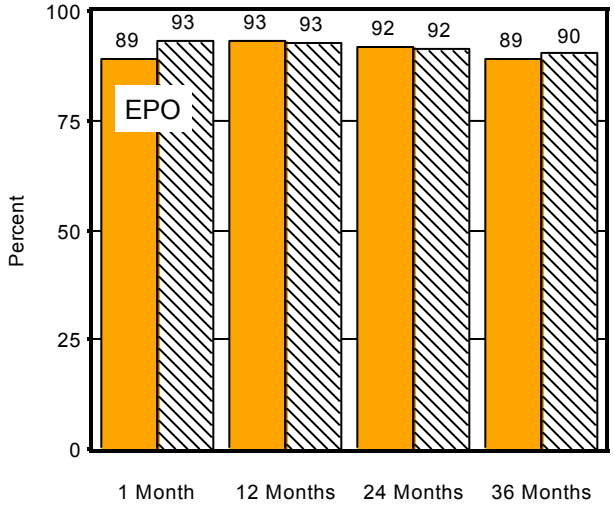


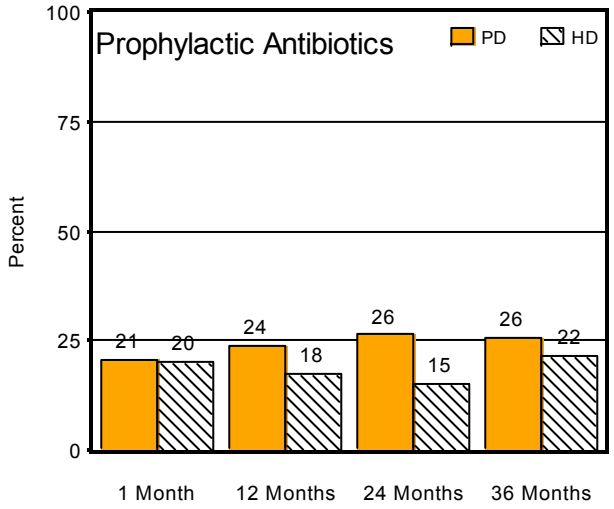
EXHIBIT 8.3 (continued)
CONCOMITANT DRUG THERAPY
Dialysis Initiation 2000 – 2007











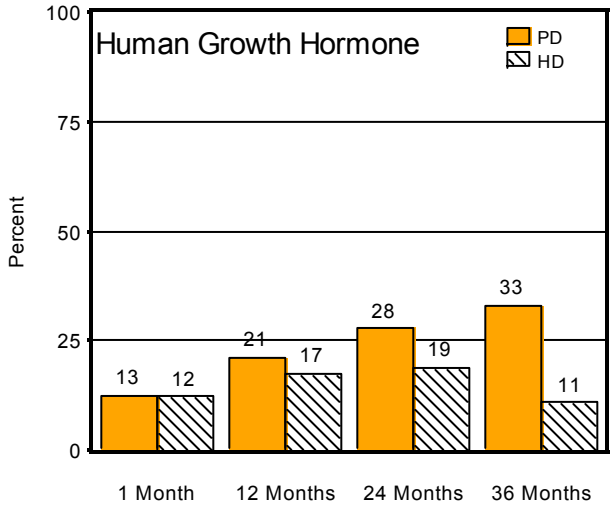
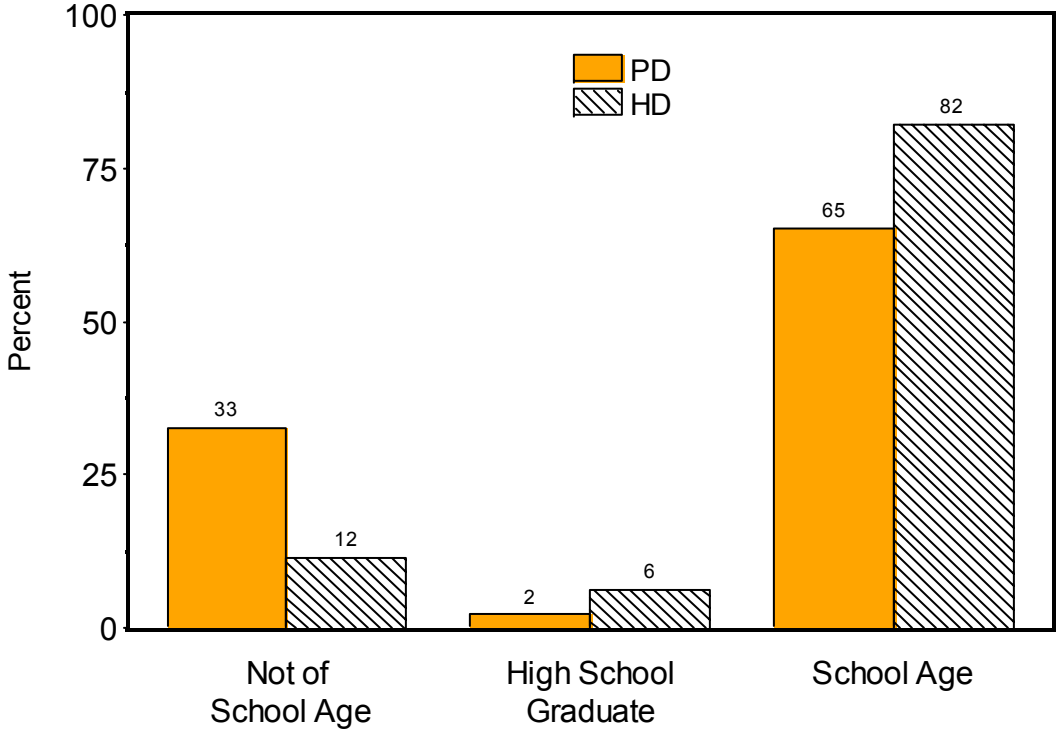


EXHIBIT 8.4
BASELINE EDUCATION STATUS

All Children



Children of School Age

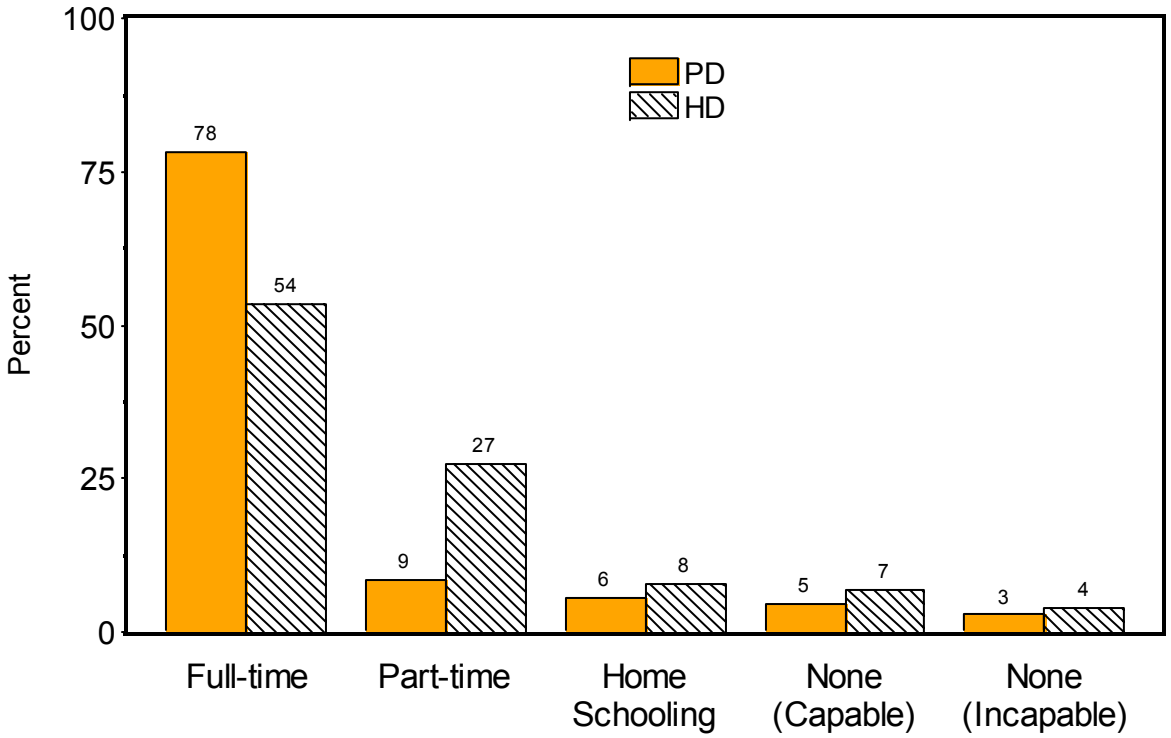


EXHIBIT 8.5
BASELINE EDUCATION STATUS BY RACE

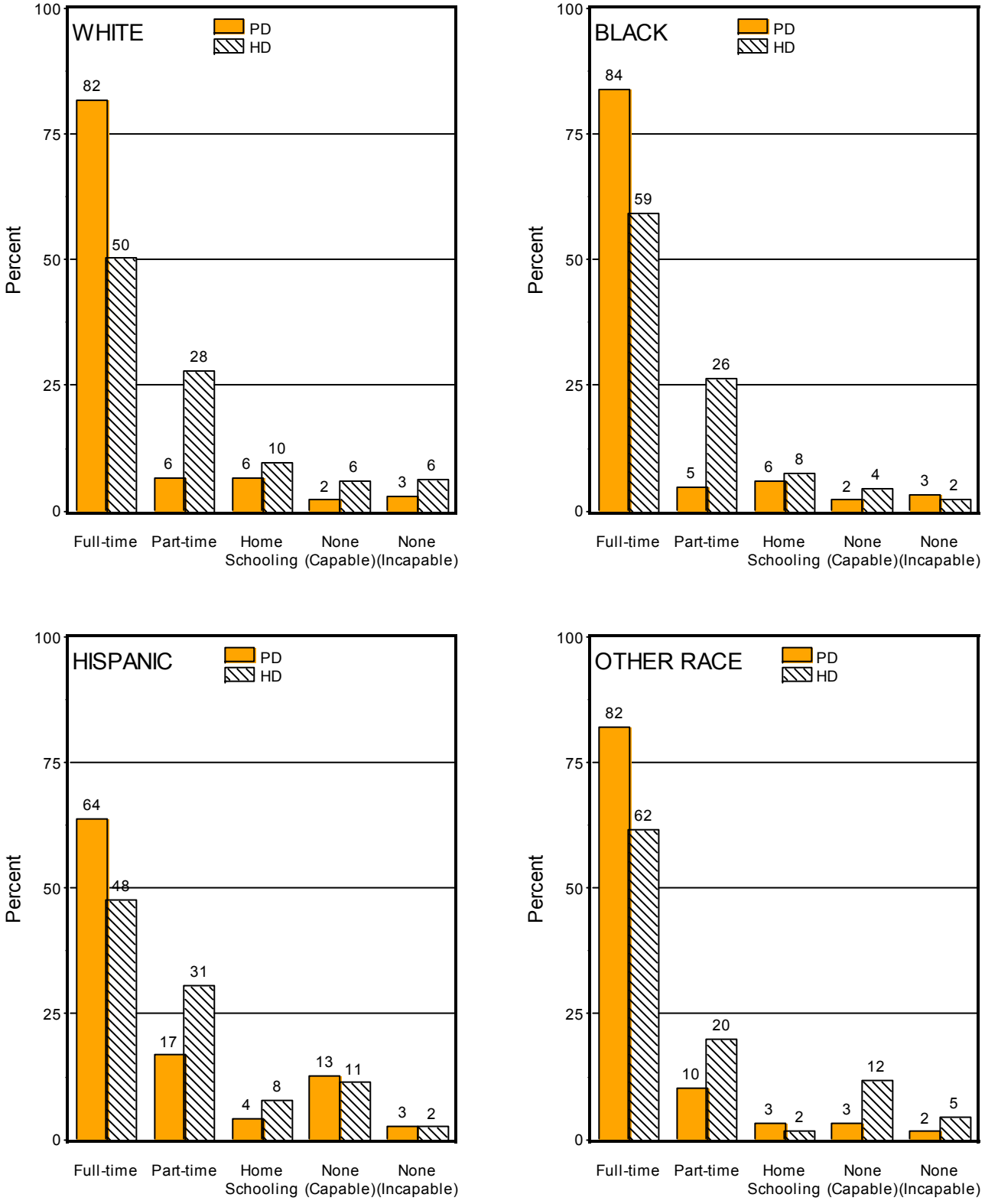


EXHIBIT 8.6
BASELINE EDUCATION STATUS BY AGE

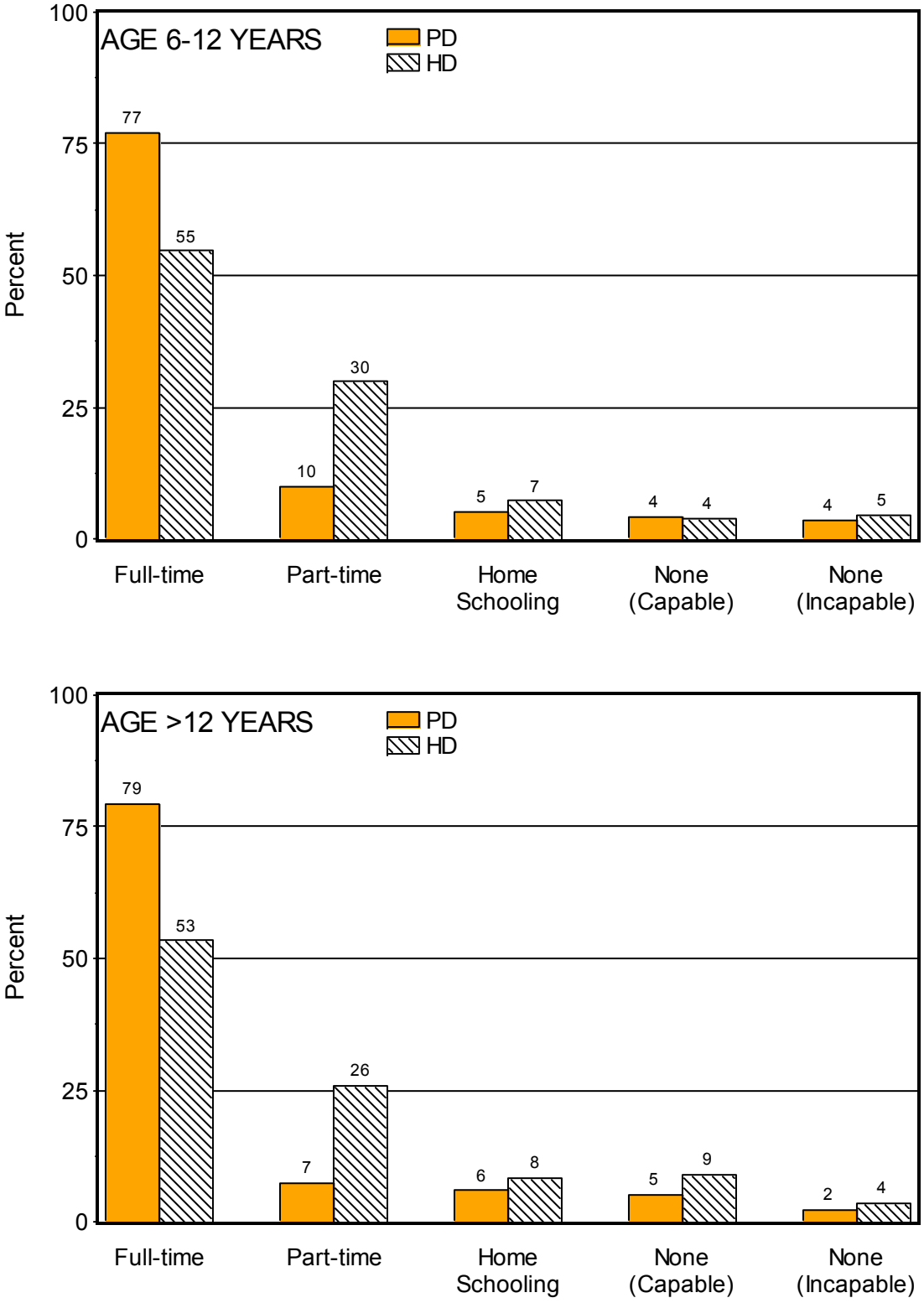
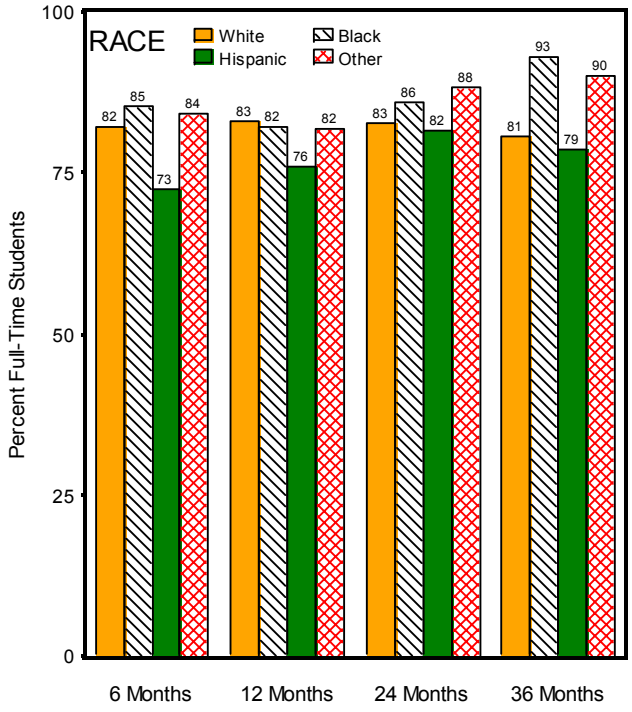
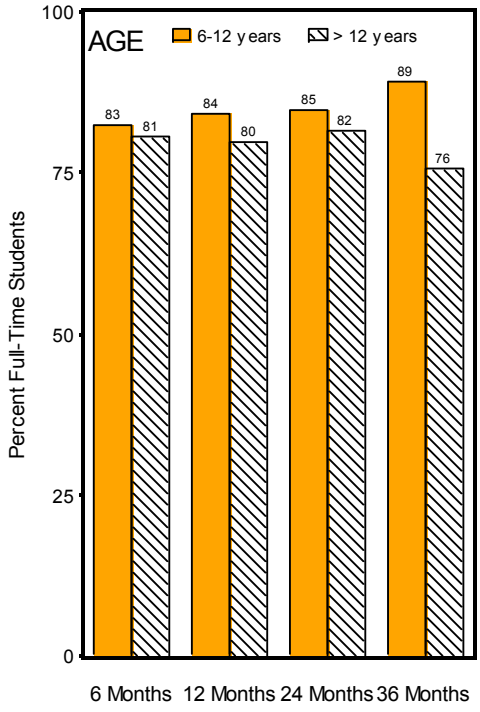


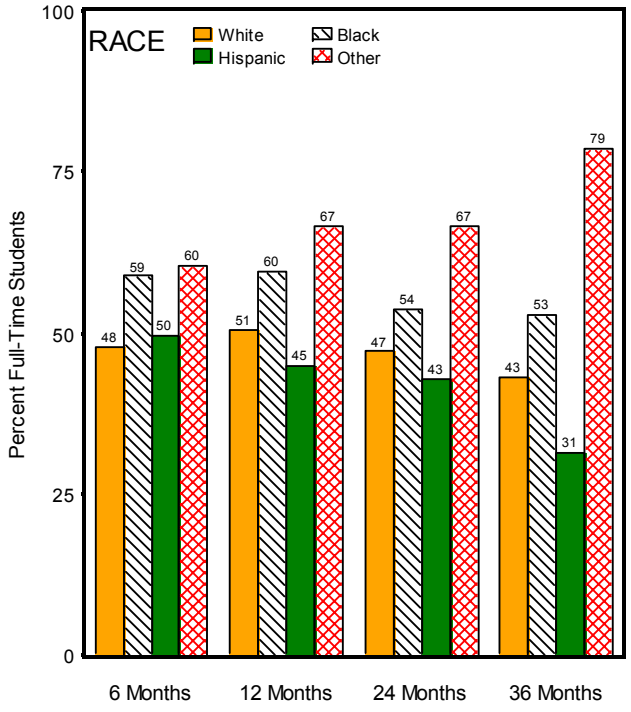
EXHIBIT 8.7
FULL-TIME SCHOOL ATTENDANCE

Peritoneal Dialysis





Hemodialysis



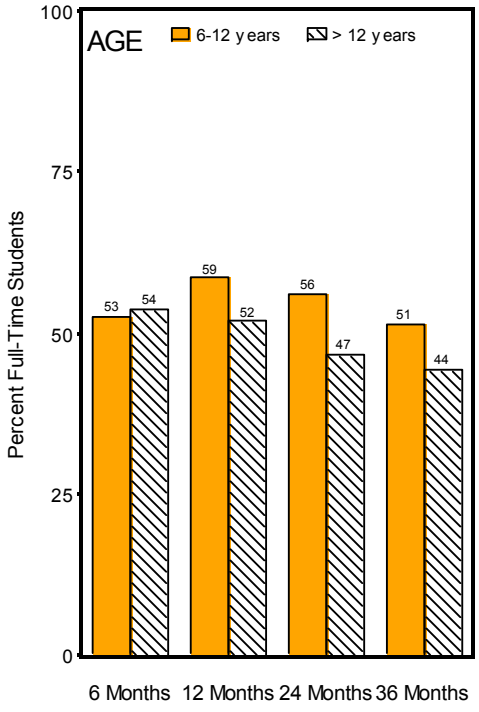
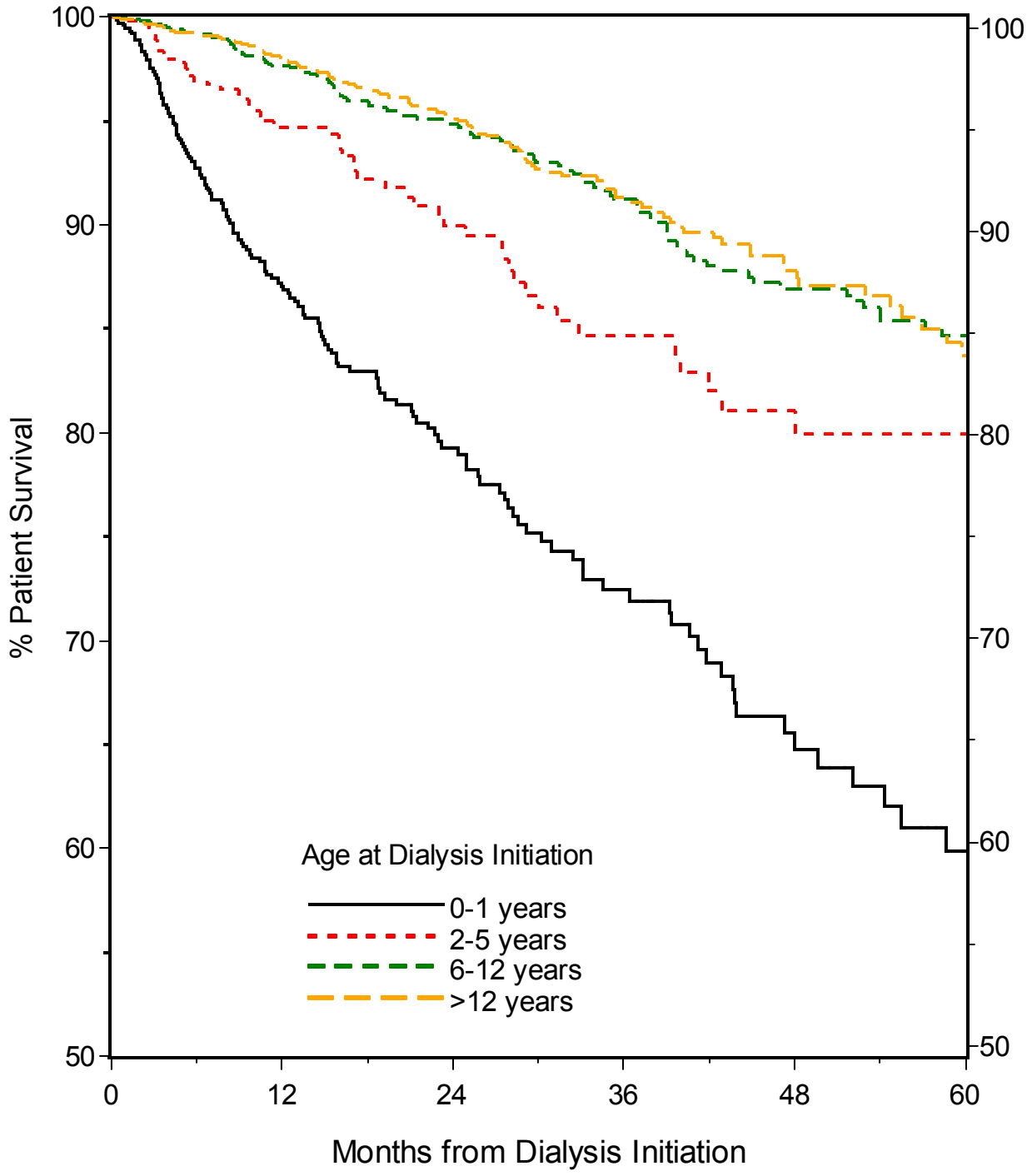


EXHIBIT 8.8
CAUSE OF DEATH BY AGE AT DIALYSIS INITIATION

	Total		Age at Index Dialysis Initiation							
			0-1 years		2-5 years		6-12 years		≥ 13 years	
	N	%	N	%	N	%	N	%	N	%
All deceased patients	488	100.0	161	100.0	61	100.0	135	100.0	131	100.0
Cause of Death										
Infection, viral	14	2.9	3	1.9	1	1.6	7	5.2	3	2.3
Infection, bacterial	54	11.1	25	15.5	6	9.8	7	5.2	16	12.2
Infection, not specified	34	7.0	12	7.5	4	6.6	8	5.9	10	7.6
Cancer/malignancy	33	6.8	5	3.1	8	13.1	12	8.9	8	6.1
Cardiopulmonary	104	21.3	38	23.6	11	18.0	26	19.3	29	22.1
Hemorrhage	21	4.3	4	2.5	1	1.6	9	6.7	7	5.3
Recurrence	6	1.2	2	1.2	1	1.6	1	0.7	2	1.5
Dialysis-related complications	15	3.1	3	1.9	2	3.3	5	3.7	5	3.8
Other	134	27.5	38	23.6	21	34.4	41	30.4	34	26.0
Unknown	73	15.0	31	19.3	6	9.8	19	14.1	17	13.0

EXHIBIT 8.9
PATIENT SURVIVAL BY AGE AT DIALYSIS INITIATION



SECTION 9: DIALYSIS ACCESS DATA

This section reports on dialysis access data. A total of 8,451 courses have been recorded since the registry began in 1992; 739 courses began before January 1, 1992 and are not further analyzed. Currently there are 5,752 index courses, i.e., patient's first NAPRTCS registered dialysis course, initiated after January 1, 1992. The focus of this section will be on the index cases after January 1, 1992 and their subsequent additional courses. This cohort represents 7,405 courses registered to 5,752 patients. 59% are peritoneal dialysis and 41% are hemodialysis courses (see Exhibit 9.1).

About 76% of the courses are terminated and the reasons are detailed in Exhibit 9.2. The majority of dialysis courses terminations are due to patient transplantation (65.7%), or to a change of modality (21.3%). When change of modality is the reason for termination, excessive infection and patient or family choice are the primary reasons. Access failure is the reason for change in about 10.3% of such cases.

A summary of peritoneal dialysis access information is shown in Exhibit 9.3A. Most catheters were of the Tenckhoff curled (61.5%) or Tenckhoff straight (26.9%) configuration. About 52.0% of catheters had single cuffs, 64.4% had a straight tunnel, and 39.9% of the exit sites had a lateral orientation. Peritoneal dialysis access by year is shown in Exhibit 9.3B. The most prevalent combinations of PD access characteristics are shown in Exhibit 9.3C. The most frequently occurring combination (14.4%) consisted of a curled catheter with a single cuff, straight tunnel with a lateral exit site.

Data on 3,047 hemodialysis (HD) access locations and devices are shown in Exhibit 9.4A. HD access devices include external percutaneous catheters (2,369 or 77.7%), external arteriovenous shunts (20 or 0.7%), internal arteriovenous fistulae (374 or 12.3%), and internal arteriovenous grafts (222 or 7.3%). Most of the percutaneous catheter accesses were in the subclavian vein (54.6%), followed by the jugular (40.1%) and femoral (4.4%) veins. HD access approaches by year of initiation are shown in Exhibit 9.4B. The use of internal AV graft has decreased from 12% in the early 90s to about 1% recently, while use of a percutaneous catheter remains common and has not shown any recent decreased utilization.

Exhibit 9.5 provides details of the current status of the 7,405 accesses, as of database closure for this report. Overall, there are 1,793 courses (24.2%) of ongoing dialysis therapy (i.e., not terminated) and 5,612 terminations. As a percent of all accesses, the terminations are due to patient transplant (3,689 or 49.8%), change of modality (1,194 or 16.1%), and other reasons (729 or 9.8%). The percent of patients terminated for transplant, by age, ranges from 44.4% for children >12 years to 57.6% for children between the ages of 2 and 5 years. Reasons for the 1,194 changes of modality include (Exhibit 9.6) excessive infection (28.1%), patient/family choice (23.0%), access failure (10.3%), other medical (23.8%), and other non-medical (14.7%). Whereas changes of modality due to excessive infection occur primarily with PD accesses, changes due to patient or family choice occur primarily with HD accesses. Modality change caused by access failure is more common in HD accesses, black patients and female patients. Excessive infection as the reason for modality change has been declining in recent years from 30% in 1992-1993 to 21% since 2001.

Patients are maintained on their index course of dialysis as follows: 11.1%±0.4% terminate by 3 months, 23.5%±0.6% by 6 months, 43.8%±0.7% by 12 months, 70.2%±0.7% by 24 months, and 83.7%±0.6% by 36 months. Exhibit 9.7 depicts time to index dialysis termination for all reasons, by modality. Although time to termination is shorter for HD (relative to PD) courses initially (30.9%±1.1% versus 19.3%±0.7% at 6 months), by 36 months of follow-up PD courses have a higher percent of terminations than HD (85.5%±0.7% PD versus 80.1%±1.1% HD). Time to dialysis termination, by age and race, are shown for each modality in Exhibit 9.8. Adolescents (age >12) tend to remain on dialysis longer than the younger children, and white patients tend to terminate dialysis sooner, particularly among HD.

Exhibit 9.9 shows time to dialysis termination for PD catheter characteristics; similar data for HD catheter access are shown in Exhibit 9.10. Dialysis courses for HD patients with an external percutaneous catheter terminate much sooner than for arteriovenous fistulae or grafts. By 3 months, 22.1%±1.1% of percutaneous catheter accesses have terminated, compared to 7.3%±1.6% for AV fistulae and 4.8%±1.8% for AV grafts. By 24 months, comparable percents are 72.1%±1.3%, 51.3%±3.4%, and 56.2%±4.4%.

Exhibit 9.11 shows time to termination, according to reason. If the reason for termination was that the patient was transplanted, then the relationship between PD and HD terminations is

similar. However for patients who terminate their index dialysis to change modalities, HD patients experience most of their terminations in the first 6 months while PD patients appear to have a slow and steady increase in terminations over time.

To compare experience of PD patients with different procedure types, 3,647 index peritoneal dialysis cases were selected. To capture the PD procedure information, we only include 3,224 patients who had submitted their Day 30 post dialysis forms where modality information was collected. Peritoneal dialysis modality included 676 (21.0%) patients with CAPD, 2187(67.8%) with APD, 213 (6.6%) with IPD, and 148 (4.6%) patients with unknown procedures. The 676 CAPD patients were 53% males, 41% white and 26% under 6 years of age while the 2,187 patients with APD were 55% male, 56% white and 32% under 6 years of age. Compared to patients who used APD, CAPD patients were significantly older when they initiated dialysis ($p<0.002$), were significantly more likely to have a minority ethnic background ($p<0.001$), and were registered in earlier years ($p<0.001$, Exhibit 9.12). Patient survival of these two groups did not differ.

A higher percentage of patients terminated dialysis due to transplantation in the CAPD group (crude rate 75.0%) than in APD group (crude rate 67.4%) ($p<0.004$) while terminations were more likely due to change of modality in APD group (19.6%) than in CAPD group (13.2%). In general, time to termination for all reasons in CAPD vs. APD patients was significantly different ($p<0.001$, Exhibit 9.13). Time to termination due to transplantation differed ($p<0.001$, Exhibit 9.14) while time to termination due to change of modality was not significantly different.

Peritonitis exposure in patients in the CAPD group was significantly different than those of the APD group ($p=0.042$), as shown in Exhibit 9.15. 50% of the cases had their first peritonitis episode in CAPD patients by 16.6 months compared to 19.2 months for APD patients. At 1 year post initiation, 45.2% of CAPD patients had experienced peritonitis compared to 40.5% of APD patients.

EXHIBIT 9.1
DIALYSIS INITIATION AND TERMINATION

	All Dialysis Courses		All Index Courses after 01/01/92		All Courses where Index course is after 01/01/92	
	N	%	N	%	N	%
Total courses	8451	100.0	5752	100.0	7405	100.0
Dialysis Course						
First	6491	76.8	5752	100.0	5752	77.7
Second	1399	16.6	0	0.0	1189	16.1
Third	395	4.7	0	0.0	326	4.4
Fourth	117	1.4	0	0.0	98	1.3
Fifth or more	49	0.6	0	0.0	40	0.5
Modality						
Peritoneal Dialysis	4957	58.7	3647	63.4	4352	58.8
Hemodialysis	3487	41.3	2101	36.5	3047	41.1
Missing	7	0.1	4	0.1	6	0.1
Terminated	6410	75.8	4407	76.6	5612	75.8

EXHIBIT 9.2
DIALYSIS TERMINATION

	All Index Courses		All Courses	
	N	%	N	%
Terminated Dialysis Courses	4407	100.0	5612	100.0
Reason for Termination				
Patient Transplanted	3028	68.7	3689	65.7
Change of Modality	819	18.6	1194	21.3
Death	112	2.5	149	2.7
Kidney Function Returned	131	3.0	142	2.5
Other/Unknown	317	7.2	438	7.8
Courses Changing Modality	819	100.0	1194	100.0
Reason for Modality Change				
Excessive infection	251	30.6	336	28.1
Patient/family choice	167	20.4	275	23.0
Access failure	84	10.3	123	10.3
Inadequate ultrafiltration	45	5.5	62	5.2
Inadequate solute clearance	20	2.4	28	2.3
Excessive hospitalization (Dialysis-related)	15	1.8	23	1.9
Other (medical)	108	13.1	171	14.4
Other (non-medical)	32	3.9	39	3.3
Unknown	97	11.8	137	11.5

EXHIBIT 9.3A
PERITONEAL DIALYSIS ACCESS

	N	%
Peritoneal Dialysis Courses	4352	100.0
Catheter		
Tenckhoff straight	1170	26.9
Tenckhoff curled	2677	61.5
Toronto western	26	0.6
Presternal	272	6.3
Other	88	2.0
Unknown/missing	119	2.7
Cuffs		
One	2263	52.0
Two	1951	44.8
Unknown/missing	138	3.2
Tunnel		
Swan neck/curved	1397	32.1
Straight	2801	64.4
Unknown/missing	154	3.5
Exit Site Orientation		
Up	535	12.3
Down	1425	32.7
Lateral	1735	39.9
Unknown/missing	657	15.1

EXHIBIT 9.3B
PERITONEAL DIALYSIS CATHETER ACCESS TYPE BY INITIATION YEAR

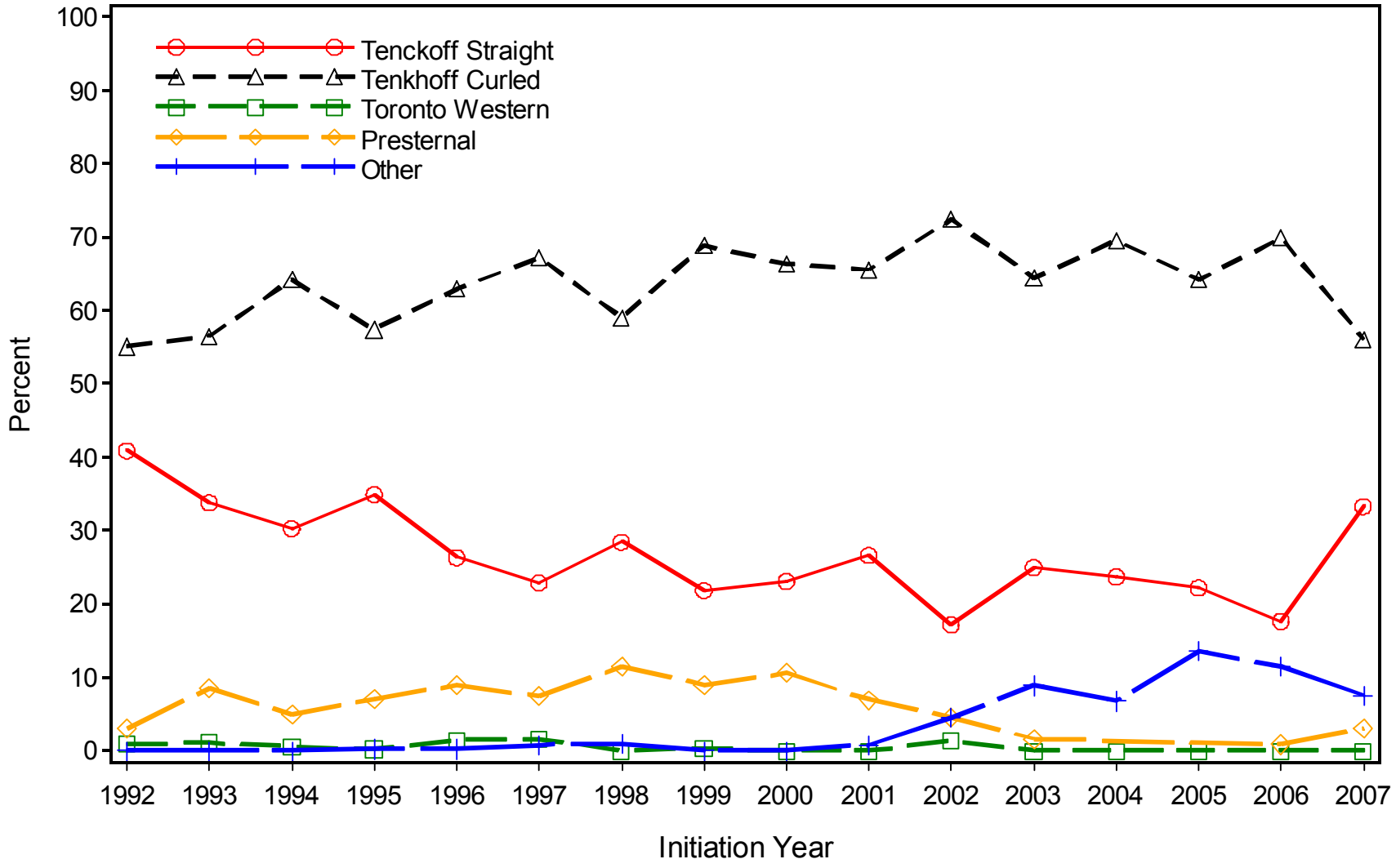


EXHIBIT 9.3C
PERITONEAL DIALYSIS ACCESS CHARACTERISTICS

Catheter	Cuffs	Tunnel	Exit Site	N (4112)*	% (100.0)
Curled	One	Straight	Lateral	593	14.4
Curled	Two	Swan necked/curved	Down	385	9.4
Curled	Two	Straight	Lateral	313	7.6
Straight	One	Straight	Lateral	301	7.3
Curled	Two	Straight	Down	270	6.6
Curled	One	Straight	Down	256	6.2
Curled	One	Straight	Up	194	4.7
Straight	One	Straight	Up	135	3.3
Presternal	Two	Swan necked/curved	Down	128	3.1
Straight	One	Straight	Unknown	122	3.0
Curled	Two	Swan necked/curved	Lateral	117	2.8
Curled	Two	Swan necked/curved	Unknown	107	2.6
Straight	One	Swan necked/curved	Lateral	104	2.5
Straight	Two	Straight	Lateral	101	2.5
Straight	One	Straight	Down	99	2.4
Curled	One	Straight	Unknown	74	1.8
Curled	One	Swan necked/curved	Down	73	1.8
Curled	One	Swan necked/curved	Lateral	63	1.5
Curled	Two	Straight	Unknown	56	1.4
Straight	Two	Straight	Up	50	1.2
Straight	Two	Swan necked/curved	Lateral	43	1.0
Curled	Two	Straight	Up	42	1.0
All other combination (<1% each)				486	11.8

*NOTE: Cases with missing elements are excluded.

EXHIBIT 9.4A
HEMODIALYSIS ACCESS

	N	%	N	%
Total			**3047**	**100.0**
External Percutaneous Catheter			**2369**	**77.7**
Subclavian vein	1294	54.6		
Jugular vein	950	40.1		
Femoral vein	105	4.4		
Missing vein	20	0.8		
Single lumen	88	3.7		
Double lumen	2226	94.0		
Missing lumen	55	2.3		
External Arteriovenous Shunt			**20**	**0.7**
Upper arm	2	10.0		
Thigh	1	5.0		
Other location	10	50.0		
Location not reported/Missing	7	35.0		
Internal Arteriovenus Fistula			**374**	**12.3**
Upper arm	37	9.9		
Lower arm	41	11.0		
Thigh	1	0.3		
Other location	17	4.5		
Location not reported/Missing	278	74.3		
Internal Arteriovenus Graft			**222**	**7.3**
Autologous vein	8	3.6		
Bovine graft	1	0.5		
PTFE graft	202	91.0		
Other graft	7	3.2		
Missing graft	4	1.8		
Upper arm	5	2.3		
Lower arm	8	3.6		
Thigh	8	3.6		
Location not reported/Missing	201	90.5		
Hemodialysis access unknown			**62**	**2.0**

EXHIBIT 9.4B
HEMODIALYSIS ACCESS TYPE BY INITIATION YEAR

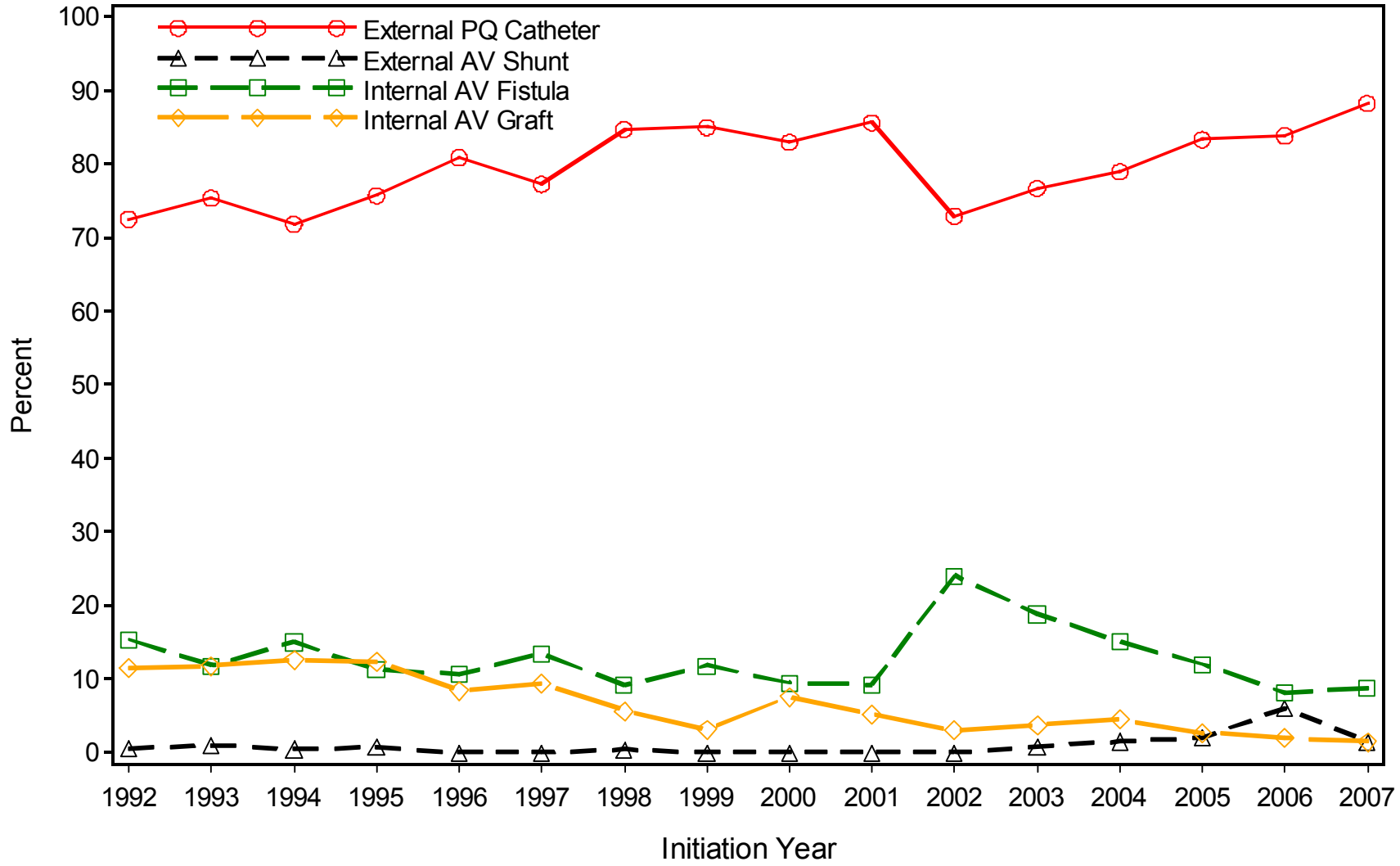


EXHIBIT 9.5
DIALYSIS ACCESS BY SELECTED CHARACTERISTCS

		Working Access		Transplanted		Change of Modality		Other	
	N	N	%	N	%	N	%	N	%
Total Courses	7405	1793	24.2	3689	49.8	1194	16.1	729	9.8
Modality									
PD	4352	889	20.4	2291	52.6	703	16.2	469	10.8
HD	3047	901	29.6	1397	45.8	490	16.1	259	8.5
Missing	6	3	50.0	1	16.7	1	16.7	1	16.7
Year initiated									
1992-1993	1082	138	12.8	589	54.4	221	20.4	134	12.4
1994-1995	1263	188	14.9	660	52.3	258	20.4	157	12.4
1996-1997	1329	278	20.9	658	49.5	250	18.8	143	10.8
1998-1999	1054	272	25.8	532	50.5	156	14.8	94	8.9
2000-2001	925	239	25.8	486	52.5	123	13.3	77	8.3
2002-2003	696	185	26.6	376	54.0	83	11.9	52	7.5
2004-2005	691	265	38.4	302	43.7	70	10.1	54	7.8
2006-2007	365	228	62.5	86	23.6	33	9.0	18	4.9
Age at initiation									
0-1 years	865	138	16.0	391	45.2	147	17.0	189	21.8
2-5 years	812	113	13.9	468	57.6	146	18.0	85	10.5
6-12 years	2222	391	17.6	1275	57.4	370	16.7	186	8.4
>12 years	3506	1151	32.8	1555	44.4	531	15.1	269	7.7
Gender									
Male	4032	954	23.7	2093	51.9	594	14.7	391	9.7
Female	3372	839	24.9	1596	47.3	600	17.8	337	10.0
Race/Ethnicity									
White	3535	700	19.8	1935	54.7	537	15.2	363	10.3
Black	1849	566	30.6	761	41.2	325	17.6	197	10.7
Hispanic	1517	404	26.6	743	49.0	246	16.2	124	8.2
Other	504	123	24.4	250	49.6	86	17.1	45	8.9

EXHIBIT 9.6
CHANGE OF DIALYSIS MODALITY BY SELECTED CHARACTERISTCS

	Total	Excessive Infection	Choice	Access Failure	Other Medical	Other/ None
	N	N	%	N	N	%
Total Changes of Modality	1194	28.1	23.0	10.3	23.8	14.7
Modality						
PD	703	42.8	8.7	8.1	27.3	13.1
HD	490	7.1	43.5	13.5	18.8	17.1
Missing	1	0.0	100.0	0.0	0.0	0.0
Year initiated						
1992-1993	221	29.9	21.3	10.9	21.3	16.7
1994-1995	258	33.3	19.4	8.1	23.6	15.5
1996-1997	250	25.6	24.8	9.6	24.8	15.2
1998-1999	156	28.2	23.1	7.7	25.6	15.4
2000-2001	123	30.1	21.1	18.7	22.8	7.3
2002-2003	83	21.7	26.5	9.6	25.3	16.9
2004-2005	70	24.3	25.7	11.4	25.7	12.9
2006-2007	33	12.1	42.4	9.1	21.2	15.2
Age at initiation						
0-1 years	147	38.1	8.8	10.2	25.2	17.7
2-5 years	146	34.2	26.0	7.5	21.2	11.0
6-12 years	370	32.4	18.4	13.0	19.7	16.5
>12 years	531	20.7	29.4	9.2	26.9	13.7
Gender						
Male	594	30.3	20.9	8.4	25.4	15.0
Female	600	26.0	25.2	12.2	22.2	14.5
Race/Ethnicity						
White	537	26.8	23.6	8.0	26.1	15.5
Black	325	24.6	24.9	14.8	20.9	14.8
Hispanic	246	37.0	19.1	7.3	23.2	13.4
Other	86	24.4	23.3	16.3	22.1	14.0

EXHIBIT 9.7
TIME TO DIALYSIS TERMINATION BY MODALITY
(Index Cases)

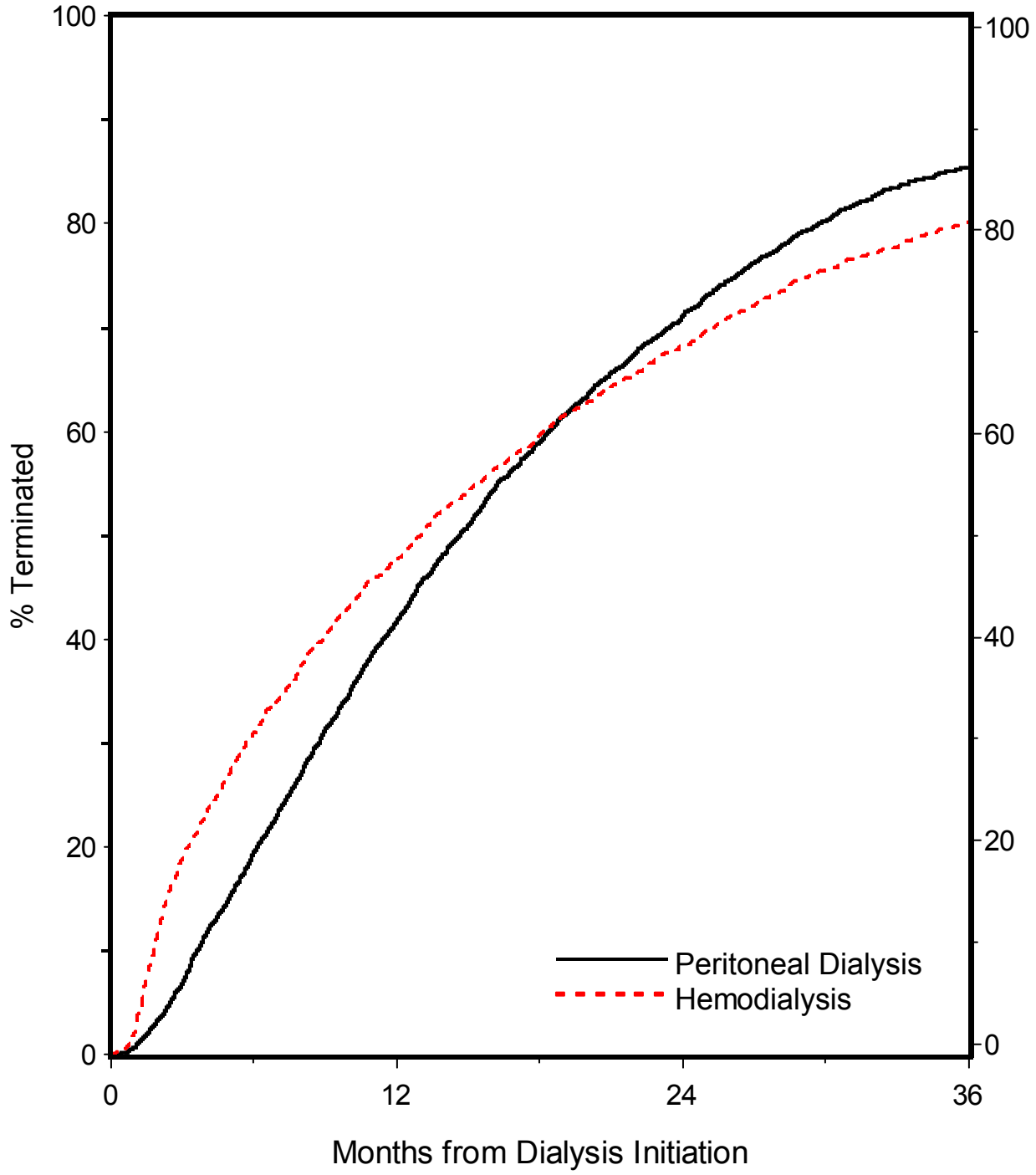
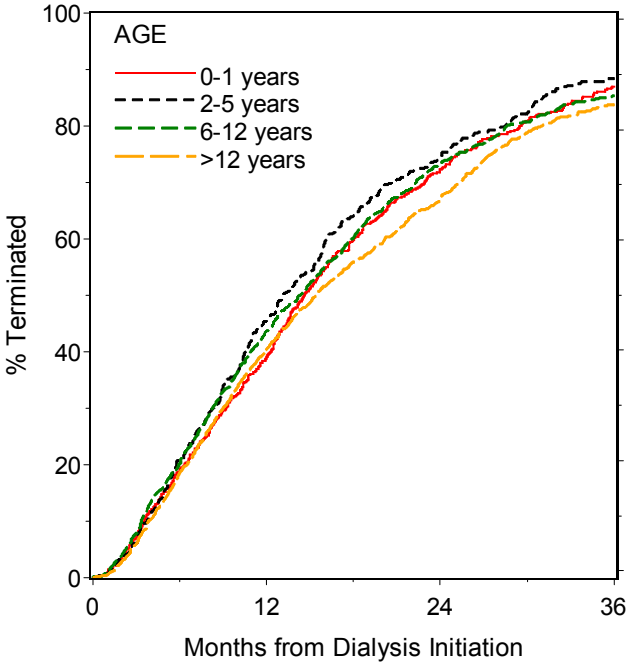
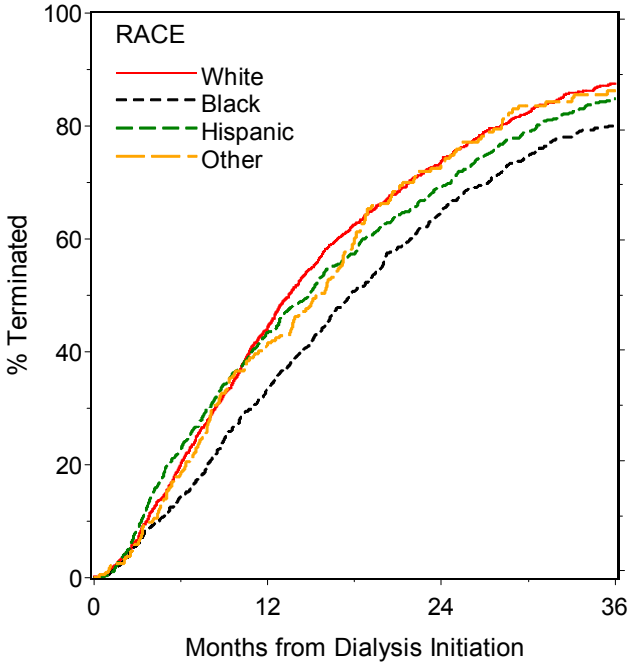


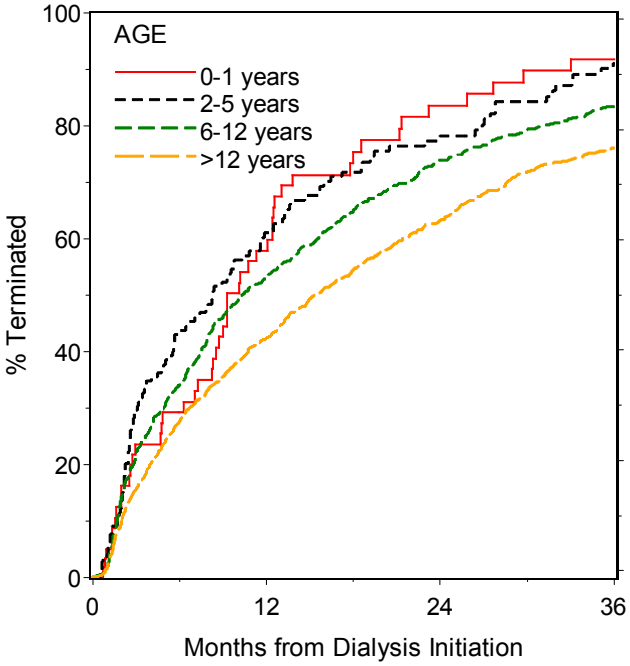
EXHIBIT 9.8
TIME TO DIALYSIS TERMINATION BY AGE AND RACE
(Index Cases)

Peritoneal Dialysis





Hemodialysis



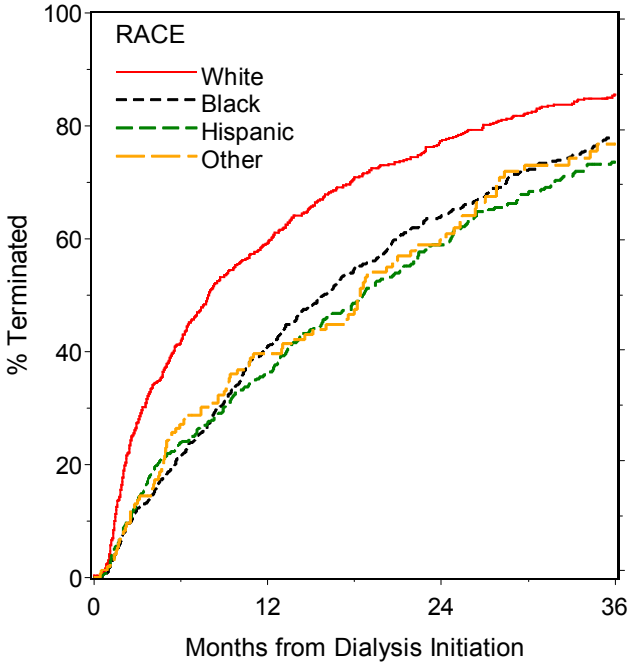
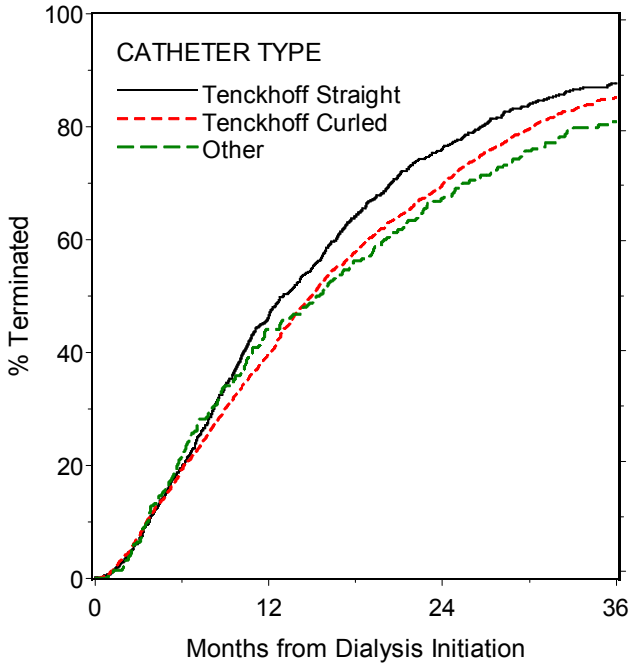
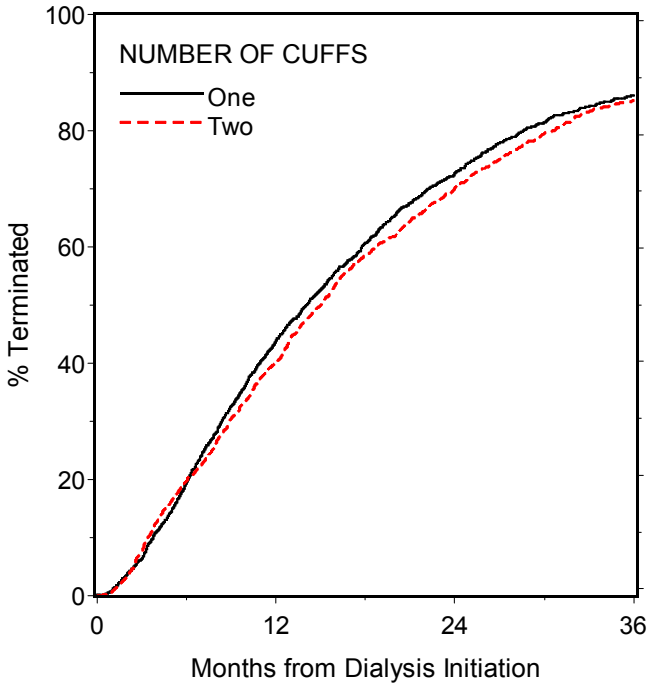
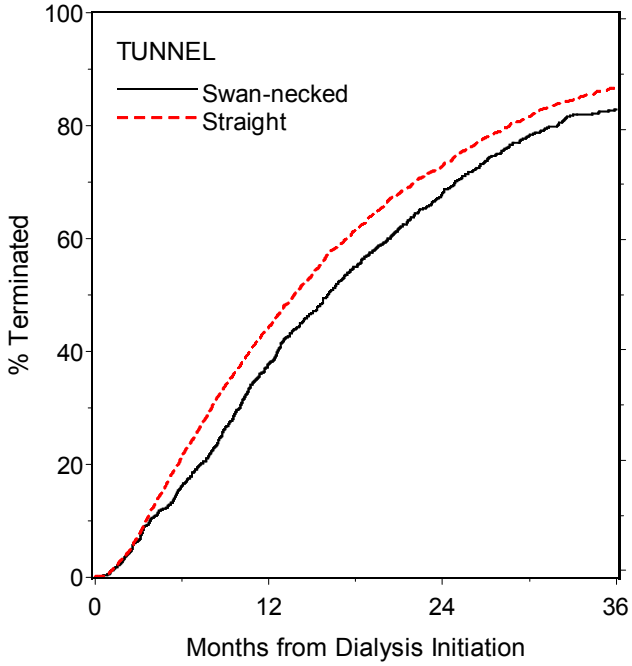


EXHIBIT 9.9
TIME TO DIALYSIS TERMINATION
BY PERITONEAL DIALYSIS ACCESS CHARACTERISTICS
(Index Cases)







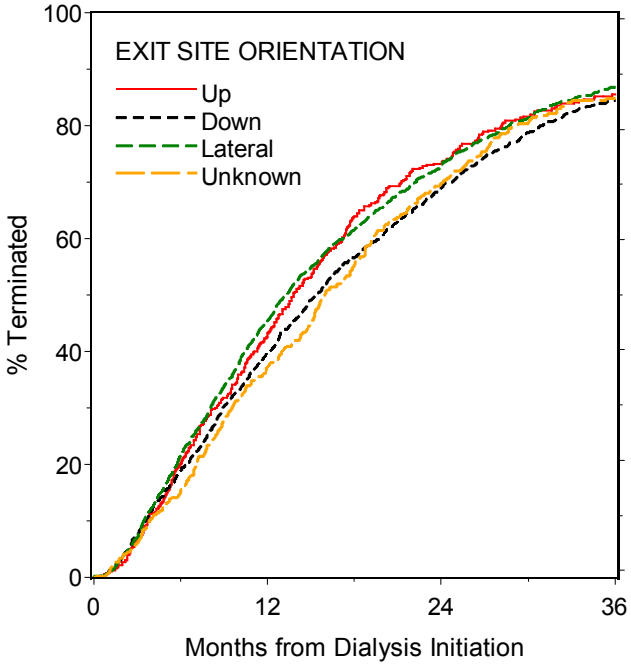


EXHIBIT 9.10
TIME TO DIALYSIS TERMINATION BY HEMODIALYSIS ACCESS
(Index Cases)

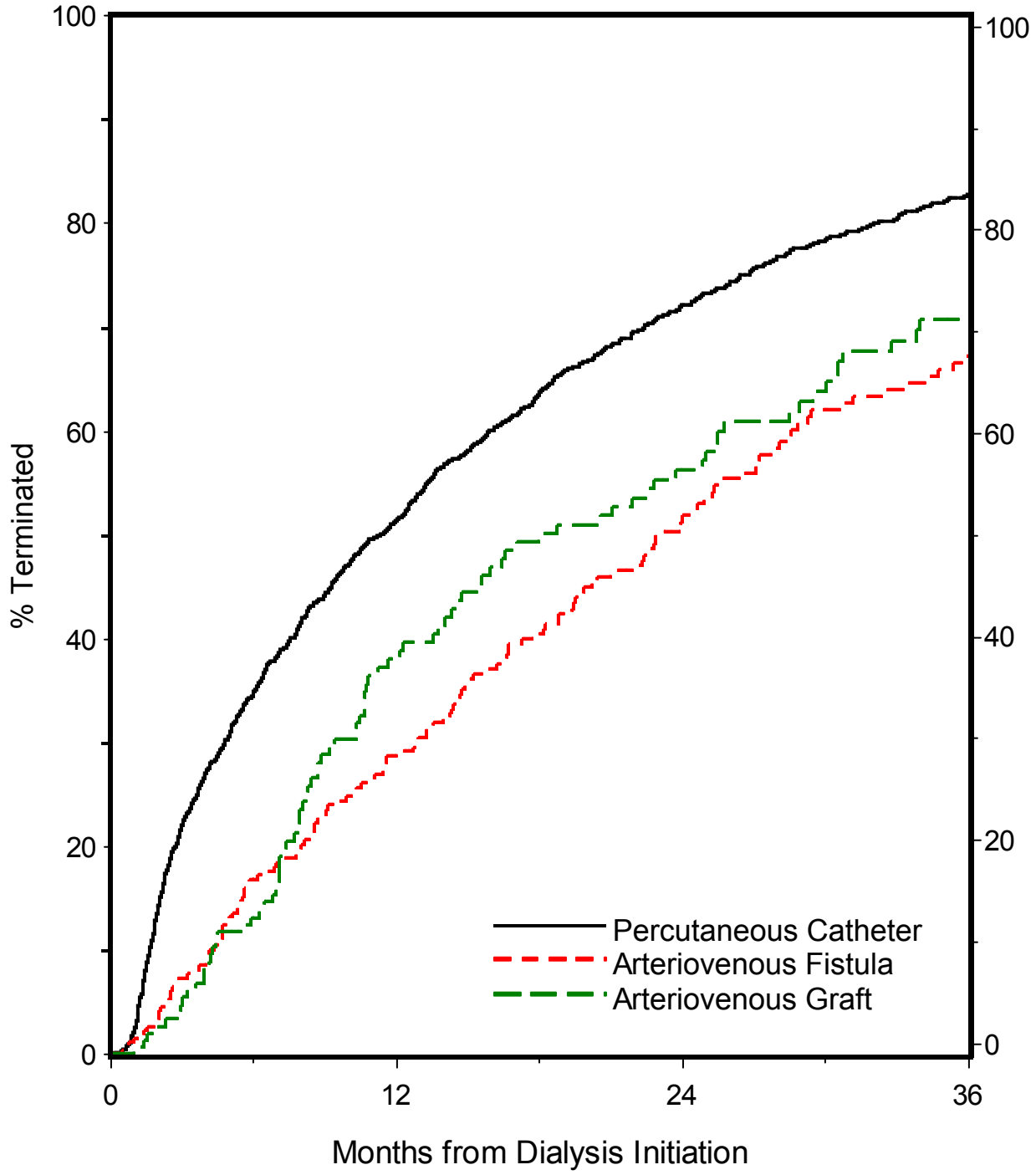
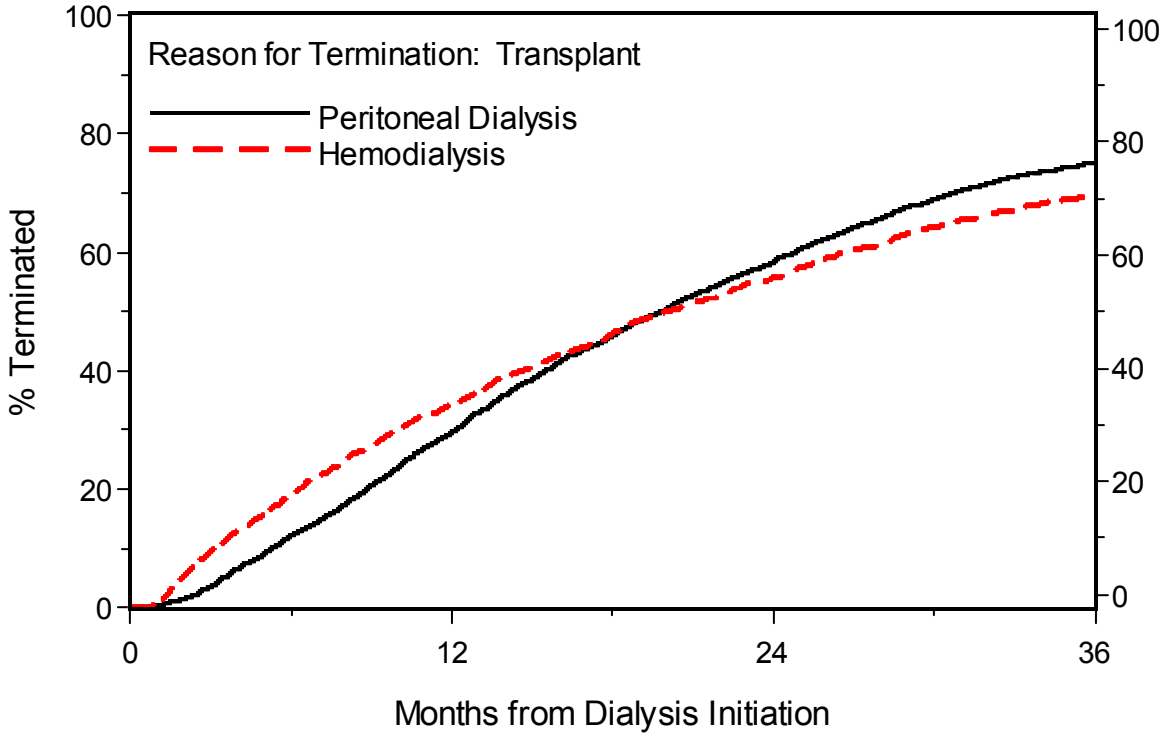


EXHIBIT 9.11
TIME TO DIALYSIS TERMINATION BY DIALYSIS MODALITY
(Index Cases)



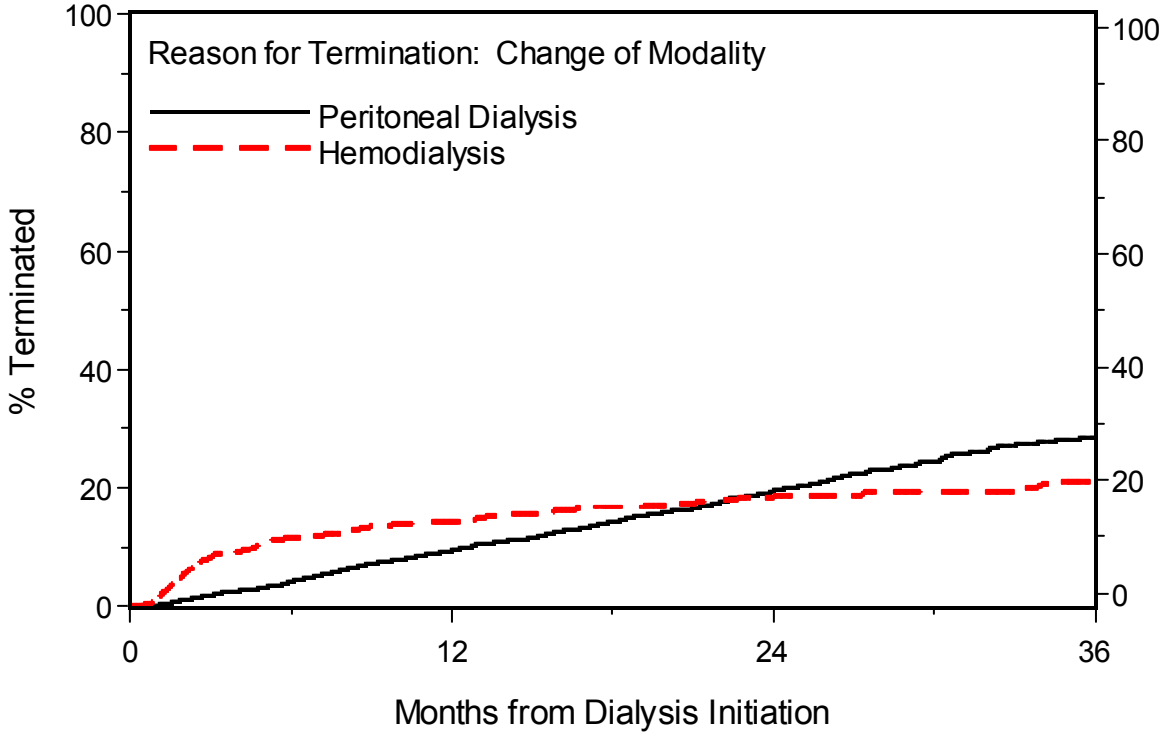


EXHIBIT 9.12
PERITONEAL DIALYSIS ACCESS BY SELECTED CHARACTERISTCS
(Index cases with 30 day data)

	CAPD		APD	
	N	%	N	%
Total	676	100.0	2187	100.0
Race/Ethnicity				
White	278	41.1	1228	56.1
Black	92	13.6	470	21.5
Hispanic	260	38.5	340	15.5
Other	46	6.8	149	6.8
Age at initiation				
0-1 years	91	13.5	434	19.8
2-5 years	84	12.4	271	12.4
6-12 years	230	34.0	647	29.6
>12 years	271	40.1	835	38.2
Gender				
Male	358	53.0	1204	55.1
Female	317	46.9	983	44.9
Missing	1	0.1	0	0.0
Year initiated				
1992-1993	150	22.2	307	14.0
1994-1995	133	19.7	356	16.3
1996-1997	113	16.7	400	18.3
1998-1999	96	14.2	297	13.6
2000-2001	74	10.9	240	11.0
2002-2003	43	6.4	230	10.5
2004-2005	37	5.5	250	11.4
2006-2007	30	4.4	107	4.9

EXHIBIT 9.13
TIME TO DIALYSIS TERMINATION BY PERITONEAL DIALYSIS MODALITY
(Index cases with 30 day data)

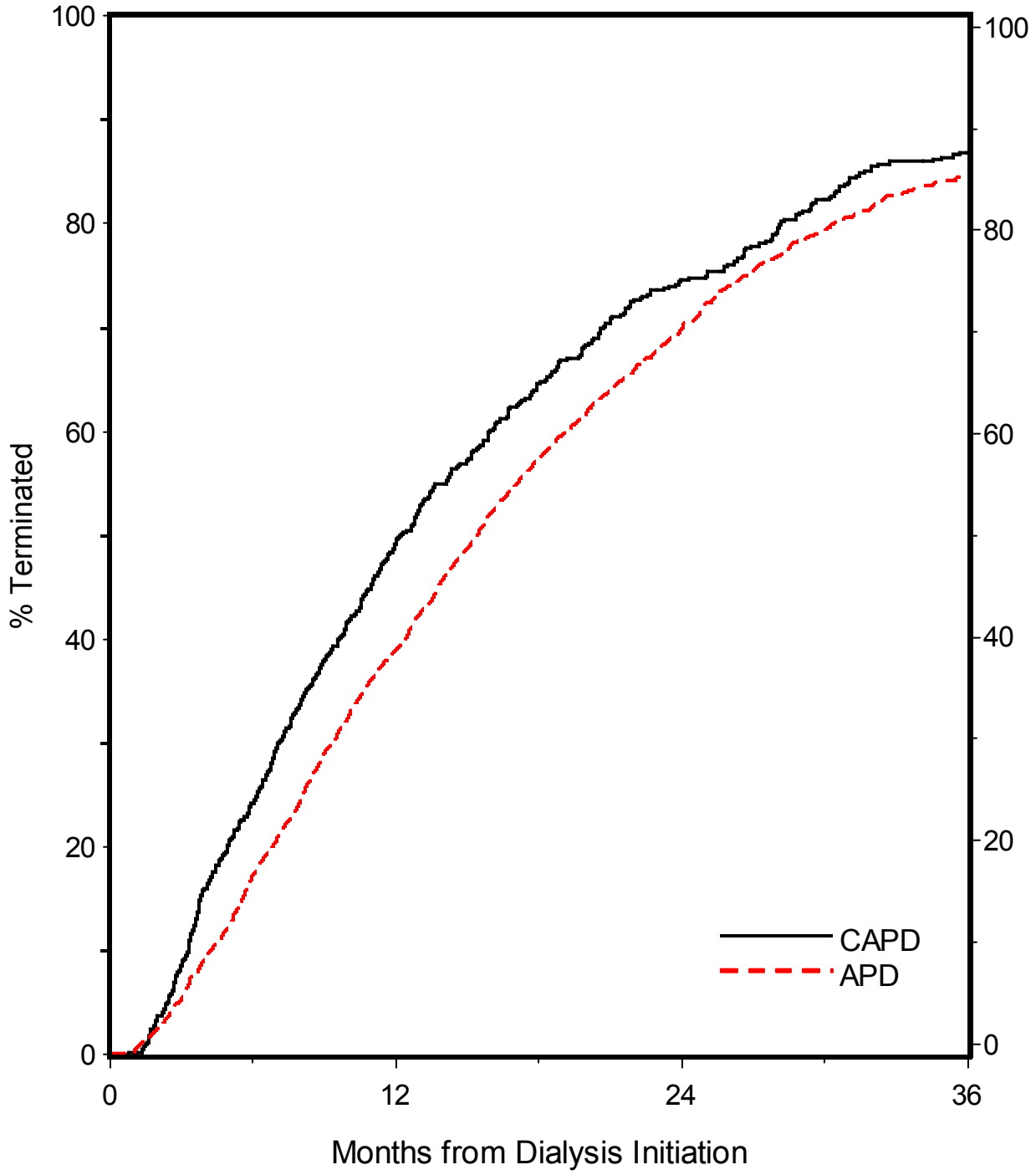
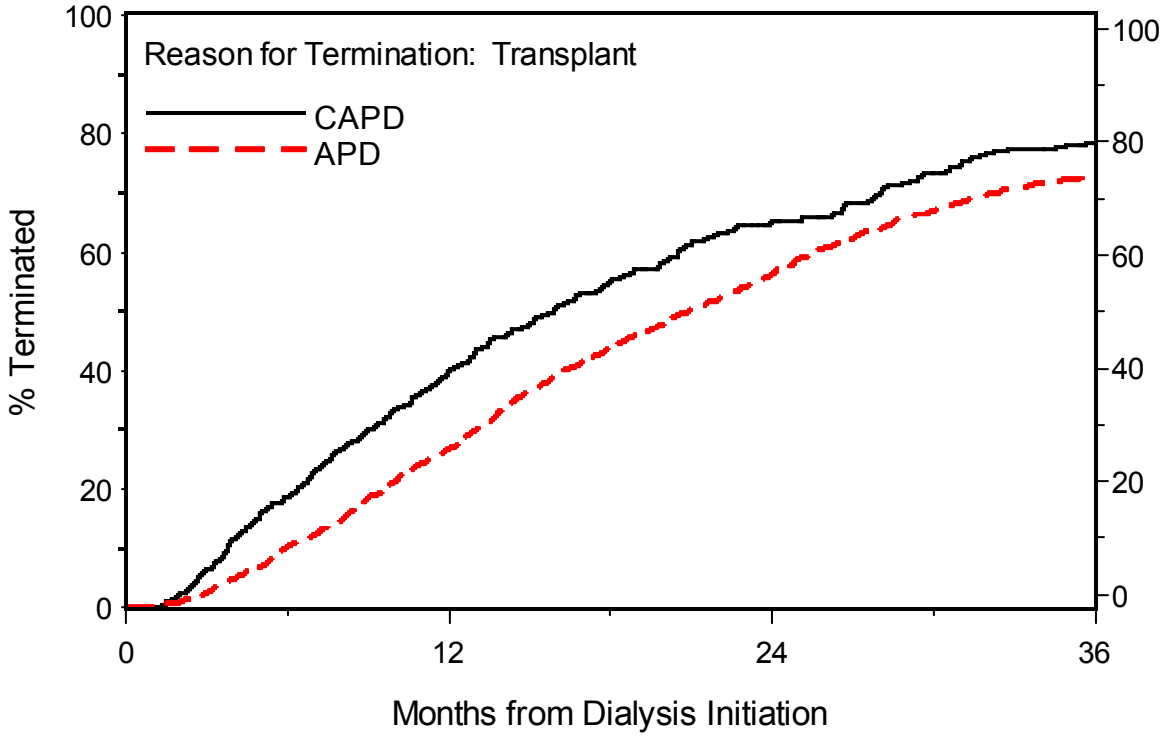


EXHIBIT 9.14
TIME TO DIALYSIS TERMINATION BY PERITONEAL DIALYSIS MODALITY
(Index cases with 30 day data)



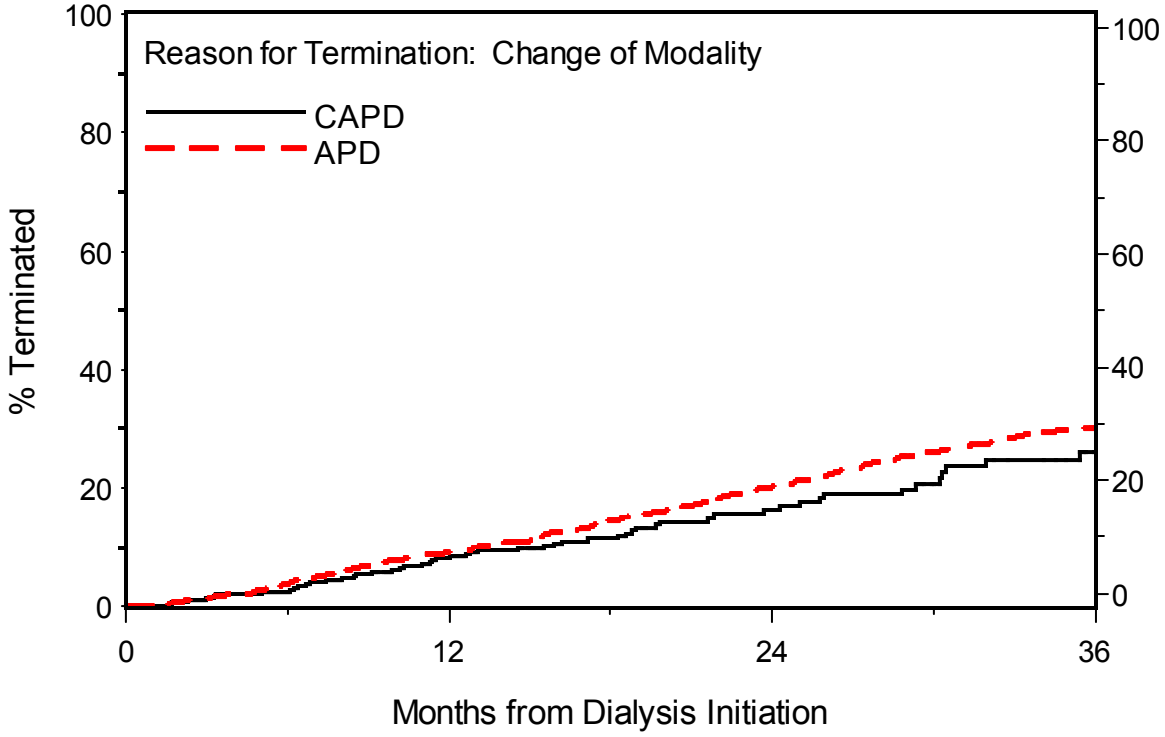
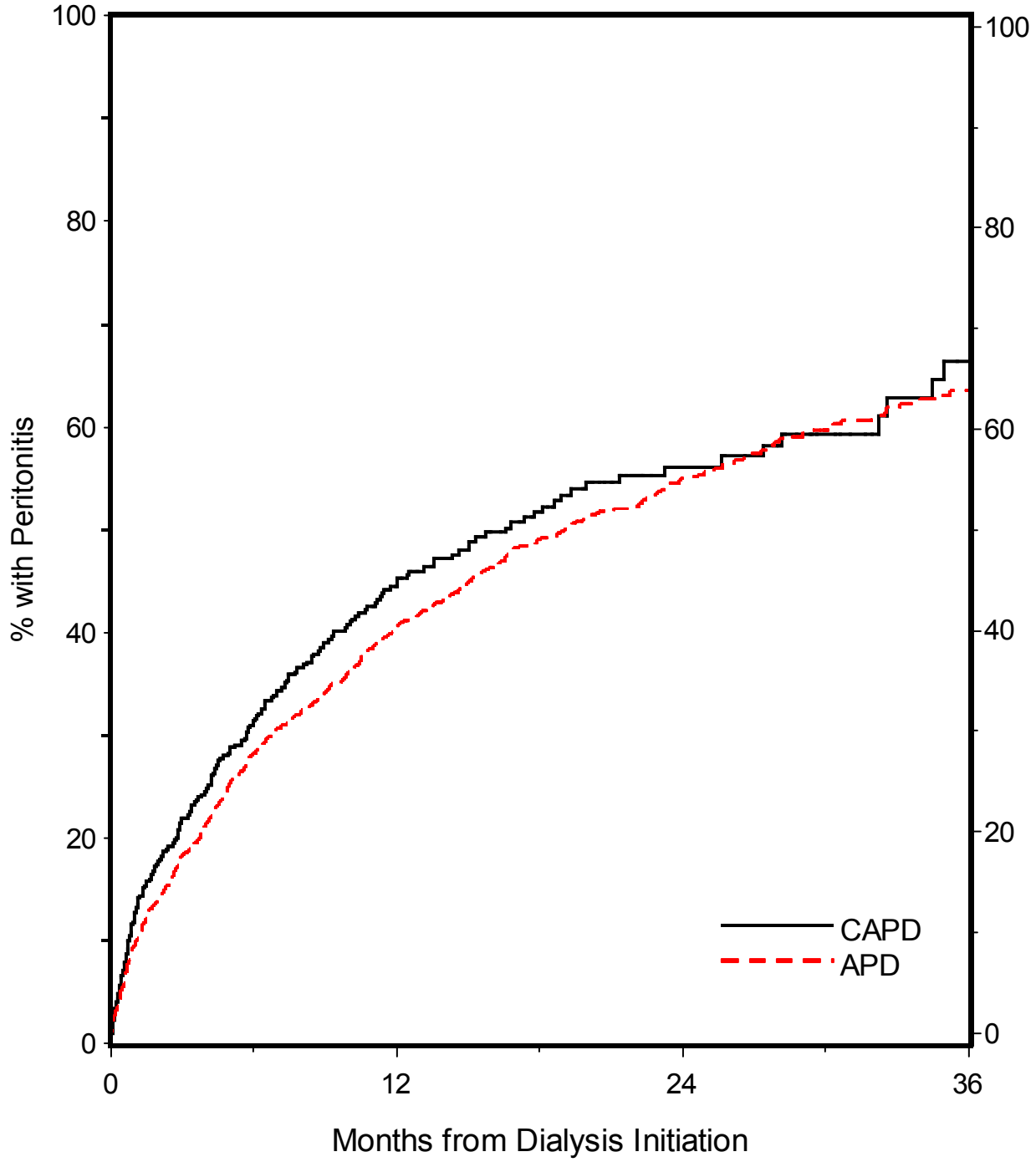


EXHIBIT 9.15
TIME TO FIRST PERITONITIS EPISODE BY PERITONEAL DIALYSIS MODALITY
(Index cases with 30 day data)



SECTION 10: ERYTHROPOIETIN USE IN DIALYSIS PATIENTS

Data on the use of erythropoietin (EPO) are presented in this section. The cohort of interest is the 5,752 cases of maintenance dialysis, as described in the preceding section, for which the *index* course of dialysis was initiated after January 1, 1992. In particular, we evaluate herein the use of EPO following the reported index initiation of dialysis for these patients.

The percent use of EPO across time is described in Exhibit 10.1 for patients with non-missing data at the post dialysis initiation times shown. The use of EPO increases from 88.7% at baseline (Day 30) to 94.5% after two years of dialysis. While EPO use is lower initially for peritoneal dialysis (PD) patients (86.9%) compared to hemodialysis (HD) patients (92.0%), by two years of dialysis therapy, EPO use in similar (94.8% for PD and 93.8% for HD). EPO use at baseline, by patient age, gender, and race/ethnicity is depicted in Exhibit 10.2. Overall, EPO is used similarly among the age groups, with 88.4%, 89.6%, 89.1%, and 88.2% of patients, respectively, in age groups 0-1, 2-5, 6-12, and >12 receiving EPO therapy initially. Since over 90% of children <6 years old are treated with peritoneal dialysis, data are sparse regarding EPO usage patterns among HD patients in this age group. Among older children and adolescents, initial use of EPO is about 6 percentage points higher for HD relative to PD patients (Exhibit 10.2). EPO usage patterns, by gender, are similar within dialysis modality group. Hispanic PD patients receive EPO therapy less frequently than their HD counterparts (81.9% versus 92.7%).

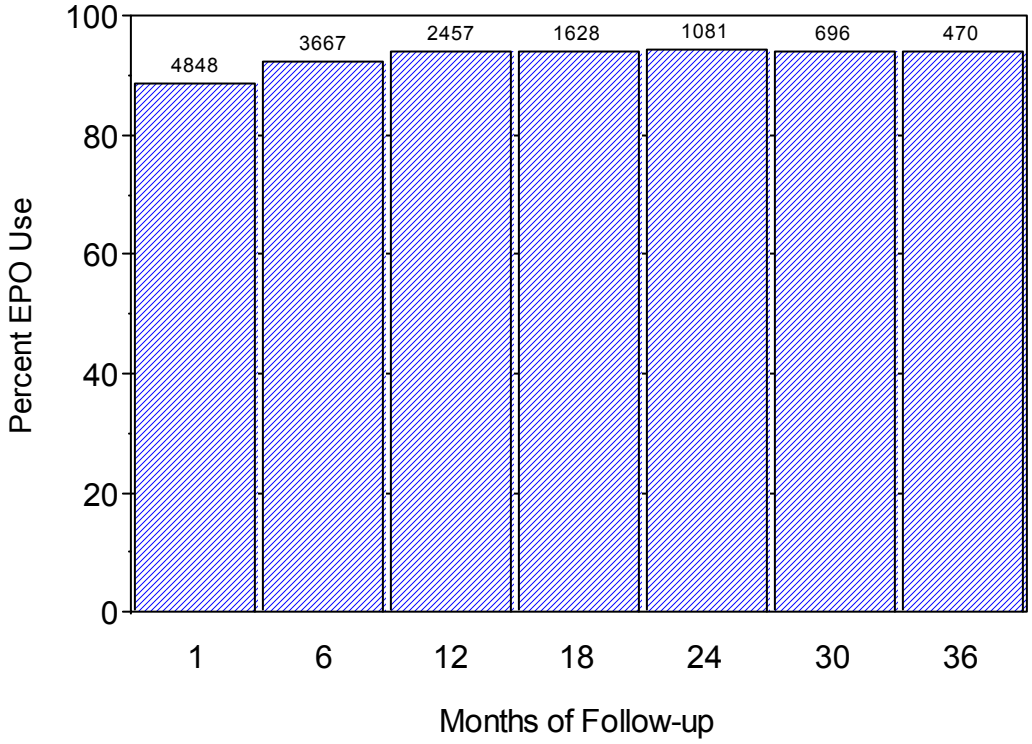
Of those treated with EPO therapy, data pertaining to route and frequency of use are described in Exhibit 10.3. As shown, most PD patients (95.5%) receive subcutaneous administration and less than 2% receive intraperitoneal administration of EPO, whereas most HD patients are treated intravenously (84.2%). Frequency of EPO administration is more varied among PD than HD. At 6 months, about 75% of PD patients are treated once or twice weekly, and about 18% are treated three times per week. The percentage of PD patients who are treated less frequently than once per week increased from 4.2% initially to 8.2% at 12 months, and remains stable afterwards. HD patients, however, are mostly treated three times per week (61%), presumably at the time of their dialysis therapy. Over the first 2 years time, 83% of the PD patients and 92% of the HD patients receive Epogen, with 6% of PD and 1% of HD receiving Procrit and 11% and 6% receiving Aranesp, respectively. Since 2004 the use of Aranesp has increased to 20% in PD patients and 12% in HD patients.

EPO dosing was examined in units per kilogram per week (Exhibit 10.4). The exhibit suggests, mean doses for the younger patients (<24 months, 2-5 years) tend to fluctuate, while mean doses for the older patients (6-12, >12) remain more stable over time. Moreover, mean doses for different gender, race, and dialysis modality groups are similar and remain stable overtime.

To assess more clearly the use and potential effect of EPO therapy on hematocrit, we considered 3,667 patients still maintained on their index course of dialysis at 6 months. By year of dialysis initiation, the percent use of EPO at Day 30 is increased from 73.3% in 1992 to 93.4% in 1996 where it remains stable. Frequency of EPO administration, by dialysis modality and patient age at initiation, is shown in Exhibit 10.5. Frequency of administration is slightly greater for infants receiving PD therapy, relative to older PD patients. Of these 3,667 patients, we have complete reporting on EPO use and hematocrit at the baseline and 6-month post dialysis initiation visits for 3,250. The percent distribution of hematocrit at 6 months, by EPO use, is shown in Exhibit 10.6. Of the 3,250 patients, 2,898 (89.2%) began EPO therapy by Day 30, 215 (6.6%) began EPO therapy after Day 30, and 137 (4.2%) had not received EPO through 6 months of dialysis therapy. Of patients who began EPO therapy by Day 30, 52% had a hematocrit level of 33% or above at 6 months. Forty-five percent of patients not treated by EPO during the first 6 months of dialysis had hematocrit levels of 33% or above at 6 months. Mean and median hematocrit levels at 6 months are shown in Exhibit 10.7 by EPO use.

EXHIBIT 10.1
ERYTHROPOIETIN USE BY FOLLOW-UP MONTH

All Patients



By Modality

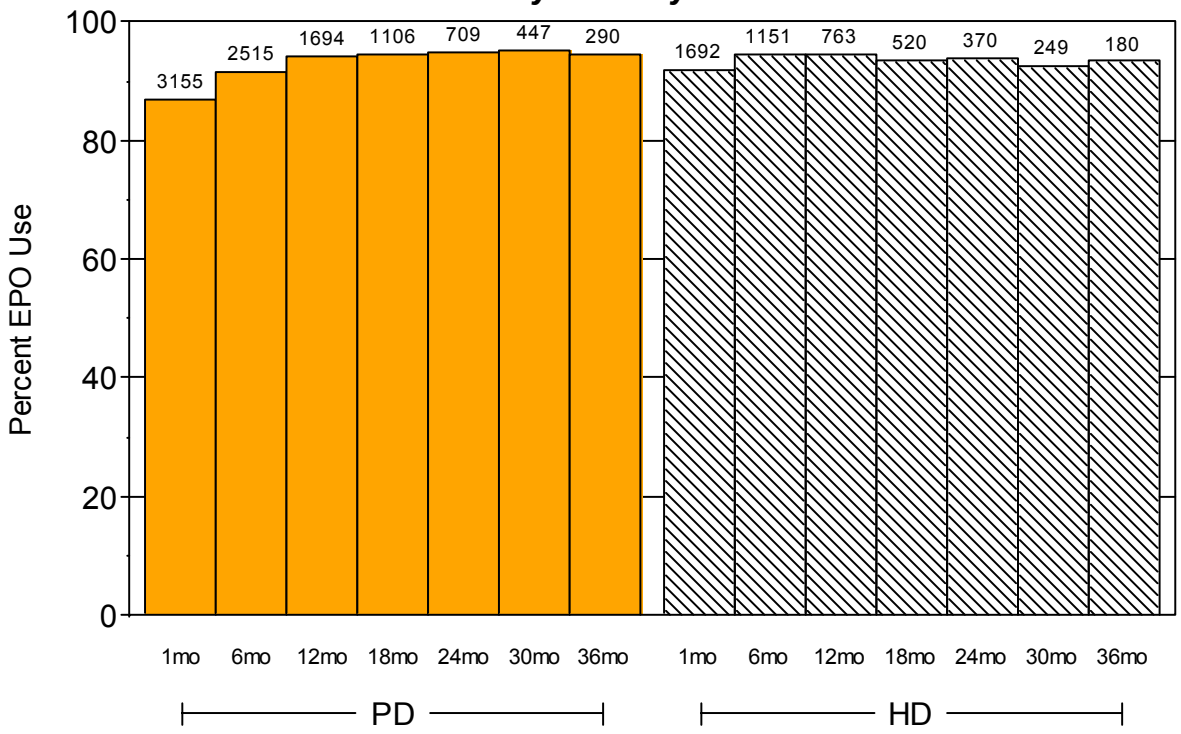
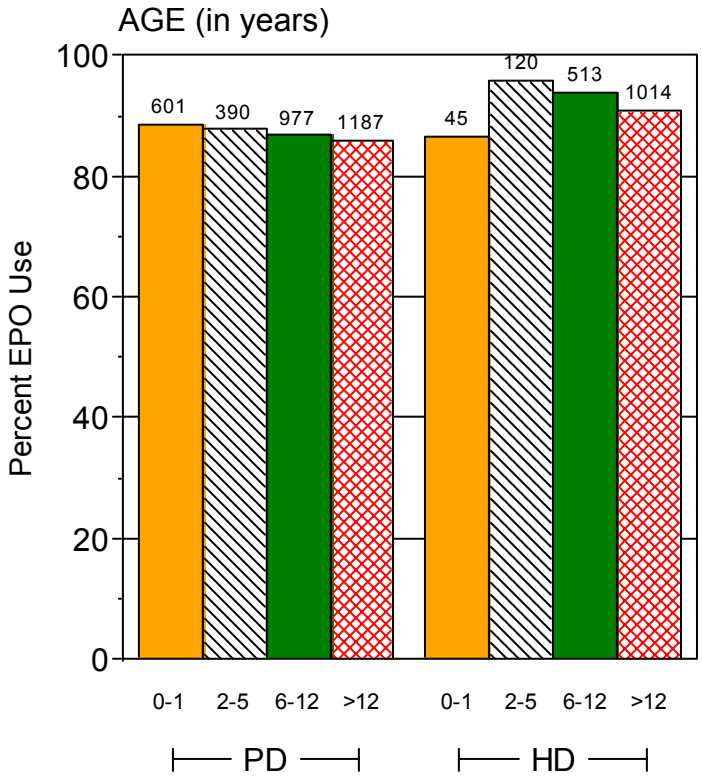
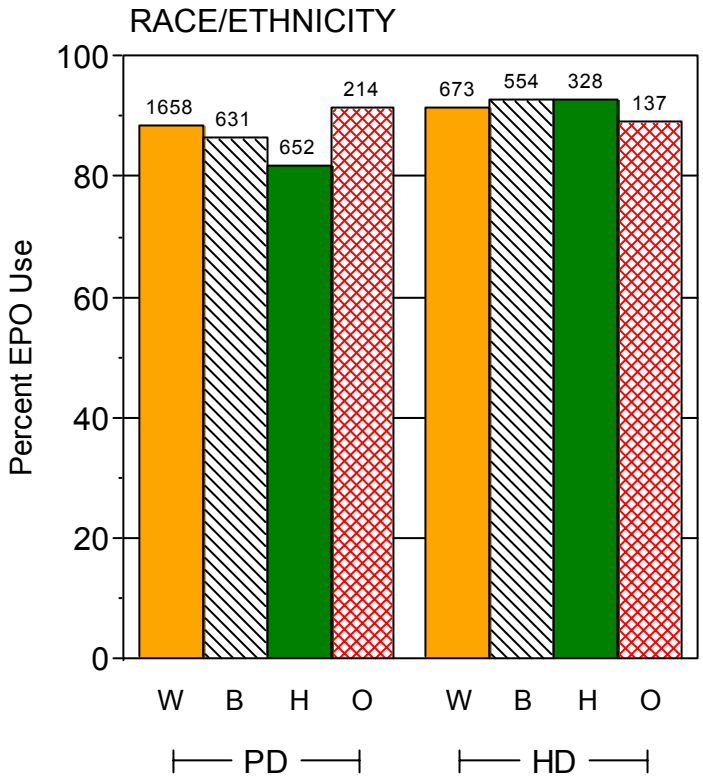


EXHIBIT 10.2
ERYTHROPOIETIN USE AT BASELINE BY PATIENT CHARACTERISTICS





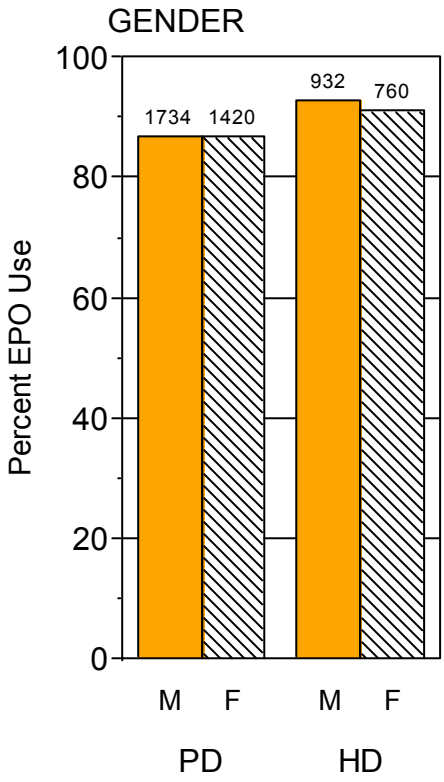
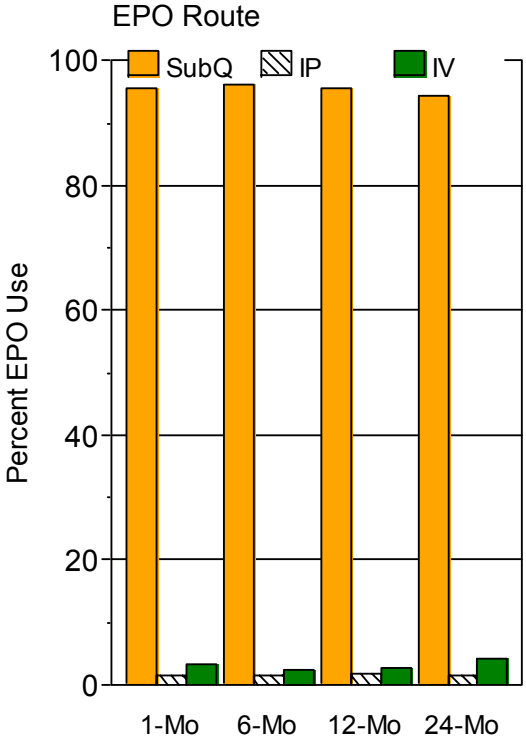
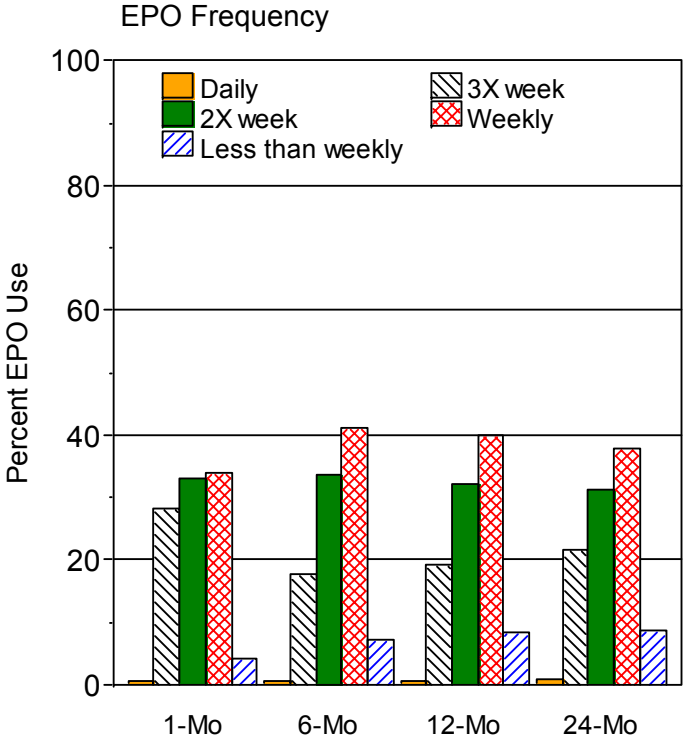


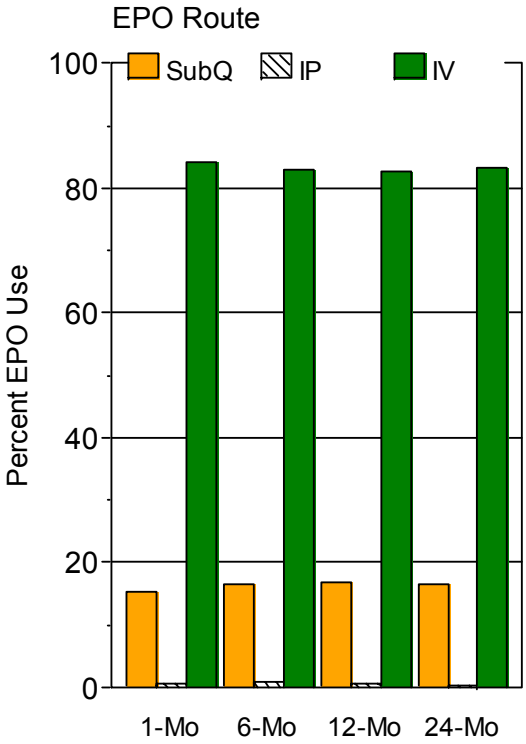
EXHIBIT 10.3
ERYTHROPOIETIN USE

Peritoneal Dialysis





Hemodialysis



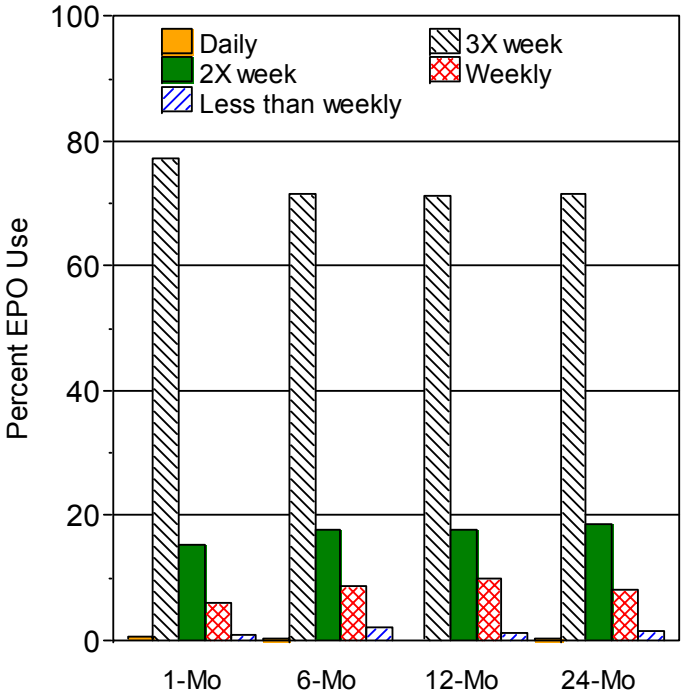
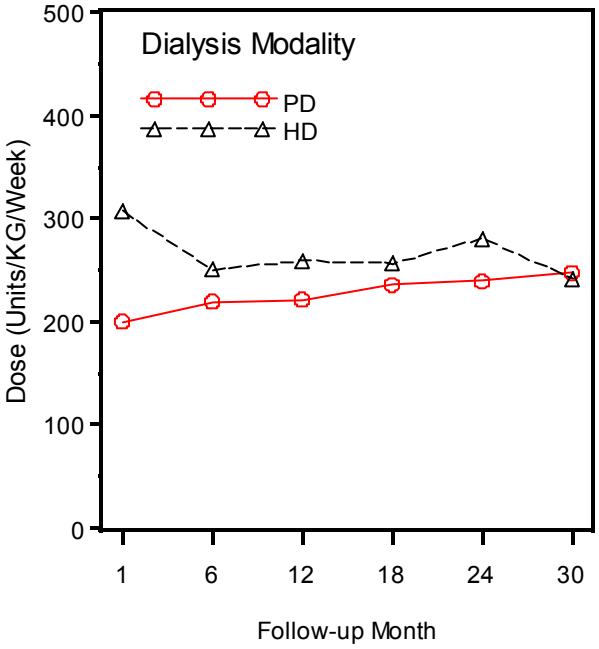
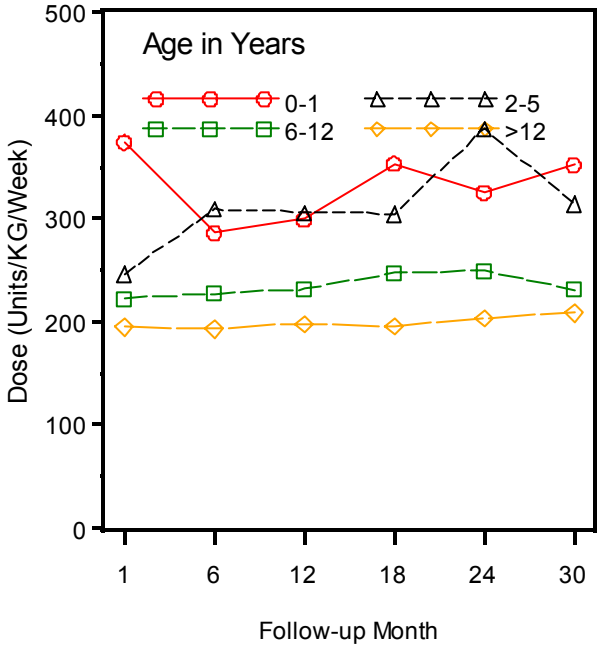
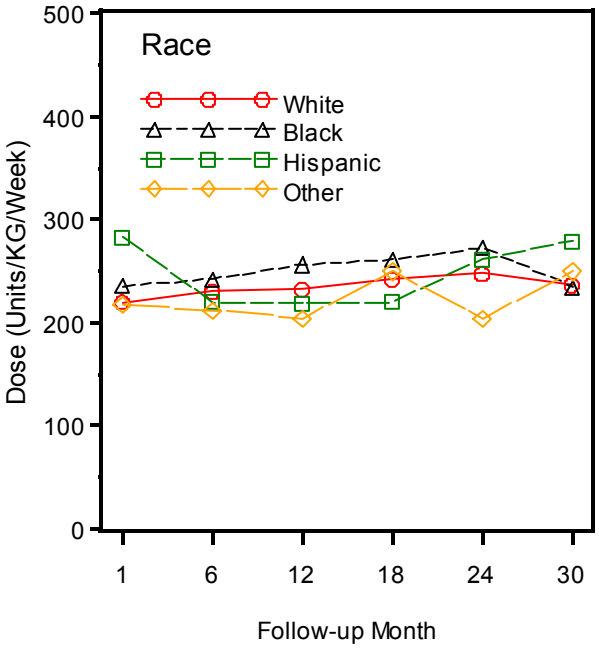


EXHIBIT 10.4
MEAN ERYTHROPOIETIN DOSE (UNITS/KG/WEEK)







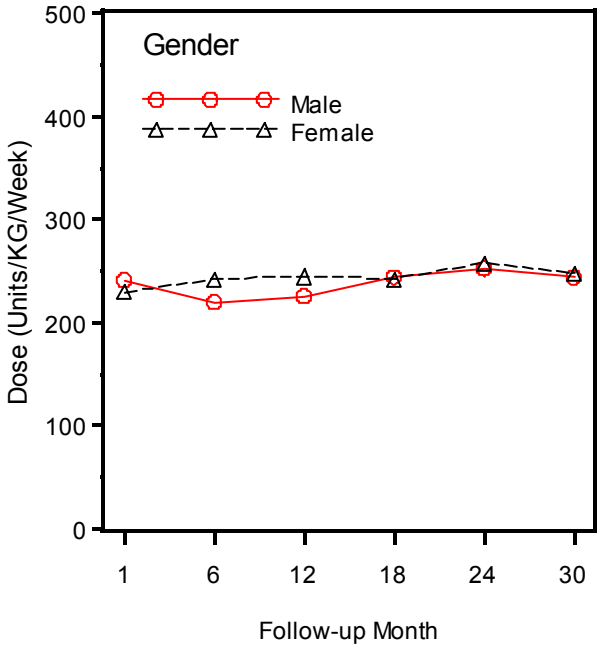


EXHIBIT 10.5
DISTRIBUTION (%) OF ERYTHROPOIETIN USE AT 6 MONTHS

	Peritoneal Dialysis				**Hemodialysis**			
	Age at index initiation (years)				Age at index initiation (years)			
EPO frequency	0-1	2-5	6-12	>12	0-1	2-5	6-12	>12
Daily	1.7	0	0.3	0.5	3.0	0	0.3	0.2
Three times/week	22.4	16.3	16.4	16.6	78.0	72.5	70.6	73.9
Two times/week	36.5	36.2	33.6	30.8	13.0	17.8	20.4	16.5
Weekly	33.8	41.7	41.9	44.3	6.0	8.4	8.1	7.7
<Weekly	5.6	5.8	7.8	7.8	0	1.4	0.7	1.6

EXHIBIT 10.6
DISTRIBUTION (%) OF HEMATOCRIT AT 6 MONTHS BY ERYTHROPOIETIN USE

		Hematocrit (%) at 6 Months				
EPO Use	Total	<25	27-30	31-33	33-35	> 35
Began EPO BY DAY 30	2898	14.0	21.1	13.5	14.4	37.1
Began EPO after day 30	215	17.7	24.2	10.7	10.7	36.7
No EPO	137	22.6	17.5	15.3	8.0	36.5

EXHIBIT 10.7
HEMATOCRIT LEVELS AT 6 MONTHS BY ERYTHROPOIETIN USE

	Hematocrit (%) at 6 Months			
EPO Use	N	Mean	SE	Median
Began EPO BY DAY 30	2898	32.8	0.1	33.0
Began EPO after day 30	215	32.2	0.4	32.0
No EPO	137	31.9	0.7	32.0

SECTION 11: DIALYSIS FOLLOW-UP

Follow-up data on peritoneal dialysis and hemodialysis initiations are presented in this section. We consider only those courses of dialysis for patients registered after January 1, 1992. This includes 4,352 courses of peritoneal dialysis with 3,647 being index courses and 3,047 courses of hemodialysis with 2101 being index courses.

Exhibit 11.1 presents follow-up data at 1 month and at 6, 12, 24, and 36 months following PD initiation. Most patients used automated peritoneal dialysis (APD) [68.5% at 1 month, 71.6% at 36 months] rather than continuous ambulatory peritoneal dialysis (CAPD) or intermittent peritoneal dialysis (IPD). At one month post-initiation, 86.3% of patients were receiving erythropoietin (EPO) and 10.0% were receiving human growth hormone (rhGH); at 6 months, 90.7% were receiving EPO and 14.9% rhGH; at 36 months, 90.1% EPO and 23.9% rhGH. Exit site infections occurred in about 20% of cases between 6-month follow-up visits. Transplant status is also characterized: at 6 months post initiation, 23.5% of patients were on the deceased donor waiting list and 32.4% had a DD or LD work-up in progress. Of the 40.7% of patients who were not transplant candidates at 6 months 75.7% had a medical reason for remaining on dialysis and 24.3% were due to family or patient preference. By 12 months, 31.5% of patients were on the deceased donor list and 28.1% had a work-up in progress.

Also shown is the number of reported peritonitis episodes. During the first 30 days of PD, 426 (11.2%) patients had a peritonitis episode, and 49 patients had two episodes. Of the 524 reported infections that occurred within the first month, 16 (3.0%) were fungal, 232 (44.3%) were Gram-positive, 100 (19.1%) were Gram-negative, 21 (4.0%) were gram-positive and negative, 136 (26%) were cultured with no growth, and 19 (3.6%) were other or not cultured. Exhibit 11.2 presents number and percent of peritonitis episodes per course, by age at dialysis initiation. Over the course of the study, 3,999 peritonitis infections have been reported in this cohort of PD patients: 825 patients have had only 1 infection, 405 patients have had two infections, 454 patients have had 3 to 7 infections, and 49 patients have had 8 or more infections. Infection rate is constant between age groups.

Peritonitis infection rates, by age and catheter characteristics, are presented in Exhibit 11.3. A total of 3,999 episodes of peritonitis have occurred in 6008 years of follow-up (4,352 PD

courses), yielding an annualized rate of 0.67, or 1 episode every 18.0 months. The annualized rate decreases with age, and is better for double cuffs, swan neck tunnels, and downward pointed exit sites. The percentage of patients using the double cuffs/swan neck/downward pointed exit site configuration increased from 5% in 1992-1995 to 18% since then. Significant improvement is seen since 2002 with the annualized rate of infection decreasing from 0.79 in 1992-1996 to 0.41 in recent years.

Time to first peritonitis infection is depicted in Exhibits 11.4, 11.5, and 11.6; Exhibit 11.4 is for all patients, Exhibit 11.5 is by age at initiation, and Exhibit 11.6 is by catheter access characteristics. Overall, 38.7% of patients have had at least one infection by 12 months; 52.2% have had an infection by 24 months. Tenckhoff straight and Tenckhoff curled catheters have similar times to first peritonitis infection. Overall, the time to first peritonitis infection is longer for two cuffs compared to one, for swan neck tunnels compared to straight tunnels, and for down exit sites compared to up and lateral (see Exhibit 11.6).

Data on PD catheter access revisions are shown in Exhibit 11.7. The revision access ratio (number of revisions / number of accesses) is 0.19. Accesses were revised due to catheter malfunction (40%), peritonitis (17%), exit site tunnel infections (15%), dialysate leaks (4%), and missing/other (24%). Percent distributions of reasons for access revisions are also shown according to catheter access characteristics. Recall that the most common access configuration is a Tenckhoff curled catheter with one cuff, a straight tunnel, and a lateral exit site orientation. The ideal access configuration (with respect to having an access revision) would be Tenckhoff curled, two cuffs, swan/curved tunnel and a downward exit site orientation.

Follow-up data on HD patients and accesses are shown in Exhibit 11.8 and Exhibit 11.9. The use of EPO in HD patients exceeds that of PD patients for the first year of dialysis (91% versus 86%), but is about 89% at 24 months for both groups. On the other hand, the use of rhGH is less in HD than in PD (14% versus 25% at 24 months). The transplant status of HD patients is similar to that observed for the PD cohort with 14% and 13% respectively on the deceased donor list at 30 days. The revision access ratio for HD is 0.83. Accesses were revised because of infection (15%), clotting (24%), malfunction (25%), to create a more permanent access (25%), and other/missing in 11%.

For the 546 index patients who were placed on the deceased donor waiting list at dialysis initiation, Exhibits 11.10 and 11.11 show the time to deceased donor transplantation by year listed and by age, respectively.

In 2003, NAPRTCS initiated collection of dialysis dose measurements with capture, at each reporting time point of most recent single pool Kt/V and Urea Reduction Ratio (URR) for hemodialysis patients and most recent weekly Kt/V for peritoneal dialysis patients. Exhibit 11.12 displays initial reported Kt/V by age grouping, race, visit timing since initiation and baseline BMI standardized score for 678 peritoneal dialysis and 532 hemodialysis patients. For peritoneal dialysis patients, dialysis dose is lower in ages > 12 years, black and higher BMI scores. The median Kt/V was 2.2, the lower quartile was 1.7 and the lowest decile was 1.4. Peritoneal dialysis strategies (CAPD versus APD versus IPD) did not differ significantly in Kt/V values. Hemodialysis patients Kt/V was lower for infants, blacks, earlier visit months, and higher BMI Z-scores. Kt/V percentiles (50^{th}, 25^{th} and 10^{th}) for hemodialysis patients are 1.6, 1.3 and 1.1. Mean URR values for selected hemodialysis patient subgroups are presented in Exhibit 11.13. Since Kt/V and URR values are highly correlated, similar differences in age, race, visit month and BMI Z-score are noted.

In addition, for patients with more than one Kt/V measurement, the mean of the first reported Kt/V was compared with the mean of their second Kt/V. This was performed separately for both hemodialysis and peritoneal dialysis patients. In an analysis of 328 HD patients, a mean difference of -0.09 was observed (p=0.050). There was no significant difference in mean values for the 434 PD patients (mean difference –0.02, p=0.710). Among 368 HD patients with more than one URR measurement, the mean of the first reported URR was compared with the mean of the second reported URR measurement. The average difference in values was –0.79 (p=0.177). Exhibit 11.14 and 11.5 show box plots for the Kt/V values over time. The box represents the 25^{th} and 75^{th} percentiles with whiskers showing the 10^{th} and 90^{th} percentiles. The median value at day 30 is 2.1, at 1 year is 2.2, and at 2 years post-initiation, the median Kt/V for PD patients is 2.3. Exhibit 11.15 displays Kt/V values over time for HD patients. For day 30, 1 year and 2 years post-initiation, the median values are 1.5, 1.6 and 1.6.

EXHIBIT 11.1
PERITONEAL DIALYSIS AT FOLLOW-UP

	1 Month		6 Month		12 Month		24 Month		36 Month	
	N	%	N	%	N	%	N	%	N	%
Total Courses	3802	100.0	3039	100.0	2101	100.0	903	100.0	373	100.0
Modality										
CAPD	783	20.6	564	18.6	378	18.0	137	15.2	56	15.0
APD	2605	68.5	2152	70.8	1479	70.4	642	71.1	267	71.6
IPD	245	6.4	181	6.0	107	5.1	36	4.0	13	3.5
Missing/Unknown	169	4.4	142	4.7	137	6.5	88	9.7	37	9.9
EPO Therapy										
Yes	3283	86.3	2755	90.7	1917	91.2	810	89.7	336	90.1
No	457	12.0	231	7.6	112	5.3	46	5.1	18	4.8
Missing/Unknown	62	1.6	53	1.7	72	3.4	47	5.2	19	5.1
hGH Therapy										
Yes	382	10.0	454	14.9	411	19.6	225	24.9	89	23.9
No	3354	88.2	2524	83.1	1614	76.8	633	70.1	267	71.6
Missing/Unknown	66	1.7	61	2.0	76	3.6	45	5.0	17	4.6
Seizures										
Yes	135	3.6	146	4.8	70	3.3	32	3.5	9	2.4
No	3544	93.2	2789	91.8	1912	91.0	798	88.4	332	89.0
Missing/Unknown	123	3.2	104	3.4	119	5.7	73	8.1	32	8.6
Exit Site Infections										
Yes	333	8.8	616	20.3	422	20.1	156	17.3	67	18.0
No	3346	88.0	2326	76.5	1571	74.8	690	76.4	284	76.1
Missing/Unknown	123	3.2	97	3.2	108	5.1	57	6.3	22	5.9
Transplant Status										
DD List	495	13.0	714	23.5	662	31.5	361	40.0	148	39.7
Work-up in progress	1418	37.3	986	32.4	590	28.1	164	18.2	52	13.9
Medical Reasons	1441	37.9	936	30.8	506	24.1	178	19.7	77	20.6
Choice	323	8.5	301	9.9	246	11.7	140	15.5	72	19.3
Missing/Unknown	125	3.3	102	3.4	97	4.6	60	6.6	24	6.4
# of Peritonitis Episodes (in period)										
0	3327	87.5	2222	73.1	1544	73.5	687	76.1	266	71.3
1	426	11.2	552	18.2	370	17.6	143	15.8	71	19.0
2	49	1.3	170	5.6	115	5.5	49	5.4	26	7.0
>2	0	0.0	95	3.1	72	3.4	24	2.7	10	2.7

EXHIBIT 11.2
PERITONEAL DIALYSIS PERITONITIS EPISODES

Number of Epsiodes per Protocol Segment	Age at Dialysis Initiation									
	Total		0-1 years		2-5 years		6-12 years		> 12 years	
	N	%	N	%	N	%	N	%	N	%
0	2619	60.2	411	54.8	328	60.6	824	60.5	1056	62.1
1	825	19.0	143	19.1	104	19.2	254	18.7	324	19.1
2	405	9.3	86	11.5	49	9.1	118	8.7	152	8.9
3	172	4.0	38	5.1	18	3.3	59	4.3	57	3.4
4	132	3.0	22	2.9	21	3.9	40	2.9	49	2.9
5	75	1.7	16	2.1	9	1.7	23	1.7	27	1.6
6-10	114	2.7	30	4.0	10	2.0	40	2.9	34	2.0
>10	10	0.2	4	0.6	2	0.4	3	0.2	1	0.1

EXHIBIT 11.3
PERITONEAL DIALYSIS PERITONITIS RATES

	N of episodes	Years of FU	Annualized Rate		Expected Months between infections	
			Rate	95% CI	Months	95% CI
Total	3999	6008	0.67	(0.64 - 0.69)	18.0	(17.5 - 18.6)
Age						
0-1 years	874	1033	0.85	(0.79 - 0.90)	14.2	(13.3 – 15.2)
2-5 years	487	730	0.67	(0.61 - 0.73)	18.0	(16.5 - 19.7)
6-12 years	1267	1949	0.65	(0.61 - 0.69)	18.5	(17.5 - 19.5)
>12 years	1371	2296	0.60	(0.57 - 0.63)	20.1	(19.1 – 21.2)
Catheter						
Straight	1142	1566	0.73	(0.69 - 0.77)	16.5	(15.6 - 17.5)
Curled	2517	3719	0.68	(0.65 - 0.70)	17.7	(17.1 - 18.5)
Presternal	220	416	0.53	(0.46 - 0.60)	22.7	(20.1 - 26.2)
Cuff						
One	2445	3207	0.76	(0.73 - 0.79)	15.7	(15.1 - 16.4)
Two	1494	2609	0.57	(0.54 - 0.60)	21.0	(19.9 – 22.1)
Tunnel						
Swan necked/curved	1022	1968	0.52	(0.49 - 0.55)	23.1	(21.8 – 24.6)
Straight	2897	3816	0.76	(0.73 - 0.79)	15.8	(15.3 - 16.4)
Exit Site Orientation						
Up	678	804	0.84	(0.78 - 0.91)	14.2	(13.2 - 15.4)
Down	1101	1984	0.56	(0.52 - 0.59)	21.6	(20.4 – 23.0)
Lateral	1744	2311	0.75	(0.72 - 0.79)	15.9	(15.2 - 16.7)
Year of Dialysis Initiation						
1992-1996	2163	2738	0.79	(0.76 - 0.82)	15.2	(14.6 - 15.9)
1997-2002	1477	2390	0.62	(0.59 - 0.65)	19.4	(18.5 – 20.5)
2003-2007	359	881	0.41	(0.37 – 0.45)	29.4	(26.7 – 32.8)

Note: Other/unknown/missing catheter, cuff, tunnel and exit site orientation not shown.

EXHIBIT 11.4
TIME TO FIRST PERITONITIS INFECTION (PD Index Cases)

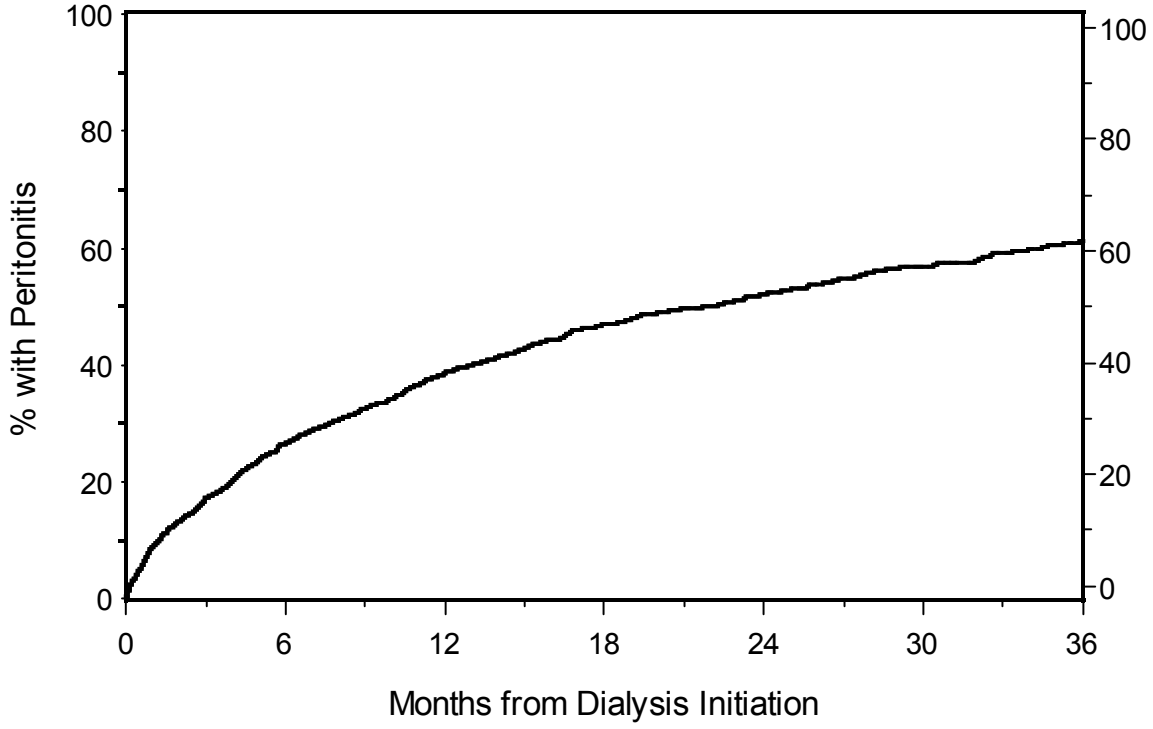


EXHIBIT 11.5
TIME TO FIRST PERITONITIS INFECTION BY AGE (PD Index Cases)

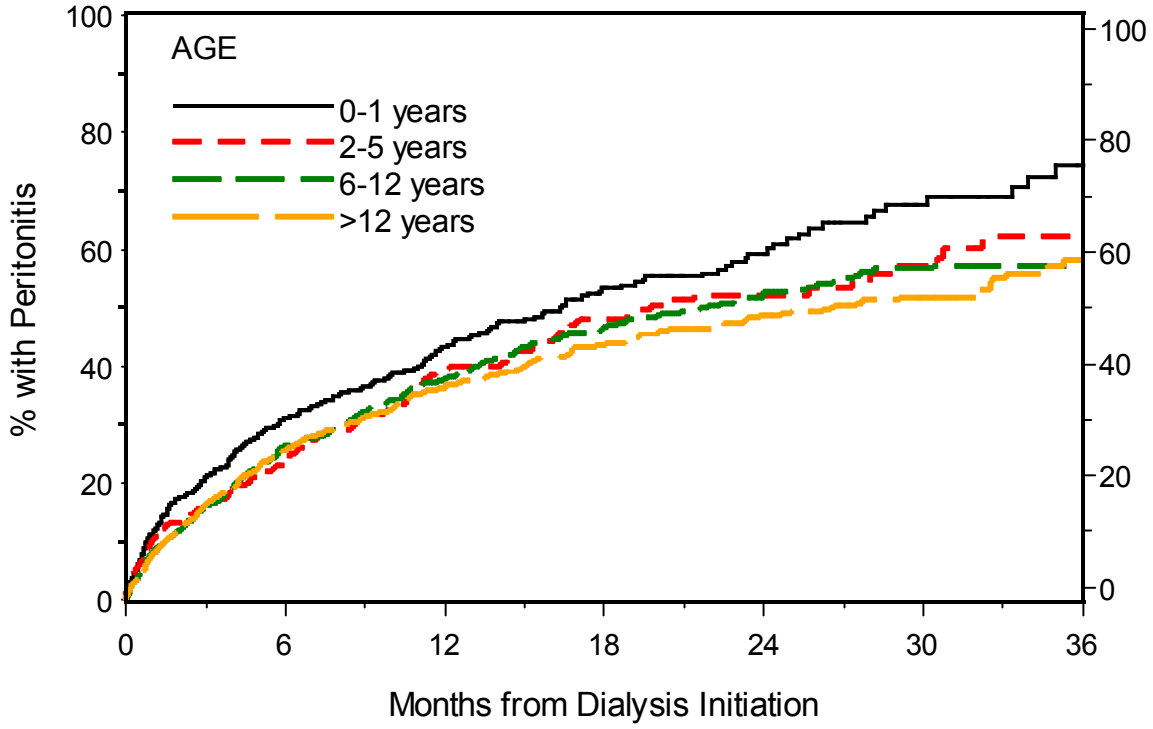
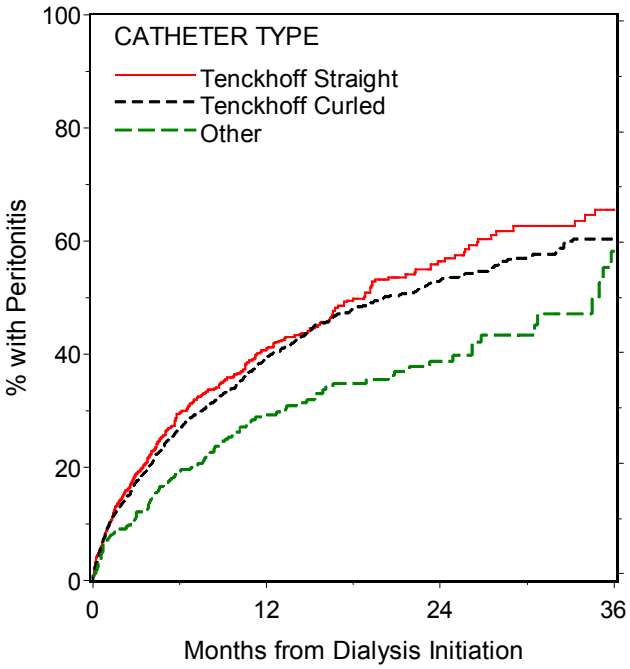
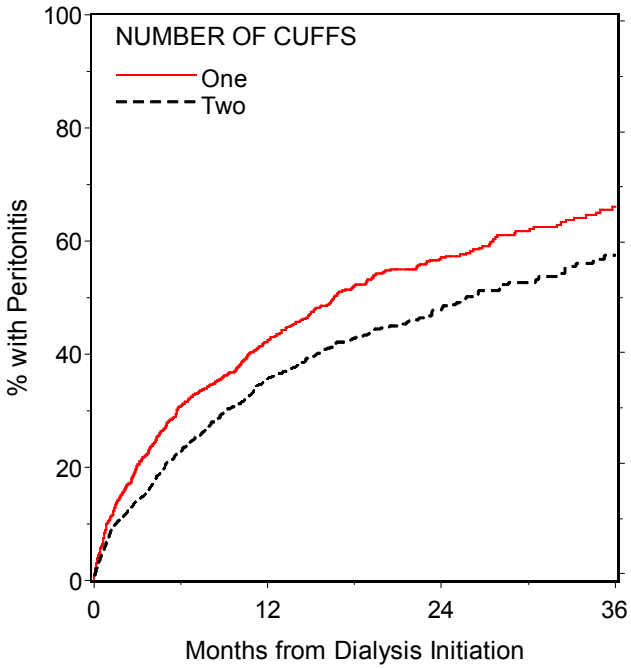
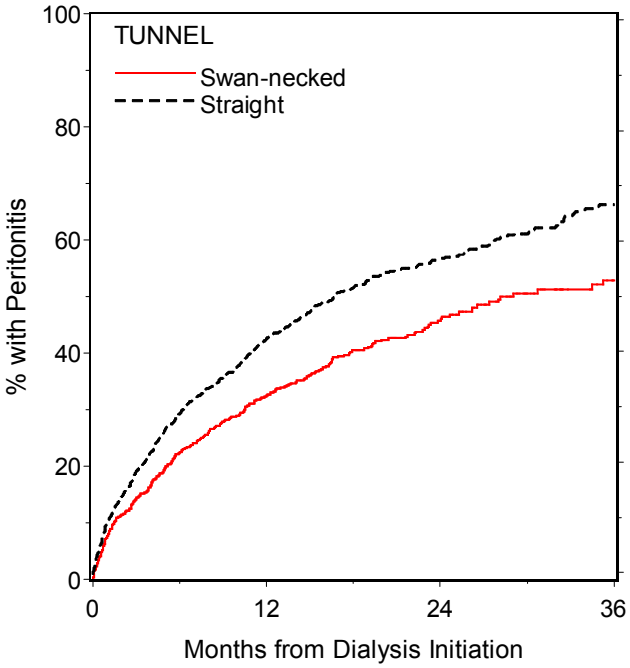


EXHIBIT 11.6
TIME TO FIRST PERITONITIS INFECTION
BY PERITONEAL DIALYSIS ACCESS CHARACTERISTICS
(PD Index Cases)







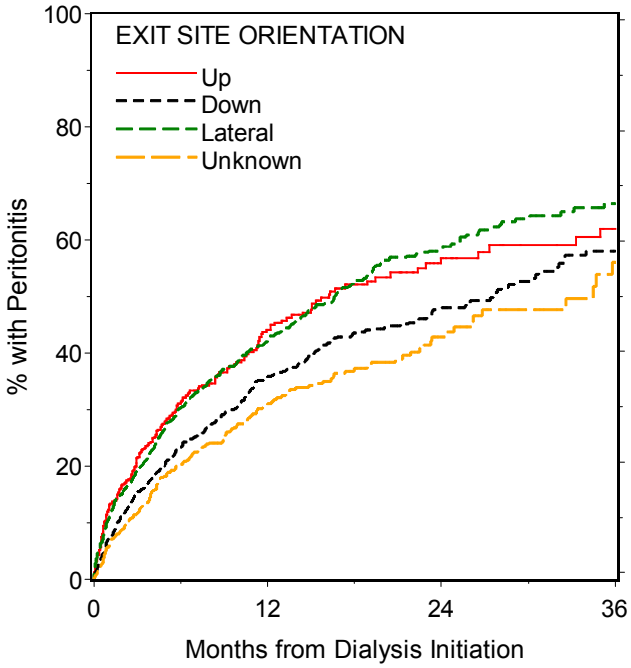


EXHIBIT 11.6 (continued)
TIME TO FIRST PERITONITIS INFECTION
BY PERITONEAL DIALYSIS ACCESS CHARACTERISTICS
(PD Index Cases)

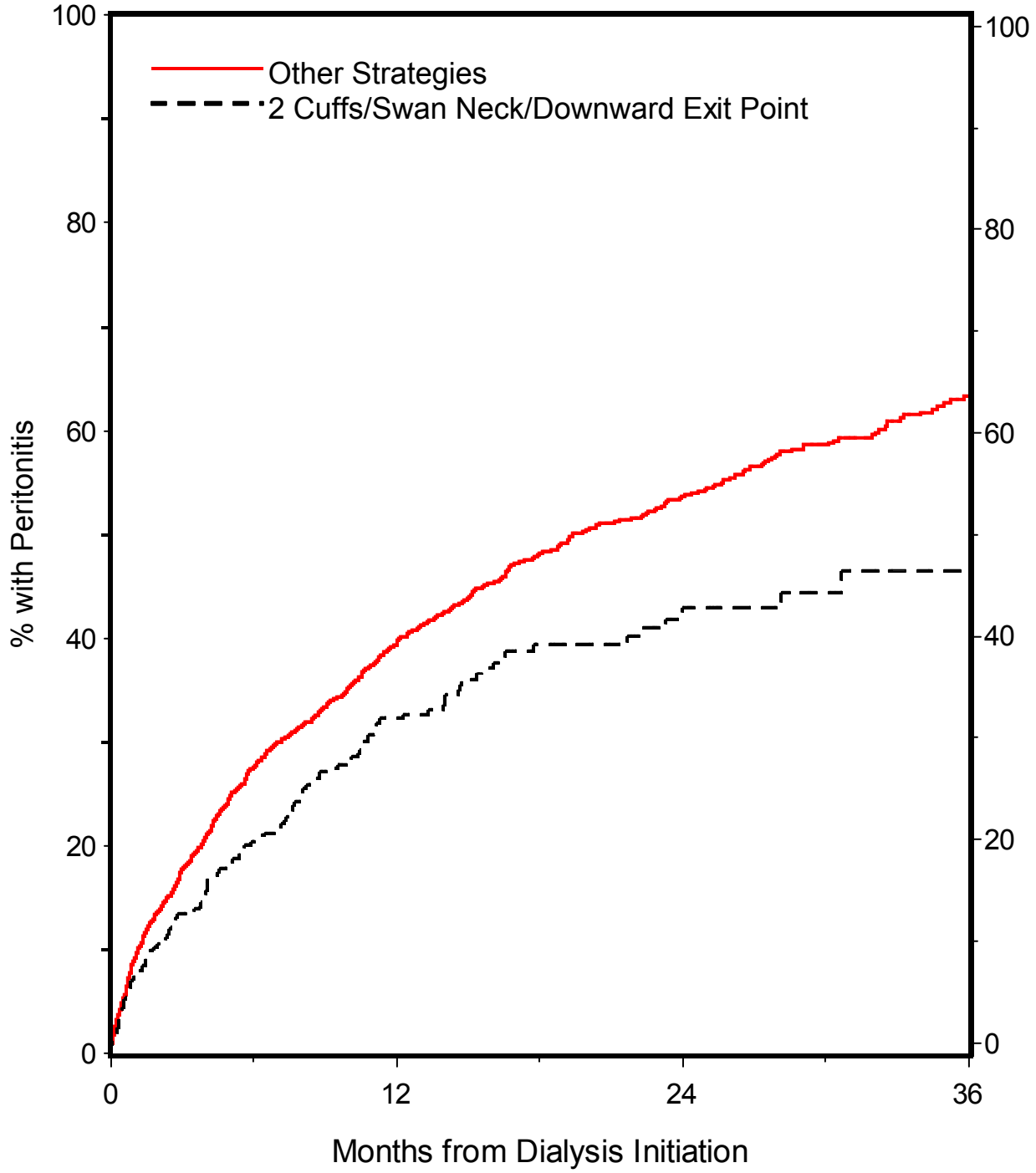


EXHIBIT 11.7
PERITONEAL DIALYSIS ACCESS REVISIONS

	Number of Accesses	Number of Revisions	Revision/ Access x 100	Reason For Access Revision											
				Infection		Leak		Malfunction		Peritonitis		Other		Missing	
				N	%	N	%	N	%	N	%	N	%	N	%
Total	4352	832	19.1	122	14.7	37	4.4	332	39.9	139	16.7	84	10.1	118	14.2
Catheter															
Tenckhoff Straight	1170	238	20.3	34	14.3	8	3.4	107	45.0	37	15.5	27	11.3	25	10.5
Tenckhoff Curled	2677	505	18.9	72	14.3	24	4.8	189	37.4	93	18.4	46	9.1	81	16.0
Toronto Western	26	5	19.2	0	0.0	0	0.0	4	80.0	1	20.0	0	0.0	0	0.0
Presternal	272	53	19.5	10	18.9	1	1.9	23	43.4	6	11.3	5	9.4	8	15.1
Other	88	9	10.2	2	22.2	2	22.2	2	22.2	1	11.1	1	11.1	1	11.1
Unknown/Missing	119	22	18.5	4	18.2	2	9.1	7	31.8	1	4.5	5	22.7	3	13.6
Cuff															
One	2263	492	21.7	61	12.4	26	5.3	199	40.4	94	19.1	41	8.3	71	14.4
Two	1951	323	16.6	58	18.0	10	3.1	126	39.0	44	13.6	41	12.7	44	13.6
Unknown/Missing	138	17	12.3	3	17.6	1	5.9	7	41.2	1	5.9	2	11.8	3	17.6
Tunnel															
Swan /curved	1397	216	15.5	40	18.5	10	4.6	80	37.0	38	17.6	25	11.6	23	10.6
Straight	2801	598	21.3	79	13.2	25	4.2	244	40.8	101	16.9	56	9.4	93	15.6
Unknown/Missing	154	18	11.7	3	16.7	2	11.1	8	44.4	0	0.0	3	16.7	2	11.1
Exit Site Orientation															
Up	535	146	27.3	20	13.7	9	6.2	55	37.7	36	24.7	9	6.2	17	11.6
Down	1425	252	17.7	40	15.9	11	4.4	103	40.9	39	15.5	27	10.7	32	12.7
Lateral	1735	316	18.2	48	15.2	14	4.4	125	39.6	46	14.6	31	9.8	52	16.5
Unknown/Missing	657	118	18.0	14	11.9	3	2.5	49	41.5	18	15.3	17	14.4	17	14.4

EXHIBIT 11.8
HEMODIALYSIS AT FOLLOW-UP

	1 Month		6 Month		12 Month		24 Month		36 Month	
	N	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
Total Courses	2437	100.0	1710	100.0	1147	100.0	572	100.0	299	100.0
EPO Therapy										
Yes	2206	90.5	1561	91.3	1041	90.8	510	89.2	256	85.6
No	164	6.7	80	4.7	55	4.8	30	5.2	16	5.4
Missing/Unknown	67	2.7	69	4.0	51	4.4	32	5.6	27	9.0
hGH Therapy										
Yes	232	9.5	185	10.8	139	12.1	82	14.3	35	11.7
No	2134	87.6	1454	85.0	953	83.1	457	79.9	235	78.6
Missing/Unknown	71	2.9	71	4.2	55	4.8	33	5.8	29	9.7
Seizures										
Yes	106	4.3	120	7.0	64	5.6	33	5.8	14	4.7
No	2223	91.2	1490	87.1	994	86.7	493	86.2	246	82.3
Missing/Unknown	108	4.4	100	5.8	89	7.8	46	8.0	39	13.0
Exit Site Infections										
Yes	215	8.8	271	15.8	149	13.0	52	9.1	22	7.4
No	2081	85.4	1309	76.5	901	78.6	466	81.5	234	78.3
Missing/Unknown	141	5.8	130	7.6	97	8.5	54	9.4	43	14.4
Transplant Status										
DD List	341	14.0	474	27.7	406	35.4	244	42.7	124	41.5
Work-up in progress	930	38.2	479	28.0	253	22.1	85	14.9	40	13.4
Medical Reasons	856	35.1	486	28.4	300	26.2	125	21.9	59	19.7
Patient/Family Choice	202	8.3	168	9.8	118	10.3	71	12.4	39	13.0
Missing/Unknown	108	4.4	103	6.0	70	6.1	47	8.2	37	12.4

EXHIBIT 11.9
HEMODIALYSIS ACCESS REVISIONS

	Number of Accesses	Number of Revisions	Revision/ Access Ratio	Reason For Access Revision											
				Infection		Clot		Malfunction		Re-access		Other		Missing	
				N	%	N	%	N	%	N	%	N	%	N	%
Total	3047	2516	82.6	373	14.8	600	23.8	629	25.0	628	25.0	222	8.8	64	2.5
HD Access															
External	2369	2139	90.3	334	15.6	410	19.2	574	26.8	580	27.1	188	8.8	53	2.5
Shunt	20	13	65.0	1	7.7	6	46.2	1	7.7	4	30.8	1	7.7	0	0.0
Fistula	374	128	34.2	10	7.8	63	49.2	23	18.0	18	14.1	11	8.6	3	2.3
Graft	222	211	95.0	24	11.4	117	55.5	23	10.9	24	11.4	20	9.5	3	1.4
Unknown/Missing	62	25	40.3	4	16.0	4	16.0	8	32.0	2	8.0	2	8.0	5	20.0

EXHIBIT 11.10
TIME TO TRANSPLANT FOR PATIENTS ON DECEASED DONOR LIST (at 30 days)

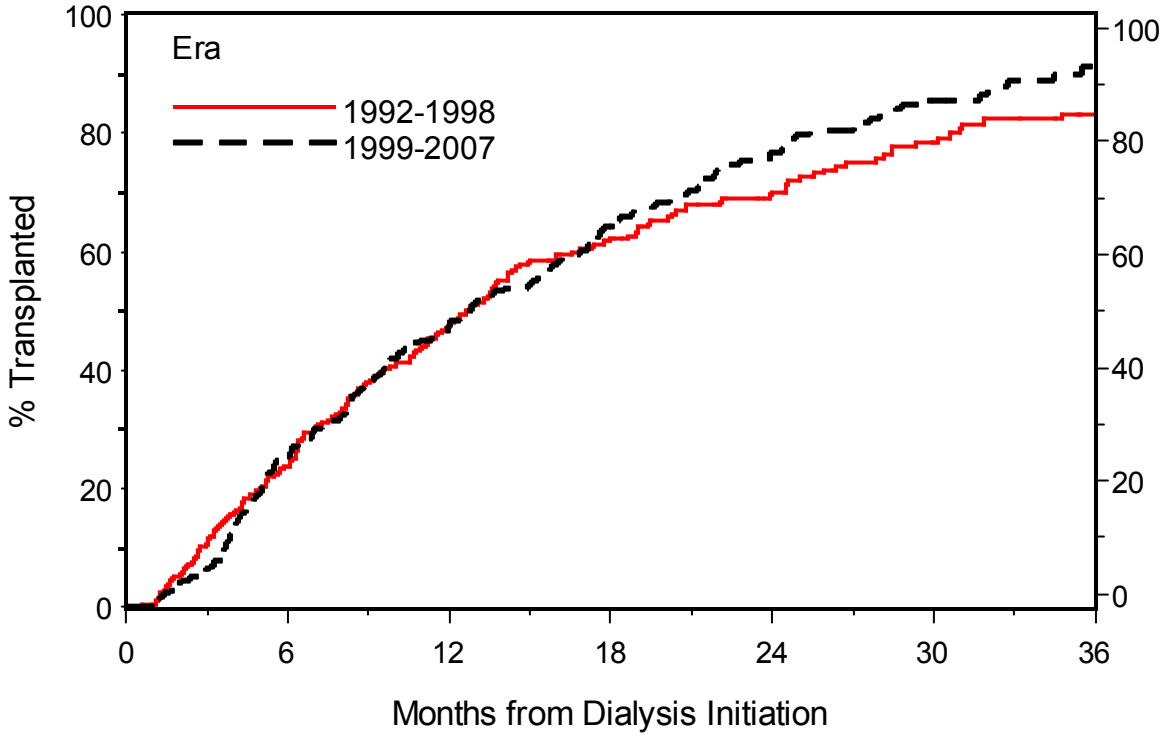


EXHIBIT 11.11
TIME TO TRANSPLANT FOR PATIENTS ON DECEASED DONOR LIST (at 30 days)

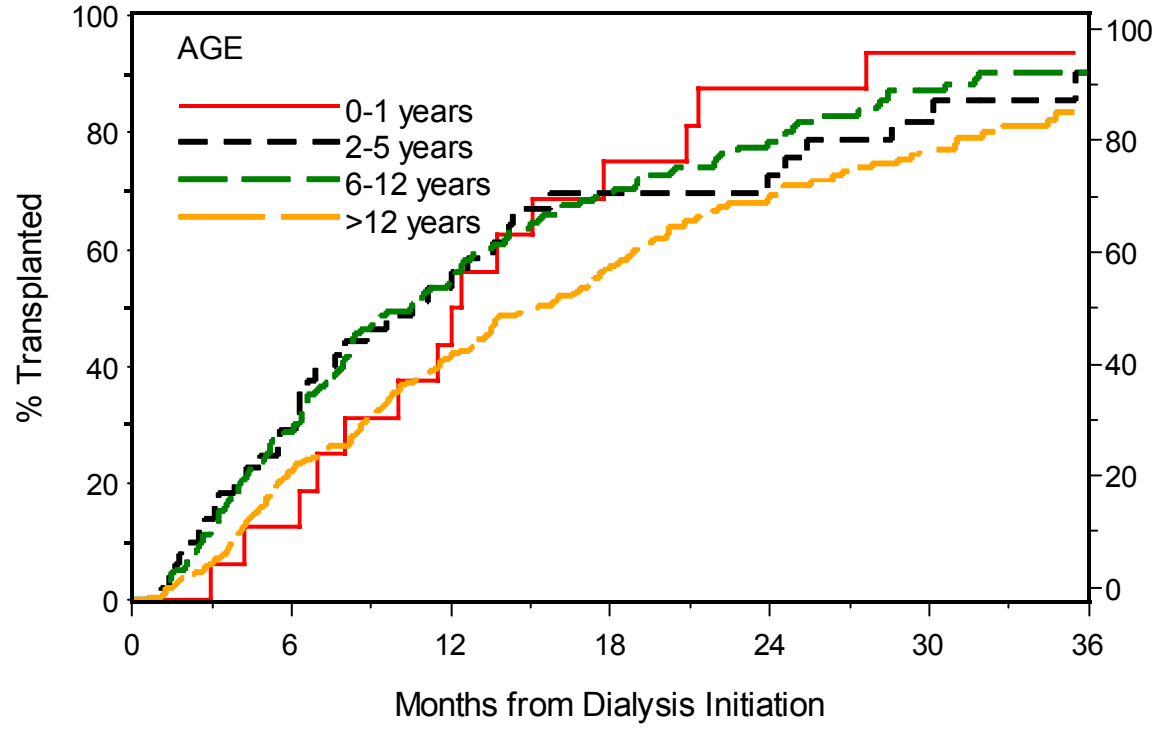


EXHIBIT 11.12
FIRST Kt/V MEASUREMENT

Peritoneal Dialysis

Kt/V	N	Mean	SE	Median
Total	678	2.41	0.04	2.20
Age				
0-1 years	114	2.46	0.08	2.30
2-5 years	88	2.52	0.11	2.30
6-12 years	201	2.56	0.08	2.30
>12 years	275	2.24	0.06	2.10
Race				
Non-Black	520	2.48	0.05	2.25
Black	158	2.17	0.07	2.00
Visit Month				
1 Month	323	2.31	0.05	2.10
6 Month	183	2.56	0.09	2.30
12 Month	65	2.44	0.14	2.20
>12 Month	107	2.40	0.09	2.20
BMI Z-score				
≤ 0	253	2.56	0.07	2.40
> 0	281	2.25	0.06	2.10
Missing	144	2.44	0.09	2.20

Hemodialysis

Kt/V	N	Mean	SE	Median
Total	532	1.61	0.02	1.55
Age				
0-1 years	16	1.40	0.10	1.40
2-5 years	44	1.71	0.08	1.60
6-12 years	159	1.69	0.04	1.60
>12 years	313	1.57	0.03	1.50
Race				
Non-Black	322	1.64	0.03	1.60
Black	210	1.57	0.03	1.50
Visit Month				
1 Month	344	1.57	0.03	1.50
6 Month	67	1.58	0.05	1.60
12 Month	47	1.67	0.06	1.70
>12 Month	74	1.77	0.05	1.70
BMI Z-score				
≤ 0	206	1.70	0.04	1.70
> 0	238	1.54	0.03	1.50
Missing	88	1.59	0.06	1.50

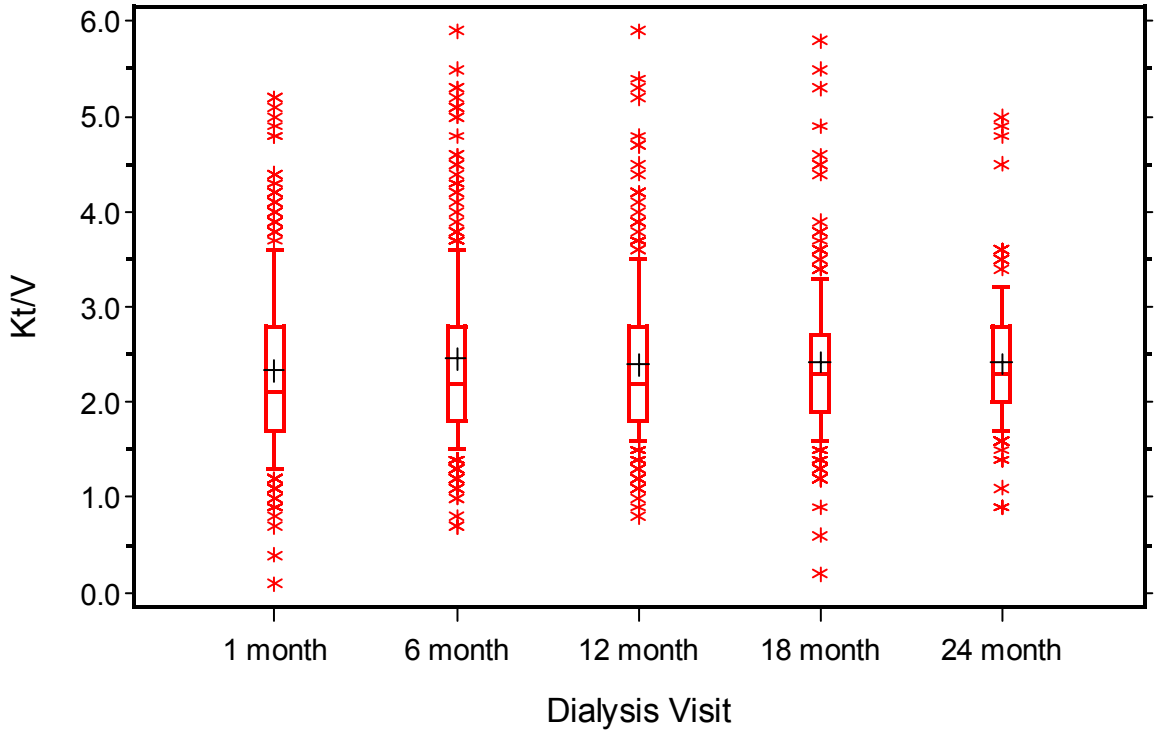
EXHIBIT 11.13
FIRST URR MEASUREMENT

Hemodialysis

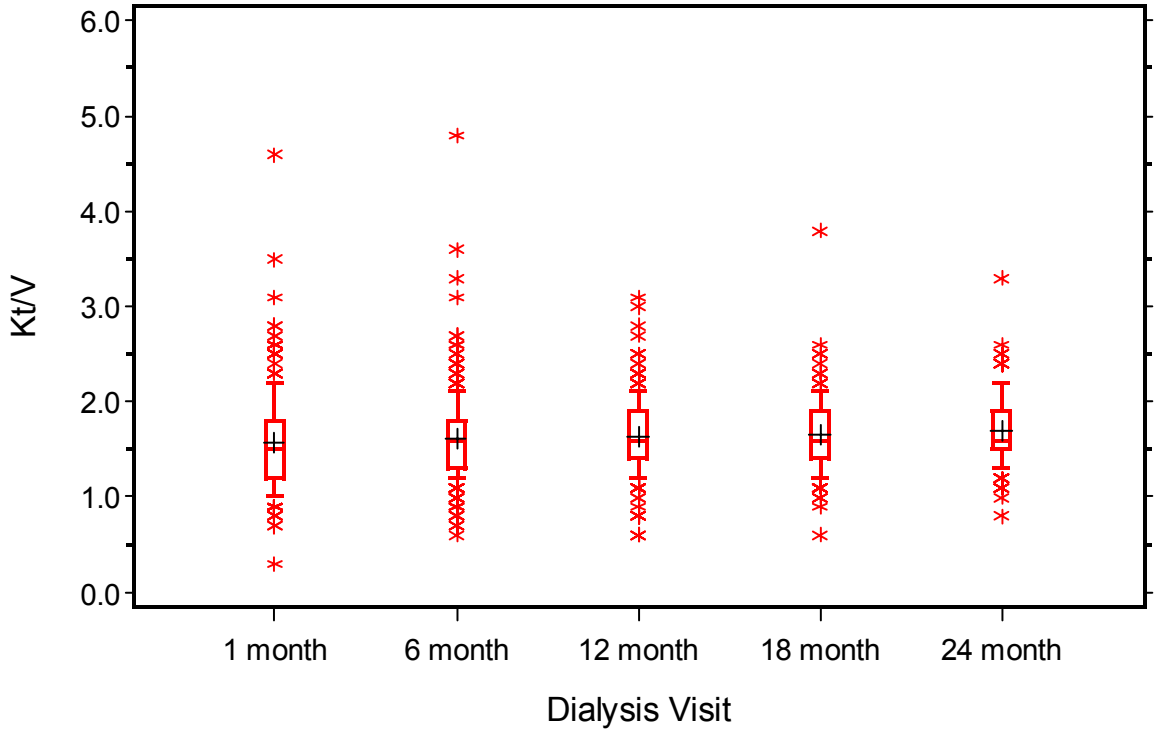
URR	N	Mean	SE	Median
Total	563	71.29	0.46	72.00
Age				
0-1 years	14	70.43	3.10	70.50
2-5 years	48	72.15	1.90	74.00
6-12 years	164	72.60	1.00	74.00
>12 years	337	70.57	0.51	71.00
Race				
Non-Black	350	71.98	0.62	73.00
Black	213	70.16	0.66	71.00
Visit Month				
1 Month	387	70.65	0.46	71.00
6 Month	60	71.17	1.92	73.50
12 Month	42	74.90	1.15	76.00
>12 Month	74	72.68	1.89	74.50
BMI Z-score				
< 0	220	72.29	0.67	73.00
> 0	249	70.04	0.77	71.00

EXHIBIT 11.14
KT/V OVER TIME

Peritoneal Dialysis



Hemodialysis



NOTE: Box represents the 25th and 75th percentiles, whiskers the 10th and 90th percentiles,
'-' is the median value ,'+' is the mean value and '*' are values above and below the 10th and 90th percentiles

SECTION 12: GROWTH

Data on growth following dialysis initiation are presented in this section. The cases with the index course of dialysis starting after January 1, 1992 are used and this is the baseline measurement that provides the reference value from which changes in height are calculated. Patients are censored from the analysis at the time of dialysis termination and do not re-enter, even if a subsequent course of dialysis is initiated. Height and weight measurements are reported at each 6-month follow-up visit, and baseline measurements are obtained 30 days following initiation. Z-scores are calculated by using the appropriate gender-age specific mean, standard deviation and adjustment parameters for the national population derived from NHANES III study (2000) of the National Center of Health Statistics. Direct comparison with early registry reports is not possible because of the use of these new standards.

Exhibit 12.1 presents mean height scores, by selected characteristics and during the first two years after dialysis initiation. One average at baseline, patients are about 1.61 standard deviations below the appropriate age- and sex-adjusted height levels. Height deficits are worse for males and for younger patients. Patients were also stratified according to baseline Z-score (<–1.88 vs. ≥–1.88 Z-score). Note that the third percentile of the normal population corresponds to –1.88 in Z-score. Post-dialysis height deficits for children with worse deficit score at baseline improve slightly from -3.21±0.03 at 1 month to -2.93±0.07 at 24 months. Children who had less deficit at baseline, -0.54±0.02, experience worse deficit by 24 months (-0.89±0.05). Median change from baseline height is -0.11 (n=1,215) and -0.20 (n=515) at 12 and 24 months, respectively, for patients whose baseline Z-score is ≥–1.88. The comparison for patients with baseline Z-score <–1.88 is 0.09 (n=851) and 0.15 (n=384) at 12 and 24 months. Although the weight deficits of dialysis patients are not as severe as for height, patients are, on average, 1.15 standard deviations below normal in weight (Exhibit 12.2). Changes from baseline in height and weight Z-score are depicted graphically in Exhibit 12.3A. Note that the sample sizes at follow-up times are relatively small for young dialysis patients. Young patients (less than 6 years) increase their weight Z-score more than older children. In Exhibit 12.3B, height changes for peritoneal dialysis and hemodialysis patients by age are shown.

Growth for rhGH-treated and untreated dialysis patients by age is shown in Exhibit 12.4. Treated patients are patients who had consistently reported rhGH use at baseline, 6 months, and one year.

Similarly, untreated patients are patients who had consistently reported no rhGH use at baseline, 6 months, and one year. There are 2 control groups, all untreated patients and those untreated patients whose baseline height Z-score was worse than –1.88 (short control). Older cases without growth hormone show no increase in standardized height in either control group versus 0.3 increase in Z-score for the older growth hormone treated cases. The growth hormone treated 0-5 year olds had a 1-year increase in height Z score or 0.81 standard deviations vs 0.57 in short controls and 0.06 in all controls. The 0-1 year old patients were examined separately with all groups experiencing some catch-up growth, 1.05 standard deviations for GH treated patients, 0.76 for short controls and 0.24 for all controls (data not shown).

EXHIBIT 12.1
HEIGHT Z SCORES
MEAN AND SE AT FOLLOW-UP

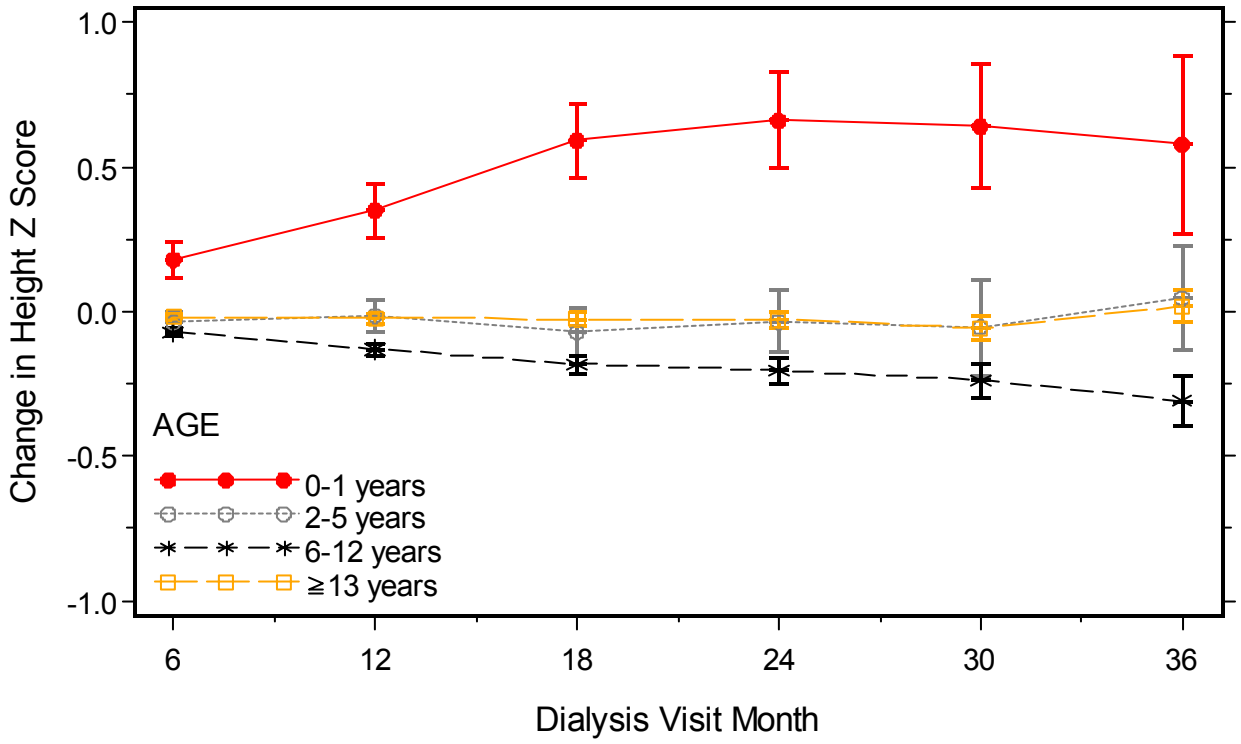
	Month 1			Month 6			Month 12			Month 24		
	N	**Mean**	**SE**	**N**	**Mean**	**SE**	**N**	**Mean**	**SE**	**N**	**Mean**	**SE**
Total	4570	-1.61	0.02	3515	-1.67	0.03	2331	-1.70	0.03	1025	-1.77	0.05
Modality												
PD	3045	-1.70	0.03	2463	-1.75	0.03	1641	-1.75	0.04	691	-1.78	0.06
HD	1524	-1.44	0.04	1052	-1.47	0.05	689	-1.59	0.07	333	-1.75	0.09
Missing	1	-0.61	0.00	0	0.00	0.00	1	-4.56	0.00	1	-1.68	0.00
Gender												
Male	2515	-1.72	0.03	1908	-1.77	0.04	1295	-1.80	0.04	571	-1.83	0.06
Female	2055	-1.47	0.04	1607	-1.55	0.04	1036	-1.58	0.05	454	-1.70	0.07
Age												
0-1 years	584	-2.56	0.07	510	-2.43	0.07	360	-2.25	0.09	144	-2.09	0.12
2-5 years	478	-1.94	0.07	367	-2.01	0.08	225	-2.07	0.10	93	-1.95	0.14
6-12 years	1440	-1.63	0.04	1075	-1.71	0.05	703	-1.73	0.06	317	-1.95	0.08
>12 years	2068	-1.25	0.03	1563	-1.31	0.04	1043	-1.41	0.05	471	-1.51	0.08
Baseline Height Deficit												
< 3%	1825	-3.21	0.03	1284	-3.07	0.03	852	-2.99	0.04	384	-2.93	0.07
>= 3%	2741	-0.54	0.02	1876	-0.67	0.02	1216	-0.73	0.03	515	-0.89	0.05
Missing	4	-2.20	0.66	355	-1.87	0.09	263	-2.03	0.10	126	-1.82	0.11

EXHIBIT 12.2
WEIGHT Z SCORES
MEAN AND SE AT FOLLOW-UP

	Month 1			Month 6			Month 12			Month 24		
	N	**Mean**	**SE**	**N**	**Mean**	**SE**	**N**	**Mean**	**SE**	**N**	**Mean**	**SE**
Total	4730	-1.15	0.03	3574	-1.09	0.03	2381	-1.06	0.04	1018	-1.09	0.05
Modality												
PD	3115	-1.26	0.03	2469	-1.13	0.03	1661	-1.05	0.04	683	-0.98	0.06
HD	1614	-0.94	0.05	1104	-1.00	0.06	719	-1.08	0.07	333	-1.33	0.11
Missing	1	1.30	0.00	1	1.18	0.00	1	-2.99	0.00	2	0.32	1.22
Gender												
Male	2611	-1.22	0.03	1955	-1.15	0.04	1320	-1.12	0.05	570	-1.14	0.07
Female	2119	-1.07	0.04	1619	-1.02	0.04	1061	-0.97	0.05	448	-1.04	0.08
Age												
0-1 years	631	-2.28	0.06	518	-1.98	0.08	369	-1.67	0.10	147	-1.05	0.14
2-5 years	506	-1.15	0.07	375	-1.07	0.08	234	-0.99	0.10	95	-0.99	0.15
6-12 years	1482	-1.11	0.04	1102	-1.07	0.05	734	-1.06	0.06	334	-1.23	0.08
>12 years	2111	-0.85	0.04	1579	-0.82	0.05	1044	-0.85	0.06	442	-1.02	0.09
Baseline Weight Deficit												
< 3%	1503	-3.16	0.03	1056	-2.86	0.04	702	-2.61	0.05	309	-2.45	0.09
≥ 3%	3223	-0.21	0.02	2242	-0.23	0.03	1470	-0.26	0.03	613	-0.38	0.05
Missing	4	-1.52	0.56	276	-1.32	0.11	209	-1.46	0.13	96	-1.28	0.19

EXHIBIT 12.3A
MEAN CHANGE FROM BASELINE (30 day) IN STANDARDIZED SCORE

Change in Height Z Score



Change in Weight Z Score

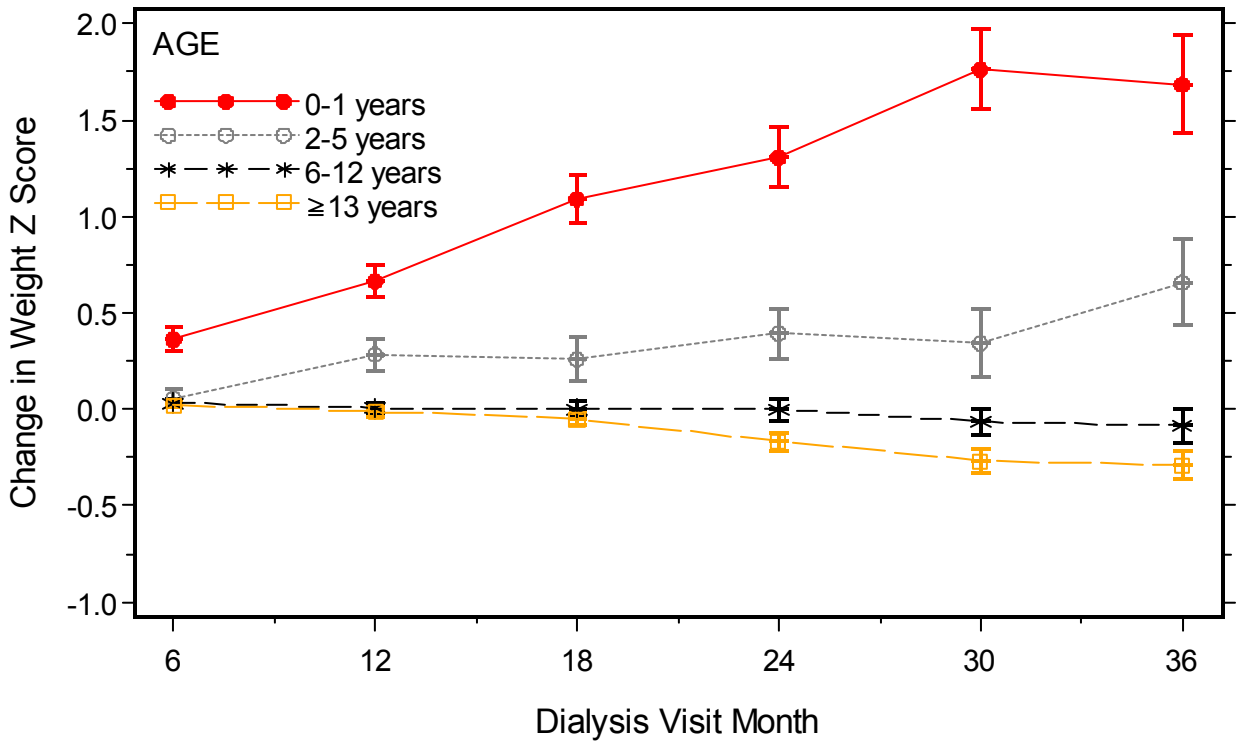
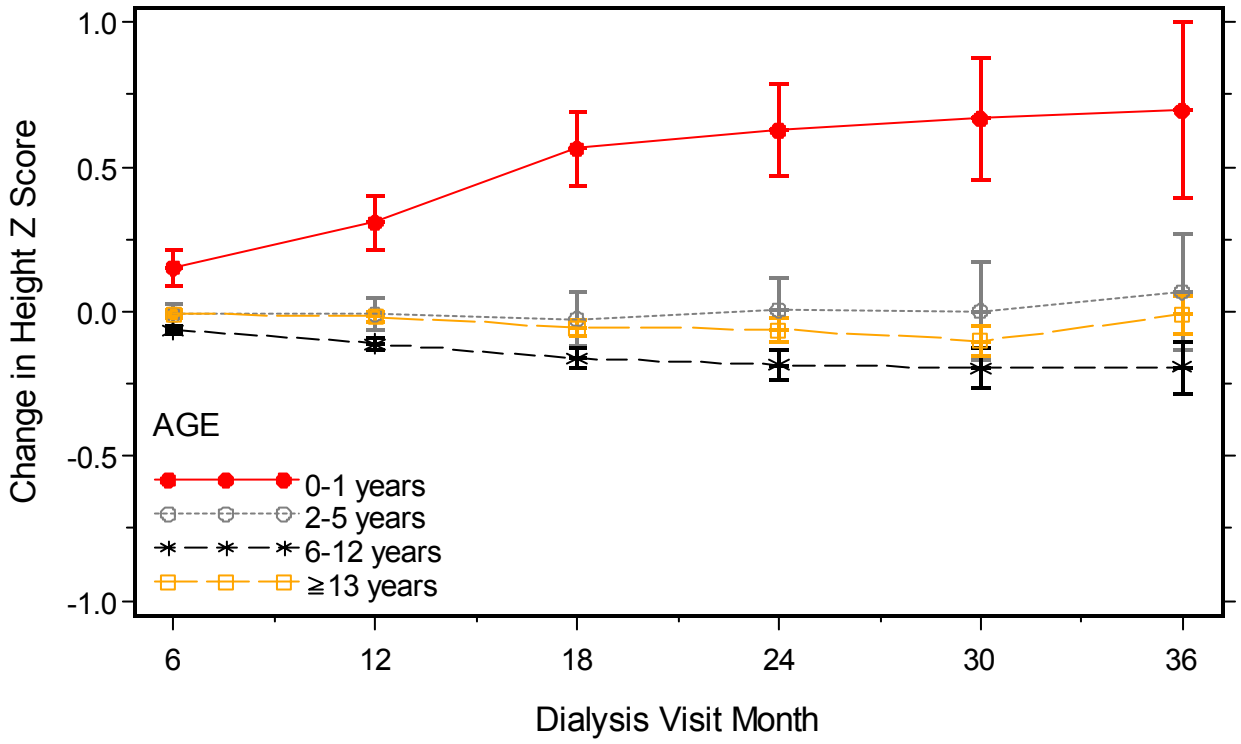


EXHIBIT 12.3B
MEAN CHANGE FROM BASELINE (30 day) IN STANDARDIZED HEIGHT SCORE

Peritoneal Dialysis: Change in Height Z Score



Hemodialysis: Change in Height Z Score

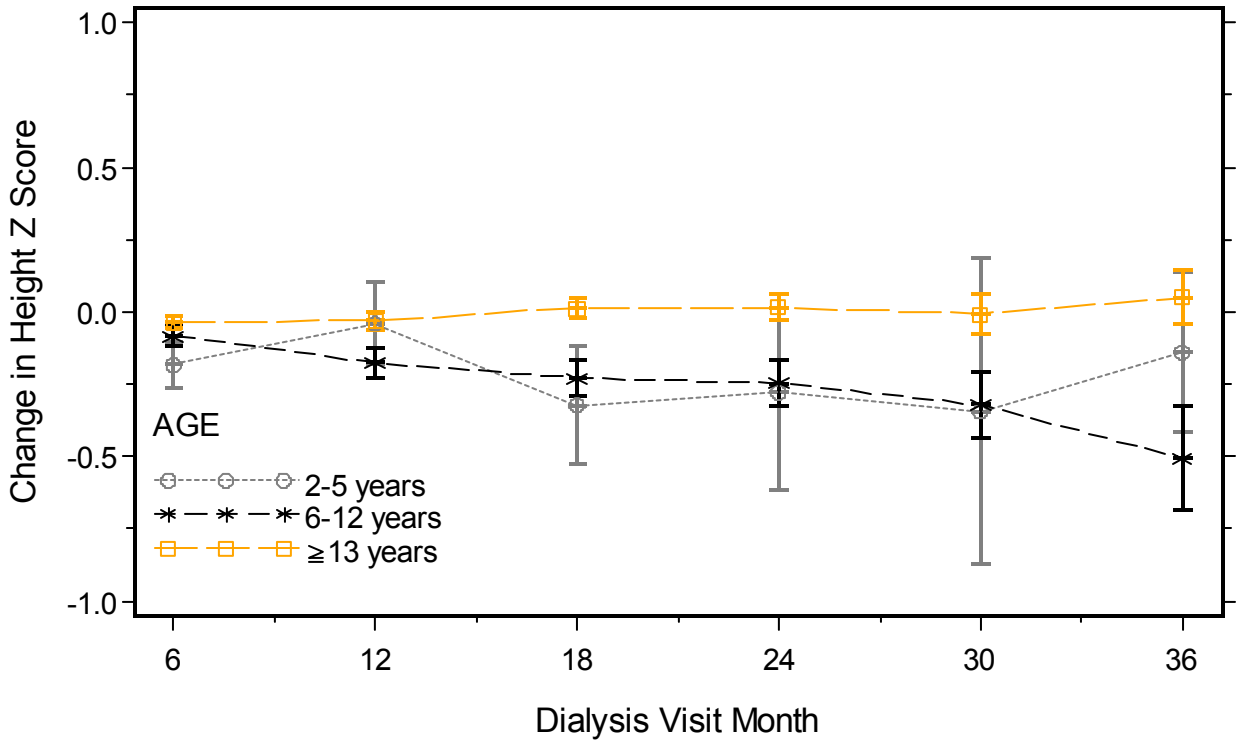


EXHIBIT 12.4
12 MONTH GROWTH DATA BY AGE

	rhGH (n=144)				Short Controls (n=554)				All Untreated Patients (1614)			
	N	Mean	SE	Median	N	Mean	SE	Median	N	Mean	SE	Median
0-5 years old at Baseline	50				168				322			
Baseline Height Z score	50	-2.65	0.20	-2.61	168	-3.55	0.10	-3.25	322	-2.18	0.10	-1.97
12 Month Height Z score	50	-1.84	0.21	-1.73	168	-2.97	0.11	-2.80	322	-2.11	0.09	-2.04
Change in Height Z score	50	0.81	0.13	0.68	167	0.57	0.10	0.43	321	0.06	0.08	-0.00
Baseline BMI Z score	33	1.05	0.19	1.10	51	0.08	0.23	0.44	132	0.27	0.13	0.59
12 Month BMI Z score	46	1.13	0.20	1.15	71	0.57	0.19	0.89	170	0.54	0.11	0.80
Change in BMI Z score	33	0.17	0.22	-0.04	51	0.36	0.22	0.17	132	0.18	0.12	0.10
>6 years old at Baseline	94				386				1292			
Baseline Height Z score	94	-2.40	0.14	-2.55	386	-3.19	0.06	-2.84	1292	-1.27	0.05	-1.13
12 Month Height Z score	94	-2.10	0.15	-1.98	386	-3.19	0.06	-2.95	1292	-1.39	0.04	-1.23
Change in Height Z score	94	0.30	0.03	0.27	385	0.00	0.03	-0.02	1289	-0.10	0.01	-0.08
Baseline BMI Z score	94	-0.16	0.14	-0.20	375	-0.29	0.07	-0.31	1271	-0.09	0.04	-0.09
12 Month BMI Z score	94	-0.05	0.14	-0.06	364	-0.29	0.07	-0.19	1252	-0.09	0.04	-0.08
Change in BMI Z score	94	0.11	0.07	0.18	362	0.01	0.06	0.02	1245	0.01	0.02	-0.00

SECTION 13: CKD PATIENT DEMOGRAPHICS

As of database closure for this report, 7,037 patients with chronic kidney disease (CKD) had been registered, with 104 new cases added in 2007. Exhibits 13.1A, 13.1B, and 13.1C present the distributions of gender, race/ethnicity, year of registration, education status, and primary renal diagnosis for these patients, as well as the percent of patients in each subgroup for which the primary renal diagnosis had been confirmed by biopsy. Of these patients, 64% were male and 61% white. Thirty-seven percent of these children were not of school age; of those school aged, 93% attend school full time. The most common primary diseases were obstructive uropathy (20.7%); renal aplasia, hypoplasia, and dysplasia (17.3%), focal segmental glomerulosclerosis (8.7%), and reflux nephropathy (8.4%); patients with polycystic kidney disease comprised 4.0% of the cohort. Other renal diseases were each present in less than 3% of patients. Data on biopsy confirmation of primary diagnosis pertain to the 6,631 (of 7,037) patients for whom we know whether a biopsy was performed. Of these cases, 30% of diagnoses were reported to be biopsy-proven.

About one-third of patients (32.0%) were between 6 and 12 years of age at entry into the study; 20.2% were less than 24 months and 3.7% were over 17 years old (Exhibit 13.2). Note that we do not collect information on age at time of CKD diagnosis. Exhibit 13.3 presents age- and race-specific percentages of selected diagnoses. About 56% of all patients have a structural anomaly. The prevalence of FSGS among blacks is three times that of whites (19% vs. 6%), and is particularly high among black adolescents, comprising 35% of this subgroup.

Information on baseline pubertal status, as measured by Tanner stage, is presented in Exhibit 13.4. Among males, reporting of baseline Tanner stage data is 80.7% complete. Missing data, however, are most prevalent among the 13 - 17 (26.8%) age group. Among females, reporting of baseline Tanner stage data is 79.4% complete. Again, missing data are most prevalent among the 13 - 17 (28.4%) age group. Among patients between 13 and 17 years of age at CKD registration, females are reported to be more physically mature: 67.0% of girls in this age group were Tanner stage IV or V, compared to 56.2% of boys.

Mean baseline laboratory measurements are presented in Exhibit 13.5. Mean serum creatinine is 2.3 mg/dL, ranging from 1.5 to 3.0 mg/dL, concordant with age. The mean Schwartz calculated creatinine clearance is 38.7 mL/min/1.73 m^2. Mean blood urea nitrogen (BUN), albumin, and carbon dioxide (CO_2) levels are 36.4 mg/dL, 3.8 g/dL, and 22.5 mEq/L, respectively. Similar data, by year of

CKD registration, are shown in Exhibit 13.6, creatinine clearance was increased from 37.3 in 1994-1995 to 41.6 since 2004.

Concomitant drug therapy is depicted in Exhibit 13.7. At baseline, 40% were being treated with anti-hypertensive medications which has increased steadily from 32% in 1994 to 48% in 2007. The use of erythropoietin has also increased from 11% in 2004 to 26% in 2007. The percentages of patients receiving alkali therapy, oral 1,25-dihydroxy vitamin D, and calcium carbonate, at registration have decreased over the years. Alkali therapy decreased from 42% in 1994 to 29% in 2007, calcium carbonate from 33% in 1994 to 17% in 2007 and oral vitamin D from 37% in 1994 to 30% in the past year. Few patients (0.5%) were treated with intravenous iron supplements; however, 28% received oral iron supplements.

Patient medical events history is shown in Exhibit 13.8. At study entry, 40% of patients had been diagnosed with fluid and electrolyte abnormalities. Urologic surgery had been performed in 31% decreasing over time from 38% (1994) to 20% (2007). The incidence of urinary tract infections (31% in our population) has also decreased from 35% in 1994 to 15% in 2007. 3% of patients had already undergone orthopedic surgery and 7% have had seizures.

Baseline renal function, by age at entry, is presented in Exhibit 13.9. Schwartz calculated creatinine clearance (mL/min/1.73 m^2) is reported according to the NKF K/DOQI guidelines: 11.7% of the CKD patients are stage 5 (cGFR <15), 26.1% are stage 4 (cGFR 15-29), 44.4% are stage 3 (cGFR 30-59) and 16.9% are stage 2 (cGFR 60-89). For comparison, in prior NAPRTCS reports cGFR was presented as <10 (4.1% of the CKD patients), 10-24 (25.4%), 25-49 (39.1%) and $\geq$50 (30.5%). Approximately 27% of infants are registered with a cGFR <15 mL/min/1.73 m^2 compared to 8% of children $\geq$2 years at registration.

Mean height, weight and BMI standardized Z-scores at entry are shown in Exhibit 13.10. Note that BMI norms are not available for children under 2 years of age. On average, patients were about 1.44 standard deviations below age- and sex-specific norms for height, and 0.88 standard deviations below weight norms. BMI Z score averaged a positive 0.21. Patients who entered the study at 13 years of age or older had less severe height (-0.92) and weight (-0.15) deficits, and a positive BMI Z score of 0.25. Grouped Z-score data are shown in Exhibits 13.11A (height) and 13.11B (weight), by age. More than 35% of the patients are less than the third percentile for height (Z score below -1.88). In infants (<1 year of age) this increases to 58% in the lower 3rd percentile, while 22% of children >12 are in this category. Corresponding deficits in weight are also seen.

Baseline renal function, by height Z-score, is depicted in Exhibit 13.12, 56% of patients with cGFR <15 mL/min/1.73 m^2 are severely height deficient, while 18% of patients with calculated clearance $\geq$ 60 have a height Z-score worse than -1.88. The average Z-score is –2.24 for cGFR <15 and -0.75. for patients with cGFR $\geq$ 60. Exhibit 13.13 shows baseline renal function by height Z-score stratified by age. Exhibit 13.14 presents patient characteristics by height SDS.

EXHIBIT 13.1A
CKD PATIENT CHARACTERISTICS

	All Patients		Renal Biopsy Confirmed Diagnosis	
	N	%	N	%
Total	7037	100.0	6631	29.8
Gender				
Male	4506	64.0	4247	26.7
Female	2522	35.8	2376	35.4
Race /Ethnicity				
White	4276	60.8	4033	25.7
Black	1310	18.6	1235	40.7
Hispanic	970	13.8	919	32.2
Other	471	6.7	438	31.5
Year of Registration				
1994-1995	2273	32.3	2208	27.5
1996-1997	1383	19.7	1323	30.9
1998-1999	891	12.7	855	32.7
2000-2001	794	11.3	742	29.6
2002-2003	630	9.0	576	31.9
2004-2005	726	10.3	643	30.0
2006-2007	340	4.8	284	29.2
Education Status				
Not of School Age	2588	36.8	2431	14.6
Completed HS	171	2.4	165	49.7
School age grades 1-12	4122	58.6	3926	37.9
Missing	156	2.2	109	49.7
Education Status (Grades 1-12)				
Attends school full-time	3817	92.6	3636	37.5
Attends school part-time	130	3.2	124	38.7
Receives home schooling only	75	1.8	72	47.2
Not attending school, capable	49	1.2	47	42.6
Not attending school, incapable	51	1.2	47	40.4

Note: Missing for gender (n=9) and race (n=10) are not included.

EXHIBIT 13.1B
CKD PRIMARY DIAGNOSIS

	All Patients		Renal Biopsy Confirmed Diagnosis	
	N	%	N	%
Total	7037	100.0	6631	29.8
Primary Diagnosis				
Obstructive uropathy	1454	20.7	1399	8.1
A/hypo/dysplastic kidney	1220	17.3	1154	7.0
FSGS	613	8.7	604	93.9
Reflux nephropathy	594	8.4	566	7.1
Polycystic disease	278	4.0	265	20.0
Prune Belly	193	2.7	182	11.5
Renal infarct	158	2.2	153	5.2
HUS	141	2.0	132	28.8
SLE nephritis	114	1.6	112	88.4
Familial nephritis	111	1.6	106	63.2
Cystinosis	104	1.5	92	8.7
Pyelo/interstitial nephritis	99	1.4	92	55.4
Medullary cystic disease	90	1.3	84	61.9
Chronic GN	82	1.2	81	75.3
Congenital nephrotic syndrome	75	1.1	70	71.4
MPGN - Type I	75	1.1	72	97.2
Berger's (IgA) nephritis	66	0.9	66	100.0
Idiopathic crescentic GN	47	0.7	46	87.0
Henoch-Schonlein nephritis	43	0.6	42	85.7
Membranous nephropathy	37	0.5	37	94.6
Wilms tumor	32	0.5	31	67.7
MPGN - Type II	30	0.4	30	100.0
Other systemic immunologic	26	0.4	24	83.3
Wegener's granulomatosis	25	0.4	25	92.0
Sickle cell nephropathy	14	0.2	13	76.9
Diabetic GN	11	0.2	11	45.5
Oxalosis	7	0.1	7	28.6
Drash syndrome	6	0.1	6	83.3
Other	1110	15.8	961	27.6
Unknown	182	2.6	168	22.6

EXHIBIT 13.1C
CKD PRIMARY DIAGNOSIS BY GENDER AND RACE

	N	%Male	%White	%Black	%Other
Total	7037	64.1	60.9	18.6	20.5
Primary Diagnosis					
Obstructive uropathy	1454	85.7	61.6	21.0	17.4
A/hypo/dysplastic kidney	1220	62.7	61.6	17.0	21.4
FSGS	613	58.1	39.2	39.5	21.2
Reflux nephropathy	594	53.1	73.4	5.9	20.7
Polycystic disease	278	55.6	71.2	11.2	17.6
Prune Belly	193	96.9	61.5	22.9	15.5
Renal infarct	158	53.2	66.5	12.7	20.9
HUS	141	55.3	81.6	7.8	10.6
SLE nephritis	114	26.3	27.2	40.4	32.5
Familial nephritis	111	83.8	59.5	13.5	27.0
Cystinosis	104	50.0	91.3	3.8	4.8
Pyelo/interstitial nephritis	99	39.4	64.6	19.2	16.2
Medullary cystic disease	90	47.8	82.2	7.8	10.0
Chronic GN	82	47.6	43.9	26.8	29.3
Congenital nephrotic syndrome	75	44.0	46.7	10.7	42.7
MPGN - Type I	75	58.7	49.3	20.0	30.7
Berger's (IgA) nephritis	66	62.1	62.1	15.2	22.7
Idiopathic crescentic GN	47	48.9	51.1	25.5	23.4
Henoch-Schonlein nephritis	43	62.8	76.7	4.7	18.6
Membranous nephropathy	37	48.6	29.7	37.8	32.4
Wilms tumor	32	53.1	62.5	18.8	18.8
MPGN - Type II	30	73.3	80.0	3.3	16.7
Other systemic immunologic disease	26	80.8	80.8	7.7	11.5
Wegener's granulomatosis	25	32.0	40.0	32.0	28.0
Sickle cell nephropathy	14	64.3	0.0	92.9	7.1
Diabetic GN	11	50.0	36.4	45.5	18.2
Oxalosis	7	71.4	85.7	0.0	14.3
Drash syndrome	6	100.0	66.7	0.0	33.3
Other	1110	58.8	63.0	15.4	21.5
Unknown	182	53.8	47.2	20.0	32.4

EXHIBIT 13.2
PATIENT AGE AT CKD REGISTRATION

	All Patients	
	N	%
Total	7036	100.0
Age at CKD Registration		
0 (<12 months)	1054	15.0
1 (12-23 months)	368	5.2
2 years	268	3.8
3 years	280	4.0
4 years	259	3.7
5 years	297	4.2
6 years	268	3.8
7 years	273	3.9
8 years	313	4.4
9 years	311	4.4
10 years	307	4.4
11 years	391	5.6
12 years	392	5.6
13 years	408	5.8
14 years	457	6.5
15 years	429	6.1
16 years	379	5.4
17 years	321	4.6
18-20 years	261	3.7
Age Grouping		
0-1 year	1422	20.2
2-5 years	1104	15.7
6-12 years	2255	32.0
13-17 years	1994	28.3
>17 years	261	3.7

NOTE: One case with missing age is not included.

EXHIBIT 13.3
DISTRIBUTION OF PRIMARY DIAGNOSES CATEGORIES BY AGE AND RACE*

	N	% Structural	% GN	% FSGS	% Other
Total	7026*	55.9	7.8	8.7	27.7
Age at Registration					
0-1 year	1422	73.0	0.4	0.6	26.0
2-5 years	1102	64.2	2.1	6.0	27.8
6-12 years	2251	58.2	6.4	7.7	27.7
>12 years	2251	38.7	16.5	16.2	28.7
White Patients	**4275**	**59.3**	**6.3**	**5.6**	**28.8**
0-1 year	859	72.5	0.3	0.3	26.8
2-5 years	677	63.8	1.3	5.6	29.2
6-12 years	1421	61.2	5.3	5.6	27.8
>12 years	1318	46.4	13.7	9.0	31.0
Black Patients	**1310**	**49.5**	**10.1**	**18.5**	**22.0**
0-1 year	254	81.1	0.0	0.4	18.5
2-5 years	181	72.9	1.7	3.3	22.1
6-12 years	350	53.7	7.1	14.6	24.6
>12 years	525	23.2	19.8	35.0	21.9
Hispanic Patients	**970**	**51.6**	**9.5**	**10.1**	**28.8**
0-1 year	201	67.2	1.0	2.0	29.9
2-5 years	165	58.2	4.8	9.7	27.3
6-12 years	333	52.0	9.0	10.5	28.5
>12 years	271	35.8	19.2	15.9	29.2
Patients of Other Race	**471**	**51.0**	**11.3**	**6.8**	**31.0**
0-1 year	108	68.5	0.9	0.0	30.6
2-5 years	79	59.5	3.8	7.6	29.1
6-12 years	147	53.1	9.5	5.4	32.0
>12 years	137	29.9	25.5	13.1	31.4

*Patients missing race or age are not included.

EXHIBIT 13.4
BASELINE TANNER STAGE

Males (Testicular size)

	Total	Missing Data	Available	Tanner Percent Distribution*				
	N	%	N	I	II	III	IV	V
All Males	4506	19.3	3635	67.3	8.7	6.2	8.1	9.7
Age at Entry								
0-1 year	1005	14.9	855	99.8	0.2	--	--	--
2-5 years	728	11.1	647	100.0	--	--	--	--
6-12 years	1369	20.1	1094	81.4	14.5	2.9	0.9	0.3
13-17 years	1244	26.8	910	6.4	16.6	20.9	29.6	26.6
>17 years	159	18.9	129	--	3.1	2.3	10.9	83.7

* Percent of non-missing values

Females (Breast development)

	Total	Missing Data	Available	Tanner Percent Distribution*				
	N	%	N	I	II	III	IV	V
All Females	2522	20.6	2002	60.2	8.9	7.0	8.9	14.8
Age at Entry								
0-1 year	414	15.0	352	99.7	0.3	--	--	--
2-5 years	374	11.5	331	100.0	--	--	--	--
6-12 years	886	20.9	701	71.6	16.1	6.3	4.6	1.4
13-17 years	746	28.4	534	3.9	11.6	17.4	26.2	40.8
>17 years	102	17.6	84	1.2	3.6	4.8	8.3	82.1

* Percent of non-missing values

EXHIBIT 13.5
BASELINE LABORATORY MEASUREMENTS
MEANS

Laboratory Measurement	Available N	All Patients Mean	Age at Registration (in years)			
			0-1	2-5	6-12	>12
Systolic blood pressure (mm Hg)	6691	114.0	98.6	105.8	114.0	126.2
Diastolic blood pressure (mm Hg)	6691	68.1	58.0	63.6	69.2	74.4
Serum creatinine (mg/dL)	7013	2.3	1.5	1.6	2.3	3.0
Creatinine clearance*	6969	38.7	28.6	41.8	41.7	40.7
Blood urea nitrogen (mg/dL)	6783	36.4	29.3	35.9	38.8	38.7
Inorganic phosphorous (mg/dL)	6299	5.1	5.6	5.2	5.1	4.8
Albumin (g/dL)	5878	3.8	3.8	3.9	3.9	3.7
Hematocrit (%)	6264	33.8	33.1	33.6	33.6	34.4
Carbon dioxide (mEq/L)	6540	22.5	22.3	22.0	22.5	22.7
Calcium (mg/dL)	6567	9.5	10.1	9.7	9.3	9.1
Alkaline phosphotase (IU/mL)	5169	260.9	359.5	256.5	267.7	201.5

*Schwartz calculated creatinine clearance (mL/min/1.73 m^2).

EXHIBIT 13.6
BASELINE LABORATORY MEASUREMENTS
MEANS BY YEAR OF CKD REGISTRATION

	CKD Registration Year														
	1994 - 1995			1996 - 1997			1998 - 2000			2001 - 2003			2004 - 2007		
Laboratory Measurement	N	Mean	SE	N	Mean	SE	N	Mean	SE	N	Mean	SE	N	Mean	SE
Systolic blood pressure (mm Hg)	2178	113.5	0.4	1328	114.6	0.5	1229	114.4	0.6	973	113.7	0.6	983	114.2	0.6
Diastolic blood pressure (mm Hg)	2178	68.2	0.3	1328	68.8	0.4	1229	68.7	0.4	973	67.1	0.5	983	66.9	0.5
Serum creatinine (mg/dL)	2270	2.3	0.0	1382	2.2	0.0	1282	2.3	0.0	1019	2.2	0.1	1060	2.2	0.1
Creatinine clearance*	2263	37.3	0.4	1377	38.6	0.5	1272	37.8	0.5	1009	40.4	0.6	1048	41.6	0.7
Blood urea nitrogen (mg/dL)	2195	37.2	0.4	1336	35.7	0.6	1237	37.5	0.6	980	35.3	0.6	1035	35.1	0.6
Inorganic phosphorous (mg/dL)	2119	5.1	0.0	1279	5.1	0.0	1106	5.1	0.0	864	5.2	0.0	931	5.1	0.0
Albumin (g/dL)	1901	4.0	0.0	1171	3.8	0.0	1060	3.7	0.0	855	3.7	0.0	891	3.8	0.0
Hematocrit (%)	1989	33.5	0.1	1243	33.5	0.2	1171	33.3	0.2	908	34.4	0.2	953	34.7	0.2
Carbon dioxide (mEq/L)	2133	22.5	0.1	1282	22.0	0.1	1192	22.4	0.1	949	22.7	0.1	984	22.7	0.1
Calcium (mg/dL)	2134	9.6	0.0	1285	9.4	0.0	1177	9.4	0.0	961	9.4	0.0	1010	9.5	0.0
Alkaline phosphotase (IU/mL)	1862	261.7	3.5	1132	259.3	5.0	989	267.7	5.6	639	258.7	6.8	547	251.3	8.0

*Schwartz calculated creatinine clearance (mL/min/1.73 m^2).

EXHIBIT 13.7
BASELINE CONCOMINANT DRUG THERAPY
PERCENT BY YEAR OFCKD REGISTRATION

Concomitant Drug Therapy	CKD Registration Year														
	Total	**1994**	**1995**	**1996**	**1997**	**1998**	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**
Anticonvulsant	3.7	3.3	4.4	3.8	4.2	3.4	4.4	3.3	2.5	5.2	2.6	3.1	4.3	2.6	3.8
Antihypertensives	40.1	31.9	35.1	38.4	39.6	39.3	46.2	44.3	44.1	45.2	46.2	45.0	51.9	45.9	48.0
Prophylactic Antibiotics	27.4	30.4	26.3	27.4	25.4	28.6	28.6	27.5	27.7	26.7	28.5	26.1	24.2	24.3	28.2
Sevelamer Hydrochloride	2.5	0.0	0.0	0.0	0.0	0.0	6.7	0.0	0.0	1.5	2.2	2.8	3.2	2.2	5.9
Alkali Therapy	33.9	41.5	39.1	34.2	34.3	28.5	34.0	32.5	31.7	31.9	25.2	28.4	24.9	22.9	29.1
Immumosuppressives	10.7	6.4	8.5	10.5	9.6	11.3	13.3	12.3	11.3	13.9	15.4	15.0	13.2	13.4	14.6
Lipid Lowering Agents	2.8	0.0	0.0	0.0	0.0	0.0	3.2	2.6	1.5	3.6	3.3	3.6	2.6	3.0	0.0
Oral Vitamin D	31.7	37.0	35.2	29.9	28.6	28.4	34.5	32.2	31.8	29.1	27.0	29.2	25.9	26.4	30.1
Other Vitamin D Compounds	6.4	8.0	7.8	8.0	7.2	5.6	4.6	6.3	2.5	3.8	4.8	5.0	5.4	5.2	8.7
Oral Iron	27.8	21.2	27.6	22.6	27.4	27.9	30.0	32.2	29.3	33.6	28.8	35.3	33.7	32.3	27.9
Intravenous Iron	0.5	0.1	0.5	0.1	0.4	1.3	0.2	0.3	0.0	1.5	0.7	1.1	1.4	0.4	0.0
Parenteral Nutrition	1.0	0.7	1.3	1.0	0.7	0.8	0.5	1.8	1.0	1.2	1.1	1.4	1.1	1.3	1.0
Supplemental Enteral Nutrition	10.5	10.8	11.1	8.3	11.2	9.8	12.6	12.2	10.1	10.8	11.4	11.2	9.7	5.2	6.7
Calcium Carbonate	29.9	32.8	34.9	32.1	32.6	27.4	33.3	32.9	27.0	29.4	22.6	20.0	20.2	21.1	17.3
Calcium Acetate	2.6	2.5	2.8	3.2	2.2	3.4	1.2	1.3	1.8	0.9	2.6	2.8	5.4	5.6	1.0
Other Calcium Supplements	2.8	3.4	3.0	2.1	3.0	1.5	2.4	2.8	2.5	3.2	3.3	3.9	1.7	2.6	5.8
Erythropoietin	18.4	11.3	14.3	15.1	19.4	18.6	21.1	24.9	24.7	25.7	23.0	23.1	22.3	21.8	26.2
Human Growth Hormone	6.3	7.7	7.8	6.2	3.7	3.0	5.6	6.6	5.8	8.7	8.0	5.3	5.7	5.1	6.8
Number at Risk	**7037**	**1165**	**1108**	**715**	**668**	**474**	**417**	**397**	**397**	**350**	**280**	**368**	**358**	**236**	**104**

EXHIBIT 13.8
BASELINE MEDICAL EVENTS HISTORY
PERCENT BY YEAR OFCKD REGISTRATION

Medical event	CKD Registration Year														
	Total	**1994**	**1995**	**1996**	**1997**	**1998**	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**
Urologic Surgery	31.4	38.3	35.6	35.7	28.6	30.9	32.6	28.2	29.5	28.1	26.5	24.8	21.4	19.5	20.2
Orthopedic Surgery	3.1	3.5	3.3	2.1	3.6	2.5	4.6	3.8	3.8	0.9	3.7	1.1	3.4	3.0	0.0
Urinary Tract Infection	30.5	35.4	35.6	34.1	31.5	32.0	31.7	29.7	26.2	25.3	26.6	23.5	19.2	17.9	14.6
Hip X-ray	6.5	9.3	9.1	6.0	5.9	4.0	7.7	8.6	4.5	5.2	2.6	2.5	3.2	2.6	10.6
Seizures	7.0	7.6	8.9	7.4	8.5	4.9	8.5	8.1	3.5	6.7	5.5	4.2	4.9	5.5	3.8
Renal Biopsy	21.8	17.3	22.9	22.1	25.0	23.8	26.9	21.7	21.2	23.2	21.0	20.7	18.7	21.7	20.2
Fluid/Electrolyte Abnormalities	40.2	41.9	45.6	47.9	45.3	42.1	48.3	33.3	34.0	36.2	30.4	32.0	33.0	23.1	20.4
Blood Transfusions	9.1	9.2	10.1	10.9	10.1	9.1	11.6	11.6	7.8	9.6	4.0	5.9	5.2	5.5	4.8
Number at Risk	**7037**	**1165**	**1108**	**715**	**668**	**474**	**417**	**397**	**397**	**350**	**280**	**368**	**358**	**236**	**104**

EXHIBIT 13.9
BASELINE RENAL FUNCTION

	All Patients		Age at CKD Registration							
			0-1 year		2-5 years		6-12 years		>12 years	
	N	%	N	%	N	%	N	%	N	%
Total	7037	100.0	1422	100.0	1104	100.0	2255	100.0	2255	100.0
Calculated GFR										
<15	822	11.7	381	26.8	81	7.3	181	8.0	179	7.9
15-29	1836	26.1	468	32.9	256	23.2	528	23.4	584	25.9
30-59	3123	44.4	465	32.7	527	47.7	1077	47.8	1053	46.7
60+	1188	16.9	91	6.4	225	20.4	457	20.3	415	18.4
Missing	68	1.0	17	1.2	15	1.4	12	0.5	24	1.1

EXHIBIT 13.10
BASELINE HEIGHT SDS, WEIGHT SDS AND BMI SDS

	Height SDS			Weight SDS			BMI SDS		
	N	Mean	SE	N	Mean	SE	N	Mean	SE
All Patients	6907	-1.44	0.02	6918	-0.88	0.02	5542	0.21	0.02
Age									
0-1 year	1349	-2.34	0.05	1390	-2.22	0.05	--	--	--
2-5 years	1087	-1.64	0.05	1096	-1.11	0.05	1093	0.20	0.05
6-12 years	2238	-1.32	0.03	2241	-0.66	0.03	2247	0.17	0.03
12-17 years	1978	-0.92	0.03	1969	-0.15	0.04	1977	0.26	0.03
>17 years	255	-0.90	0.11	222	-0.17	0.12	225	0.11	0.11
Gender									
Male	4425	-1.44	0.03	4437	-0.90	0.03	3457	0.23	0.02
Female	2482	-1.43	0.03	2481	-0.85	0.04	2085	0.16	0.03

EXHIBIT 13.11A
BASELINE HEIGHT SDS

	All Patients		Age at CKD Registration							
			0-1 year		2-5 years		6-12 years		>12 years	
	N	%	N	%	N	%	N	%	N	%
Total	6907	100.0	1349	100.0	1087	100.0	2238	100.0	2233	100.0
Height SDS										
-1.88 or worse	2455	35.5	786	58.3	448	41.2	727	32.5	494	22.1
-1.88 to 0	3233	46.8	457	33.9	524	48.2	1110	49.6	1142	51.1
Better than 0	1219	17.6	106	7.9	115	10.6	401	17.9	597	26.7

EXHIBIT 13.11B
BASELINE WEIGHT SDS

	All Patients		Age at CKD Registration							
			0-1 year		2-5 years		6-12 years		>12 years	
	N	%	N	%	N	%	N	%	N	%
Total	6918	100.0	1390	100.0	1096	100.0	2241	100.0	2191	100.0
Weight SDS										
-1.88 or worse	1894	27.4	808	58.1	312	28.5	470	21.0	304	13.9
-1.88 to 0	2843	41.1	476	34.2	550	50.2	997	44.5	820	37.4
Better than 0	2181	31.5	106	7.6	234	21.4	774	34.5	1067	48.7

EXHIBIT 13.12
BASELINE RENAL FUNCTION BY HEIGHT Z SCORE

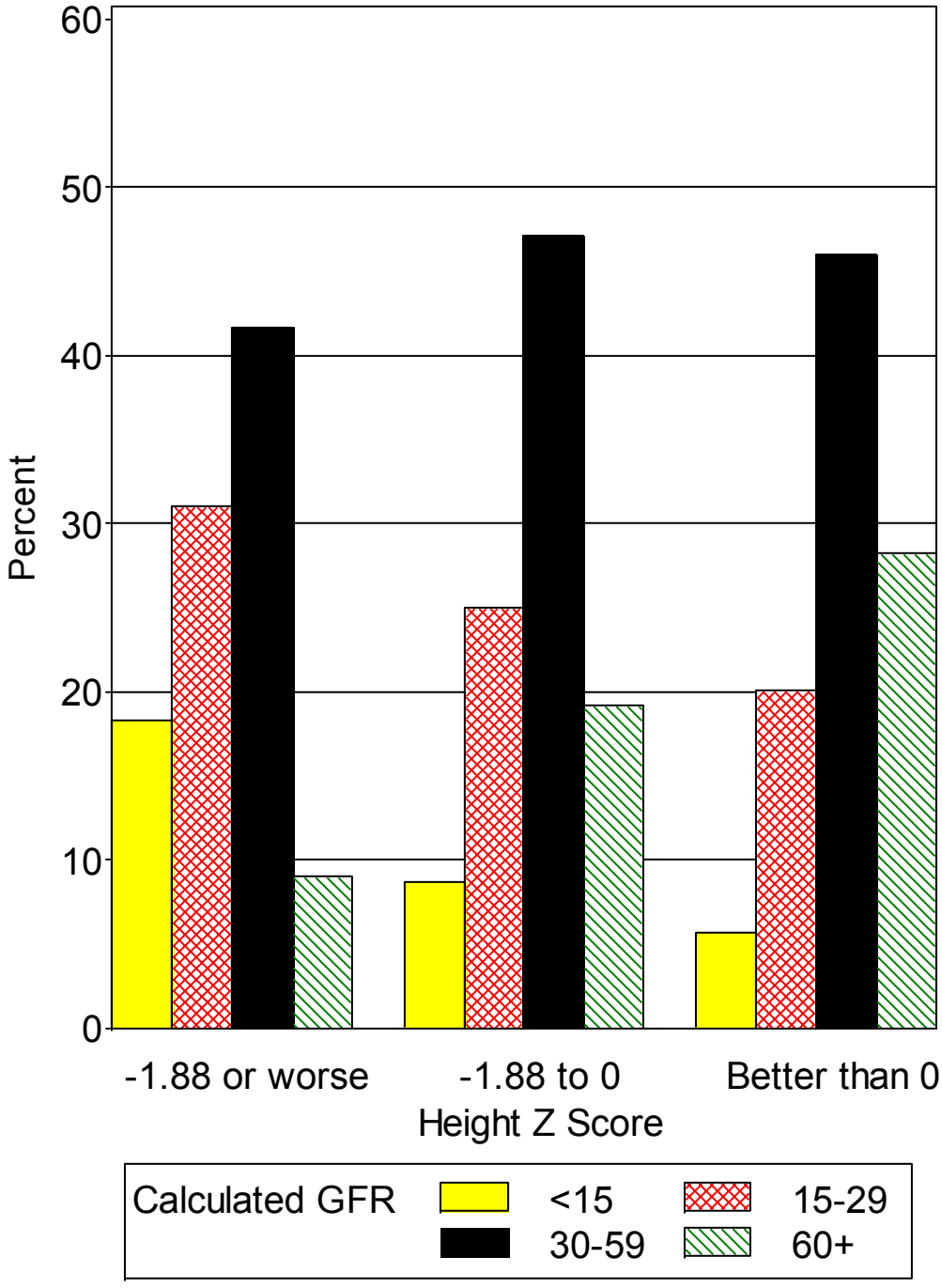


EXHIBIT 13.13
BASELINE RENAL FUNCTION BY HEIGHT Z SCORE

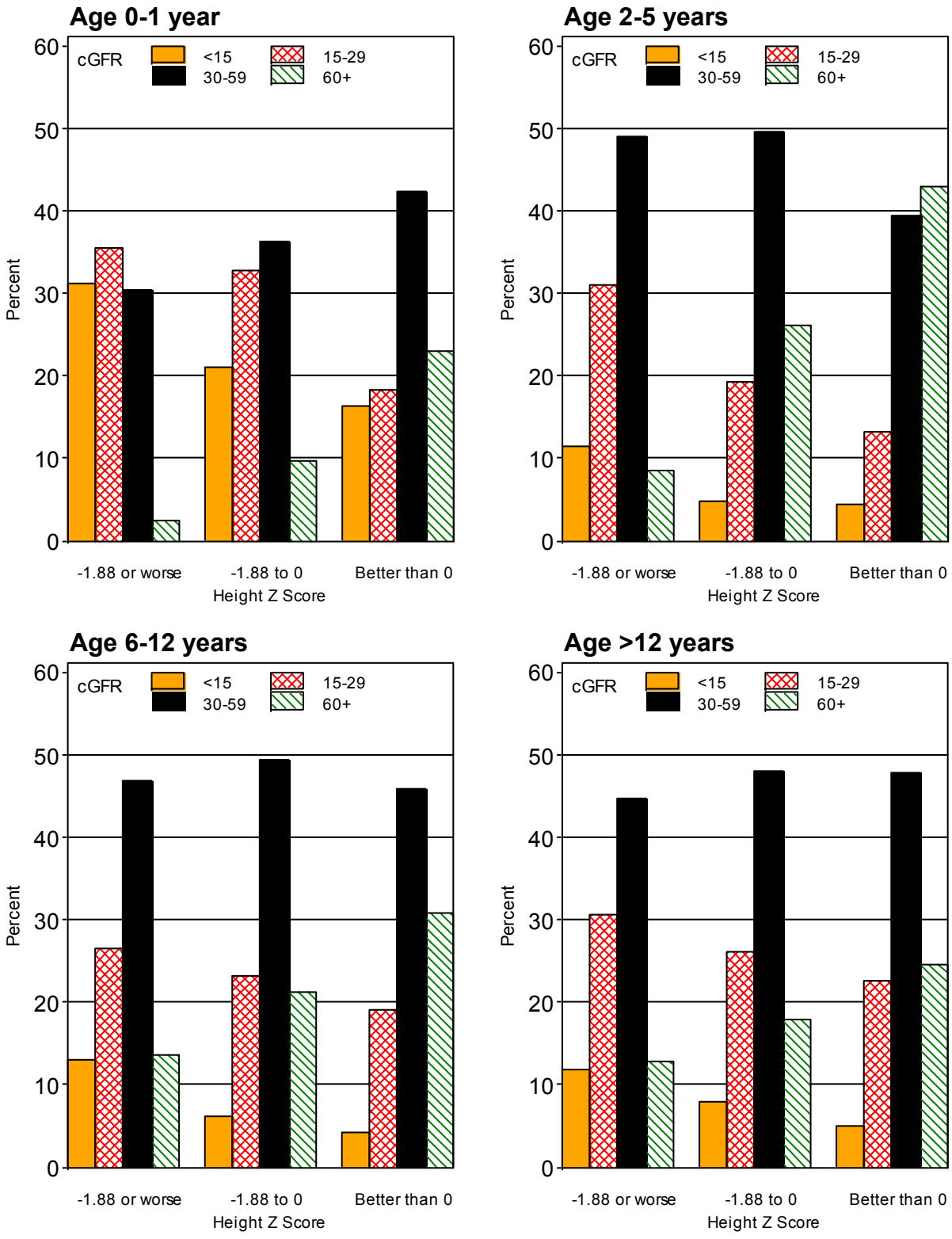
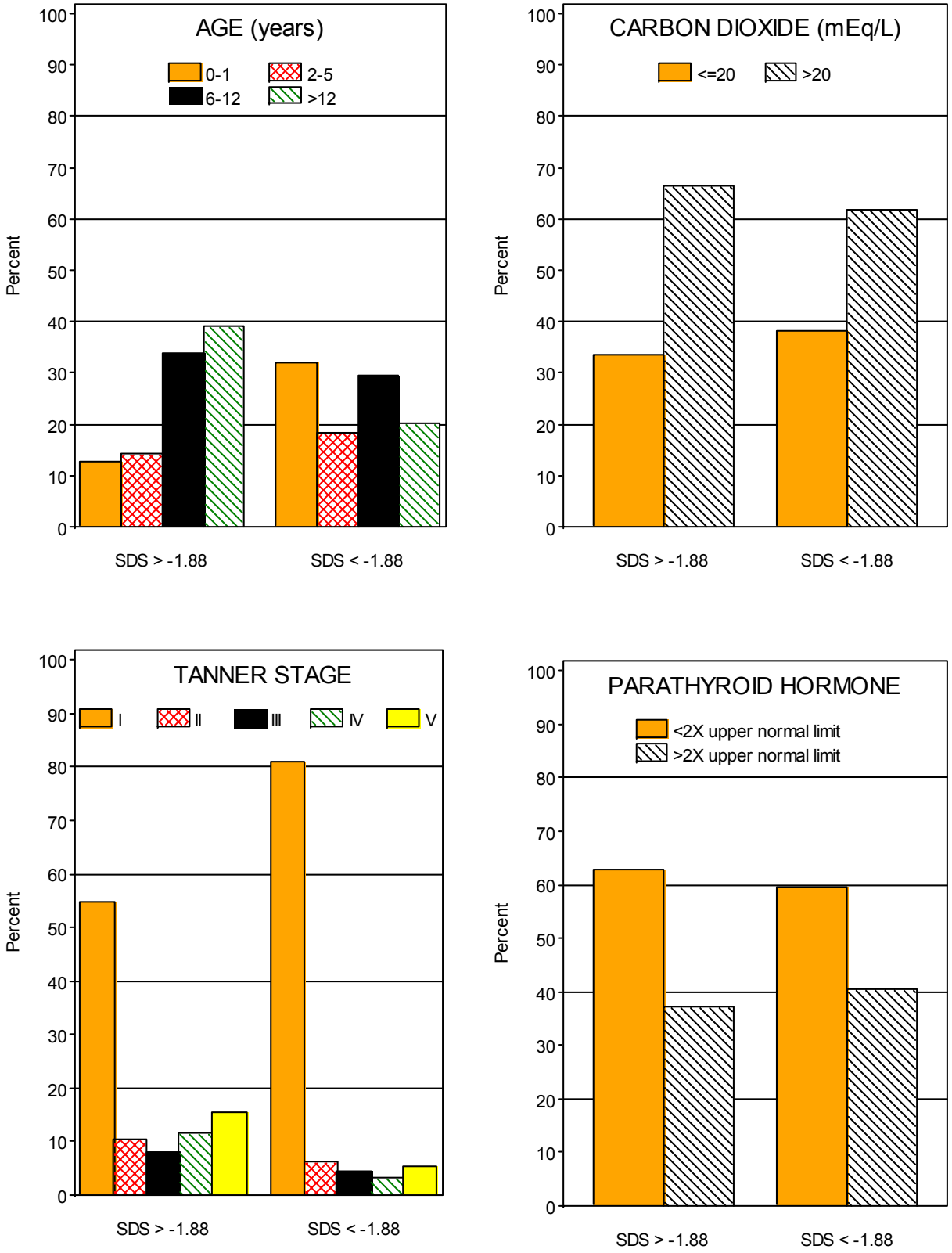


EXHIBIT 13.14
BASELINE HEIGHT SDS BY SELECTED PATIENT CHARACTERISTICS



SECTION 14: TERMINATION OF CHRONIC KIDNEY DISEASE STATUS

As of database closure, there have been 3,236 reports of termination from the chronic kidney disease (CKD) representing 46% of 7,037 registered cases, as summarized in Exhibit 14.1. In the absence of a CKD Termination Form, the date of termination was established by the independent report of maintenance dialysis initiation or renal transplantation. Note that this occurred only seven times in the data file. There are a total of 2,790 CKD cases with progression to ESRD, which is defined as either receiving a transplant or initiating dialysis. The majority of ESRD cases (60.1%) were due to dialysis initiation. Apparent preemptive transplant patients accounted for about 39.9% of ESRD related terminations. Patient death as a reason for termination is uncommon occurring in 118 (3.6%) with cardiopulmonary and infection complications being the leading causes. Other causes of termination include transfer to adult program, transfer to another hospital, lost to follow-up and administrative closure.

CKD termination is further characterized in Exhibit 14.2. Shown for each patient characteristic are the numbers of patients and terminations, the percent terminated, and the percentage distribution of reasons for termination, including transplantation and dialysis initiation. There is a noticeable difference in the percentage of white versus black patients who terminated the CKD Registry by receiving a transplant (42% vs. 17%), while transplant as the reason of termination is also common in patients with higher albumin (45%) and lower in patients with FSGS (19%). Age at entry, primary diagnosis, baseline renal function and laboratory readings are statistically important, independent predictors of progression to ESRD. Multivariate Cox regression analyses of progression to ESRD, where ESRD is defined as terminating the registry because of transplant or dialysis, are summarized in Exhibit 14.3. Since a significant portion (3,503/7,037 or 49.8%) of CKD patients had no baseline parathyroid hormone level (PTH) information (unknown or not reported), analyses including and excluding baseline PTH as a factor are both presented in Exhibit 14.3. The estimates of relative risk of progression to ESRD were similar in both columns of the table. The results revealed that primary diagnoses was a significant factor: compared to Focal Segmental Glomerulosclerosis (FSGS) patients, patients with other primary diagnosis were less likely (RH ~ 0.4 to 0.7) to progress to ESRD. The risk of progression to ESRD was also inversely proportional to baseline calculated creatinine clearance (mL/min/1.73 m^2), but concordant with age. Moreover, patient whose baseline albumin was below 4 g/dL, inorganic phosphorous above 5.5 mg/dL, calcium below 9.5 mg/dL, BUN above 20 mq/dL or hematocrit below 33% had significantly higher risk of reaching ESRD ($p<0.001$).

By 12, 24, and 36 months following the initial CKD report, 16.3%, 28.2%, and 36.1% of cases, respectively, had reached ESRD (Exhibit 14.4). As indicated previously, rate of progression to ESRD is inversely proportional to baseline renal function, as displayed in the table below and in Exhibit 14.5. Estimates of progression rate to ESRD according to patient race, sex, age at entry, and primary diagnosis are presented in Exhibit 14.6. Baseline laboratory results by progression to ESRD are presented in Exhibit 14.7. Race-specific rates are shown in Exhibit 14.8 for termination due solely to transplantation (first panel) or dialysis initiation (second panel).

CKD PROGRESSION TO ESRD PERCENTAGES (±STANDARD ERRORS)					
CKD Follow-up (months)	Baseline Creatinine Clearance (mL/min/1.73 m^2)				
	<10	10 - 25	25 - 50	≥50	ALL
12	53.0±3.1	35.9±1.2	9.5±0.6	3.9±0.5	16.3±0.5
24	67.8±3.0	54.0±1.3	21.6±0.9	9.1±0.7	28.2±0.6
36	74.8±2.9	63.7±1.3	30.3±1.0	14.0±0.9	36.1±0.7
48	78.9±2.8	70.0±1.3	38.5±1.2	17.7±1.1	42.4±0.7
60	82.0±2.8	74.8±1.3	45.0±1.3	21.8±1.2	47.9±0.8

EXHIBIT 14.1
CKD TERMINATION SUMMARY

	N	%
Total CKD Registrations	7037	100.0
Total CKD Terminations	3236	46.0
Reason for Termination		
Kidney Transplant	1113	34.4
Dialysis initiation	1677	51.8
Native renal function regained	96	3.0
Patient death	118	3.6
Other	229	7.1
Missing	3	0.1
All CRI Terminations	3236	100.0

EXHIBIT 14.2
CKD TERMINATION BY SELECTED PATIENT CHARACTERISTICS AT BASELINE

	Number of Patients	Number of Terminations	Percent Terminations	Reason for Termination (%)				
				Transplant	Dialysis	Native Function Returned	Death	Other/ Unknown
All CKD Terminations	7037	3236	46.0	34.4	51.8	3.0	3.6	7.2
Creatinine Clearance								
<10	291	221	75.9	28.1	67.4	0.5	3.2	0.9
10-24	1787	1212	67.8	39.2	54.1	0.2	3.4	3.1
25-49	2748	1212	44.1	34.9	51.4	2.9	4.0	6.8
50+	2143	567	26.5	25.4	42.0	10.2	3.5	18.9
Missing	68	24	35.3	37.5	45.8	0.0	4.2	12.5
Race								
White	4276	1944	45.5	42.0	45.0	2.4	3.4	7.3
Black	1310	625	47.7	17.0	68.0	3.2	4.3	7.5
Hispanic	970	452	46.6	27.2	57.3	4.6	2.9	8.0
Other	471	215	45.6	31.6	55.3	4.2	5.1	3.7
Missing	10	0	0.0	--	--	--	--	--
Gender								
Male	4515	2036	45.1	35.9	50.0	3.1	3.3	7.7
Female	2522	1200	47.6	31.8	54.8	2.8	4.3	6.3
Age at Entry								
0-1 years	1423	581	40.8	32.2	47.0	8.6	6.5	5.7
2-5 years	1104	503	45.6	39.0	48.5	3.4	4.0	5.2
6-12 years	2255	1148	50.9	37.6	51.9	1.5	3.0	5.9
13-17 years	1994	906	45.4	30.9	56.8	1.3	2.0	8.9
>17 years	261	98	37.5	18.4	50.0	0.0	7.1	24.5

EXHIBIT 14.2
CKD TERMINATION BY SELECTED PATIENT CHARACTERISTICS AT BASELINE (continued)

	Number of Patients	Number of Terminations	Percent Terminations	Reason for Termination (%)				
				Transplant	Dialysis	Native Function Returned	Death	Other/ Unknown
Primary Diagnosis								
Obstructive Uropathy	1454	648	44.6	40.4	45.4	3.5	2.0	8.6
Renal Plasias	1220	576	47.2	42.5	45.3	3.0	4.2	5.0
Reflux Nephropathy	594	196	33.0	39.3	43.9	3.1	1.5	12.2
FSGS	613	368	60.0	19.0	73.1	1.6	1.1	5.2
Other/Unk/Missing	3156	1448	45.9	31.7	53.0	3.0	5.1	7.2
Albumin (g/dL)								
≤ 4	3204	1670	52.1	28.1	59.1	2.6	3.9	6.2
> 4	2678	1080	40.3	44.9	39.5	3.2	2.8	9.5
Missing	1155	486	42.1	32.5	54.1	3.5	4.7	5.1
Phosphrous (mg/dL)								
≤ 5.5	4405	1831	41.6	37.4	46.9	2.5	3.7	9.5
> 5.5	1894	1115	58.9	32.1	57.4	3.5	3.0	3.9
Missing	738	290	39.3	24.5	61.4	3.8	5.5	4.8
Calcium (mg/dL)								
≤ 9.5	3220	1662	51.6	30.0	58.1	1.5	3.6	6.7
> 9.5	3358	1374	40.9	40.8	42.9	4.6	3.6	8.2
Missing	459	200	43.6	26.5	61.0	4.0	4.5	4.0
Hematocrit								
< 33 %	2653	1607	60.6	33.0	58.1	1.6	3.7	3.6
≥ 33 %	3618	1369	37.8	37.5	44.7	3.7	3.5	10.7
Missing	766	260	33.9	26.9	50.4	8.1	3.8	10.8
Parathyroid Hormone								
< 2X upper normal limit	2179	851	39.1	39.7	45.7	1.8	2.7	10.1
> 2X upper normal limit	1355	892	65.8	36.0	58.6	0.1	2.7	2.6
Unknown/Missing	3503	1493	42.6	30.4	51.2	5.4	4.8	8.2

EXHIBIT 14.3
RELATIVE HAZARD (HR) OF PROGRESSION TO ESRD

Characteristic	Comparison Group	Reference Group	PTH excluded (n=5074)		PTH included (n=2800)	
			RH	p-value	RH	p-value
Sex	Male	Female	0.94	0.172	0.99	0.907
Recipient Race	Black	Non-black	1.00	0.959	0.96	0.566
Age	6-12 years 13+ years	0-5 years	1.65 1.96	<0.001 <0.001	1.43 2.00	<0.001 <0.001
Creatinine Clearance	<10 10-24 25-49	≥50	8.93 4.41 1.99	<0.001 <0.001 <0.001	10.87 4.97 2.10	<0.001 <0.001 <0.001
Primary Diagnosis	Obst Uropathy Renal plasias Reflux Nephr Other/Unk	FSGS	0.49 0.46 0.42 0.61	<0.001 <0.001 <0.001 <0.001	0.53 0.53 0.46 0.70	<0.001 <0.001 <0.001 0.002
Albumin (g/dL)	≤4	>4	1.42	<0.001	1.46	<0.001
Phosphorus (mg/dL)	>5.5	≤5.5	1.31	<0.001	1.28	<0.001
Calcium (mg/dL)	≤9.5	>9.5	1.38	<0.001	1.31	<0.001
Hematocrit (%)	<33%	≥33%	1.29	<0.001	1.22	0.001
BUN (mg/dL)	>45 31-45 20-30	<20	2.95 2.09 1.47	<0.001 <0.001 <0.001	3.01 2.05 1.46	<0.001 <0.001 0.021
Parathyroid Hormone	<2X UNL	>2X UNL	--	--	1.34	<0.001

EXHIBIT 14.4
PROGRESSION TO ESRD

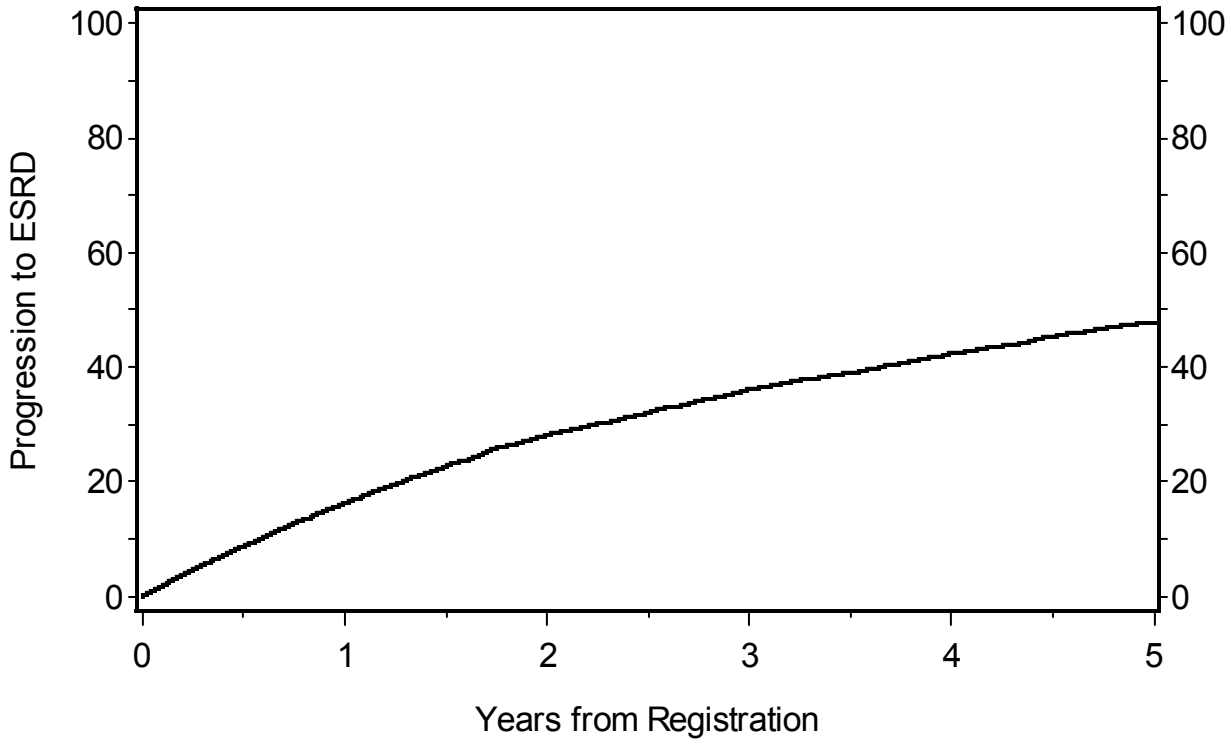


EXHIBIT 14.5
PROGRESSION TO ESRD
BY BASELINE CALCULATED CREATININE CLEARANCE (mL/min/1.73 m^2)

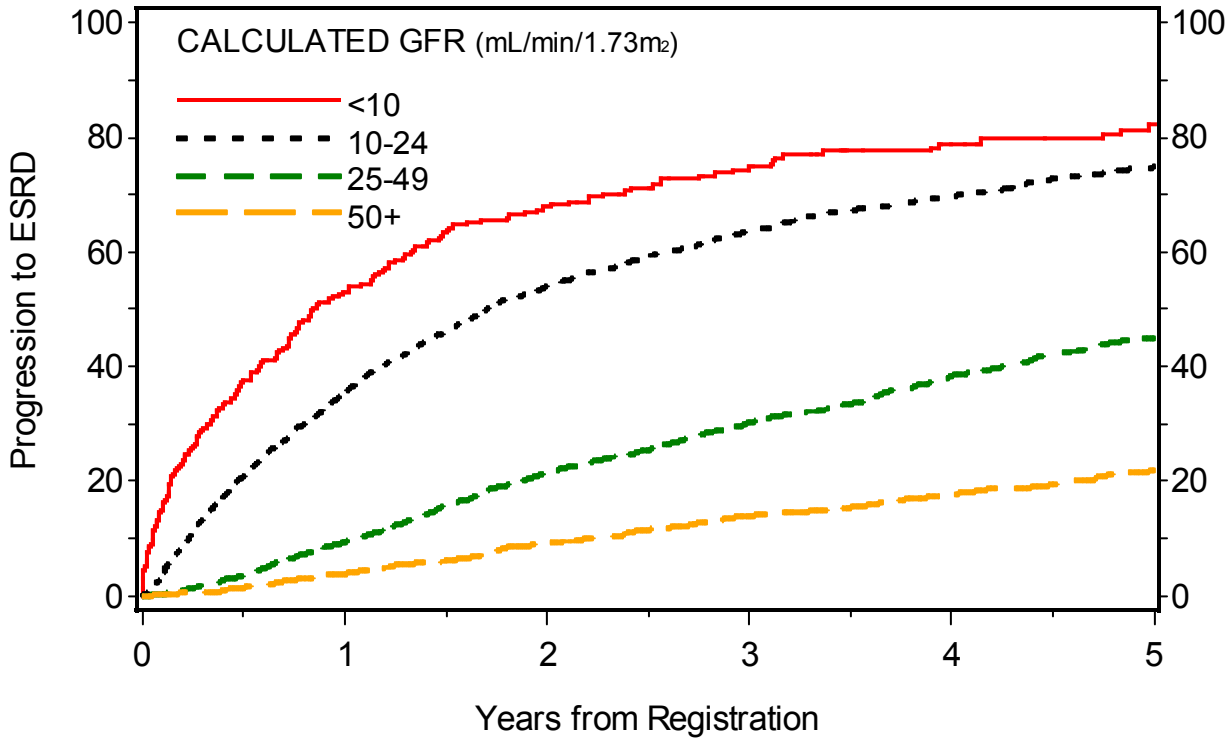
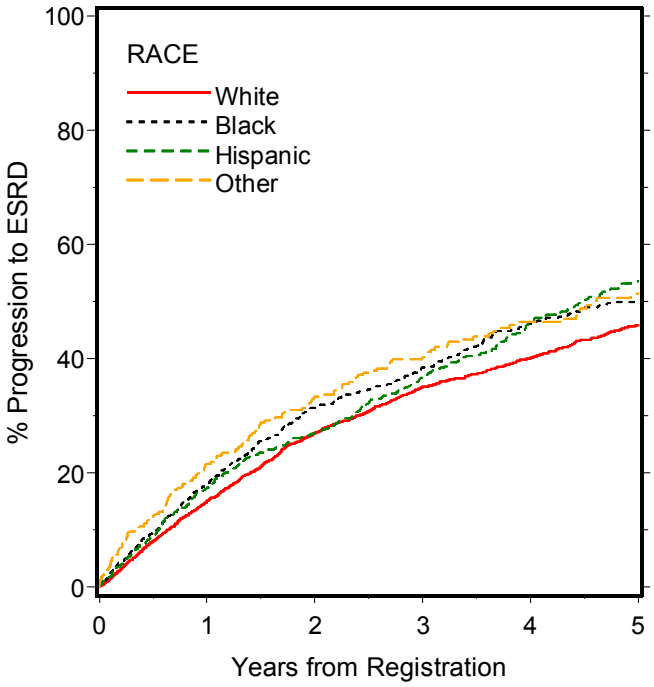
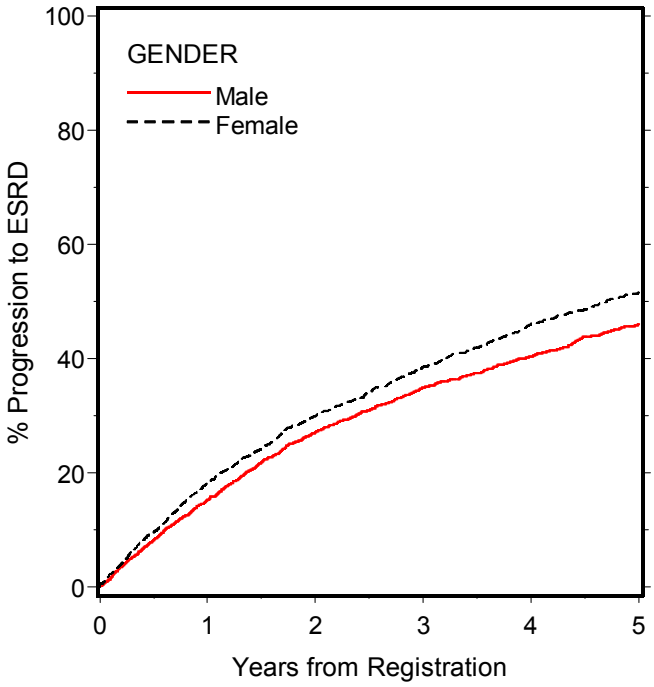
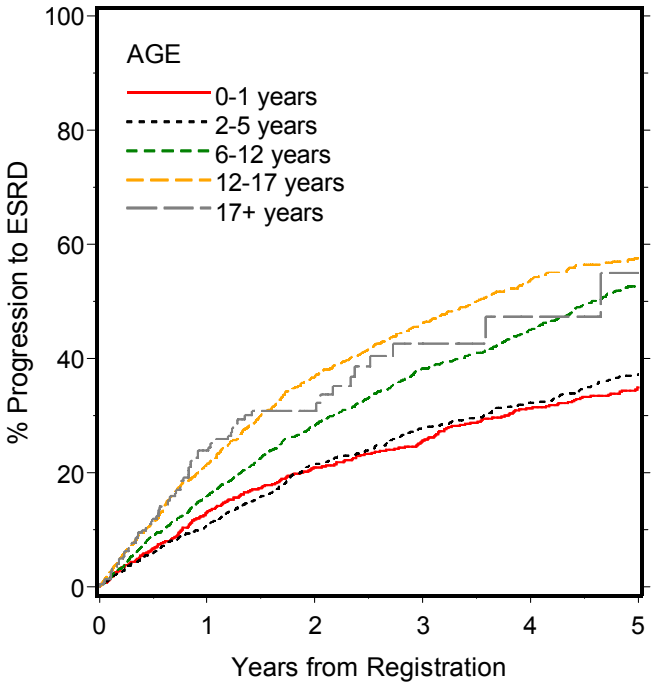


EXHIBIT 14.6
PROGRESSION TO ESRD BY SELECTED PATIENT CHARACTERISTICS







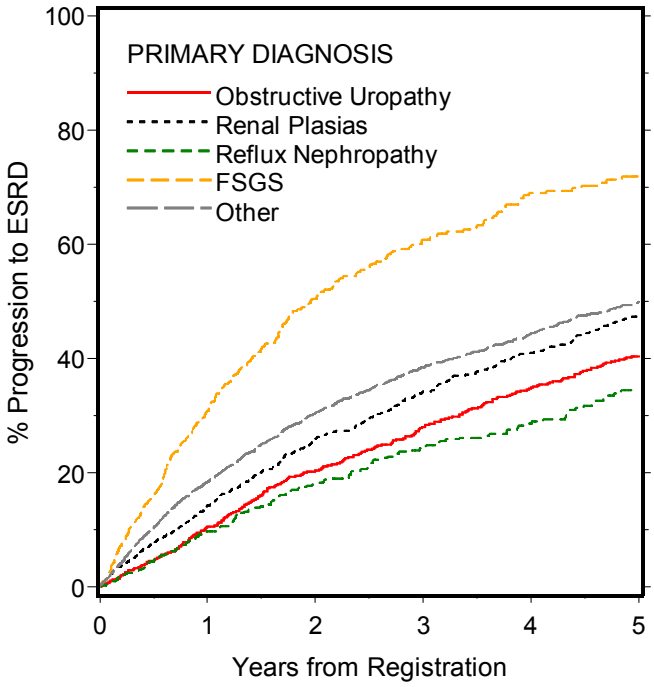
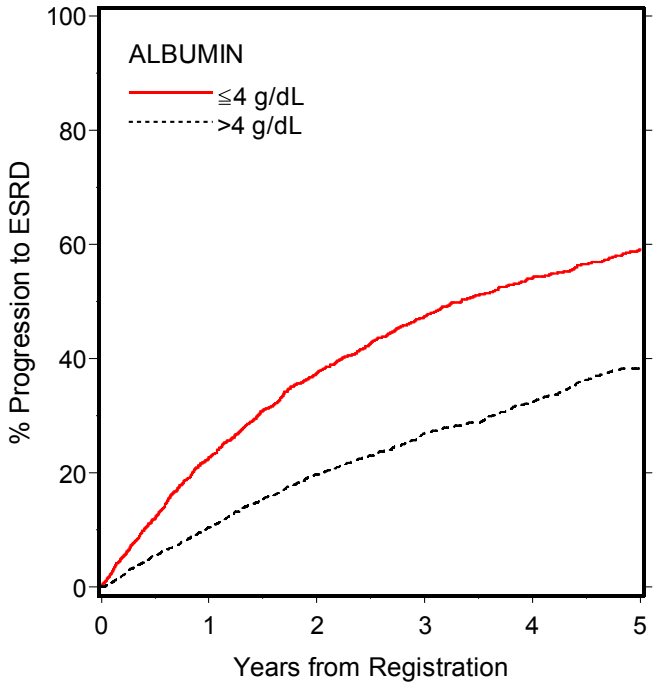
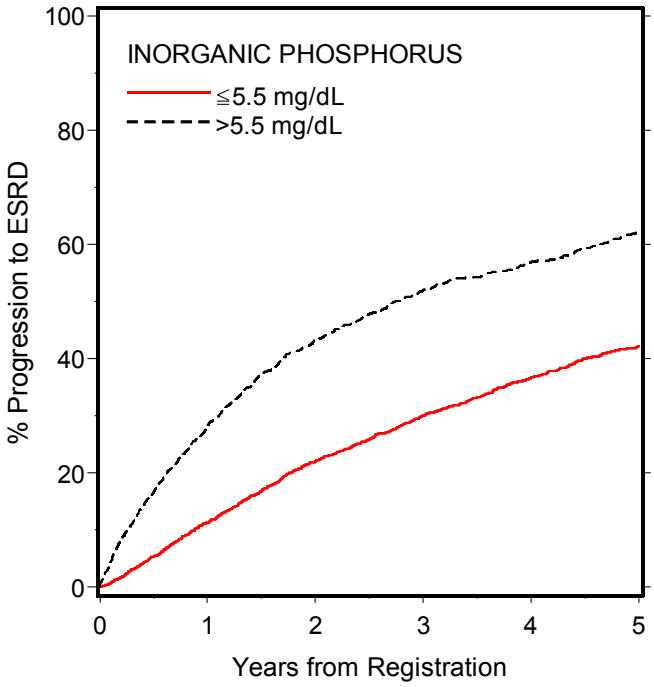
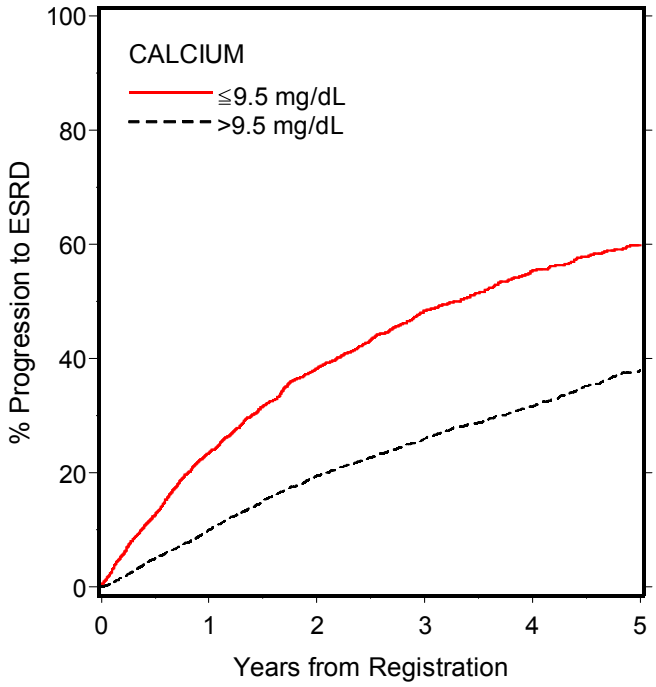


EXHIBIT 14.7
PROGRESSION TO ESRD BY SELECTED LABORATORY VALUES







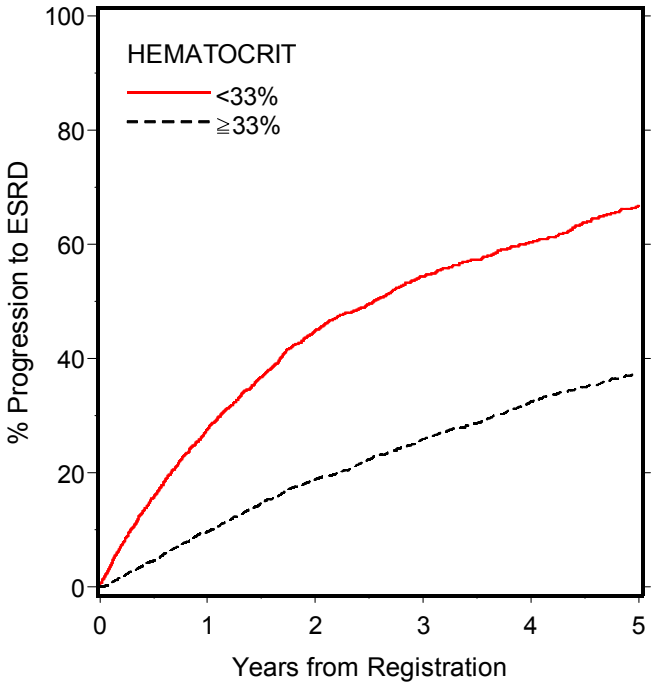
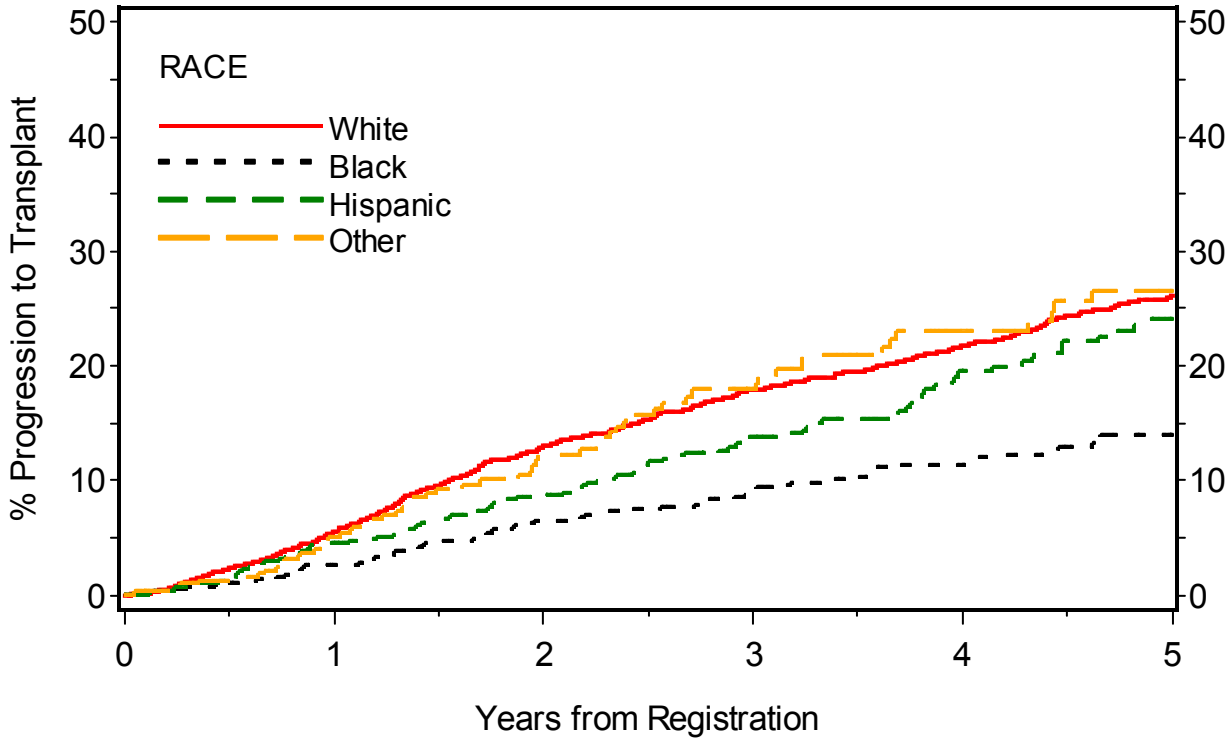
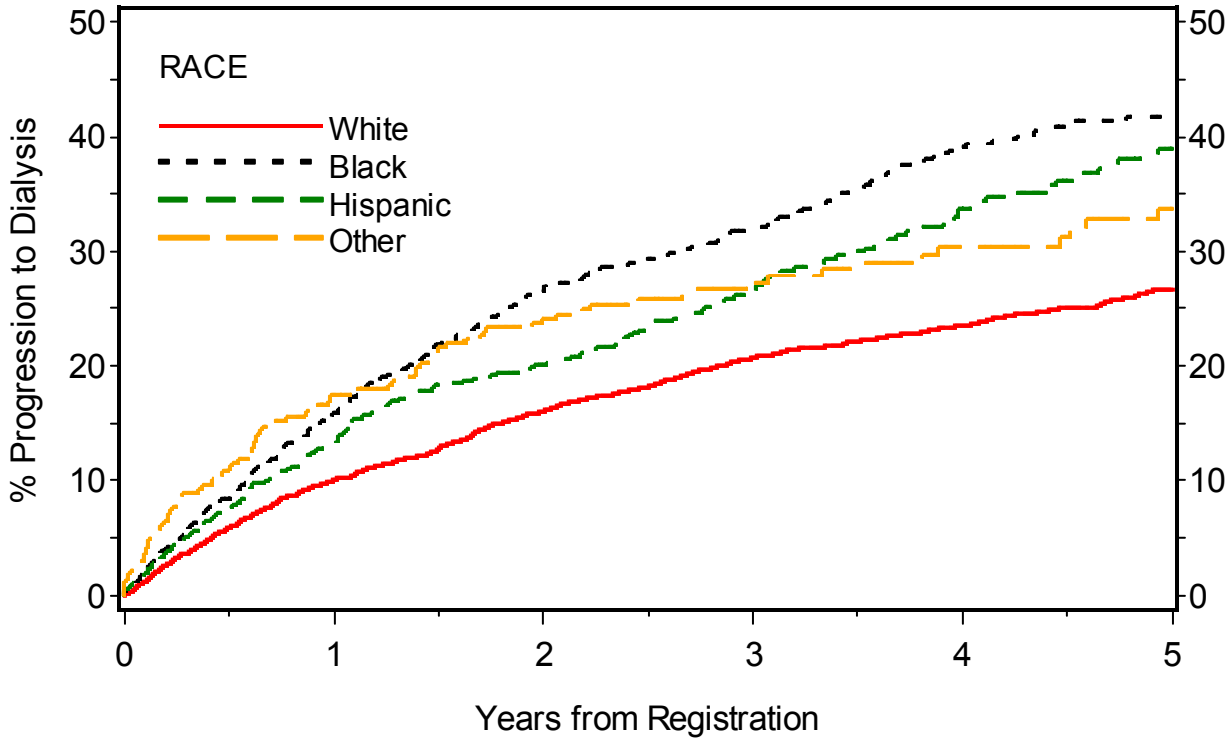


EXHIBIT 14.8

Progression to Transplant



Progression to Dialysis



SECTION 15: CKD FOLLOW-UP DATA

For the 7,037 CKD registry patients with baseline data, we have received CKD follow-up forms representing completed study visits for 5,348 patients at 6 months following registration, 4,512 patients at 12 months, and 3,153 at 24 months. In addition, at the time of database closure, forms had been received for 2,242 36-month visits, 1,604 48-month visits and 1,194 60-month visits.

Point-prevalence data are presented in Exhibit 15.1 describing the use of erythropoietin and growth hormone, parathyroid hormone (PTH) levels, medical events data, and hospitalization event data. (The PTH data exclude cases where the level was reported as "unknown" – about half of submitted forms.) At baseline, 18.4% of all patients were receiving rhEPO therapy and 6.3% were treated with rhGH. By the 24-month visit, percentage use had increased to 19.3% (EPO) and 15.9 (rhGH) of patients still being followed. Throughout 60 follow-up months, between 62% and 69% of patients had a PTH less than twice the upper normal limit. The medical events data, at baseline, describe any history of the event. For the semi-annual follow-up visits, these data describe whether the event has occurred in the last 6-month report period. About 32.7% of patients entered the study with a history of urologic surgery, during the first 6 months 6.6% had urologic surgery, with 4.6% from 6 – 12 months, 3.6% from 18 – 24 months decreasing steadily to 2.0% from 54 – 60 months. The duration and reason for hospitalizations in the 6-month report periods were collected at the semi-annual follow-up visits. Should hospitalization occur, the median duration was typically 5 days in the 6-month intervals during the first 2 years of follow-up. The main reason for hospitalization was infection, which caused 36.2% and 43.0% of all hospitalizations at the 6-month and 24-month visits.

Standardized Height and Weight

Standardized height and weight data are presented in Exhibits 15.2 - 15.5. Pediatric growth data of NHANES III made available by the CDC have been adopted as the standardization reference in this annual report. For height and weight, the mean standardized scores and mean changes from baseline in standardized Z-scores with standard errors, are shown. At baseline, patients were 1.44 Z-score *below* age- and sex-adjusted norms for height or at about the seventh percentile of their peers. Mean standardized height increases slightly over time at -1.39 ± 0.02, -1.36 ± 0.02, and -1.31 ± 0.03, respectively, at the 6-, 12-, and 24-month CKD visits.

Standardized height data are shown in Exhibit 15.2, according to age at study entry, sex, baseline calculated creatinine clearance (i.e., GFR), and baseline hematocrit values. Adolescents (≥ 13 years old) had less severe height deficits (-0.92±0.03) at baseline, relative to infants (-2.34±0.05; age <24 months) and toddlers (-1.64±0.05; age 2-5 years). The height deficit for males was the same as females (-1.44 and -1.43 at baseline), and patients with worse baseline GFR had more severe growth retardation than the patients with better baseline GFR (-2.00 for cGFR<25, -1.45 for cGFR 25-49 and -0.90 for cGFR ≥ 50 at baseline). Anemic patients (baseline Hematocrit <33%) had worse height deficit than non-anemic patients (-1.67 versus -1.31 at baseline). Mean change from baseline in height Z-score is shown in Exhibit 15.3. At 6, 12, and 24 months following study entry, the overall mean changes in height Z-score were 0.09±0.01, 0.10±0.01, and 0.18±0.02. Of patients followed at four years, mean change in height Z-score from baseline was 0.28±0.04. Infants appear to experience a period of accelerated growth over the first 6-month with a 0.45 increase in height Z-score; continued height gains are observed over the next 3 years in children who remain in the CKD component. Age-specific mean (±SE) and median change in height Z-score at the 24-month CKD visit are listed in the table below. A comparison of the mean and median scores suggests that the means are not overly affected by extreme values. Exhibits 15.4 and 15.5 present standardized data for weight and weight changes, in a format similar to that for height and height changes.

CHANGE FROM BASELINE IN HEIGHT Z SCORE AT 24 MONTHS				
Age at Registration	N	Mean	SE	Median
0-1 years	629	0.74	0.07	0.62
2-5 years	508	0.07	0.03	0.01
6-12 years	948	-0.01	0.02	-0.01
≥ 13 years	675	-0.02	0.02	-0.03

Renal Function

Renal function data are presented in Exhibit 15.6A for serum creatinine and calculated GFR. Overall kidney function for patients who remain in the registry (i.e., do not develop ESRD) is relatively stable over time. Mean serum creatinine values, with standard errors, at baseline, 6 months, 12 months, and 24 months are 2.27±0.03, 2.27±0.03, 2.27±0.03, and 2.24±0.03.

Comparable values for calculated GFR are 38.7±0.2, 41.6±0.4, 42.8±0.4, and 44.0±0.05. As indicated in Exhibit 15.6A, an increase in calculated creatinine clearance over time occurs among the youngest enrolled patients.

Data presented in Exhibits 15.6B and 15.6C include Schwartz Calculated Creatinine Clearance over time by primary diagnosis. The most dramatic decreases in cGFR are seen for patients with a primary diagnosis of FSGS.

To evaluate renal function, growth, and the use of growth hormone therapy, we defined 12- and 18-month cohorts as follows. Patients receiving rhGH therapy at baseline, 6 months, and 12 months were defined as the 12-month rhGH group. Similarly an 18-month rhGH group was defined. Untreated "all" control groups include all untreated patients, while patients in short control group had baseline height Z-score shorter than or equal to -1.88 or the third percentile of their age and gender-specific peers. Exhibit 15.7A presents the 12-month data for the rhGH patients and the two control group patients. For each outcome (i.e., height Z-score, serum creatinine, and calculated creatinine clearance), we present the mean and median baseline value, the mean and median 12-month value, and the mean and median change from baseline. Similar data for 18 months of follow-up are presented in Exhibit 15.8A. Exhibits 15.7B and 15.8B exclude 0 – 1 year olds at time of entry.

Growth Hormone Utilization

In order to investigate the utilization of recombinant human growth hormone therapy (rhGH), we identified two cohorts of patients. The first cohort was selected to assess time trends and the second to assess "current" usage; each is described below. Patients in both groups were selected based on their likelihood to be candidates for rhGH therapy, as follows: age-sex-appropriate (i.e., males <16 years old and females <15 years old), height Z-score of -1.88 or worse, and Tanner stage I, II, or III. Tanner stage is defined by testicular size for boys and breast development for girls.

The data presented in Exhibit 15.9 describe patients who, at the baseline (n=1,886), 6-month (n=1,274), or 12-month (n=988) CKD visit, satisfied the aforementioned selection criteria for age, sex, height deficit, and pubertal development. Overall, rhGH use increased from 11.1% at baseline to 22.1% by the 12-month visit. In addition to the demographic factors shown in the table, rhGH use is shown for patients according to levels of CO_2 and PTH, since clinically

optimal levels of these two parameters are desirable in order to maximize the effectiveness of growth hormone. A cross-tabulation of CO_2 and PTH levels revealed that rhGH utilization was highest at baseline among patients with CO_2>20 mEq/L and PTH greater than twice the upper normal limit. Growth hormone use was greater for patients enrolled in the earlier years (1994 and 1995) of the registry compared to the late 90s. However, these patients at baseline were more likely to have been followed by study physicians before the CKD registry was initiated, compared to patients enrolled in 1996 or later whose baseline visit is more likely to have coincided with their first physician visit. Growth hormone utilization for the subset of 680 patients who satisfied the selection criteria at all three visits (baseline, 6-month, 12-month) is described in Exhibit 15.10. Children over 12 years old, but still meeting the entrance criteria are most likely to be on growth hormone at all three time points (25.6% at baseline, 35.7% at 6 months, and 43.7% at 1 year).

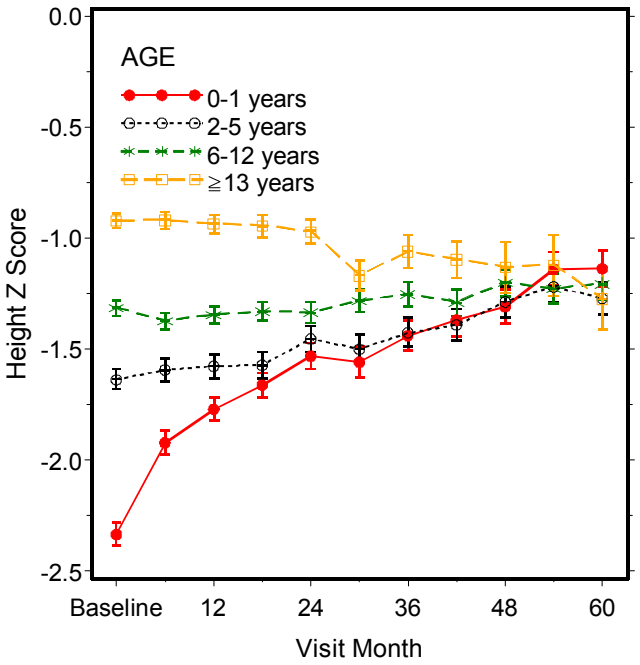
The second cohort (Exhibit 15.11) consisted of 285 patients who at their last follow-up, in addition to meeting the age, sex, height, and Tanner stage criteria, were last seen between 2000 and 2007. These patients were not terminated from the CKD registry. At this time, about 21.1% of patients were receiving rhGH therapy. Growth hormone is more commonly used in children of white race (24.1%) and children between 2-5 years of age (26.7%) (see Exhibit 15.11).

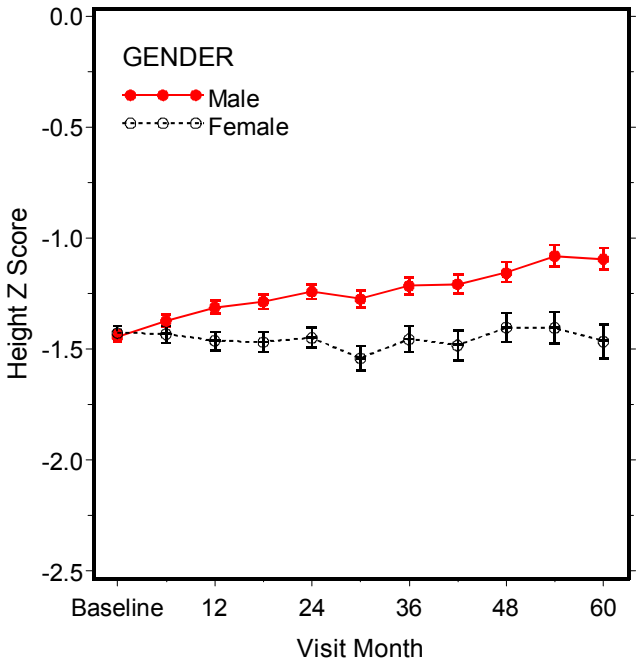
EXHIBIT 15.1
CKD FOLLOW-UP DATA

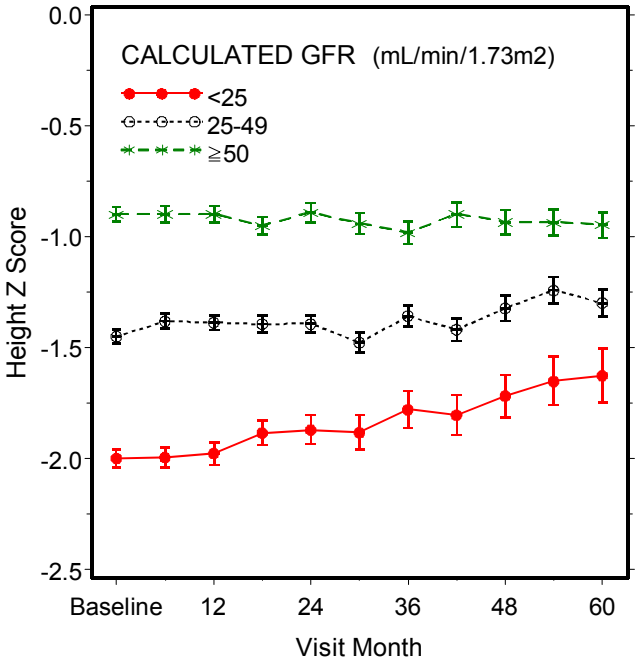
	Entry	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months
Number of visits	7037	5348	4512	3153	2242	1604	1194
EPO use (%)	18.4	22.7	21.8	19.3	19.3	17.7	17.7
rhHG use (%)	6.3	10.3	12.6	15.9	16.3	16.4	17.3
PTH <2X UNL (%)*	61.7	66.2	67.8	67.8	69.3	66.2	67.6
Events Data							
Urologic Surgery (%)	32.7	6.6	4.6	3.6	3.1	2.6	2.0
Orthopedic Surgery (%)	3.2	0.7	0.8	0.7	0.8	0.9	1.0
UTI (%)	34.3	11.2	9.7	9.0	8.0	7.7	8.2
Hip X-ray (%)	7.4	2.9	2.4	2.0	1.6	0.8	1.4
Seizure (%)	7.6	1.9	1.2	1.3	1.7	1.9	1.4
Renal Biopsy (%)	22.7	3.2	1.1	0.6	0.6	0.8	0.5
Fluid/Electrolyte Abnormal (%)	44.1	19.7	16.7	14.5	14.1	10.5	11.7
Blood Transfusion (%)	11.1	1.7	0.9	0.5	0.5	0.4	0.3
Hospitalization Data							
Hospitalized patients (%)	--	18.8	14.6	10.1	8.4	8.0	7.0
All Patients							
Days hospitalized (mean)	--	1.8	1.3	0.7	0.5	0.4	0.4
Days hospitalized (median)	--	0.0	0.0	0.0	0.0	0.0	0.0
Hospitalized patients only							
Days hospitalized (mean)	--	9.7	8.7	7.5	5.6	4.9	6.1
Days hospitalized (median)	--	5.0	5.0	5.0	4.0	3.0	4.0
Hospitalization Reason							
Infection (%)	--	36.2	41.6	43.0	35.6	37.3	42.5
Hypertension (%)	--	9.8	4.8	6.7	5.9	4.1	7.5
Other Cardiovascular (%)	--	7.7	3.9	7.6	5.4	3.3	1.3

* Excludes unknown parathyroid hormone data

EXHIBIT 15.2
HEIGHT Z SCORE (MEAN ± SE)
BY SELECTED BASELINE CHARACTERISTICS







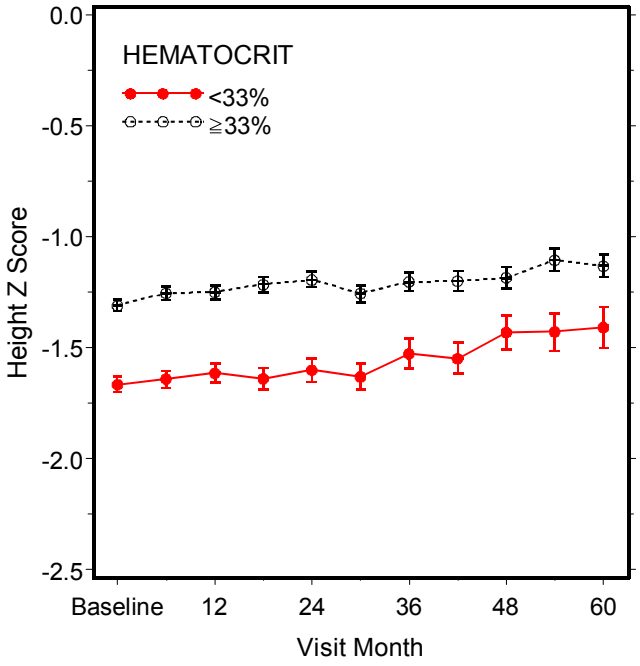


EXHIBIT 15.3
CHANGE FROM BASELINE IN HEIGHT Z SCORE (MEAN ± SE) BY SELECTED BASELINE CHARACTERISTICS

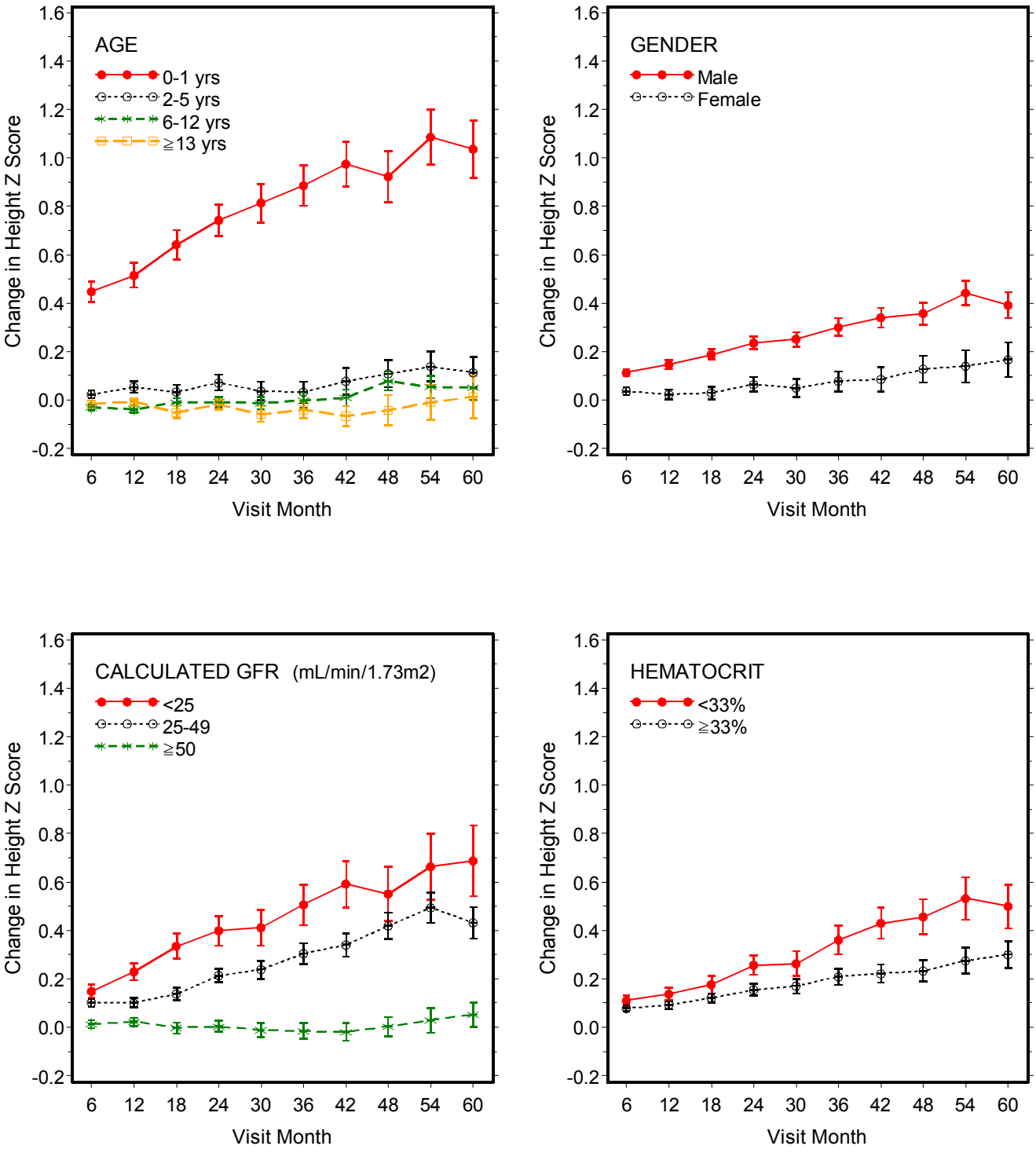


EXHIBIT 15.4
WEIGHT Z SCORE (MEAN ± SE)
BY SELECTED BASELINE CHARACTERISTICS

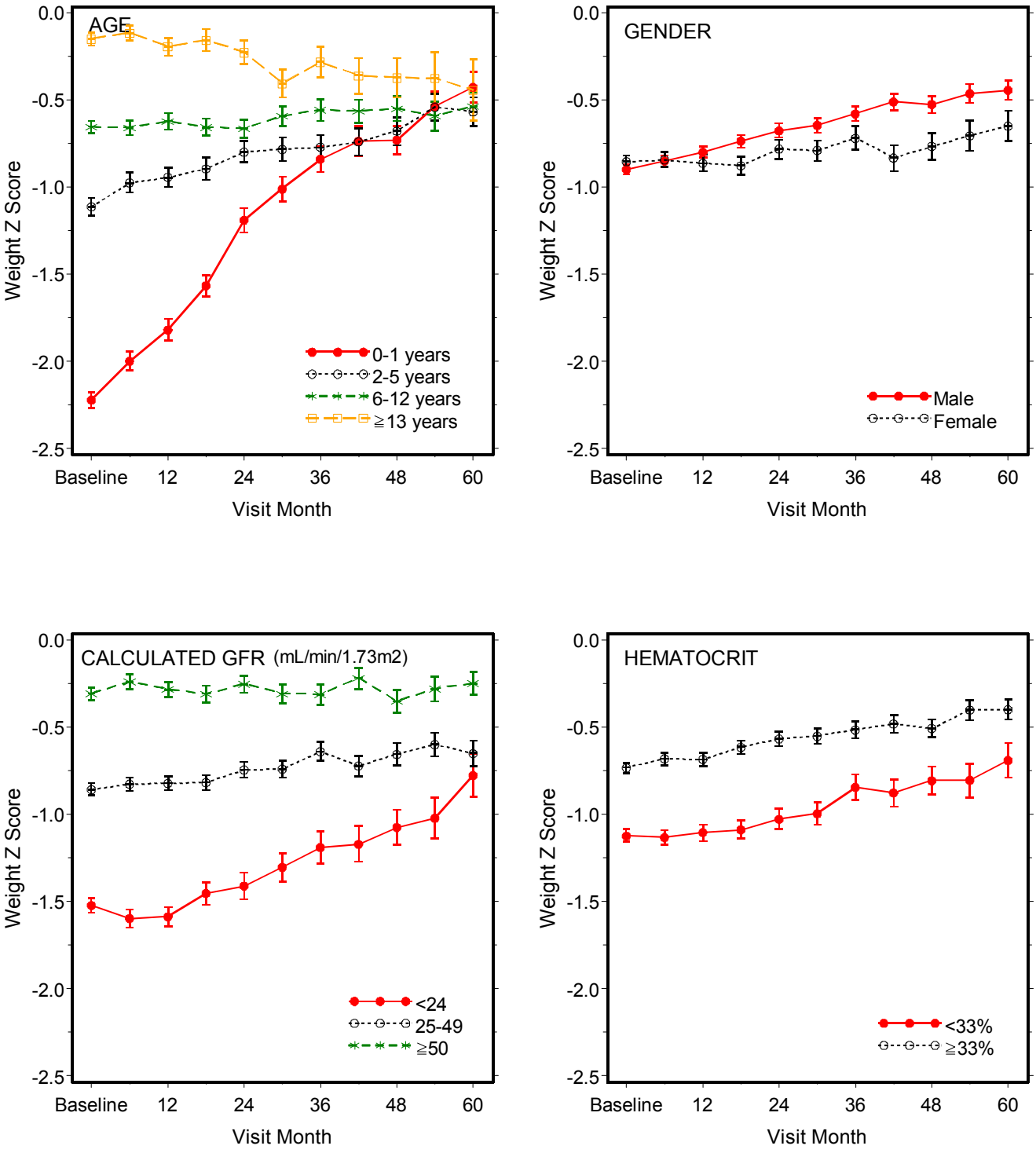
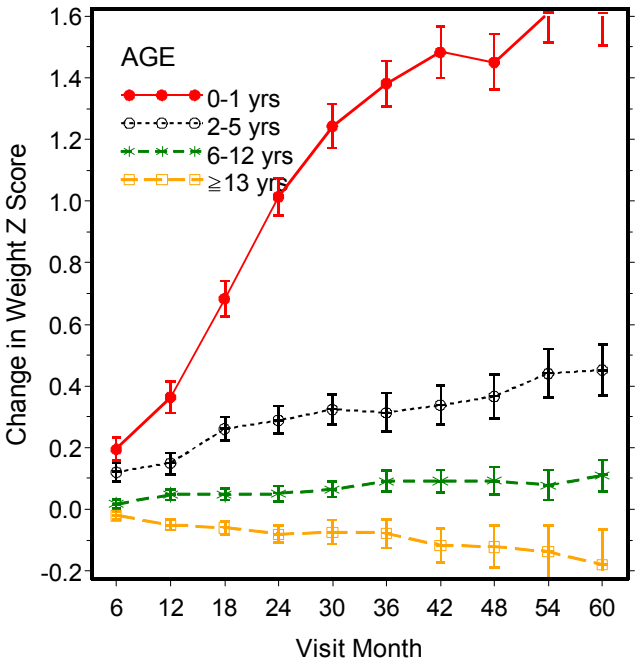
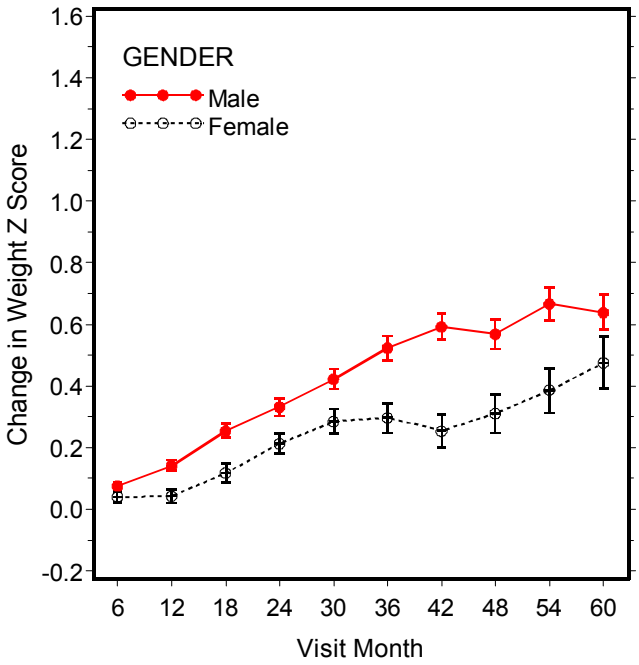
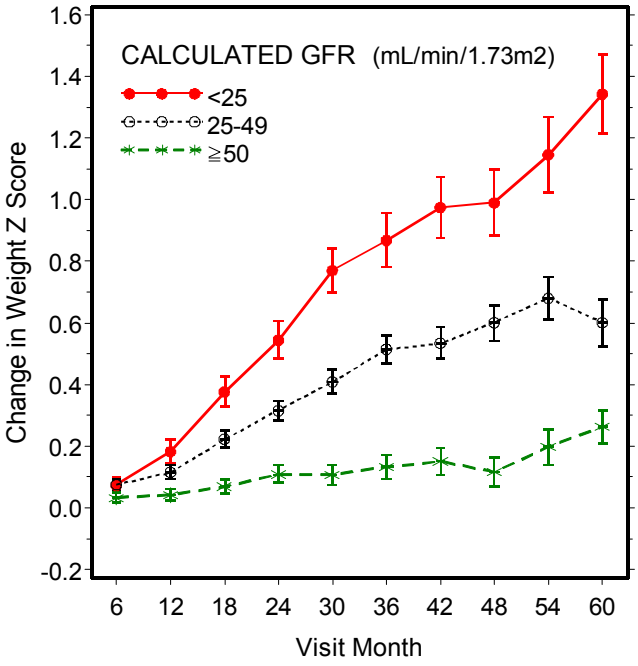


EXHIBIT 15.5
CHANGE FROM BASELINE IN WEIGHT Z SCORE (MEAN ± SE) BY SELECTED BASELINE CHARACTERISTICS







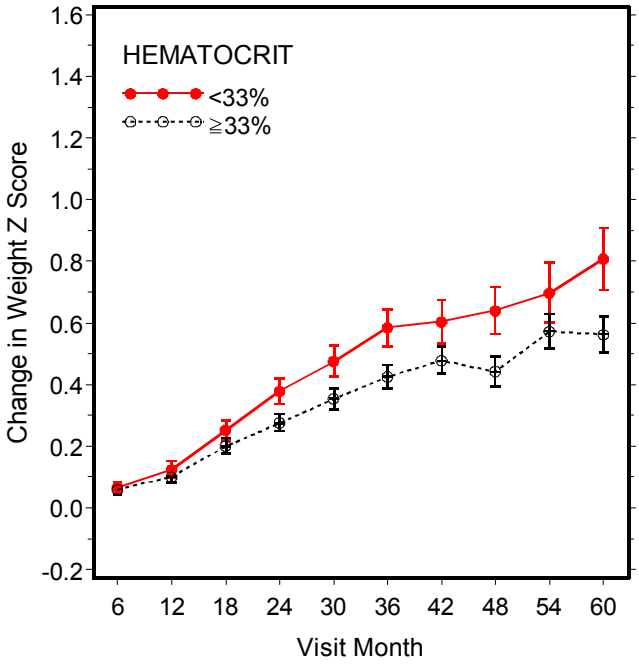
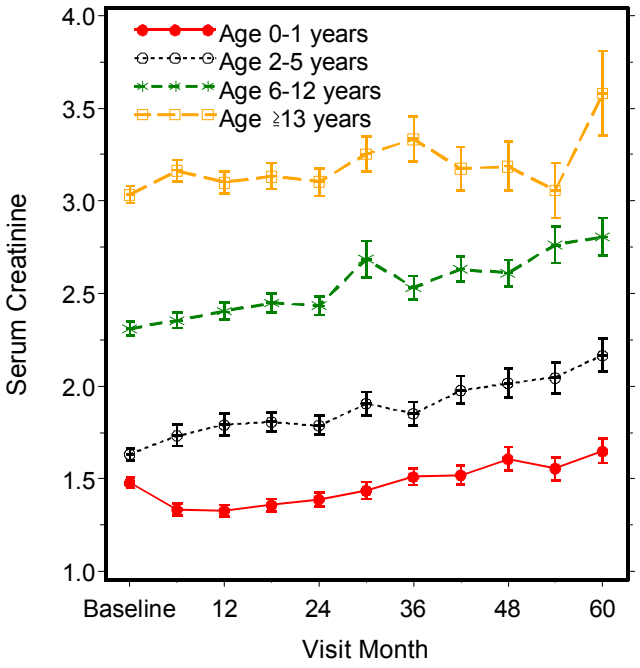


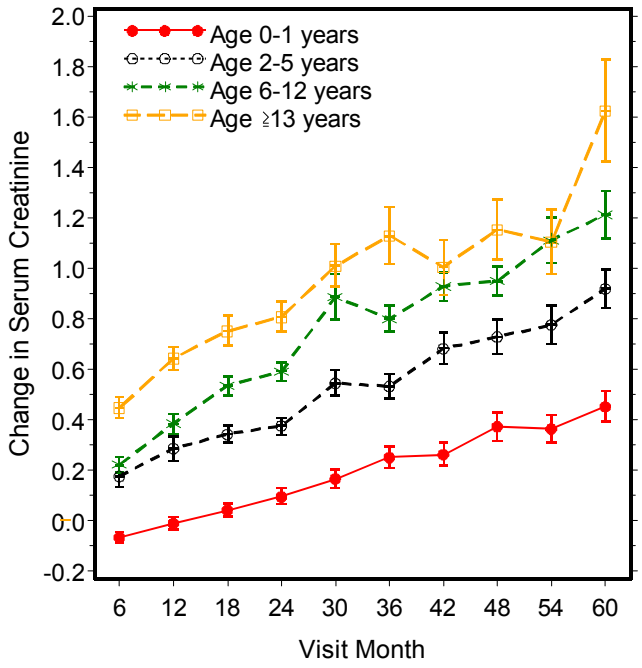
EXHIBIT 15.6A
SERUM CREATININE AND CALCULATED CREATININE CLEARANCE
VISIT MEANS AND CHANGE FROM BASELINE MEANS (+SE)

Serum Creatinine (mg/dL)

Visit Means

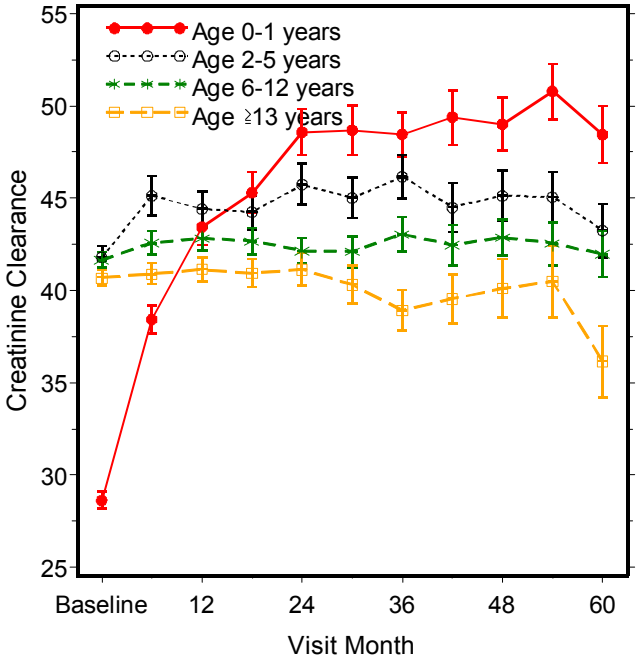


Change from Baseline Means



Creatinine Clearance (mL/min/1.73m^2)

Visit Means



Change from Baseline Means

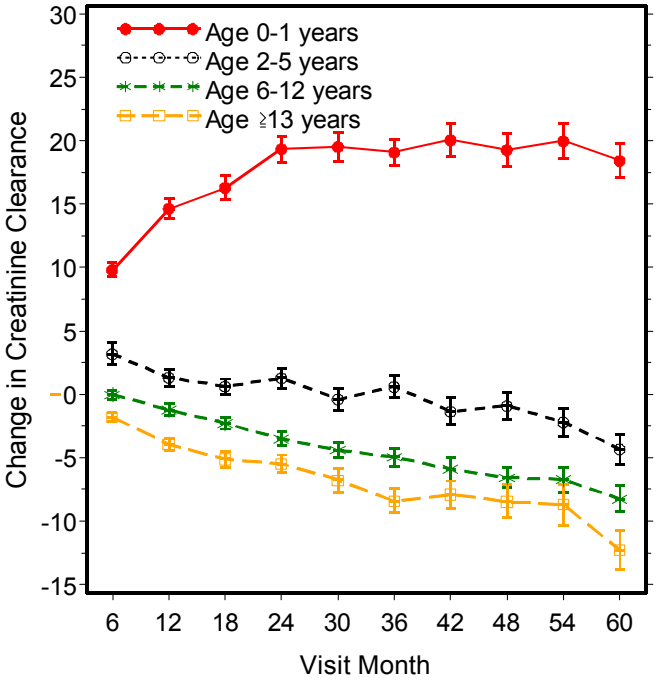


EXHIBIT 15.6B
CALCULATED CREATININE CLEARANCE
BY PRIMARY DIAGNOSIS (MEAN ±SE)

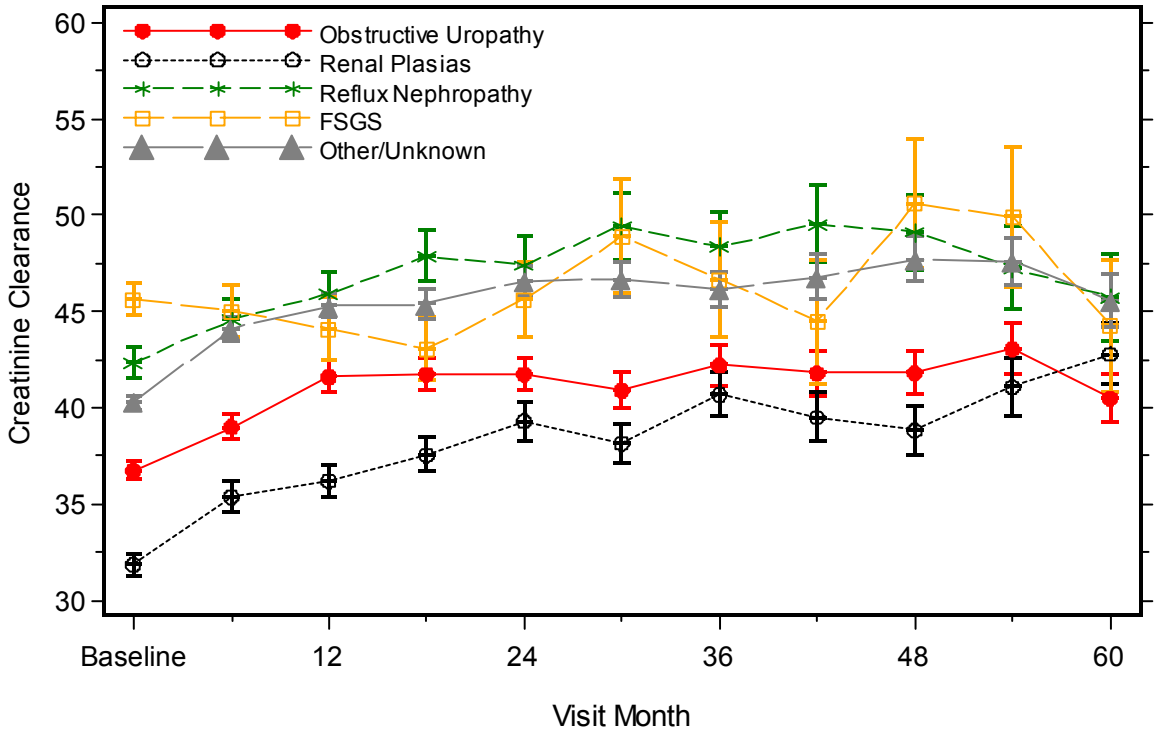


EXHIBIT 15.6C
CHANGE FROM BASELINE IN CALCULATED CREATININE CLEARANCE
BY PRIMARY DIAGNOSIS (MEAN ±SE)

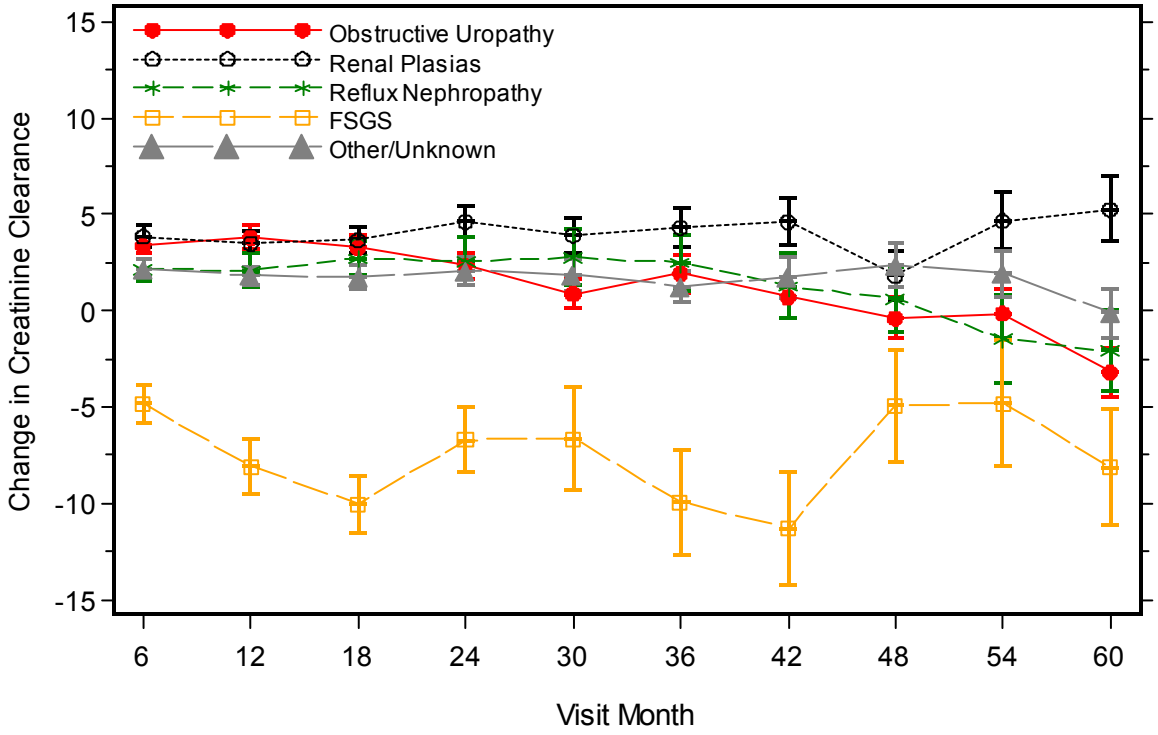


EXHIBIT 15.7A
12 MONTH GROWTH DATA AND RENAL FUNCTION DATA

	rhGH (n=209)			Short Controls (n=956)			All Untreated Patient (n=2988)		
	Mean	SE	Median	Mean	SE	Median	Mean	SE	Median
Height SDS									
Baseline	-2.11	0.08	-2.05	-3.37	0.05	-2.79	-1.38	0.04	-1.19
12 Month	-1.75	0.07	-1.69	-2.77	0.05	-2.49	-1.29	0.03	-1.16
Change from baseline	0.37	0.05	0.29	0.60	0.05	0.17	0.09	0.03	-0.02
Serum Creatinine									
Baseline	2.21	0.08	1.80	1.76	0.04	1.40	1.89	0.02	1.60
12 Month	2.77	0.12	2.30	1.96	0.05	1.50	2.23	0.03	1.70
Change from baseline	0.56	0.07	0.30	0.20	0.03	0.10	0.34	0.02	0.10
Calculated GFR									
Baseline	35.14	1.12	32.14	33.84	0.56	31.53	41.09	0.35	40.25
12 Month	32.82	1.28	28.98	39.68	0.80	35.34	43.62	0.46	40.17
Change from baseline	-2.33	0.73	-2.21	5.84	0.65	1.99	2.53	0.37	-0.44

EXHIBIT 15.7B
12 MONTH GROWTH DATA AND RENAL FUNCTION DATA
EXCLUDING PATIENTS AGE 0-1 YEAR

	rhGH (n=189)			Short Controls (n=558)			All Untreated Patient (n=2279)		
	Mean	SE	Median	Mean	SE	Median	Mean	SE	Median
Height SDS									
Baseline	-2.05	0.08	-2.00	-3.08	0.06	-2.64	-1.09	0.03	-0.95
12 Month	-1.74	0.08	-1.64	-3.04	0.06	-2.63	-1.17	0.03	-1.00
Change from baseline	0.32	0.04	0.28	0.04	0.03	-0.01	-0.08	0.02	-0.05
Serum Creatinine									
Baseline	2.27	0.09	1.90	2.04	0.05	1.60	2.07	0.03	1.70
12 Month	2.83	0.13	2.30	2.42	0.07	1.90	2.53	0.04	2.00
Change from baseline	0.56	0.08	0.30	0.39	0.05	0.20	0.47	0.03	0.20
Calculated GFR									
Baseline	36.42	1.18	35.10	39.32	0.72	38.07	44.80	0.38	44.61
12 Month	33.54	1.33	29.73	38.34	0.88	34.53	43.18	0.50	40.18
Change from baseline	-2.88	0.76	-2.37	-0.97	0.59	-1.55	-1.62	0.36	-2.64

EXHIBIT 15.8A
18 MONTH GROWTH DATA AND RENAL FUNCTION DATA

	rhGH (n=150)			Short Controls (n=672)			All Untreated Patient (n=2158)		
	Mean	SE	Median	Mean	SE	Median	Mean	SE	Median
Height SDS									
Baseline	-2.11	0.09	-2.10	-3.31	0.06	-2.77	-1.31	0.04	-1.13
18 Month	-1.63	0.08	-1.55	-2.60	0.05	-2.44	-1.19	0.04	-1.11
Change from baseline	0.48	0.06	0.42	0.71	0.06	0.27	0.11	0.03	-0.02
Serum Creatinine									
Baseline	2.14	0.09	1.90	1.68	0.04	1.40	1.80	0.02	1.50
18 Month	3.14	0.17	2.60	1.97	0.06	1.50	2.24	0.04	1.70
Change from baseline	1.00	0.12	0.50	0.29	0.04	0.10	0.43	0.03	0.20
Calculated GFR									
Baseline	34.92	1.28	31.87	34.35	0.67	32.04	41.80	0.40	40.98
18 Month	30.45	1.45	26.09	41.47	0.90	37.76	44.36	0.55	41.80
Change from baseline	-4.48	0.94	-2.86	7.11	0.77	3.20	2.56	0.48	-0.69

EXHIBIT 15.8B
18 MONTH GROWTH DATA AND RENAL FUNCTION DATA
EXCLUDING PATIENTS AGE 0-1 YEAR

	rhGH (n=133)			Short Controls (n=383)			All Untreated Patient (n=1637)		
	Mean	SE	Median	Mean	SE	Median	Mean	SE	Median
Height SDS									
Baseline	-2.05	0.09	-2.07	-2.97	0.06	-2.57	-1.03	0.04	-0.88
18 Month	-1.61	0.09	-1.51	-2.92	0.07	-2.63	-1.11	0.04	-0.98
Change from baseline	0.44	0.05	0.40	0.05	0.04	0.07	-0.08	0.02	-0.06
Serum Creatinine									
Baseline	2.21	0.10	1.90	1.96	0.06	1.60	1.97	0.03	1.70
18 Month	3.25	0.19	2.70	2.46	0.09	1.90	2.54	0.04	2.00
Change from baseline	1.04	0.14	0.50	0.49	0.05	0.20	0.57	0.03	0.30
Calculated GFR									
Baseline	36.29	1.36	34.71	40.32	0.88	38.57	45.71	0.44	45.58
18 Month	30.95	1.53	26.68	39.06	1.07	36.40	43.24	0.57	41.23
Change from baseline	-5.34	0.99	-3.72	-1.26	0.77	-1.74	-2.47	0.43	-3.10

EXHIBIT 15.9
GROWTH HORMONE UTILIZATION
HEIGHT Z SCORE ≤-1.88 AND TANNER STAGE I, II, III (age/sex appropriate) AT THE BASELINE OR 6 MONTHS OR 12 MONTH VISITS

	Baseline			6 Months			12 Months		
	N	# on rhGH	% on rhGH	N	# on rhGH	% on rhGH	N	# on rhGH	% on rhGH
All Patients	1886	210	11.1	1274	247	19.4	988	218	22.1
Gender									
Male	1226	134	10.9	811	162	20.0	621	131	21.1
Female	660	76	11.5	463	85	18.4	367	87	23.7
Race									
White	1144	147	12.8	789	177	22.4	611	146	23.9
Black	292	28	9.6	192	33	17.2	155	28	18.1
Hispanic	305	25	8.2	213	25	11.7	162	27	16.7
Other	145	10	6.9	80	12	15.0	60	17	28.3
Age									
0-1 year	710	24	3.4	407	32	7.9	262	37	14.1
2-5 years	411	54	13.1	318	74	23.3	262	51	19.5
6-12 years	607	104	17.1	428	105	24.5	355	89	25.1
>12 years	158	28	17.7	121	36	29.8	109	41	37.6
Enrollment Year									
1994 – 1995	716	92	12.8	546	122	22.3	450	99	22.0
1996 – 1997	418	32	7.7	279	44	15.8	218	39	17.9
1998 – 1999	371	33	8.9	206	35	17.0	155	41	26.5
2000 – 2002	224	34	15.2	136	27	19.9	95	24	25.3
2003 – 2007	157	19	12.1	107	19	17.8	70	15	21.4
$C0_2$ (mEq/L)									
≤20	633	66	10.4	402	81	20.1	304	71	23.4
>20	1153	132	11.4	796	154	19.3	621	141	22.7
Unknown	100	12	12.0	76	12	15.8	63	6	9.5
Parathyroid Hormone									
<2X UNL	583	86	14.8	532	118	22.2	428	106	24.8
>2X UNL	365	53	14.5	268	63	23.5	204	59	28.9
Unknown	938	71	7.6	474	66	13.9	356	53	14.9
CO_2 ≤20 mEq/L and									
PTH<2X UNL	166	25	15.1	137	31	22.6	121	31	25.6
PTH>2X UNL	143	16	11.2	103	28	27.2	74	25	33.8
CO_2 ≥20 mEq/L and									
PTH<2X UNL	400	58	14.5	366	82	22.4	293	72	24.6
PTH>2X UNL	207	35	16.9	156	33	21.2	118	34	28.8

EXHIBIT 15.10
GROWTH HORMONE UTILIZATION
HEIGHT Z SCORE ≤-1.88 AND TANNER STAGE I, II, III (age/sex appropriate)
AT THE BASELINE AND 6 MONTHS AND 12 MONTH VISITS

	N	Baseline		6 Months		12 Months	
		# on rhGH	% on rhGH	# on rhGH	% on rhGH	# on rhGH	% on rhGH
All Patients	680	65	9.6	135	19.9	177	26.0
Gender							
Male	417	31	7.5	80	19.3	100	24.0
Female	263	34	12.9	55	21.0	77	29.3
Race							
White	418	44	10.6	94	22.5	118	28.2
Black	106	8	7.5	16	15.1	21	19.8
Hispanic	113	9	8.0	16	14.2	25	22.1
Other	43	4	9.3	9	22.0	13	30.2
Age							
0-1 year	230	7	3.1	17	8.3	25	14.0
2-5 years	171	14	8.2	34	19.9	42	23.5
6-12 years	240	34	14.2	64	26.0	79	31.5
>12 years	39	10	25.6	20	35.7	31	43.7
Enrollment Year							
1994 – 1995	314	38	12.1	72	22.9	84	26.8
1996 – 1997	161	7	4.3	22	13.7	32	19.9
1998 – 1999	106	12	11.3	24	23.3	31	29.2
2000 – 2002	60	6	10.0	14	23.3	22	36.7
2003 – 2007	39	2	5.3	3	7.7	8	20.5
CO_2 (mEq/L)							
≤20	229	26	11.4	51	21.9	59	28.6
>20	426	38	8.9	79	19.4	112	26.0
Unknown	25	1	4.0	5	13.5	6	14.0
Parathyroid Hormone							
<2X UNL	227	29	12.8	64	22.5	88	28.8
>2X UNL	110	14	12.7	36	26.1	43	33.6
Unknown	343	22	6.4	35	13.7	46	18.7
CO_2 ≤20 mEq/L and							
PTH<2X UNL	67	10	14.9	22	25.6	25	32.1
PTH>2X UNL	44	5	11.4	19	31.1	20	47.6
CO_2 ≥20 mEq/L and							
PTH<2X UNL	153	18	11.8	39	21.3	60	27.8
PTH>2X UNL	65	9	13.8	17	22.7	23	29.1

EXHIBIT 15.11
GROWTH HORMONE UTILIZATION
HEIGHT Z SCORE ≤-1.88 AND TANNER STAGE I, II, III (age/sex appropriate)
AT THE MOST RECENT COMPLETED VISIT SINCE 2000

	N	# on rhGH	% on rhGH
All Patients	285	60	21.1
Gender			
Male	175	35	20.0
Female	110	25	22.7
Race			
White	170	41	24.1
Black	34	7	20.6
Hispanic	54	8	14.8
Other	27	4	14.8
Age			
0-1 year	54	3	5.6
2-5 years	86	23	26.7
6-12 years	110	26	23.6
>12 years	35	8	22.9
Time of last FU			
Baseline	60	10	16.7
6-12 months	60	8	13.3
18-24 months	54	14	25.9
30-60 months	67	17	25.4
>60 months	44	11	25.0
CO_2 (mEq/L)			
≤20	87	10	11.5
>20	183	45	24.6
Unknown	15	5	33.3
Parathyroid Hormone			
<2X UNL	117	26	22.2
>2X UNL	70	23	32.9
Unknown	98	11	11.2
CO_2 ≤20 mEq/L and			
PTH<2X UNL	37	4	10.8
PTH>2X UNL	24	5	20.8
CO_2 ≥20 mEq/L and			
PTH<2X UNL	78	22	28.2
PTH>2X UNL	43	17	39.5

Note: This table excludes all terminated patients.

V. APPENDICES

APPENDIX A

PARTICIPATING CENTERS AND CONTACT PHYSICIANS

NORTH AMERICAN PEDIATRIC RENAL TRIALS AND COLLABORATIVE STUDIES

PARTICIPATING CENTERS AND CONTACT PHYSICIANS

CENTER	CITY, STATE	PRINCIPAL INVESTIGATOR
A		
Alberta Children's Hospital	Calgary, AB, Canada	Lorraine Hamiwka, M.D. Julian Midgley, M.D.
Alfred I. duPont Institute	Wilmington, DE	Laszlo Hopp, M.D.
All Children's Hospital	St. Petersburg, FL	Sharon Perlman, M.D.
Arkansas Children's Hospital	Little Rock, AR	Eileen Ellis, M.D.
B		
Babies and Children's Hospital of NY	New York, NY	Martin A. Nash, M.D. Robert L. Seigle, M.D.
BC Children's Hospital	Vancouver, BC, Canada	Douglas Matsell, M.D. Mina Matsuda-Abedini, M.D. Colin White, M.D.
C		
Cardinal Glennon Hospital	St. Louis, MO	Ellen Wood, M.D.
Carolina's Medical Center	Charlotte, NC	Susan Massengill, M.D.
Cedars-Sinai Medical Center	Los Angeles, CA	Elaine Kamil, M.D. Dechu Puliyanda, M.D.
Children's Healthcare of Atlanta @ Egleston	Atlanta, GA	Larry A. Greenbaum, M.D., Ph.D. Barry L. Warshaw, M.D.
Children's Healthcare of Atlanta @ Scottish Rite	Atlanta, GA	Julius Sherwinter, M.D.
Children's Hospital & Med Ctr-Seattle	Seattle, WA	Ruth McDonald, M.D. Joseph Flynn, M.D.
Children's Hospital @ Albany Medical Center	Albany, NY	Elisabeth Simon, M.D.
Children's Hospital Central California	Madera, CA	Jerome Murphy, M.D.
Children's Hospital Medical Ctr-Akron	Akron, OH	Abubakr Imam, M.D.
University of Alabama at Birmingham/Children's Health System	Birmingham, AL	Mark Benfield, M.D.
Children's Hospital of Austin	Austin, TX	Phillip Berry, M.D.
Children's Hospital of Buffalo	Buffalo, NY	James Springate, M.D.
Children's Hospital of Eastern Ontario	Ottawa, ON, CN	Guido Filler, M.D., Ph.D.
Children's Hospital of Los Angeles	Los Angeles, CA	Gary Lerner, M.D. Carl Grushkin, M.D.
Children's Hospital of Michigan	Detroit, MI	Tej Mattoo, M.D.
Children's Hospital of Oklahoma	Oklahoma City, OK	Martin Turman, M.D.
Children's Hospital of Philadelphia	Philadelphia, PA	H. Jorge Baluarte, M.D. Mary B. Leonard, M.D. Kevin Meyers, M.D.
Children's Hospital of Pittsburgh	Pittsburgh, PA	Demetrius Ellis, M.D.

NORTH AMERICAN PEDIATRIC RENAL TRIALS AND COLLABORATIVE STUDIES

PARTICIPATING CENTERS AND CONTACT PHYSICIANS

CENTER	CITY, STATE	PRINCIPAL INVESTIGATOR
Children's Hospital of the Kings Daughters	Norfolk, VA	Irene Restaino, M.D.
Children's Hospital of Winnipeg	Winnipeg, MB, Canada	Tom Blydt-Hansen, M.D.
Children's Hospital-Boston	Boston, MA	William Harmon, M.D.
Children's Hospital-Denver	Denver, CO	Gary Lum, M.D.
Children's Hospital-New Orleans	New Orleans, LA	Matti Vehaskari, M.D.
Children's Medical Center-Dallas	Dallas, TX	Mouin Seikaly, M.D.
Children's Memorial Hospital-Chicago	Chicago, IL	Richard A. Cohn, M.D.
Children's Mercy Hospital	Kansas City, MO	Bradley A. Warady, M.D.
Children's National Medical Center	Washington, DC	Asha Moudgil, M.D.
Children's Renal Center-Galveston	Galveston, TX	Amita Sharma, M.D.
Cincinnati Children's Hospital Medical Center	Cincinnati, OH	Jens Goebel, M.D. Mark Mitsnefes, M.D. C. Frederic Strife, M.D.
Cleveland Clinic Foundation	Cleveland, OH	Charles A. Davis, M.D.
Connecticut Children's Medical Center	Hartford, CT	Majid Rasoulpour, M.D.
Cook Children's Medical Center	Fort Worth, TX	Deogracias Pena, M.D.
E		
East Carolina University	Greenville, NC	
ETSU Physicians & Associates Pediatrics	Johnson City, TN	Ahmad Wattad, M.D.
H		
Hackensack University Medical Center	Hackensack, NJ	Kenneth Lieberman, M.D.
Hospital for Sick Children-Toronto	Toronto, ON, Canada	Denis Geary, M.D.
Hospital Infantil de Mexico	Mexico 7, D.F.	Ricardo Munoz, M.D.
Hospital National de Ninos	San Jose, Costa Rica	Gilbert Madrigal, M.D.
Hospital St. Justine	Montreal, Quebec, CN	Veronique Phan, M.D.
I		
Inova Hospital for Children	Fairfax, VA	Glenn Bock, M.D.
J		
Johns Hopkins University	Baltimore, MD	Barbara Fivush, M.D. Alicia Neu, M.D.
JW Riley Hospital for Children	Indianapolis, IN	Corina Nailescu, M.D.
K		

NORTH AMERICAN PEDIATRIC RENAL TRIALS AND COLLABORATIVE STUDIES

PARTICIPATING CENTERS AND CONTACT PHYSICIANS

CENTER	CITY, STATE	PRINCIPAL INVESTIGATOR
L		
LAC+USC Medical Center	Los Angeles, CA	Donna Elliott, M.D.
Lebonheur Children's Medical Center	Memphis, TN	Robert J. Wyatt, M.D.
Loma Linda University Medical Center	Loma Linda, CA	Shobha Sahney, M.D.
Lutheran General Children's Medical Center	Park Ridge, IL	Ronald Kallen, M.D.
M		
Maine Pediatric Specialty Group	Portland, ME	Matt Hand, M.D.
Maria Fareri Children's Hospital at Westchester Medical Center	Valhalla, NY	Robert A. Weiss, M.D.
Mary Bridge Children's Hospital	Tacoma, WA	Robert Holleman, M.D.
Massachusetts General Hospital	Boston, MA	Julie Ingelfinger, M.D.
Mayo Clinic	Rochester, MN	Dawn S. Milliner, M.D.
Medical College of Wisconsin	Milwaukee, WI	Cynthia Pan, M.D.
Mercy Children's Hospital	Toledo, OH	Martin DeBeukelaer, M.D. Ridwan Tarabishi, M.D.
Michigan State University	Lansing, MI	Pinhas Geva, M.D.
Michigan State University-Kalamazoo	Kalamazoo, MI	Alfonso Torres, M.D.
Montefiore Medical Center	Bronx, NY	Rick Kaskel, M.D.
Montreal Children's Hospital	Montreal, QB, Canada	Lorraine Bell, M.D.
Mount Sinai Hospital	New York, NY	Lisa Satlin, M.D.
N		
Nationwide Children's Hospital	Columbus, OH	Donald L. Batisky, M.D.
New York Hospital	New York, NY	Valerie Johnson, M.D., Ph.D.
North Shore University Hospital	Manhasset, NY	Manju Chandra, M.D.
Northwest Pediatric Kidney Specialists	Portland, OR	Randy Jenkins, M.D.
O		
Oregon Health Sciences University		Amira Al-Uzri, M.D.
P		
Pediatric Consultants	Reno, NV	Michael Pokroy, M.D.
Pediatric Specialty Center	Hollywood, FL	Michael Freundlich, M.D.
Penn State Hershey Children's Hospital	Hershey, PA	Steven J. Wassner, M.D.
Phoenix Children's Hospital	Phoenix, AZ	Mark Joseph, M.D.

NORTH AMERICAN PEDIATRIC RENAL TRIALS AND COLLABORATIVE STUDIES

PARTICIPATING CENTERS AND CONTACT PHYSICIANS

CENTER	CITY, STATE	PRINCIPAL INVESTIGATOR
R		
Rainbow Babies & Children's Hospital	Cleveland, OH	Katherine M Dell, M.D.
S		
Schneider Children's Hospital	New Hyde Park, NY	Howard Trachtman, M.D.
St. Barnabas Medical Center	Livingston, NJ	Isabel Roberti, M.D.
St. Christopher's Hospital for Children	Philadelphia, PA	Susan B. Conley, M.D.
St. Francis Renal Institute-Honolulu	Honolulu, HI	James E. Musgrave, M.D.
St. Louis Children's Hospital	St Louis, MO	S. Paul Hmiel, M.D.
Stanford University Medical Center	Stanford, CA	Steven R. Alexander, M.D.
T		
Texas Children's Hospital	Houston, TX	Eileen D. Brewer, M.D. Stuart L. Goldstein, M.D.
Texas Tech University	Amarillo, TX	Deogracias R. Pena, M.D.
Tulane University Medical Center	New Orleans, LA	Frank G. Boineau, M.D.
U		
UCLA School of Medicine	Los Angeles, CA	Ora Yadin, M.D.
University of California at San Diego UCSD & Rady Children's Hospital	San Diego, CA	Nadine Benador, M.D.
UCSF Children's Renal Center	San Francisco, CA	Anthony Portale, M.D.
UMDNJ Robert Wood Johnson Medical School	New Brunswick, NJ	Lynne Weiss, M.D.
University of Alberta Hospital	Edmonton, AB, Canada	Manjula Gowrishankar, M.D. Verna Yiu, M.D.
University of Florida	Gainesville, FL	Vikas R. Dharnidharka, M.D.
University of Illinois	Chicago, IL	Eunice G. John, M.D.
University of Iowa Hospitals	Iowa City, IA	Patrick Brophy, M.D.
University of Louisville/Kosair Pediatric Center	Louisville, KY	Larry Shoemaker, M.D.
University of Maryland Medical Center	Baltimore, MD	Susan Mendley, M.D.
University of Miami / Children's Hosp Ctr	Miami, FL	Carolyn Abitbol, M.D.
University of Michigan	Ann Arbor, MI	David Kershaw, M.D.
University of Mississippi Medical Ctr	Jackson, MS	Radharkrishna Baliga, M.D.
University of Missouri	Columbia, MO	Ted D. Groshong, M.D.
University of Nebraska Medical Center	Omaha, NE	Helen Lovell, M.D. Tancy Jahn, M.D.
University of New Mexico	Albuquerque, NM	John Brandt, M.D.
University of North Carolina, Chapel Hill	Chapel Hill, NC	Maria Ferris, M.D. Debbie Gipson, M.D. William Primack, M.D.

NORTH AMERICAN PEDIATRIC RENAL TRIALS AND COLLABORATIVE STUDIES

PARTICIPATING CENTERS AND CONTACT PHYSICIANS

CENTER	CITY, STATE	PRINCIPAL INVESTIGATOR
University of Rochester Medical Center	Rochester, NY	Marc Lande, M.D.
University of South Florida	Tampa, FL	Alfonso Campos, M.D.
University of Tennessee Medical Center	Knoxville, TN	Maricarment Malagon-Rogers, M.D.
University of Texas HSC @ Houston	Houston, TX	Rita Swinford, M.D.
University of Texas HSC @ San Antonio	San Antonio, TX	Mazen Y. Arar, M.D.
University of Vermont	Burlington, VT	Ann P. Guillot, M.D.
University of Virginia Medical Center	Charlottesville, VA	John Barcia, M.D.
University of Wisconsin Hospital and Clinics	Madison, WI	Sharon M. Bartosh, M.D.
V		
Vanderbilt University Medical	Nashville, TN	Kathy Jabs, M.D.

APPENDIX B

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90. Bartosh SM, Ho PL, Stablein DM, Harmon WE. Improving adult height for pediatric renal transplant recipients: a report from the North American Pediatric Renal Transplant Cooperative Study (NAPRTCS). Presented, ATC. Washington, DC, 2003.

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93. Harmon WE, Stablein DM, Sayegh MH. Trends in immunosuppressive strategies in pediatric kidney transplantation. Presented, ATC. Washington, DC, 2003.

94. Dharnidharka V, Stablein DM, Harmon WE. Risk of hospitalization due to infection now exceeds risk due to acute rejection at early and late time points in pediatric renal transplant recipients. Presented, ATC. Washington, DC, 2003.

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98. Kist-van Holthe J. Outcome of children after renal transplantation for Wilms tumor and Drash syndrome: a report of the North American Pediatric Renal Transplant Cooperative Study. Presented, World Congress of Nephrology. Berlin, Germany, 2003.

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102. Furth SL, Cole SR, Mims MM, Munoz A, Warady BA. Design and methods of a prospective cohort study of chronic kidney disease in children (CKiD). Presented, ASN. St. Louis, 2004.

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106. Dharnidharka VR, Stablein, DM. IL-2 receptor antibodies and malignancy: an analysis of early pediatric renal transplant registry data. Presented, ATC. Boston, 2004. (Am J Transplant 2004;8(Suppl):1060A).

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110. Benfield M. Relevance of clinical trials in pediatric transplantation. Lecture, International Congress on Immunosuppression. San Diego, December 2004.

111. Omoloja A, Mitsnefes M, Talley L, Neu A. Racial differences in graft survival: Study from the North American Pediatric Transplant Cooperative Study (NAPRTCS). Presented, ASPN/PAS. Washington, DC, 2005. (Published PAS 2005: 57: 1085)

112. Richards C. NAPRTCS- Who are We and What Do We Do? Poster presentation, ANNA 36th Annual Symposium. Las Vegas, Nevada. April 2005.

113. Hmiel SP, Talley L, Stablein DM. Adolescence and prior dialysis as risk factors for pediatric kidney transplant failure- a report of the North American Pediatric Renal Transplant Cooperative Study. Poster presented, ATC. Seattle, May 2005.

114. Puliyanda DP, Stablein D, Dharnidharka VR. Risk factors for hospitalization for infection in the first 2 years post transplantation in pediatric renal transplant recipients. A NAPRTCS report. Oral presentation, IPTA. Innsbruck, Austria, August 2005. (Published Pediatr Transplant 2005;9(S):171A)

115. Benfield M. Pre-congress symposium: A rational approach to pediatric immunosuppression. Lecture, IPTA. Innsbruck, Austria, August 2005.

116. Benfield M. State-of-the-art-lecture: Immunosuppression: the next generation. Lecture, IPTA. Innsbruck, Austria, August 2005.

117. Ellis EN, Ilyas M, Pennington KL, Blaszak RT: Long term pediatric renal transplant function: a NAPRTCS report. Oral presentation, ASN. Philadelphia, November 2005. (Published J Am Soc Nephrol, 2005;16:687A)

118. Ellis EN, Ilyas M, Pennington KL, Blaszak RT: Factors related to renal transplant (RTx) loss after 10 years of transplant function in children: a NAPRTCS report. Oral presentation, ASN. Philadelphia, November 2005. (Published J Am Soc Nephrol, 2005;16:696A)

119. Smith JM, Dharnidharka VR, Talley L, McDonald R. BK Virus Nephropathy (BKVN) in pediatric renal transplant recipients: an analysis of the NAPRTCS registry. Oral presentation, ASN. Philadelphia, November 2005. (Published J Am Soc Nephrol, 2005;16:p88A)

120. Staples A, Smith J, Talley L, Gipson D, Wong C. Anemia-associated risk of hospitalization and death in pediatric chronic kidney disease (CKD): An analysis of the NAPRTCS. Presentation, ASN. Philadelphia, November 2005.

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121. Yiu V, Stablein D, Seikaly M, Gipson D. Body Mass index and incidence of obesity in children with chronic kidney disease - a NAPRTCS report. Presentation, ASN. Philadelphia, November 2005.

122. Dharnidharka VR, Talley L, Stablein DM, Fine RN. Recombinant human growth hormone (rhGH) use pre-transplant and risk of lymphoproliferative disease post-transplant. Oral presentation, World Transplant Congress. Boston, July 2006.

123. Staples A, Smith J, Gipson D, Wong C, Filler G, Warady B, Talley L, Martz K, Greenbaum L. Anemia-associated risk of disease progression in pediatric chronic kidney disease (CKD): An analysis of the NAPRTCS. Presentation, ASN, 2006.

124. Nguyen S, Martz K, Stablein D, Neu A. Waitlist Status of Pediatric Dialysis Patients in North America. Platform presentation, IPTA. Cancun, Mexico, March 2007.

125. Dharnidharka VR, Martz KL, Stablein DM. Sirolimus use at day 30 is associated with higher risk of post-transplant lymphoproliferative disease (PTLD) in children post-kidney transplant. Oral presentation, IPTA. Cancun, Mexico, March 2007.

126. Dharnidharka VR, Martz KL, Stablein DM. Post-transplant lymphoproliferative disease (PTLD): a report of the NAPRTCS registry. Oral presentation, IPTA. Cancun, Mexico, March 2007.

127. Dharnidharka VR, Martz KL, Stablein DM. IL-2R antibody induction is not associated with higher PTLD incidence: a report of the NAPRTCS. Oral presentation, IPTA. Cancun, Mexico, March 2007.

128. Gerson AC, Stablein D, Fivush BA, Neu AM. Physician Identified Nonadherence Associated Graft Failure: A Retrospective Cohort Analysis of NAPRTCS Data 1988-2006. Poster presentation, PAS Annual Meeting. 2007.

129. Fadrowski J, Martz K, Stablein D, Fivush B, Furth S, Neu A. Association Between Vascular Access Type and Complications: A NAPRTCS Study. Poster presentation, PAS Annual Meeting. 2007.

130. Staples A, Smith J, Gipson D, Wong C, Filler G, Warady B, Martz K, Greenbaum L. Risk Factors Associated with Progression of Pediatric Chronic Kidney Disease (CKD). Presentation, Society of Pediatric Research. 2007.

131. Staples A, Smith J, Gipson D, Wong C, Filler G, Warady B, Martz K, Greenbaum L. Risk Factors Associated with Progression of Pediatric Chronic Kidney Disease (CKD). Poster Presentation, PAS Annual Meeting, May 2007.

132. Luckritz K, Smith J, Wong C, Mitsnefes M, Stablein D, McDonald R. Hyperphosphatemia-associated Risk of Hospitalization and Death in Pediatric Chronic Kidney Disease (CKD): A NAPRTCS Analysis. Poster Presentation, ASN, Nov 2007.

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133. Icard PF, Gipson D, Martz K, Hooper SR, Stablein D. The Prevalence of Seizures and Anticonvulsant Mediacation use in Pediatric Chronic Kidney Disease. Poster Presentation, ASN, Nov 2007.

134. Moudgil A, Martz K, Stablein S, Puliyanda D. Predictors of Estimated Glomerular Filtration Rate (eGFR) at 1 Month Post-Transplantation: An Analysis of NAPRTCS data. Poster presentation, AST, Toronto, Ontario. 2008.

135. Novak T, Mathews R, Fivush B, Martz K, Stablein D, Neu A. Progression to End-Stage Renal Disease in Children with Vesicoureteral Reflux: Results from the North American Pediatric Renal Trials and Collaborative Studies (NAPRTCS). Poster presentation, ASPN/PAS, 2008.

136. Novak TE, Neu A, Martz K, Fivush B, Stablein D, Mathews RI. Progression to End-stage Renal Disease in Children with Vesicoureteral Reflux (VUR): Insights from an Analysis of the North American Pediatric Renal Trials and Collaborative Studies (NAPRTCS) Database. Accepted for Platform presentation, AAP, 2008.

137. Foster BJ, Martz K, Gowrishankar M, Stablein D, Al-Uzri A. Natural History of Weight Change and Risk Factors for Unhealthy Weight Gain in Pediatric Renal Transplantation: Analysis of the North American Pediatric Renal Trial and Collaborative Studies Registry (NAPRTCS). Presented American Transplant Congress, June 2008.

138. Atkinson M, Martz K, Stablein D, Fivush B, Neu A. Racial Disperity in Anemia in Children with Chronic Kidney Disease (CKD): A NAPRTCS Study. Poster Presentation ASPN/PAS, May 2008.

APPENDIX C

SPECIAL STUDIES AND ANALYSES

NORTH AMERICAN PEDIATRIC RENAL TRIALS AND COLLABORATIVE STUDIES

SPECIAL STUDIES AND ANALYSES

Lead Investigator	Topic	Status
2007		
Ayesa Mian, M.D.	Outcomes of renal transplants performed during the first year of life	Accepted for Presentation
Meredith Atkinson, M.D.	Racial and ethnic disparities in the prevalence and severity of anemia in children with chronic kidney disease	Accepted for Presentation
Asha Moudgil, M.D. Dechu Puliyanda, M.D.	Investigation of Estimated Glomerular Filtration Rate (eGFR) Changes after Renal Transplantation in Children and Analysis of Risk Factors Associated with Deterioration of eGFR	Presented
2006		
Amira Al-Uzri, M.D. Beth Foster, M.D. Manjula Gowrishankar, M.D. Sam Crafter, M.D. Robin Erikson, M.D.	Predictors of obesity and its impact in pediatric renal transplant recipients	Presented
Alicia Neu, M.D. Jeffrey Fadrowski, M.D.	Associations between vascular access type and hospitalization/transplant/intermediate outcomes	Presented
Kera Luckritz, D.O. Craig Wong, M.D. Ruth McDonald, M.D. Jodi Smith, M.D.	Impact of hyperphosphatemia on morbidity in the CKD and dialysis population	Presented
2005		
Michelle Baum, M.D.	Analysis of low growth hormone utilization in the NAPRTCS CRI and dialysis registries	Completed
Meredith Atkinson, M.D.	GFR at dialysis initiation and impact on clinical outcomes in the first year of dialysis	Completed
Arlene Gerson, Ph.D.	Evaluation of the relationship between graft type, gender and age on medication adherence post transplant	Presented
Amy Staples, M.D. Larry Greenbaum, M.D.	Anemia, erythropoietin use and adverse clinical outcomes in pediatric patients with CKD	Presented
2004		
Eileen Ellis, M.D.	Factors related to long-term renal transplant function in children	Presented
William Carey, M.D.	Outcomes of renal replacement therapy initiated during the neonatal period (birth to three months)	Published
Vikas Dharnidharka, M.D. Jodi Smith, M.D.	BK virus nephropathy (BKVN) in pediatric renal transplantation	Published
Dechu Puliyanda, M.D.	Risk factors for infection in pediatric renal recipients	Accepted

NORTH AMERICAN PEDIATRIC RENAL TRIALS AND COLLABORATIVE STUDIES

SPECIAL STUDIES AND ANALYSES

Lead Investigator	Topic	Status
Stuart Goldstein, M.D.	Allograft removal and anemia in children who return to dialysis	Published
Alicia Neu, M.D. Mark Mitsnefes, M.D. Abi Omoloja, M.D.	Racial differences in graft survival	Published
Vikas Dharnidharka, M.D.	Increased risk for post-transplant lymphoproliferative disease (PTLD) with recombinant human growth hormone (rhGH) use pre- and post-renal transplant	Presented
2003		
Alicia Neu, M.D.	Tacrolimus vs. cyclosporine A as primary immunosuppression in pediatric renal transplantation: A NAPRTCS study	Published
Vikas Dharnidharka, M.D.	Profile of infections post-transplantation in NAPRTCS	Published
Paul Hmiel, M.D. Ph.D.	Graft survival after preemptive kidney transplantation	Presented
Mark Mitsnefes, M.D.	Analysis of hypertension in children on chronic dialysis	Published
Minnie Sarwal, M.D.	Complete steroid free immunosuppression achieves unprecedented advantages in growth and graft function in pediatric renal transplantation: a single center and NAPRTCS analysis	Published
2002		
Coral Hanevold, M.D. Paul McEnery, M.D.	The impact of obesity on pediatric renal transplant outcome	Published
Michelle Baum, M.D.	Outcome of children with Wilms' tumor as a primary diagnosis following renal transplant	Published
2001		
Alicia Neu, M.D.	Tacrolimus vs. Cyclosporine as primary immunosuppression in pediatric renal transplant patients	Published
Mark Mitsnefes, M.D.	Blood pressure changes in renal function in children with chronic renal insufficiency	Published
Peter Yorgin, M.D.	Comparison of effects of recombinant human growth hormone in children with chronic renal insufficiency and on dialysis	
Michael Braun, M.D. Lorraine Bell, M.D. Lorraine Hamiwka, M.D.	Transplantation in Children with Membranoproliferative Glomerulonephritis	Published
2000		
Sharon Bartosh, M.D.	Outcomes of pediatric renal transplantation in children receiving non-primary transplants using tacrolimus as primary immunosuppression	Presented

NORTH AMERICAN PEDIATRIC RENAL TRIALS AND COLLABORATIVE STUDIES

SPECIAL STUDIES AND ANALYSES

Lead Investigator	Topic	Status
Susan Furth, M.D.	Does poor growth predict morbidity and mortality in children with ESRD?	Published
Ira Davis, M.D.	The impact of advanced hepatobility disease on the survival of patients with autosomal recessive polycystic kidney diseases following renal transplantation	Presented
Peter Yorgin, M.D.	The effect of recombinant human growth hormone in children with chronic renal insufficiency	Presented
1999		
Richard Cohn, M.D.	Outcome after renal transplantation for Drash Syndrome	Presented
Mary Leonard, M.D.	The dose of hemodialysis and outcomes in children	Published
Alicia Neu, M.D.	Comparison of CMV disease in pediatric renal transplant patients receiving azathioprine vs. mycophenolate mofetil	Presented
Scott Schurman, M.D.	Changes in renal function through puberty in children with chronic renal insufficiency	Presented
1998		
Sharon Bartosh, M.D.	Outcomes in children with ESRD secondary to systemic lupus erythematosus	Published
Mary Leonard, M.D.	Comparison of mortality risks of maintenance dialysis and renal transplantation	Published
Valerie Panzarino, M.D.	The effect of donor sex on renal allograft survival in pediatric renal transplantation	Published
Blanche Chavers, M.D.	Outcome of renal transplantation in pediatric peritoneal dialysis patients	Published
1997		
Amira Al-Uzri, M.D.	Post transplant diabetes mellitus	Published
1996		
Scott Schurman, M.D.	Impact of transplant center volume on pediatric allograft outcome	Published
Anup Singh, M.D.	Risk factors that impact on renal graft thrombosis in the NAPRTCS registry	Published
Bradley A. Warady, M.D.	Fungal peritonitis in children receiving long-term peritoneal dialysis	Published
Alicia Neu, M.D.	Beneficial effect of maternal vs. paternal kidney donation in pediatric renal transplant patients	Published
Ellen Wood, M.D.	Risk factors in young children on dialysis	Published
Amira Al-Uzri, M.D.	Living-unrelated transplantation	Published

NORTH AMERICAN PEDIATRIC RENAL TRIALS AND COLLABORATIVE STUDIES

SPECIAL STUDIES AND ANALYSES

1995		
The NAPRTCS Investigators	Controlled clinical trial in pediatric transplantation	Presented
Albert Quan, M.D.	Graft outcome of patients with hemolytic uremic syndrome	Published
Kathy Jabs, M.D.	Graft loss and decreased function in adolescent recipients of LRD grafts	Presented
Susan Furth, M.D.	Vaccine-preventable illness in pediatric renal patients	Published
Noosha Baqi, M.D.	Graft outcome of patients with Down Syndrome	Published
1994		
Glenn Bock, M.D.	Post-transplant CMV infection	Published
Benjamin Brouhard, M.D.	Education status of children with ESRD	Published
Diane Hebert, M.D.	Post-transplant malignancies	Presented
Bradley Warady, M.D.	Socioeconomic status and mortality of children with ESRD	Completed
1993		
Aaron Friedman, M.D.	Serial serum creatinine assessments and graft outcome	Completed
Kathy Jabs, M.D.	Daily versus alternate day steroids and graft outcome	Published
Ronald Kerman, M.D.	MLR hyporesponsiveness	Published
Melanie Kim, M.D.	Graft outcome of patients with congenital nephrotic syndrome	Published
Paul McEnery, M.D.	Primary diagnosis and graft outcome	Published