Appendix G

Table 8.2.5 **PREDICT - Serious or Potentially Serious Adverse Events Treated Population (n=854)**

Tx Group Region# - Subject #	Age	Sex	Tx Duration (days)	Relation to Medication	Event
OTC (N= 499)					
10-3604	49	M	28	Unrelated	Myocardial Infarction
17-3343	60	M	141	Unrelated	Coronary heart disease
18-3006	56	M	7	Unrelated	Perforated stomach ulcer
19-3006	62	M	161	Unrelated	Gastroesophageal reflux disease
21-3636	57	M	134	Unrelated	Myocardial infarction
21-3642	83	F	125	Unrelated	Bladder cancer/bladder removal
25-3345	56	M	62	Unrelated	Tumor, right hilum lung
25-3627	56	M	178	Unrelated	Ureterolithiasis
26-3008	52	M	97	Unrelated	Incision and drainage rectal abscess
26-3038	65	M	28	Unrelated	Prostate cancer
26-3042	53	M	42	Unrelated	Cholecystectomy
26-3345	65	M	87	Unrelated	Prostate cancer
Rx (N= 355)					
10-4627	61	F	151	Unrelated	Breast cancer
12-4304	57	M	129	Unrelated	Myocardial infarction
15-4619	71	F	38	Unrelated	Wrist infection
15-4627	62	M	42	Unrelated	Urethral blockage
19-4032	53	M	169	Unrelated	Coronary heart disease
19-4623	63	M	60	Unrelated	Transurethral resection of prostate
20-4620	70	M	13	Unrelated	Prostate cancer
28-4325	62	M	41	Unrelated	Coronary vessel stenosis

Subject 10-3604 (OTC Group), a 49 year old white male with a family history of heart disease reported that he had a mild heart attack 28 days after starting Pravachol 10 mg. The subject took the study drug for 28 days; he did not consult a study physician. Information about the heart attack was noted from the Week 24 questionnaire returned by the subject. The study physician then contacted the subject by telephone. Concomitant medication included garlic. Following the event, the subject discontinued Pravachol 10 mg and was placed on Lipitor by his personal physician. No cholesterol levels were available. The investigator did not attribute the event to study medication.

Subject 17-3343 (OTC Group), a 60 year old white male who consulted the study physician before taking Pravachol 10 mg, underwent a stress test to evaluate recurrent dyspnea and chest pain on exertion 141 days after starting study medication. The subject experienced chest pain during the stress test and underwent successful rotation

atherectomy and stent placement a week after the stress test. Concomitant medications included a multivitamin, aspirin, ginseng, vitamin E, vitamin C and Taurus male nutrient. Post-operatively, the subject's private physician increased his dose of Pravachol to 40 mg and he completed the study on prescription therapy. LDL-C at the end of the study was 104 mg/dl. The investigator did not attribute the event to study medication.

Subject 18-3006 (OTC Group), a 56 year old white male who consulted the study physician before taking Pravachol 10 mg , was hospitalized for surgical repair of a perforated gastric ulcer 7 days after starting study medication. The day prior to hospitalization, the subject complained of shoulder discomfort that worsened as the evening progressed. The subject went to the emergency room and underwent surgery to repair a perforated stomach ulcer and was discharged four days later. Concomitant medications included allopurinol and a multivitamin. Pravachol 10 mg therapy was discontinued. The investigator did not attribute the event to study medication.

Subject 19-3006 (OTC Group), a 62 year old white male who consulted the study physician before taking Pravachol 10 mg, experienced nausea with emesis, dizziness and chest pain radiating to the shoulders and was hospitalized for evaluation 161 days after starting study medication. Results of a stress test and cardiac enzymes were negative for coronary disease. The subject was diagnosed with gastroesophageal reflux disease. Concomitant medications included loratidine, aspirin and Centrum Silver. The subject continued Pravachol 10 mg therapy and completed the study. The investigator did not attribute the event to study medication.

Subject 21-3636 (OTC Group), a 57 year old white male who consulted the study physician before taking Pravachol 10 mg, was hospitalized for a myocardial infarction 134 days after starting study medication. This subject's risk factors included age, family history and low HDL-C. The subject underwent a cardiac catheterization with stent placement at the time of the event. Concomitant medications included ibuprofen. Pravachol 10 mg was discontinued and Lipitor 10 mg was initiated. Lipid profile results

obtained 2 weeks after Lipitor was started and 16 days post myocardial infarction included: TOTAL-C of 197 mg/dl, HDL-C 32 mg/dl, and triglycerides 431 mg/dl. An LDL-C level could not be calculated due to the elevation in triglyceride level. The investigator did not attribute the event to study medication.

Subject 21-3642 (OTC Group), a 83 year old white female, was diagnosed with bladder cancer approximately 125 days after starting Pravachol 10 mg. The subject took study drug for 9 days before consulting the study physician. The subject underwent surgery for bladder removal. Concomitant medications included Ascriptin. Study medication was interrupted for three days. The subject restarted Pravachol 10 mg and completed the study. The investigator did not attribute the event to study medication.

Subject 25-3345 (OTC Group), a 56 year old white male who consulted the study physician the day he began taking Pravachol 10 mg, was diagnosed with a tumor of the right hilum of the lung; CT scan findings were consistent with carcinoma. The subject took Pravachol 10 mg for 62 days but had discontinued treatment 105 days prior to the diagnosis. Concomitant medications included a multivitamin, vitamin E, and glucosamine sulfate. The investigator did not attribute the event to study medication.

Subject 25-3627 (OTC Group), a 56 year old Hispanic male who consulted the study physician before taking Pravachol 10 mg, was hospitalized for ureterolithiasis 178 days after starting study medication. The subject underwent an intravenous pyelogram, which diagnosed a recently passed stone. The subject was not taking concomitant medications. Pravachol 10 mg therapy was discontinued. The investigator did not attribute the event to study medication.

Subject 26-3008 (OTC Group), a 52 year old white male who consulted the study physician before taking Pravachol 10 mg, was admitted to the hospital for incision and drainage of a rectal abscess 97 days after starting study medication. Concomitant medications included B complex, garlic and vitamin C. The subject continued Pravachol

10 mg therapy and completed the study. The investigator did not attribute the event to study medication.

Subject 26-3038 (OTC Group), a 65 year old white male who consulted the study physician before taking Pravachol 10 mg, had a prior history of prostate cancer and was admitted to the hospital for prostatic seeding. The subject took Pravachol 10 mg for 28 days and discontinued treatment of his own accord one month prior to hospitalization. Concomitant medications included loratidine, captopril, amlodipine besylate and bumetanide. The investigator did not attribute the event to study medication.

Subject 26-3042 (OTC Group), a 53 year old white male who consulted the study physician before taking Pravachol 10 mg, had a history of cholelithiasis and recurrent gallbladder pain and was hospitalized for a cholecystectomy 42 days after starting study medication. The subject was discharged a day later. Concomitant medications included famotidine and acetaminophen with diphenhydramine. Pravachol 10, which had been interrupted for one day, was restarted and the subject completed the study. The investigator did not attribute the event to study medication.

Subject 26-3345 (OTC Group), a 65 year old white male with a history of benign prostatic hypertrophy consulted the study physician before taking Pravachol 10 mg. Pravachol 10 mg was initiated and subsequently titrated to 20 mg. The subject underwent a transurethral prostate resection that revealed prostate cancer 87 days after starting Pravachol therapy. The subject was taking Pravachol 20 mg at the time of the event. Concomitant medications included enalapril maleate, terazosin HCL, ibuprofen and vitamins C and E. The subject continued on Pravachol 20 mg, was titrated to 40 mg and completed the study. Subsequently, the subject underwent a total resection and removal of the prostate 2 days after completing the study. The investigator did not attribute the event to study medication.

Subject 10-4627 (Rx Group), a 61 year old white female who had been taking estropipate tablets for 21 years, was diagnosed with cancer of the right breast 151 days after starting Pravachol 10 mg. The subject underwent a bilateral mastectomy (the left breast removed prophylactically). Other concomitant medications included nicotine transdermal system. The subject continued on Pravachol 10 mg and completed the study. The investigator did not attribute the event to study medication.

Subject 12-4304 (Rx Group), a 57 year old white male who experienced chest discomfort and nausea, was hospitalized and diagnosed with a myocardial infarction 129 days after starting Pravachol 10 mg and underwent angioplasty at that time. Concomitant medications included a multivitamin, vitamin E and garlic tablets and post-operative aspirin and clopidogrel. The subject continued on Pravachol 10 mg and completed the study. The LDL cholesterol level at the end of the study was 110 mg/dl. The investigator did not attribute the event to study medication.

Subject 15-4619 (Rx Group), a 71 year old white female was hospitalized for treatment of a post-operative infection 38 days after starting Pravachol 10 mg. The subject had undergone surgery of the left wrist on an out-patient basis ten days earlier. Relevant medical history included rheumatoid arthritis and osteoarthritis of both hands. Concomitant medications included aspirin, calcium carbonate, folic acid, prednisone and methotrexate sodium. Pravachol 10 mg, which had been interrupted for four days, was restarted. The subject completed eight weeks of Pravachol 10 mg, discontinuing study drug of her own accord. The investigator did not attribute the event to study medication.

Subject 15-4627 (Rx Group), a 62 year old white male developed a urethral obstruction 42 days after starting Pravachol 10 mg. The subject underwent surgery for placement of a urethral stent and was discharged one day later. Concomitant medications included: verapamil, multivitamin, fish oil, saw palmetto, gingko biloba, coenzyme, doxazosin, aspirin and oxaprozin. After stopping study medication for 5 days, the subject restarted

Pravachol 10 mg and completed the study. The investigator did not attribute the event to study medication.

Subject 19-4032 (Rx Group), a 53 year old white male with a history of hypertension, was started on Pravachol 10 mg and was subsequently titrated 20 mg. The subject reported atypical chest pain 128 days after starting Pravachol therapy. Forty-one days later, the subject was hospitalized and underwent a cardiac catheterization with stent placement. Concomitant medications included dyazide. The subject continued on Pravachol 20 mg, was then titrated to 40 mg, and completed the study. LDL-C at the end of the study was 87mg/dl The investigator did not attribute the event to study medication.

Subject 19-4623 (Rx Group), a 63 year old white male with a history of an enlarged prostate, had an elective transurethral resection of the prostate 60 days after starting Pravachol 10 mg. Other secondary diagnoses included: rosacea, arthritis and ilioinguinal nerve damage with pain in the right testicle. Concomitant medications included: gabapentin, doxazosin mesylate, tetracycline and psyllium. The subject continued Pravachol 10 mg and completed the study. The investigator did not attribute the event to study medication.

Subject 20-4620 (Rx Group), a 70 year old white male with a history of benign prostatic hypertrophy, was diagnosed with prostate cancer approximately 13 days after starting Pravachol 10 mg. The subject was hospitalized for surgical removal of a tumor (Gleason Grade V) and was discharged five days later. Concomitant medications included: ibuprofen, magnesium chloride, a multivitamin, vitamin E, folic acid, niacin and vitamin C. Pravachol 10 mg was discontinued. The investigator did not attribute the event to study medication.