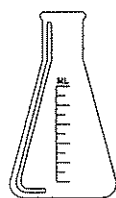


## Biopharmaceutical Section



American Statistical Association

# Biopharmaceutical Report

Volume 5, No. 3

Fall/Winter 1997

Chair: *Bob Davis*

Editors: *Anne Meibohm, Curtis Wiltse and Bill Huster*

## Report of October 1996 Survey of Biopharmaceutical Section Members

**Philip J. Pichotta**

*Abbott Laboratories*

### Abstract

A 41-item survey of the 1770 members of the Biopharmaceutical Section was conducted to collect information on demography, education, employment, continuing education activities, and services provided by the Biopharmaceutical Section. The survey was returned by 1139 members (64%).

The results showed that most members are male (69%); White (75%) or Asian (22%); are employed by a pharmaceutical company (52%), by academia (18%), or by a CRO (13%); and have a doctorate (49%) or a masters (40%) in statistics. Most (57%) earn \$46-90 thousand/year, but 29% earn over \$90 thousand/year. Most are satisfied with their job, but pressure to produce is a common problem.

### Introduction

Other than their names and addresses, very little was known about members of the Biopharmaceutical Section before this survey was taken. Location of members, membership in other ASA sections and ASA subscriptions were obtained when the mailing list was received for this survey and, therefore, were not included as questions. In order to better serve the membership, this survey was conducted to collect information about demographics, continuing education activities, and employment activities.

The survey took a year to plan, and there were numerous revisions to the questionnaire. Some questions that didn't make the final survey were about tobacco-use and alcohol-use. We often collect tobacco- and alcohol-use information in clinical trials but often don't do much with the data. However, these questions were quickly nixed by those who reviewed the survey, so we didn't have to worry about that. I also proposed some silly questions to make the survey a little more fun (e.g., Are you politically correct all the time, some of the time, none of the time, or what do you mean by politically correct?), but again these were nixed. I was urged to concentrate on the information that we wanted. Salary was an important item, and I originally proposed to collect it to the nearest thousand dollars; but to ensure a better response, a categorization of salary ranges was suggested. Arriving at a categorization for salary was difficult because there was little knowledge about the salary distribution, especially at the upper incomes. The question about primary writing hand was prompted by my observation that many statisticians in my work groups were left-handed. Since I was the author of the survey, I included the question.

When the survey was being planned, I naively estimated that we would get 1200 responses. Some people experienced in conducting surveys thought that we would do well if we got a 20% response. I had faith that our membership wanted to know the information gathered by this survey and am grateful for all the members who took the time to complete the survey questionnaire and return it. The T-shirt probably helped increase the response rate, but 260 members who sent back the questionnaire didn't send back the postcard for the free T-shirt. Our members are smart enough to know that they could have sent back the postcard without completing the questionnaire and no one would be the wiser. Including postage for US members helped increase the response rate, but we still got a good response rate from our foreign members who had to supply the postage to return the survey and the postcard. We would have included postage for foreign members but didn't know how this could be done. Near the due date, reminder postcards were sent to US members who hadn't returned a postcard to encourage a response, but this did-

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n't appear to be effective. The cost for the preparation and mailing of the survey was \$4,620 and the cost of the T-shirts and mailing them was \$8,146 for a total cost of \$12,766. The free T-shirts may not have been necessary, but we were trying to reduce the surplus in the Section's treasury. We were also looking for something to give to members that would provide identification with the Section and believe that the T-shirt met that goal. The distribution of T-shirt sizes (876) was fairly symmetric (S -2%, M-10%, L-39%, XL-40%, XXL-9%).

A commercially-prepared machine-readable questionnaire was considered but that would have been about twice as expensive and would have taken more preparation time. The survey was printed on one-sided paper because there was the possibility of scanning in the forms and 2-sided paper would have made that process more difficult. However, the data were entered into a database and were stored as a SAS dataset. It was good that this survey was not considered as a pivotal confirmatory survey according to the new ICH guidelines because the analyses were not preplanned. Descriptive statistics were used to summarize the results; however, formal statistical analysis can be performed if desired. Since our members are experienced in evaluating data and because of the volume of the data, no graphics were used to summarize the results.

### Method

A 41-item questionnaire was sent to 1770 Biopharmaceutical Section members (as of August 26, 1996) between October 7-9, 1996 (20 surveys were returned as undeliverable). The questionnaire was returned anonymously. To encourage response, a return postcard to get a free Biopharmaceutical Section T-shirt was included and was returned to a different address to maintain confidentiality. Questionnaires were to be returned by October 31, 1996. Reminder postcards were sent to U.S. members who hadn't returned a postcard in mid November 1996 extending the due date to end of November 1996. Final cutoff was mid January 1997.

### Results

The survey was a success in that 64% of the Biopharmaceutical Section members returned the survey. Most respondents completed all the items. One item that had a lot of non responses was sex/gender, with 111 missing responses. The results for each question are provided in the Appendix.

### Demographic Characteristics

The Biopharmaceutical Section membership is primarily located in the US (91%). Most members are male (69%). The vast majority of members are between 26 and 54 years old (87%). Most members are white (75%) or Asian (22%). Only a small percentage were Black, Hispanic or Other ethnic group. The percentage of Asians is highest in members between 26-34 years old (32%) and decreases steadily in the older age groups (10% in 65+ age group) (Table 1). Similarly, the percentage of females was highest in the 26-34 year old group (41%) and decreased steadily until there were no females in the 65+ age group (Table 2). These results are similar to those presented in a National Science Foundation presentation entitled "NSF Study - Technical Careers" by Linda Parker and Lawrence Burton (July 2, 1997 at Abbott Laboratories). The speaker also mentioned that few Blacks and Hispanics are employed in technical fields,

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so our section is not unusual in that respect. The data do not necessarily imply that more women are becoming Biopharmaceutical Section members because this was not a longitudinal study. Only 9% of members were left handed which is not much different from the national average. The percentage of left-handers was 12% in Whites and only 0.9% in Asians. The large number of Asians in our membership brought down the overall percentage of left-handers as few Asians are left-handed. Most members considered clinical (79%) to be their primary pharmaceutical interest with pre-clinical a very distant second (6%). Most members have either a doctorate (49%) or masters (40%) in statistics. Not many members have a higher degree in a non-statistical field than their statistics degree (Table 3).

### ASA and Section Membership

About one-third (36%) of our members have belonged to the ASA for 5 years or less. Almost one-half (43%) of the members have belonged to the ASA for 11 or more years. Most (65%) of our members have belonged to our section for 5 years or less, so it appears many members joined the ASA a few years before joining the Biopharmaceutical Section.

Forty-five percent (45%) pay the ASA dues with their own money. An identical percentage of members pay Section membership dues with their own money. With almost one-half of our members paying ASA and section dues with their own money, we should consider what impact changes in dues and fees will have on our membership. Interestingly, most members in academia (73%) and virtually all members in government (98%) and the self-employed (94%) paid the dues with their own money, while in the pharmaceutical industry only 20% of members paid the dues with their own money (Table 4). Within the pharmaceutical industry, the percentage of members who had to pay ASA dues with their own money was smaller in the larger pharmaceutical companies than in the smaller companies (Table 5).

A high percentage of members employed by a pharmaceutical company or a contract research organization (CRO) considered the Biopharmaceutical Section as their primary ASA section (Table 6). However, less than 50% of members employed by academia, government, HMO (health maintenance organization)/formulary/insurance company or Other employer considered the Biopharmaceutical Section as their primary ASA section. Seventy-two percent (72%) of our members also belong to a local ASA chapter which suggests that our members are involved with professional activities. Our members frequently belong to other professional associations, e.g., the Biometrics Society (43%), DIA (30%), and the Society for Controlled Clinical Trials (20%). Membership in the ASQC was highest for Other (25%) and Self-employed (13%) (Table 8). Membership in the Biometrics Society was highest for Government (65%) and Academia (61%). Membership in the Society for Controlled Clinical Trials was similar across the employer types. As might be expected, membership in the DIA was highest among CRO (42%) and Pharmaceutical Industry (41%) members. Membership in the IMS was highest among Academia (29%) and Government (20%) members. Very few members belong to the ISCB, but that is not surprising since it is primarily an European organization.

Our members were generally well satisfied with our section. Blacks seemed more satisfied and Other ethnic group members seemed less satisfied than most members (Table 9), but the numbers are small. Satisfaction with the Biopharmaceutical

Section appeared to increase with increasing age (Table 10) and with increasing years in the section (Table 11). The high number of members who had been in the section less than one year and were neither satisfied nor dissatisfied with the section may indicate that these members hadn't received a *Biopharmaceutical Report* or any other communication from our section and therefore didn't have enough information on which to make an opinion. Satisfaction with the Biopharmaceutical Section was also a little higher in members who considered the section as their primary section (Table 12).

### **Employment Characteristics**

Six percent (6%) of our members indicated that they were unemployed; however, 69% of the unemployed were students. Over one-half of our members are employed in the pharmaceutical industry, 18% are employed in academia, and 13% are employed by a CRO. It was interesting to have information about the number of statisticians employed by a CRO because of the growth of CROs in the last few years. Thirty percent (30%) of the members had been employed in the pharmaceutical field between 1 and 5 years. Many of the members are employed in work groups with either no other statisticians (14%) or 1 to 5 other statisticians in their work unit (33%). This information is important because information from large pharmaceutical companies may not be representative of our membership. Somewhat surprisingly, 39% of our members considered themselves as formal supervisors. This percentage was lower in HMO/Formulary/Insurance Co. (18%) and Self-employed (27%) members (Table 13). The percentage of supervisors was higher for males (43%) than for females (29%) (Table 14). The percentage of supervisors was lower for non-Whites than for Whites (Table 15). Regardless of employer, over 20% of members reported that they worked over 50 hours/week (Table 16). Supervisors tended to work more than non-supervisors (Table 17).

Our membership appears to be satisfied with their jobs. The percentage of members who were very satisfied with their jobs tended to increase with longer total work hours (Table 18). The percentage of members who were dissatisfied with their job also increased with longer total work hours. Members in academia and the self-employed were the most satisfied (Table 19). Job satisfaction was reasonably consistent regardless of pharmaceutical interest (Table 20). Males were more satisfied with their jobs than were females (Table 21). Supervisors were more satisfied with their jobs than non-supervisors (Table 22).

Rating of problems by type of employer are presented in Tables 23-36. Generally, Pressure to Produce, Overwork, Poor Data Quality, and Non-statistical Tasks were common problems (>20%) while Lack of Respect, Job Security, Unethical Conduct, Racial/Ethnic Bias, and Sex/Gender Bias were infrequent problems (<10%). The other problem areas were rated as Common 10-20% of the time. The percentage of members who rated Lack of Respect as a Common problem was the lowest for the Self-employed. Low Pay was more of a problem in Academia and in HMO/Formulary/Insurance Co. Job Security was more of a problem in Academia and for Self-employed members. Overwork and Pressure to Produce were somewhat less of a problem for Government, Self-employed and Other. Educational Advancement was less of a problem in Government, HMO/Formulary/Insurance Co., and the Self-employed. Advancement Opportunities was more of a problem in Government and less of a problem in the Self-employed. The

problem of Advancement Opportunities and Educational Advancement were more common problems for those with a masters degree (Tables 37 and 38, respectively) than for other degrees.

Overall, perception of bias that members personally experienced was relatively low. However, when problems with racial bias were summarized by ethnic group (Table 39), 13% of Blacks and 9% of Asians and Hispanics rated racial bias as a common problem. Only 5% of females rated sex/gender bias as a common problem (Table 40).

The salaries (including usual bonuses) of members with a Master or Doctorate degree were highest in the Self-employed and Pharmaceutical Industry (Tables 42.1 and 42.2). Salaries for members with <1 year in the Biopharmaceutical field were commonly \$30-45 thousand/year for those with a Master degree and \$61-75 thousand/year for those with a Doctorate. Salaries increased with experience in the Biopharmaceutical field (Tables 43.1 and 43.2). For those with a Doctorate, 20% of those with 11-25 years of experience and 35% of those with >25 years of experience earned over \$135 thousand/year. Salaries were higher for males than for females (Tables 44.1 and 44.2). Salaries were higher for Whites than for Asians (Tables 45.1 and 45.2). The differences in salaries for sex/gender and ethnic groups are probably reflected by the differences in the years of experience between the sex/gender and ethnic groups.

### **Continuing Education Activities**

Members rated their Peers as the most important way that they learn/update their statistical skills, with over one-half of the members rating Peers as Very Important (Table 49). Reading books was rated as Very or Somewhat Important by over 80% of members (Table 50). Statistical meetings, short courses, journals, and software were somewhat less important in how members update their statistical skills (Tables 46, 47, 51, and 52). Statistics meetings and journals were more important to those with a doctorate in learning/updating their statistical skills, while short courses were more important to those with a masters in learning/updating their statistical skills. University courses for credit were Very Important to those with a bachelor degree but much less so for those with a master or doctorate degree (Table 48). Statistical meetings and reading journals were more important for those in academia in learning/updating their statistical skills (Tables 53 and 58). Short courses were less important for those in government and the self-employed in learning/updating their statistical skills (Table 54). University courses were rated as less important for those in government and the self-employed (Table 55). Peers were rated less important for those in government, HMO/formulary/insurance co., and the self-employed in learning/updating their statistical skills (Table 56). Reading statistics books was important to those in academia and the self-employed in learning/updating their statistical skills (Table 57). Software was less important for those in government than for others (Table 59). The number of statistical books bought by members in the last 5 years for their personal use increased with higher educational degree (Table 60). The number of statistical books bought was highest by those in academia and lowest in CROs and pharmaceutical industry (Table 61).

About one-third of members haven't attended an ASA annual meeting in the last five years. Attendance at the ASA annual meetings was higher with a more advanced degree (Table 62.1) About two-thirds of those who attended the ASA annual meet-

ings rated them as good to excellent (Table 62.2). Those in government tended to attend more ASA annual meetings than those employed by other types of employers (Table 63.1) and also tended to rate the meetings more favorably (Table 63.2).

### Computer Use

Most members use a networked PC or workstation at work and most use a computer at home. Over 80% of members use E-mail and over 60% use web browsers. Only 16% indicated that they did not use the Internet. Internet use was highest in government and academia and lowest in CROs and the self-employed (Table 64). Internet use did not differ with respect to supervisor status (Table 65).

### Conclusions

With a 64% response rate, the survey was successful in obtaining information about the membership of the Biopharmaceutical Section. Members are generally satisfied with their jobs but work hard. Most members have been members for <5 years. Workshops and sessions are important services provided by the section. Members update statistical skills by consulting with peers and taking short courses.

### Additional Results

This survey presented a wealth of information about our membership. If there are additional summaries that you would like to see, please contact me (philip.pichotta@abbott.com, 847-937-3708) and I will try to provide additional results. These may be presented in the Section's electronic newsgroup. It would be nice to have the entire database available to our members, but this would raise some confidentiality issues even though the survey was anonymous.

### Acknowledgment

The Biopharmaceutical Section wishes to thank MedFocus, DesPlaines, IL for data entry. Thanks to members who completed and returned the survey.

Table 1: Percentage of Ethnic Groups by Age Group (Entries are % of Row Total)

Age Group (N)	White	Black	Asian	Hispanic	Other
≤25yr (40)	85	0	5	2	8
26-34yrs (317)	65	1	32	2	1
35-44yrs (394)	71	3	24	1	<1
45-54yrs (277)	85	1	13	1	<1
55-64yrs (80)	83	0	14	1	2
65+yrs (20)	90	0	10	0	0

Table 2: Percentage of Sex by Age Group (Entries are % of Row Total)

Age Group (N)	Male	Female
≤25yr (37)	32	68
26-34yrs (298)	41	59
35-44yrs (366)	33	67
45-54yrs (241)	24	76
55-64yrs (69)	13	87
65+yrs (17)	0	100

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Table 3: Highest Statistics Degree vs Highest Non-Statistics Degree

Highest Stat. Degree	None	Bachelor	Masters	Doctorate/ MD/JD	Other
None	1	15	23	52	0
Bachelor	18	13	1	3	1
Masters	98	239	78	30	4
Doctorate	105	257	157	20	2

Table 4: Percentage of Members Who Pay ASA Dues with Own Money by Type of Employer

Employer (N)	Percent
Academia (191)	73%
CRO (134)	40%
Government (40)	98%
HMO/Formulary/Insurance Co. (12)	83%
Pharmaceutical Industry (542)	20%
Self-employed (53)	94%
Other (81)	46%

Table 5: Percentage of Members Who Pay ASA Dues with Own Money for Members Employed in Pharmaceutical Industry by Number of Statisticians Employed in Work Group

Number of Statisticians (N)	Percent
≤11 Statisticians (277)	25%
>11 Statisticians (264)	14%

Table 6: Primary Biopharmaceutical Section Membership by Pharmaceutical Interest

Pharmaceutical Interest (N)	Percent
Animal Health (22)	77
Clinical (876)	78
Devices (32)	66
Diagnostics (19)	47
Information Management (40)	73
Manufacturing/Stability (11)	45
Pre-Clinical (72)	67
Other (34)	38

Table 7: Primary Biopharmaceutical Section Membership by Type of Employer

Employer (N)	Percent
Academia (190)	46
CRO (135)	88
Government (38)	45
HMO/Formulary/Insurance Co. (12)	42
Pharmaceutical Industry (540)	90
Self-employed (53)	74
Other (80)	46

Table 8: Membership in Other Professional Societies by Type of Employer (Entries are % of Employer Total)

Employer (N)	ASQC	Biometrics Society	Controlled Clinical Trials	DIA	IMS	ISCB
Academia (193)	5	61	21	10	29	6
CRO (137)	3	37	23	42	5	4
Government (40)	8	65	25	13	20	3
HMO/Formulary/Insurance Co. (12)	0	33	25	8	0	0
Pharmaceutical Industry (549)	5	42	19	41	6	5
Self-employed (53)	13	40	19	38	17	2
Other (81)	25	27	26	9	11	1

Table 9: Satisfaction with Biopharmaceutical Section by Ethnic Group (Entries are % of Row Total)

Ethnic Group (N)	Very Satisfied	Satisfied	Neither Satisfied Nor Dissatisfied	Dissatisfied	Very Much Dissatisfied
White (823)	14	52	33	1	0
Black (17)	35	59	6	0	0
Asian (233)	10	52	34	1	2
Hispanic (13)	15	46	38	0	0
Other (10)	0	30	70	0	0

Table 10: Satisfaction with Biopharmaceutical Section by Age Group (Entries are % of Row Total)

Age Group (N)	Very Satisfied	Satisfied	Neither Satisfied Nor Dissatisfied	Dissatisfied	Very Much Dissatisfied
≤25 years (38)	8	53	39	0	0
26-34 years (310)	9	50	40	1	0
35-44 years (388)	14	50	34	1	1
45-54 years (271)	17	54	28	<1	0
55-64 years (78)	13	56	29	1	0
65+ years (20)	20	65	15	0	0

Table 11: Satisfaction with Biopharmaceutical Section by Years in Biopharmaceutical Section (Entries are % of Row Total)

Years in Biopharmaceutical Section (N)	Very Satisfied	Satisfied	Neither Satisfied Nor Dissatisfied	Dissatisfied	Very Much Dissatisfied
<1 year (157)	7	45	48	0	0
1-5 years (539)	14	49	35	1	1
6-10 years (190)	13	58	27	2	1
>10 years (200)	17	58	25	0	0

Table 12: Satisfaction with Biopharmaceutical Section by Primary Biopharmaceutical Section Membership (Entries are % of Row Total)

Primary Biopharmaceutical Section Membership (N)	Very Satisfied	Satisfied	Neither Satisfied Nor Dissatisfied	Dissatisfied	Very Much Dissatisfied
Yes (809)	14	55	30	1	<1
No (280)	10	44	44	1	1

Table 13: Supervisor Status by Type of Employer

Employer (N)	% Supervisor
Academia (172)	44
CRO (135)	40
Government (36)	44
HMO/Formulary/Insurance Co. (11)	18
Pharmaceutical Industry (516)	38
Self-employed (49)	27
Other (75)	39

Table 14: Supervisor Status by Sex/Gender

Sex/Gender (N)	% Supervisor
Female (284)	29
Male ((622)	43

Table 15: Supervisor Status by Ethnic Group

Ethnic Group (N)	% Supervisor
White (750)	43
Black (13)	23
Asian (205)	27
Hispanic (12)	33
Other (7)	14

Table 16: Total Hours Worked (hours/week) by Type of Employer (Entries are % of Row Total)

Type of Employer (N)	≤35	36-40	41-45	46-50	51-60	>60
Academia (187)	13	9	10	24	30	16
CRO (136)	9	13	26	21	14	17
Government (40)	0	18	20	25	27	10
HMO/Formulary/Insurance Co. (11)	18	27	0	27	18	9
Pharmaceutical Industry (544)	1	18	30	25	15	10
Self-employed (48)	31	13	15	19	15	8
Other (78)	10	14	24	29	14	8

Table 17: Total Hours Worked (hours/week) by Supervisor Status (Entries are % of Row Total)

Supervisor Status (N)	≤35	36-40	41-45	46-50	51-60	>60
Yes (383)	2	8	17	28	27	18
No (601)	10	21	29	21	11	8

Table 18: Job Satisfaction by Total Hours Worked (hours/week) (Entries are % of Row Total)

Total Hours Worked (N)	Very Satisfied	Satisfied	Neither	Dissatisfied	Very Much Dissatisfied
≤35 hours/week (69)	26	51	20	3	0
36-40 hours/week (161)	24	53	16	7	0
41-45 hours/week (248)	20	56	15	6	2
46-50 hours/week (255)	26	51	17	5	1
51-60 hours/week (188)	37	42	14	6	1
>60 hours/week (120)	35	40	15	8	2

Table 19: Job Satisfaction by Type of Employer (Entries are % of Row Total)

Type of Employer (N)	Very Satisfied	Satisfied	Neither	Dissatisfied	Very Much Dissatisfied
Academia (193)	38	42	12	7	1
CRO (135)	21	50	19	9	2
Government (39)	28	59	10	0	3
HMO/Formulary/Ins. Co. (11)	18	27	18	36	0
Pharmaceutical Industry (544)	24	53	18	5	1
Self-employed (52)	46	42	10	2	0
Other (80)	31	49	10	9	1

Table 20: Job Satisfaction by Pharmaceutical Interest (Entries are % of Row Total)

Mathematical Interest (N)	Very Satisfied	Satisfied	Neither	Dissatisfied	Very Much Dissatisfied
Animal Health (20)	25	50	15	10	0
Clinical (834)	28	49	16	6	1
Devices (32)	19	53	22	6	0
Diagnostics (16)	12	75	12	0	0
Information Management (37)	16	57	16	11	0
Manufacturing/ Stability (10)	50	50	0	0	0
Pre-Clinical (65)	31	51	12	5	2
Other (25)	36	32	16	16	0

Table 21: Job Satisfaction by Sex/Gender (Entries are % of Row Total)

Sex/Gender (N)	Very Satisfied	Satisfied	Neither	Dissatisfied	Very Much Dissatisfied
Female (297)	23	49	19	8	1
Male (655)	30	49	15	6	1

Table 22: Job Satisfaction by Supervisor Status (Entries are % of Row Total)

Supervisor Status (N)	Very Satisfied	Satisfied	Neither	Dissatisfied	Very Much Dissatisfied
Yes (386)	39	47	10	4	1
No (606)	21	51	20	8	1

Table 23: Problem of Lack of Power by Type of Employer (Entries are % of Row Total)

Employer (N)	No Problem	Rarely	Sometimes	Common
Academia (187)	21	26	41	12
CRO (133)	17	30	39	14
Government (39)	5	28	51	15
HMO/Formulary/Insurance Co. (12)	25	25	42	8
Pharmaceutical Industry (537)	9	32	46	13
Self-employed (46)	24	22	43	11
Other (75)	17	31	39	13

Table 24: Problem of Lack of Respect by Type of Employer (Entries are % of Row Total)

Employer (N)	No Problem	Rarely	Sometimes	Common
Academia (187)	36	30	27	6
CRO (134)	31	41	22	7
Government (39)	21	46	31	3
HMO/Formulary/Insurance Co. (12)	25	25	50	0
Pharmaceutical Industry (544)	23	35	34	8
Self-employed (48)	46	38	12	4
Other (75)	33	32	23	12

Table 25: Problem of Computer Support by Type of Employer (Entries are % of Row Total)

Employer (N)	No Problem	Rarely	Sometimes	Common
Academia (187)	36	21	28	14
CRO (135)	33	31	31	4
Government (39)	18	31	36	15
HMO/Formulary/Insurance Co. (12)	58	17	25	0
Pharmaceutical Industry (544)	24	32	33	10
Self-employed (47)	34	32	23	11
Other (75)	39	35	19	8

Table 26: Problem of Low Pay by Type of Employer (Entries are % of Row Total)

Employer (N)	No Problem	Rarely	Sometimes	Common
Academia (188)	24	21	26	28
CRO (135)	31	32	31	6
Government (39)	26	38	31	5
HMO/Formulary/Insurance Co. (12)	25	17	42	17
Pharmaceutical Industry (540)	35	30	26	9
Self-employed (47)	49	23	26	2
Other (76)	46	26	17	11

Table 27: Problem of Job Security by Type of Employer (Entries are % of Row Total)

Employer (N)	No Problem	Rarely	Sometimes	Common
Academia (187)	49	21	19	11
CRO (135)	35	32	26	7
Government (39)	44	41	15	0
HMO/Formulary/Insurance Co. (11)	36	27	36	0
Pharmaceutical Industry (541)	35	38	22	5
Self-employed (47)	47	17	21	15
Other (76)	42	28	24	7

Table 28: Problem of Overwork by Type of Employer (Entries are % of Row Total)

Employer (N)	No Problem	Rarely	Sometimes	Common
Academia (187)	11	12	37	40
CRO (135)	9	12	37	42
Government (39)	5	21	49	26
HMO/Formulary/Insurance Co. (12)	25	8	25	42
Pharmaceutical Industry (542)	5	17	38	40
Self-employed (48)	12	12	46	29
Other (76)	14	22	36	28

Table 29: Problem of Pressure to Produce by Type of Employer (Entries are % of Row Total)

Employer (N)	No Problem	Rarely	Sometimes	Common
Academia (186)	12	14	37	37
CRO (135)	8	13	33	46
Government (39)	8	23	54	15
HMO/Formulary/Insurance Co. (12)	25	0	33	42
Pharmaceutical Industry (543)	4	17	39	40
Self-employed (47)	9	17	45	30
Other (76)	11	26	36	28

Table 30: Problem of Poor Data Quality by Type of Employer (Entries are % of Row Total)

Employer (N)	No Problem	Rarely	Sometimes	Common
Academia (185)	12	21	39	27
CRO (136)	4	18	50	27
Government (39)	3	18	56	23
HMO/Formulary/Insurance Co. (12)	8	25	33	33
Pharmaceutical Industry (542)	6	30	43	21
Self-employed (48)	4	13	52	31
Other (75)	4	16	48	32

Table 31: Problem of Unethical Conduct by Type of Employer (Entries are % of Row Total)

Employer (N)	No Problem	Rarely	Sometimes	Common
Academia (185)	49	34	13	4
CRO (134)	49	35	13	4
Government (38)	39	50	11	0
HMO/Formulary/Insurance Co. (12)	58	33	8	0
Pharmaceutical Industry (539)	52	36	11	2
Self-employed (47)	40	43	15	2
Other (74)	50	27	19	4

Table 32: Problem of Racial/Ethnic Bias by Type of Employer (Entries are % of Row Total)

Employer (N)	No Problem	Rarely	Sometimes	Common
Academia (185)	71	16	8	5
CRO (135)	70	21	4	4
Government (39)	62	26	13	0
HMO/Formulary/Insurance Co. (12)	83	17	0	0
Pharmaceutical Industry (542)	67	21	10	2
Self-employed (47)	89	6	4	0
Other (74)	77	14	8	1

Table 33: Problem of Sex/Gender Bias by Type of Employer (Entries are % of Row Total)

Employer (N)	No Problem	Rarely	Sometimes	Common
Academia (186)	65	18	9	8
CRO (135)	67	22	10	1
Government (39)	59	26	13	3
HMO/Formulary/Insurance Co. (12)	67	33	0	0
Pharmaceutical Industry (543)	65	23	11	2
Self-employed (48)	81	8	6	4
Other (73)	77	12	10	1

Table 34: Problem of Educational Advancement by Type of Employer (Entries are % of Row Total)

Employer (N)	No Problem	Rarely	Sometimes	Common
Academia (178)	80	8	6	6
CRO (135)	61	14	12	13
Government (36)	78	8	8	6
HMO/Formulary/Insurance Co. (11)	64	27	0	9
Pharmaceutical Industry (528)	56	16	17	11
Self-employed (46)	80	11	2	7
Other (73)	59	8	16	16

Table 35: Problem of Advancement Opportunities by Type of Employer (Entries are % of Row Total)

Employer (N)	No Problem	Rarely	Sometimes	Common
Academia (184)	45	21	20	14
CRO (135)	30	21	32	18
Government (38)	21	21	29	29
HMO/Formulary/Insurance Co. (12)	25	33	25	17
Pharmaceutical Industry (544)	16	26	39	19
Self-employed (46)	63	17	13	7
Other (75)	33	16	27	24

Table 36: Problem of Non-Statistical Tasks by Type of Employer (Entries are % of Row Total)

Employer (N)	No Problem	Rarely	Sometimes	Common
Academia (186)	16	16	36	32
CRO (134)	8	19	37	37
Government (39)	0	18	41	41
HMO/Formulary/Insurance Co. (12)	17	8	33	42
Pharmaceutical Industry (543)	5	15	47	33
Self-employed (48)	15	17	37	31
Other (76)	11	18	43	28

Table 37: Problem of Advancement Opportunities by Highest Degree (Entries are % of Row Total)

Highest Degree (N)	No Problem	Rarely	Sometimes	Common
Bachelor (30)	27	30	30	13
Masters (396)	16	24	35	25
Doctorate/MD/JD (601)	33	22	30	14

Table 38: Problem of Educational Advancement by Highest Degree (Entries are % of Row Total)

Highest Degree (N)	No Problem	Rarely	Sometimes	Common
Bachelor (30)	63	13	13	10
Masters (391)	37	20	23	20
Doctorate/MD/JD (580)	81	9	6	4

Table 39: Problem of Ethnic Bias by Ethnic Group (Entries are % of Row Total)

Ethnic Group (N)	No Problem	Rarely	Sometimes	Common
White (776)	83	15	2	<1
Black (15)	27	20	40	13
Asian (217)	29	35	27	9
Hispanic (11)	45	18	27	9
Other (9)	67	22	11	0

Table 40: Problem of Sex/Gender Bias by Sex/Gender (Entries are % of Row Total)

Sex/Gender (N)	No Problem	Rarely	Sometimes	Common
Female (295)	45	30	20	5
Male (643)	76	18	4	2

Table 41: Publication Credit Given for Statistical Work by Type of Employer (Entries are % of Row Total)

Employer (N)	Always	Usually	Sometimes	Rarely	Never	Not Applicable
Academia (193)	18	44	18	5	0	17
CRO (134)	7	23	26	13	5	27
Government (37)	11	51	16	5	0	16
HMO/Formulary/Insurance Co. (11)	0	18	9	18	0	55
Pharmaceutical Industry (543)	6	32	26	17	4	15
Self-employed (52)	6	31	21	15	2	25
Other (80)	4	34	19	10	2	31

Table 42.1: Salary by Type of Employer where Highest Degree = Masters (Salary in Thousands of US Dollars/year) (Entries are % of Row Total)

Employer (N)	<30	30-45	46-60	61-75	76-90	91-105	106-120	121-135	>135
Academia (34)	56	26	12	6	0	0	0	0	0
CRO (60)	3	33	42	7	7	8	0	0	0
Pharmaceutical (229)	1	7	28	30	22	6	3	2	<1
Self-employed (17)	0	0	24	29	24	6	6	0	12
Other (40)	8	27	25	20	12	3	5	0	0

Table 42.2: Salary by Type of Employer where Highest Degree = Doctorate (Salary in Thousands of US Dollars/year) (Entries are % of Row Total)

Employer (N)	<30	30-45	46-60	61-75	76-90	91-105	106-120	121-135	>135
Academia (147)	3	13	24	19	13	10	6	3	10
CRO (63)	2	5	14	17	16	8	14	6	17
Government (31)	0	0	19	23	32	10	13	0	3
Pharmaceutical (285)	0	<1	5	22	21	13	15	7	16
Self-employed (29)	10	3	10	3	10	21	17	0	24
Other(32)	3	3	16	22	22	22	3	0	9

Table 43.1: Annual Salary by Years in Biopharmaceutical Field where Highest Degree = Masters (Salary in Thousands of US Dollars/year) (Entries are % of Row Total)

Years (N)	<30	30-45	46-60	61-75	76-90	91-105	106-120	121-135	>135
<1yr (45)	29	44	24	0	2	0	0	0	0
1-5yr (135)	7	27	41	19	4	1	1	0	0
6-10yr (111)	3	3	30	41	14	4	3	2	1
11-25yr (75)	1	4	11	19	45	13	3	1	3
>25yr (20)	0	0	5	5	30	25	25	10	0

Table 43.2: Annual Salary by Years in Biopharmaceutical Field where Highest Degree = Doctorate (Salary in Thousands of US Dollars/year) (Entries are % of Row Total)

Years (N)	<30	30-45	46-60	61-75	76-90	91-105	106-120	121-135	>135
<1yr (34)	6	18	21	32	9	9	0	0	6
1-5yr (150)	2	6	25	37	18	6	5	0	1
6-10yr (127)	2	4	11	16	27	15	12	6	8
11-25yr (170)	1	1	5	12	20	16	19	6	20
>25yr (88)	0	0	1	9	10	16	18	10	35

Table 44.1: Salary by Sex/Gender where Highest Degree = Masters (Salary in Thousands of US Dollars/year) (Entries are % of Row Total)

Sex/Gender (N)	<30	30-45	46-60	61-75	76-90	91-105	106-120	121-135	>135
Female (162)	6	16	33	25	14	3	1	1	0
Male (198)	7	16	24	22	16	7	5	2	2

Table 44.2: Salary by Sex/Gender where Highest Degree = Doctorate (Salary in Thousands of US Dollars/year) (Entries are % of Row Total)

Sex/Gender (N)	<30	30-45	46-60	61-75	76-90	91-105	106-120	121-135	>135
Female (112)	3	5	16	26	21	9	11	4	5
Male (413)	1	4	12	19	17	14	12	6	15

Table 45.1: Salary by Ethnic Group where Highest Degree = Masters (Salary in Thousands of US Dollars/year) (Entries are % of Row Total)

Ethnic Group (N)	<30	30-45	46-60	61-75	76-90	91-105	106-120	121-135	>135
White (302)	5	14	28	22	18	7	3	2	3
Asian (72)	11	19	33	24	11	0	1	0	0

Table 45.2: Salary by Ethnic Group where Highest Degree = Doctorate (Salary in Thousands of US Dollars/year) (Entries are % of Row Total)

Ethnic Group (N)	<30	30-45	46-60	61-75	76-90	91-105	106-120	121-135	>135
White (428)	2	4	11	17	19	14	13	4	17
Asian (140)	1	6	18	31	16	6	9	6	6

Table 46: Importance of Statistical Meetings in Learning/Updating Statistical Skills by Highest Degree (Entries are % of Row Total)

Highest Degree (N)	Very Important	Somewhat Important	Not Very Important	Not Important
Bachelor (43)	19	44	19	19
Masters (426)	21	47	22	10
Doctorate/MD/JD (615)	29	46	15	9

Table 47: Importance of Short Courses in Learning/Updating Statistical Skills by Highest Degree (Entries are % of Row Total)

Highest Degree (N)	Very Important	Somewhat Important	Not Very Important	Not Important
Bachelor (43)	21	44	26	9
Masters (424)	42	38	12	8
Doctorate/MD/JD (604)	31	36	19	14

Table 48: Importance of University Courses in Learning/Updating Statistical Skills by Highest Degree (Entries are % of Row Total)

Highest Degree (N)	Very Important	Somewhat Important	Not Very Important	Not Important
Bachelor (46)	80	9	2	9
Masters (423)	31	23	22	24
Doctorate/MD/JD (556)	12	12	20	56

Table 49: Importance of Peers in Learning/Updating Statistical Skills by Highest Degree (Entries are % of Row Total)

Highest Degree (N)	Very Important	Somewhat Important	Not Very Important	Not Important
Bachelor (45)	71	22	4	2
Masters (430)	58	33	7	2
Doctorate/MD/JD (611)	51	38	7	4

Table 50: Importance of Reading Books in Learning/Updating Statistical Skills by Highest Degree (Entries are % of Row Total)

Highest Degree (N)	Very Important	Somewhat Important	Not Very Important	Not Important
Bachelor (46)	43	37	20	0
Masters (433)	40	45	13	2
Doctorate/MD/JD (615)	42	46	10	3

Table 51: Importance of Reading Journals in Learning/Updating Statistical Skills by Highest Degree (Entries are % of Row Total)

Highest Degree (N)	Very Important	Somewhat Important	Not Very Important	Not Important
Bachelor (46)	30	39	22	9
Masters (432)	28	49	20	3
Doctorate/MD/JD (621)	44	41	11	4

Table 52: Importance of Software in Learning/Updating Statistical Skills by Highest Degree (Entries are % of Row Total)

Highest Degree (N)	Very Important	Somewhat Important	Not Very Important	Not Important
Bachelor	35	39	24	2
Masters (431)	32	43	19	6
Doctorate/MD/JD (611)	24	46	24	7

Table 53: Importance of Statistical Meetings in Learning/Updating Statistical Skills by Type of Employer (Entries are % of Row Total)

Employer (N)	Very Important	Somewhat Important	Not Very Important	Not Important
Academia (185)	35	41	13	11
CRO (132)	22	49	20	9
Government (39)	38	44	13	5
HMO/Formulary/Insurance Co. (10)	20	50	20	10
Pharmaceutical Industry (529)	24	49	18	8
Self-employed (50)	16	40	26	18
Other (78)	27	36	24	13

Table 54: Importance of Short Courses in Learning/Updating Statistical Skills by Type of Employer (Entries are % of Row Total)

Employer (N)	Very Important	Somewhat Important	Not Very Important	Not Important
Academia (182)	24	27	25	24
CRO (129)	34	42	13	11
Government (38)	16	58	13	13
HMO/Formulary/Insurance Co. (10)	40	40	0	20
Pharmaceutical Industry (530)	43	38	13	5
Self-employed (50)	16	38	24	22
Other (76)	38	34	14	13

Table 55: Importance of University Courses in Learning/Updating Statistical Skills by Type of Employer (Entries are % of Row Total)

Employer (N)	Very Important	Somewhat Important	Not Very Important	Not Important
Academia (179)	24	15	13	49
CRO (126)	22	15	23	40
Government (34)	6	12	24	59
HMO/Formulary/Insurance Co. (11)	27	9	27	36
Pharmaceutical Industry (493)	18	18	23	40
Self-employed (47)	11	11	13	66
Other (74)	25	16	27	31

Table 56: Importance of Peers in Learning/Updating Statistical Skills by Type of Employer (Entries are % of Row Total)

Employer (N)	Very Important	Somewhat Important	Not Very Important	Not Important
Academia (186)	59	33	4	5
CRO (129)	57	35	5	4
Government (38)	42	50	8	0
HMO/Formulary/Insurance Co. (10)	40	40	10	10
Pharmaceutical Industry (531)	55	36	7	2
Self-employed (50)	44	42	8	6
Other (79)	58	34	5	3

Table 57: Importance of Reading Books in Learning/Updating Statistical Skills by Type of Employer (Entries are % of Row Total)

Employer (N)	Very Important	Somewhat Important	Not Very Important	Not Important
Academia (188)	54	38	6	2
CRO (132)	38	43	15	4
Government (39)	44	44	13	0
HMO/Formulary/Insurance Co. (11)	36	55	9	0
Pharmaceutical Industry (532)	35	50	12	3
Self-employed (50)	54	30	10	6
Other (79)	42	48	9	1

Table 58: Importance of Reading Journals in Learning/Updating Statistical Skills by Type of Employer (Entries are % of Row Total)

Employer (N)	Very Important	Somewhat Important	Not Very Important	Not Important
Academia (191)	54	31	13	2
CRO (132)	30	46	17	6
Government (39)	38	54	8	0
HMO/Formulary/Insurance Co. (11)	27	55	18	0
Pharmaceutical Industry (533)	34	47	16	3
Self-employed (50)	28	50	8	14
Other (80)	34	42	21	3

Table 59: Importance of Software in Learning/Updating Statistical Skills by Type of Employer (Entries are % of Row Total)

Employer (N)	Very Important	Somewhat Important	Not Very Important	Not Important
Academia (186)	28	46	19	6
CRO (132)	30	41	21	8
Government (38)	16	53	21	11
HMO/Formulary/Insurance Co. (11)	27	64	9	0
Pharmaceutical Industry (528)	26	44	24	6
Self-employed (50)	30	52	14	4
Other (79)	32	43	18	8

Table 60: Number of Statistical Books Bought in Last Five Years by Highest Degree (Entries are % of Row Total)

Highest Degree (N)	0	1-2	3-5	6-10	11-20	>20
Bachelor (46)	17	28	20	20	7	9
Masters (431)	13	23	25	23	9	8
Doctorate/MD/JD (617)	9	11	25	25	15	15

Table 61: Number of Statistical Books Bought in Last Five Years Meetings by Type of Employer (Entries are % of Row Total)

Employer (N)	0	1-2	3-5	6-10	11-20	>20
Academia (190)	3	8	16	27	24	23
CRO (127)	10	20	32	21	9	8
Government (37)	14	22	16	24	14	11
HMO/Formulary/Insurance Co. (11)	0	18	18	36	9	18
Pharmaceutical Industry (536)	14	18	27	25	8	8
Self-employed (49)	14	8	31	8	18	20
Other (80)	8	19	25	20	12	16

Table 62.1: Number of ASA Annual Meetings Attended in Last Five Years by Highest Degree (Entries are % of Row Total)

Highest Degree (N)	0	1	2	3	4	5
Bachelor (36)	75	14	6	3	0	3
Masters (391)	41	29	16	8	4	2
Doctorate/MD/JD (557)	21	22	22	17	8	10

Table 62.2: Quality of ASA Annual Meetings Attended in Last Five Years by Highest Degree (Entries are % of Row Total)

Highest Degree (N)	Excellent	Good	Fair	Poor
Bachelor (11)	18	73	0	9
Masters (222)	11	47	37	5
Doctorate/MD/JD (447)	11	53	33	3

Table 63.1: Number of ASA Annual Meetings Attended by Type of Employer (Entries are % of Row Total)

Employer (N)	0	1	2	3	4	5
Academia (162)	27	23	19	10	9	11
CRO (113)	40	20	18	12	9	2
Government (36)	8	25	17	28	6	17
HMO/Formulary/Insurance Co. (11)	45	27	9	0	9	9
Pharmaceutical Industry (489)	26	26	21	14	6	6
Self-employed (44)	41	18	16	16	2	7
Other (73)	38	19	19	11	5	7

Table 63.2: Quality of ASA Annual Meetings by Employer (Entries are % of Row Total)

Employer (N)	Excellent	Good	Fair	Poor
Academia (126)	15	62	20	3
CRO (68)	9	53	35	3
Government (33)	21	52	27	0
HMO/Formulary/Insurance Co. (6)	0	33	50	17
Pharmaceutical Industry (354)	8	49	40	3
Self-employed (27)	15	44	33	7
Other (46)	9	48	35	9

Table 64: Internet Use by Type of Employer (Entries are % of Employer Total)

Employer (N)	Use E-mail	Use WWW	Use FTP	Do Not Use Internet
Academia (193)	92	82	66	8
CRO (137)	73	42	26	23
Government (40)	88	83	45	10
HMO/Formulary/Insurance Co. (12)	83	50	33	17
Pharmaceutical Industry (549)	78	56	28	18
Self-employed (53)	72	53	38	21
Other (81)	84	73	43	14

Table 65: Internet Use by Supervisor Status (Entries are % of Status Total)

Employer (N)	Use E-mail	Use WWW	Use FTP	Do Not Use Internet
Yes (388)	79	61	31	16
No (608)	80	60	39	18

## Appendix

Complete results for each survey question are presented below:

### 1. Where do you live?

U.S.	1039	91%
Canada	26	2%
Europe	48	4%
Japan	9	1%
Mexico/Central/S. America	4	<1%
Other	12	1%

### 2. What is your sex/gender?

Female	320	31%
Male	708	69%

### 3. What is your age?

≤25yr	40	4%
26-34yr	320	28%
35-44yr	399	35%
45-54yr	278	24%
55-64yr	80	7%
≥65yr	20	2%

### 4. What is your ethnic group?

White	842	75%
Black	18	2%
Asian	245	22%
Hispanic	13	1%
Other	10	1%

### 5. What is your primary writing hand?

Right	979	91%
Left	102	9%

### 6. How many years have you been a member of the ASA?

<1yr	83	7%
1-5yr	335	29%
6-10yr	235	21%
11-20yr	291	26%
>20yr	195	17%

### 7. How many years have you been a member of the Biopharmaceutical Section of the ASA?

<1yr	165	15%
1-5yr	555	50%
6-10yr	193	17%
>10yr	204	18%

### 8. Do you pay the ASA dues with your own money?

Yes	504	45%
No	623	55%

### 9. Do you pay the Biopharmaceutical Section dues with your own money?

Yes	510	45%
No	616	55%

### 10. Do you consider the Biopharmaceutical Section to be your primary ASA section?

Yes	833	74%
No	288	26%

### 11. Do you belong to a local ASA chapter?

Yes	792	72%
No	316	28%

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### 12. What other professional societies do you belong to?

ASQC	78	7%
DIA	339	30%
IMS	129	11%
Biometrics Society	484	43%
ISCB	49	4%
Society for Controlled Clinical Trials	224	20%

### 13. What is your primary pharmaceutical interest?

Animal Health	22	2%
Clinical	882	79%
Devices	33	3%
Diagnostics	19	2%
Information Management	41	4%
Manufacturing/ Stability	11	1%
Pre-Clinical	72	6%
Other	34	3%

### 14. Not employed? (If Yes, skip to Question 25)

Yes 72 (6%)

### 15. What is your current employment?

Academia	193	18%
CRO	137	13%
Government	40	4%
HMO/Formulary/Insurance Co.	12	1%
Pharmaceutical Industry	549	51%
Self-employed	53	5%
Other	81	8%

### 16. How many years have you been employed in the biopharmaceutical field?

<1yr	85	8%
1-5yr	308	30%
6-10yr	254	25%
11-25yr	262	25%
>25yr	122	12%

### 17. How many other statisticians are employed in your work unit?

None	152	14%
1-53	55	33%
6-10	173	16%
11-25	201	19%
>25	182	17%

### 18. Rate whether the following are problems you face as a statistician? (Entries are % of Row Total)

Problem Area (N)	No Problem	Rarely	Some-times	Com-mon
Lack Power (1030)	14	30	43	13
Lack Respect (1040)	28	35	29	7
Computer Support (1040)	29	30	31	10
Low Pay (1038)	34	28	26	12
Job Security (1037)	39	33	22	7
Overwork (1040)	8	15	39	38
Pressure to Produce (1039)	7	17	38	38
Poor Data Quality (1038)	7	24	45	24
Unethical Conduct (1030)	50	36	12	2
Racial/Ethnic Bias (1035)	70	19	8	3
Sex/Gender Bias (1037)	66	21	10	3
Educational Advancement (1008)	63	14	13	10
Advancement Opportunities (1035)	26	23	32	18
Non-statistical tasks (1039)	8	16	42	33

19. Are you given adequate credit in medical publications for your statistical work?

Always	87	8%
Usually	355	34%
Sometimes	244	23%
Rarely	138	13%
Never	30	3%
Not applicable	201	19%

20. How satisfied are you with your job?

Very Satisfied	292	28%
Satisfied	524	50%
Neither Satisfied nor Dissatisfied	164	15%
Dissatisfied	66	6%
Very Dissatisfied	11	1%

21. Are you a formal supervisor?

Yes	388	39%
No	608	61%

22. What is your annual salary, including usual bonuses? (US dollars in thousands)

Salary	N	%
<30	44	4%
30-45	100	10%
>45-60	190	19%
>60-75	214	21%
>75-90	178	17%
>90-105	97	10%
>105-120	83	8%
>120-135	34	3%
>135	86	8%

23. How many hours/week should you normally work (excluding overtime)? (categorized)

Hr/wk	N	%
<20	42	4%
21-30	18	2%
31-35	42	4%
36-40	759	73%
41-45	60	6%
46-50	76	7%
51-60	40	4%
>60	8	1%

24. How many hours/week of overtime do you work? (average over the last 3 months, categorized)

Hr/wk	N	%
0	206	21%
1-5	269	28%
6-10	254	26%
11-15	83	8%
16-20	64	7%
>20	99	10%

25. What is your highest degree earned in a statistics field?

None	91	8%
Bachelor	36	3%
Masters	452	40%
Doctorate	545	49%

26. What is your highest degree earned in a non-statistics field?

None	222	20%
Bachelor	524	47%
Masters	261	23%
Doctorate/MD/JD	109	10%
Other	7	1%

27. Are you a student (full or part-time) working for an advanced statistical degree?

Yes	171	15%
No	953	85%

28. Which statistics meetings have you attended in the last five years?

Number of Statistical Meetings Attended (Entries are % of Row Total)

Meeting (N)	0	1	2	3	4	≥5
ASA Annual Meetings (985)	31	24	19	13	6	7
ENAR (851)	63	19	10	4	3	2
WNAR (756)	95	3	1	1	<1	0
MBSW (776)	82	9	5	2	1	1
Applied Statistical Conf. (772)	84	11	4	1	<1	0
DIA Meetings (839)	59	18	11	6	2	4
Controlled Clinical Trials (794)	75	14	6	3	1	1
Internal Company (802)	59	7	9	8	5	12
Other Statistical Mtgs (883)	43	16	16	9	5	11

Average Quality of Statistical Meetings (Entries are % of Row Total)

Meeting (N)	Excellent	Good	Fair	Poor
ASA Annual Meetings (680)	11	51	34	4
ENAR (324)	26	54	18	2
WNAR (39)	18	46	28	8
MBSW (136)	33	51	12	4
Applied Statistical Conf. (124)	19	58	20	2
DIA Meetings (334)	13	58	26	3
Controlled Clinical Trials (195)	19	56	21	4
Internal Company (328)	14	61	22	3
Other Statistical Mtgs (488)	16	61	21	2

29. How many statistical short courses have you attended in the last five years?

Number of Statistical Short Courses Attended (Entries are % of Row Total)

Course (N)	0	1	2	3	4	≥5
ASA (881)	59	19	13	5	2	2
Local ASA Chapter (792)	74	11	9	3	1	1
Academia (784)	72	14	8	3	1	2
Commercial (787)	70	13	10	4	1	2
Internal Company (816)	61	10	11	8	5	5
Pharmaceutical Industry (757)	80	14	4	2	<1	<1

Average Quality of Statistical Short Courses Attended (Entries are % of Row Total)

Course (N)	Excellent	Good	Fair	Poor
ASA (354)	20	57	18	5
Local ASA Chapter (197)	20	59	18	3
Academia (211)	33	52	12	3
Commercial (219)	24	54	19	3
Internal Company (304)	22	59	17	2
Pharmaceutical Industry (146)	29	55	12	4

30. Do you regularly read any of the following statistical journals?

Amstat News	1027	90%
JASA	692	61%
American Statistician	711	62%
Biometrics	541	48%
Technometrics	172	15%
Statistics in Medicine	445	39%
Controlled Clinical Trials	335	29%
Other	191	17%

31. How do you rate the Biopharmaceutical Report?

Excellent	150	14%
Very Good	438	39%
Good	390	35%
Poor	22	2%
Never Read it	115	10%

32. What type of computer do you primarily use for statistical work?

Stand alone PC/Workstation	199	18%
Networked PC/Workstation	824	73%
Dumb Terminal	97	9%
None	8	1%

33. Do you use a computer at home?

Yes	921	82%
No	204	18%

34. Do you use the Internet in your work?

E-mail	919	81%
WWW	706	62%
FTP	437	38%
Do not use Internet	183	16%

35. How many statistical books have you bought in the last 5 years for your own personal use (excluding those for college credit courses)? (categorized)

None	121	11%
1-2	178	16%
3-5	276	25%
6-10	263	24%
11-20	136	12%
21-425	127	12%

36. How Important are the below in learning/updating your statistical skills? (Entries are % of Row Total)

Method (N)	Very Important	Somewhat Important	Not Very Important	Not Important
Statistical Meetings (1090)	25	47	18	10
Short Courses (1078)	35	37	16	12
University Courses (1030)	23	16	20	41
Peers (1093)	55	36	7	3
Read Books (1100)	41	45	11	3
Read Journals (1106)	37	44	15	4
Software (1094)	27	44	22	7
Other Journals (1032)	14	37	30	18
Other (178)	27	17	5	51

37. How satisfied are you with the biopharmaceutical section? (Entries are % of Row Total)

Very Satisfied	148	13%
Satisfied	574	52%
Neither	373	34%
Dissatisfied	8	1%
Very Much Dissatisfied	4	<1%

38. How important are the services that the biopharmaceutical section provides? (Entries are % of Row Total)

Method (N)	Very Important	Somewhat Important	Not Very Important	Not Important
Sponsor Sessions (1057)	48	36	10	7
Publish Newsletter (1084)	42	43	11	4
Provide Refreshments at JSM (1062)	6	16	33	45
Provide Fellowship (1064)	30	41	18	11
Provide Web Pages (1066)	25	43	19	13
Sponsor Workshops (1073)	49	36	9	6
Provide Awards for Best Papers (1050)	12	33	31	24
Other Services (235)	11	14	17	58

39. Please suggest ways to improve Biopharmaceutical Section - 11 pages of responses

40. Please suggest ways to provide recognition of members of Biopharmaceutical Section - 5 pages of responses

41. Please suggest topics for future sessions or workshops - 9 pages of responses

## Section News

### Best Contributed Paper Award

**Sandy Heft**

Each year at the ASA Joint Statistical Meetings, the Biopharmaceutical Section recognizes the best papers presented at the contributed papers sessions using responses from the attendees who fill out forms evaluating the presentations. Evaluations are based on contribution, organization, verbal delivery, and visuals used. At the 1997 Meetings, there were 487 responses filled out for the 18 sessions covered. The presentations achieving the top three scores are the following:

- First Place: Devan V. Mehrotra (Merck Research Laboratories) "ANOVA with Unequal Variance—Correcting a Popular Strategy"
- Second Place: Joseph F. Heyes (Merck) and Joseph G. Pigeon (Villanova) "A Cautionary Note About Assessing the Fit of Logistic Regression Models"
- Third Place: Ronald W. Helms (University of North Carolina) "Baseline Values are Random, Too: Using Baseline in Mixed Models"

Monetary awards and plaques will be presented to these presenters at the 1998 ASA Joint Statistical Meeting.

### Minutes of ASA Biopharmaceutical Section Executive Committee Meeting

**August 11, 1997, Anaheim, California**

#### Attendees:

Demissie Alemayehu	Bill Fox	Gary Neidert
Jim Bergum	Kalyan Ghosh	Phil Pichotta
Tom Capizzi	Larry Gould	Bruce Rodda
Chuck Davis	Sally Greenberg	Denise Roe
Bob Davis	Sandy Heft	Bob Small
Greg Enas	Ken Koury	Steve Snapinn
Richard Entsuaeh	Jeff Meeker	Liang Yuh

Bob Davis introduced new members and visitors. Other members introduced themselves. Davis reviewed the volunteer list. Davis requested any suggestions for the Deming Lecture be forwarded to Bob Starbuck. The next meeting of the Executive Committee will be Wednesday, October 29, 8:00-Noon, in the Executive Board Room of the Bethesda Hyatt.

### ENAR Meeting Minutes

The minutes of the March 25 meeting held at ENAR in Memphis, Tennessee, were approved with two corrections to the Council of Sections report. The first is that the issue of discounted fees on continuing education courses to students and in other special cases requested by the Biometrics Section would be discussed further at the August Council of Sections Governing Board meeting. The second is that the question from the Council of Sections Governing Board should read "What other electronic services do sections want?" rather than E-mail services.

### Treasurer's Report

Jeff Meeker distributed the final 1996 income and expenses of the Section and the income and expenses through June, 1997. The format of the report has changed significantly, which makes it difficult to determine with which activity various expenses were associated. However, the statement is more complete. Specifically, it included for the first time accounting for the 1996 Section Workshop on Adverse Events. We showed a loss of \$1169.22 for the first half of 1997.

Meeker also reported on the meeting of section treasurers. Steve Porzio, the new Director of Finance at ASA, indicated they are working on standardization of financial reports to sections and on improving the timeliness of those reports. He indicated his office is instituting a rule that all expenses must be approved by the treasurer. Sections can still require other approvals, if desired. The treasurers generally requested the financial report also indicate a breakdown by activity, such as proceedings, newsletter, or conference.

A request was made by Kenneth Suman, coordinator of the 1998 Undergraduate Data Analysis Contest, for a donation to support the contest. The Section approved a donation of \$500.

There was a discussion of ASA's attempts to upgrade their computer system. They have given up on the system that was developed and are purchasing another system. This system is based on already available software and is hoped to be in place by the end of the year.

### Manual of Operations Update

Meeker presented the proposed update in the Manual of Operations for the Section associated with the addition of the Communications Committee and the restructuring of the Section publications. The changes were approved.

**Assignment:** Meeker will finalize the changes and distribute the Manual of Operations.

### PhRMA Biostatistics Executive Committee

Greg Enas reported the PhRMA Biostatistics Section Steering Committee has been renamed the Biostatistics Executive Committee. It has a revised thrust to work with the FDA to speed the drug approval process. To reduce redundancies between the Biostatistics Executive Committee and the Section, he requested a liaison be appointed between the two organizations. The liaison would be appointed by the Biostatistics Executive Committee. The Section approved the proposal.

## Invited and Contributed Paper Sessions, 1997 Joint Statistical Meeting (JSM)

Lianng Yuh reported there are 14 contributed, four special contributed, and three invited sessions at the 1997 meetings. He indicated that in some sessions, he overprojected attendance, so the rooms are overly large.

### Short Courses, 1997 JSM

The two short courses scheduled for the 1997 JSM are:

**Bruce Rodda and Bob Starbuck**—*An Overview of the Role of the Biopharmaceutical Statistician: For Students and Statisticians Considering a Career in the Pharmaceutical Industry.*

**Craig Trost**—*An Introduction to the Quantitative Basis of Laboratory Medicine.*

Yuh reported the first course was held on Saturday and attendance was only about 20 students. The second course is scheduled for Tuesday. It was felt the low attendance at the first course was probably due to the Saturday schedule, but also noted there were two other similar courses.

**Assignment:** Yuh will recommend to the ASA Committee on Continuing Education that they coordinate courses to reduce redundancy, proposing combined courses if necessary.

### Round Tables, 1997 JSM

- Richard Entsuaah indicated there are eight round tables at the JSM. He also indicated he has received three summaries from the 1996 round tables.

**Assignment:** Entsuaah will forward the summaries to the editor of the *Biopharmaceutical Report* for publication.

- Interest was expressed in forming a work group on Meta-analysis.

**Assignment:** Sally Greenberg will explore through the mailing list who would be interested in forming such a working group.

### 1997 Best Paper Presentations

It was decided the section will ask speakers if they were interested in feedback from the best paper surveys and provide it, if possible.

### 1997 Best Student Papers

Denise Roe reported there were 13 entries from nine universities. The winners are:

**Thomas Bradstreet** (Temple University)—*Two Sample Hypothesis Testing for a Stopping Rule of Order  $k$  in Passive Avoidance Testing.*

**George Carides** (Temple University)—*Semiparametric Estimation of Mean Treatment Cost in the Presence of Right-censoring.*

**Paulette Ceesay** (Temple University)—*A Bayesian Approach for Assessing the Superiority of a Combination Drug.*

**Ping Hu** (Harvard School of Public Health)—*Estimating the Parameters in the Cox Model when Covariate Variables are Measured with Error.*

## Biopharmaceutical Report, Fall/Winter 1997

**Jin-Whan Jung** (University of North Carolina, Chapel Hill)—*A Nonparametric Strategy for the Analysis of Crossover Studies with Two Treatment Sequences.*

The awards will be presented at the Section business meeting. Roe also raised four issues. A question was raised as to whether graduates should be eligible for two years or should we restrict it to one year. The Executive Committee decided to leave it at two years so as not to put students who graduate at a certain time of the year at a disadvantage. A question was also raised as to whether students who have other funding to the meetings should be eligible (these are intended as travel grants). The Section decided that problem cases would be few and decided not to restrict eligibility. The Committee proposed the deadline for submission be moved to May 1 to allow more time to review the papers. The Executive Committee agreed with the change. The Student Awards Committee also proposed the Committee members be appointed for three years, with a new Committee member named each year. The Chair would be appointed from among the three members by the Chair-elect. The Program Chair would also be a member of this Committee. This structure would provide greater continuity. The Executive Committee agreed with the proposal.

**Assignment:** Meeker will make the necessary changes in the Manual of Operations to incorporate this last change and propose them for adoption at the October 29 Transition meeting.

Methods of more widely publicizing the awards were discussed. It was decided a flyer would be mailed with the letter announcing the awards each year. Also, an announcement would be sent to *Amstat News*.

### 1996 Best Paper Awards

Bill Fox will present the awards for Shein-Chung Chow at the Biopharmaceutical Section business meeting. The winners are:

- **First place**—Brian Wiens, Joseph Heyse, and Holly Matthews. *Similarity of Three Treatments, with Application to Vaccine Development.*
- **Second Place**—Gregory Campbell. *Statistical Issues in Medical Devices: A Regulatory Perspective.*
- **Third Place**—Karen M. Higgins. *The Effect of Serial Dilution Error on Assay Calibration.*

**Assignment:** Sandy Heft will write rules for the Best Paper awards for discussion at the October 29 transition meeting.

### Council of Sections

Chuck Davis reported on the Council of Sections annual meeting.

David Hoaglin reported on activities of the ASA Committee on Strategic Planning. They are addressing five areas: 1) electronic technology, 2) revenue generation, 3) education, 4) meetings and member support, and 5) archival of material. The expect to have a final report by the end of the year.

Richard Gunst reported on the ASA Board of Directors. There is a quality improvement program underway at the ASA office. The budget will end the year balanced. The 10 year process of converting to a new computer system continues. The Board allocated \$270,000 to purchase new hardware and soft-

ware. The conversion is targeted for the end of the year. If sections have issues with the Web site, now is the time to address them. There is a significant concern with the size of the program at the JSM. Proposals include allowing an individual to present only once (rather than one of each type), dropping a discussant on invited paper sessions and dropping the 5 minute introduction and discussants on special contributed paper sessions and regular contributed paper sessions. Other ideas include referee abstracts (there are strong objections to this), referee abstracts and shift some papers to posters, and group posters by topic or section and have them in smaller rooms. David Scott is the 1998 program chair.

Bruce Trumbo reported on the ASA Web site. The majority of abstracts were submitted by the Web. The membership list is more easily searchable. They are considering redoing the site to make it quicker and better organized. The 50th anniversary index to the *American Statistician* will be available for free on the Web site.

John McKenzie reported on several issues from the Constitution Committee. One issue being considered is committees, and there will be changes in some of them. Specifics include the elimination of the Elections Committee and realigning the term on the Fellows Committee and Nominations Committee so the term is three years, in line with other ASA Committees. The Affiliate Membership will be eliminated (this was recommended by both the Council of Chapters and the Committee on Membership). Two unresolved issues include: 1) the length of term of ASA President (should it be two years rather than one), 2) whether the Executive Director should be a voting member of the ASA Board of Directors, and 3) whether Canadian members should be eligible for the International Representative to the Board of Directors.

Jon Kettenring, ASA President, made several remarks. ASA finances are in good shape. Membership is declining after the membership campaigns of a few years ago. Protecting our major resources, membership and publications, is a big issue. There is an increasing focus on customer satisfaction. Current priorities include office optimization with renewed quality management emphasis and issues of image, outreach and advocacy. He stressed that sections should evangelize for section membership.

Boris Iglewicz, chair of the Career Development Committee, reported on a proposed salary survey. They are considering a more expansive survey than the current survey of academics. Questions include what industry areas should be included, who should the survey be sent to, and what questions should be asked?

**Assignment:** Phil Pichotta will contact Iglewicz to discuss issues from the Biopharmaceutical Section survey, which included salary questions.

Meredith Warshaw, chair of the Committee on Applied Statisticians, discussed how sections can help applied statisticians. Cathy Crocker encouraged sections to sponsor workshops and CE courses.

The *Journal of Statistics Education* requested funding from ASA sections.

The Executive Committee refused the request for funding.

There was also a request for funds from the poster competition and the project competition. They are seeking donations of \$500-\$1000. They need \$4500 total.

The Executive Committee indicated they needed more information for the request.

**Post Meeting Note:** The additional funding is to enable the organizers to increase the number of awards for winning posters/projects.

Porzio reported they are trying to improve financial statements and to develop more flexibility in reports.

## **Fellows Nominations Committee**

Rodda reported there will be six new fellows from the Section. An issue was discussed as to whether the Section should include a letter indicating the support of the Section in the nomination package. Larry Gould, next year's chair, proposed writing guidelines for putting together a nomination package.

## **SPAIG Initiative**

Rodda reported the initial conference on the interaction between academia, government, and industry was successful. Approximately 80-90 people, evenly divided among the three areas, attended. Attendance also included five former ASA presidents.

## **Deming Conference on Applied Statistics**

Kalyan Ghosh reported the conference will be held in Atlantic City on December 8-12. The program from the Section includes three one-hour tutorials on December 8-10:

**Damaraju Raghavarao**—*Sample Size Methods*.

**William Blackwelder**—*Equivalence or Similarity Trials*.

**Weichung Joe Shih**—*Sample Size Re-estimation and Conditional Power for Clinical Trials*.

The two-day short course on December 11-12 will be *Multiple Comparisons—Applications and Case Studies* by Peter Westfall and Dror Rom. There is a Web site for the conference at <http://nimbus.temple.edu/~kghosh/deming>.

**Assignment:** Greenberg will provide a link from the Section Web site.

## **Proceedings of the Biopharmaceutical Section**

The deadline for manuscripts to be included in the Proceedings is October 17. There will be several papers from the Midwest Biopharmaceutical Statistics Workshop.

## **Biopharmaceutical Report**

The second issue of the *Biopharmaceutical Report* was mailed prior to the JSM. A third issue is planned for the end of the year. The lead article will be by Pichotta on the membership survey. Biographies of new ASA fellows will also be included. We need to include summaries from the round tables and to announce candidates for next year's elections. Word files for the first two issues are needed to be included on the Web page. An Associate Editor still needs to be appointed.

## Web Site

Greenberg reported a number of additions have been made since the March Executive Committee Meeting, including:

- All materials received for the JSM, plus a link to the ASA site to get a list of the Section sessions.
- A "What's new" section.
- A full issue of the *Biopharmaceutical Report*.
- The flyer for the fall workshop. As of last week 19 people had preregistered by printing the registration form from the Web site.
- An information page on the E-mail list. Several subscriptions have originated from there.
- Automatic E-mail notification of changes as an option for users.
- Page access statistics on all pages created since the first of the year.

Converting more issues of the *Biopharmaceutical Report* is in progress. Proposed enhancements include graphic and other cosmetic enhancements and an automatic subscription script for the Section's mailing list.

Greenberg now has some increased software capabilities including scanning to Adobe Acrobat format, so page creation is faster and easier.

Greenberg requested that those submitting text provide exactly the text you want to present. Editing information from electronic copy frequently takes more time than doing the page design and conversion. She also indicated not to worry about how the document looks, unless it is to be scanned. Also, she requested everyone to avoid WordPerfect tables, Word tables, and anything with extensive page layout features.

## E-mail List

Greenberg reported that as of August 9, there were 102 subscribers. She has not observed any abuses of the list to date. Greenberg requested more ideas for generating discussion. Earlier this year, Greenberg moved everyone to individual message format. If the list gets busy, individual digest preferences will be reinstated. Some corporate mailing systems have security procedures that prevent automatic subscription.

## Midwest Biopharmaceutical Statistics Workshop

Jim Bergum reported the 1996 Midwest Biopharmaceutical Statistics Workshop was held at Ball State university in Muncie, Indiana, on May 19-21. There was a record attendance with more than 180 registered participants. The plenary speaker was Douglas Montgomery, who discussed some aspects of generalized linear models for designed experiments. The banquet speaker was Robert Hogg. There was also a special session, *What's New in the Last 10 Years*. Other than these sessions, there were three parallel concurrent tracks in the clinical, nonclinical, and preclinical areas.

The Planning Committee met on July 17 to start organizing the 1998 Workshop, to be held on May 18-20. The workshop chair is Pat O'Meara and the program chairs are Walt Offen, Paul Huber, and Frank Shen. The tentative theme will be *Resampling*

## Biopharmaceutical Report, Fall/Winter 1997

*Methods in the Pharmaceutical Industry*. Tentative sessions include:

- *Use of Resampling to Address the Issue of Multiple Endpoints*.
- *Pathology/Toxicology Issues in the Pharmaceutical Industry*.
- *In vitro/In vivo Correlation/Dissolution Issues*.
- *Computer Intensive Methods: Missing Data Problems*.
- *Data Mining Opportunities in the Pharmaceutical Industry*.
- *Individual Bioequivalence*.
- *Street Smarts for Statisticians*.
- *Adverse Event Analysis*.
- *Drug Interaction Studies*.

## 1997 Workshop: FDA/Industry Interaction

The program for the Workshop is complete. The announcement appeared in the June issue of *Amstat News* and the recent issue of *Biopharmaceutical Report*. Registration forms are available both on the Web site and the July issue of *Amstat News*. Currently, the limit for workshop attendance is 300. If necessary, we can extend the capacity to 350.

## 1998 Workshop Proposal

Starbuck has proposed a workshop on Meta-analysis. Specifically, the title would be *Strategies for Grouping Data for Analysis and Reporting*. Bob Small will chair the Workshop. Specifics of the proposal will be discussed at the October 29 transition meeting.

## Membership Committee

Pichotta has started sending a welcoming letter to new members. A poster of the results of the survey will be at the Noon, Wednesday poster session. The survey will also be published in *Biopharmaceutical Report*.

## 1998 ENAR Program

Capizzi indicated the ENAR Program Committee allocated three sessions to us and the following resulted from the negotiations:

- *Impact of Recent Therapeutic Advances in Clinical Trial Design and Analysis*. Tony Lachenbruch.
- *Exploratory Data Analysis Using Classification Trees: Biomedical Applications*. Frank Shen.
- *Role of DSMBs and Impact of Accumulating Evidence on Conduct of Clinical Trials*. Des Thompson and Roz Stone.

In addition, we had input into two sessions:

- *Statistical Challenges in Ratio Estimation*, Ghosh.
- *Surrogate Markers*.

## 1998 JSM Program

Tom Capizzi reported that the number of session allocated to the Section is unknown; however, proposals to date include:

- *Design Considerations for Phase I Trials*. William Rosenberger.
- *Immunogenicity and Efficacy Issues in Vaccine Clinical Trials*. Brian Wiens and Tony Lachenbruch.
- *Methodological Issues in the Analysis of Drug Product Stability Data*. David Pack.

- *Assessment of the FDA Draft Guidance on Statistical Procedures for Bioequivalence Studies*. J.P. Liu.

Two other possibilities include:

- *Statistical Issues in Computational Chemistry*. Stanley Young.
- *Active Control Trials*. Laura Meyerson.

**Post Meeting Note:** We were allocated three sessions.

There has been no allocations of Special Contributed Sessions, although Capizzi has four proposals.

## 1998 Round Tables

Entsuaht indicated he is looking for topics. About 20 were found in the Section membership survey.

**Assignment:** Entsuaht will provide an E-mail list of the proposals to the Executive Committee for their vote.

## 1998 Best Presentations

Sandy Heft will handle this effort.

## 1998 Short Courses

Capizzi reported a proposal for a short course in 1998:

*Design and Analysis of Clinical Trials* based on text by Liu and Chow. It consists of four 90 minute lectures.

## Workshop on Graphical Displays of Laboratory Data

## Committee on Nominations

Gary Neidert reported the following individuals have been nominated and agreed to run for the following positions in the 1998 Section election:

**Chair-Elect:** Capizzi, Yuh

**Program Chair-Elect:** Small, Curt Wiltse

**Secretary/Treasurer:** Greenberg, Pichotta

**Council of Sections Representative:** Meeker, Nancy Smith

# Minutes of ASA Biopharmaceutical Section Business Meeting August 12, 1997, Anaheim, California

Bob Davis welcomed the section members and guests and introduced the current Section officers. He also introduced the three newly elected officers for 1997: Chair-elect, Steve Snapinn; Program Chair-elect, Christy Chuang-Stein; and Publications Officer, Denise Roe.

## Activity Review

Davis reviewed the many Section activities for 1997:

- Continued our program to reduce cash on hand.
- Greatly expanded the Section Web Site and Electronic Discussion Group
- Provided awards to winners of the Outstanding Student

Paper and Best Biopharmaceutical Section Contributed Paper Competitions.

- Produced three issues of the *Biopharmaceutical Report* in each of the last two years.
- Formed a Communications Committee chaired by Roe and including Sally Greenberg, Webmaster and Mail List Moderator, and Curt Wiltse, Editor of the *Biopharmaceutical Report*.
- Fall Workshops:  
1996—Adverse Events  
1997—FDA and Industry—Working Together to Expedite the Development of New Pharmaceutical Products
- Strong programs at ENAR and Joint Statistical Meetings
- ASA Fellows Committee
- Membership Survey.

## Treasury Report

The final financial statement from the Biopharmaceutical Section Restricted Treasury for 1996 and the statement through June 30, 1997, were distributed. In 1996 the Section lost \$26751.27, which was close to our goal. These losses resulted from a reduction in dues, a reduction in the cost of Proceedings of the Section for 1997, the Adverse Events workshop, and a one-time Section membership survey.

## 1996 Best Presentations of a Contributed Paper Award

Bill Fox presented the awards for the Best Presentation of a Contributed Paper Award for papers presented at the 1996 Joint Statistical Meetings. The winners were:

- **First place**—Brian Wiens, Joseph Heyse, and Holly Matthews. *Similarity of Three Treatments, with Application to Vaccine Development*.
- **Second Place**—Gregory Campbell. *Statistical Issues in Medical Devices: A Regulatory Perspective*.
- **Third Place**—Karen M. Higgins. *The Effect of Serial Dilution Error on Assay Calibration*.

## 1996 Student Paper Competition Award

Roe presented the winners of the 1997 Student Paper Competition Award, in alphabetical order, with their plaques and checks:

**Thomas Bradstreet** (Temple University)—*Two Sample Hypothesis Testing for a Stopping Rule of Order  $k$  in Passive Avoidance Testing*.

**George Carides** (Temple University)—*Semiparametric Estimation of Mean Treatment Cost in the Presence of Right-censoring*.

**Paulette Ceesay** (Temple University)—*A Bayesian Approach for Assessing the Superiority of a Combination Drug*.

**Ping Hu** (Harvard School of Public Health)—*Estimating the Parameters in the Cox Model when Covariate Variables are Measured with Error*.

**Jin-Whan Jung** (University of North Carolina, Chapel Hill)—*A Nonparametric Strategy for the Analysis of Crossover Studies with Two Treatment Sequences*.

Roe thanked the other committee members for their help.

## Fall Workshop

Davis reported for Chuang-Stein on plans for the Biopharmaceutical Section sponsored workshop on the FDA/Industry Partnership to be held on October 27-28 at the Bethesda Hyatt. The cost of the workshop to Section members will be \$125.

## Fellows Committee

Bruce Rodda reported that the Section Fellows Nominations Committee has been established. There are six new fellows from the Biopharmaceutical Section this year. Larry Gould will chair the Committee next year. Gould requested suggestions for ASA fellow from the Section.

## 1997 Joint Statistical Meeting (JSM) Review

Liang Yuh, 1997 Section Program Chair, reviewed the Section's activities at the JSM. We sponsored two short courses: *An Overview of the Role of the Biopharmaceutical Statistician: For Students and Statisticians Considering a Career in the Pharmaceutical Industry* by Rodda and Bob Starbuck, and *An Introduction to the Quantitative Basis of Laboratory Medicine* by Craig Trost. We organized three contributed paper sessions: *Decision Analysis in the Pharmaceutical Industry* by Jay Anderson, *The Impact of ICH-9 Biostatistics Guidelines* by Frank Rockhold, and *Applications of Bayesian Methods in Clinical Trials* by Don Berry; and four special contributed papers: *Impact of Trial Conduct Change in Clinical Trials* by James Hung, *Health-related Quality of Life Assessment in Cancer Clinical Trials* by Wayne Weng, *FDA Session on Special Statistical Issues* by Satya Dubey, and *Robust Inferences/Analysis of Clinical Trials* by Norman Bohidar. In addition, we had 14 contributed paper sessions and 8 round table discussions.

## Section Internet Activity

Greenberg reported the Section Web site has been active for 1.5 years. It is her goal to include future issues of the *Biopharmaceutical Report*. There is also a section discussion group (E-mail list). Information can be obtained through the Web site. The Web site will move in the near future, so the easiest way to access the site is through the ASA home page, <http://www.amstat.org>.

## Section Membership Survey

Phil Pichotta, Membership chair, indicated there is a poster session on Wednesday on results from the Section survey. Approximately 1770 surveys were mailed with 1139 responses or 64%.

## 1998 Meetings

Tom Capizzi, 1998 program chair, reported the section is sponsoring three sessions at ENAR:

**Tony Lachenbruch**—*Impact of Recent Therapeutic Advances in Clinical Trial Design and Analysis*.

**Frank Shen**—*Exploratory Data Analysis Using Classification Trees: Biomedical Applications*.

**Des Thompson and Roz Stone**—*Role of DSMBs and Impact of Accumulating Evidence on Conduct of Clinical Trials*.

## Biopharmaceutical Report, Fall/Winter 1997

For the 1998 JSM he has six proposals for invited sessions. We expect to receive two to four sessions, plus what we get from competition. Two workshop proposals have been approved.

**Post Meeting Notes:** We received three allocated sessions. In addition, the instructors of one workshop wanted to deter the workshop until 1999.

## Nominations Committee

Gary Neidert, chair of the Nominations Committee, announced the nominations for 1998 Biopharmaceutical Section elections:

**Chair-Elect:** Capizzi, Liang Yuh

**Program Chair-Elect:** Bob Small, Wiltse

**Secretary/Treasurer:** Greenberg, Pichotta

**Council of Sections Representative:** Jeff Meeker, Nancy Smith

He also presented methods, described in the Section Constitution, of adding names to the Nominations Committee's list.

## American Statistician

Greenberg reported that at the meeting of Journal editors, the editor of the *American Statistician* indicated he was interested in case studies and novel applications papers.

## 1996 JSM ROUND TABLE LUNCHEON DISCUSSIONS

### Adverse Event Reporting Leader: Janet Wittes

The participants at the round table discussion shared a sense of frustration about the current standard in adverse event reporting from clinical trials. The backgrounds of the participants varied considerably. While we were all statisticians, we came from different types of organizations. There was at least one person each from a large pharmaceutical company, a small pharmaceutical company, a contract research organization, a consulting firm, and a company that produces products for veterinary medicine. The group generally agreed that:

- The statistical paradigm used to assess efficacy is not directly applicable to safety.
- WHO codes, COSTART codes, and other standard dictionaries can create uninterpretable long lists of adverse events. Study-specific dictionaries built to reflect the disease being investigated, though time-consuming to create, are potentially more useful than general dictionaries.
- The goal of adverse event reporting should be to enhance the signal. Since the data tend to be very noisy, exploratory methods of data analysis and flexibility in categorization should be encouraged.
- Laboratory data are often particularly messy. Commonly, the summarized data include egregious errors that even quite simple error-checking routines could identify.

The luncheon concluded with the sense that the discussion was valuable, because it afforded the group an opportunity to learn that other people share similar experiences. We agreed that statisticians should become more involved in adverse event and laboratory data; we need to be aggressive in ensuring that we have a meaningful role.

## **Bayesian Methods and Ideas in Medical Research**

**Leader: Donald A. Berry**

Topics discussed included:

1. Flexible designs of clinical trials: Dropping arms, adding arms, changing arms, early stopping, etc.
2. Hierarchical modeling: In meta-analysis, multicenter trials, multiple comparisons, pharmacokinetic modeling, etc.
3. Roles of predictive probabilities: Data monitoring, designing new trials and rethinking existing trials, communicating the "power" of study results, etc.
4. Decision analysis: Pharmaceutical company decision making, patient screening procedures, genetic testing, quality of life analyses using patient assessments of health states.
5. Availability/utility of Bayesian software.

### References:

- Berry, DA (1996). *Statistics: A Bayesian Perspective*. Belmont, California: Duxbury Press.
- Berry, DA, Stangl DK (1996). *Bayesian Biostatistics*. New York: Marcel Dekker.
- Berry, DA (1989). *Statistical Methodology in the Pharmaceutical Sciences*. New York: Marcel Dekker.

## **Adaptive Techniques in Clinical Trials**

**Leader: Roy N. Tamura**

Eleven participants attended this round table with a nice mixture of statisticians from universities and from pharmaceutical or other research companies. The conversation was spirited and interesting in spite of the poor acoustics of the location.

Some of the topics we discussed included dose response type designs, adaptive randomization, combined Phase II/Phase III designs, reestimation of sample size designs, sequential monitoring, and data monitoring boards. There was general agreement that applications for all of these designs exist in the pharmaceutical industry and that more of these designs should be considered. There was also consensus that we need to understand the operating characteristics of design prior to implementation. Several of the participants had done extensive simulations to study properties of specific designs. The role of the FDA in encouraging or discouraging adaptive trials was also discussed, and we agreed that the FDA needs to be informed early about plans to do adaptive trials.

We discussed adaptive dose response type designs; these designs seem especially attractive in early phases of compound development (Phase I or II). Because of the complexities involved in blinding, dose allocation, and monitoring of the trial, adaptive dose response designs would appear to be better

suited for single site studies. An idea to blend both dose titration (within patient adaption) with adaptive dose response (across patient adaption) was suggested in order to ensure a more ethical early phase trial.

Sequential monitoring of large studies appears to be well established, especially in Europe; the PEST and EaSt software has been very useful in implementing these designs. Reestimation of sample size trials have also been conducted; however, there was disagreement at our table about the appropriateness of reestimating sample sizes based on observed treatment differences within the trial. The use of data monitoring boards appears to be well established in pharmaceutical clinical trials, and many companies use completely external data monitoring boards for long term and/or life threatening diseases.

In summary, many of the round table participants believed that adaptive trials have a role in drug development. There needs to be a better understanding under what conditions such designs can be implemented successfully.

## **Letter from the Chairman**

**Bob Davis**

Since my term as chairman ended in December, I would like to use some of this space to thank the officers and volunteers who made it such an easy year for me. First, Secretary-Treasurer Jeff Meeker always completed the minutes promptly and made sure we spent enough money to reduce the cash surplus. Lianng Yuh, 1997 Program Chair, put together excellent programs at ENAR and JSM. The 1998 programs organized by Tom Capizzi look equally interesting. Christy Chuang-Stein, our Continuing Education guru, ran highly successful workshops in Bethesda the last two years. The round table luncheons Richard Entsuah organized at JSM were quite productive, also.

Sally Greenberg has been busy with her jobs as Web site Editor and Electronic Mail List Coordinator. Our three editors of the *Biopharmaceutical Report* have produced three great issues this year. Special thanks go to Bill Huster, who steps down as past editor. Curt Wiltse and Anne Meibohm remain editors for 1998.

Of the appointed executive committee members, only Shein Chung Chow rolls off this year. Over the last three years Shein helped with the section's Best Student Paper competition. Bill Fox ably stepped in as a pinch hitter last summer. Sandy Heft ran the section's Best Presentation awards at Anaheim, having already determined the winners and polished up the rules for future years.

The survey which began in 1996 was completed this year under Phil Pichotta's enthusiastic direction. You can read the details in this issue of the *Biopharmaceutical Report*. I'd also like to thank Sally Greenberg and Chuck Davis for representing us so well at the Council of Sections. Special thanks go to Bruce Rodda, Charlie Goldsmith, and Larry Gould who, as our Fellows Committee, successfully pushed several of our members for ASA Fellow.

I would like to add my gratitude to Gary Neidert who has served our section as Chairman and as executive committee member. Among other accomplishments, Gary brought the Manual of Operations up to date, reestablished the Continuing

Education and Fellows committees, and got the fall workshops started.

Communicating with the members continues to be a high priority for the Section. Bob Small created a Communications Committee to coordinate the news and views going out to members. Denise Roe, newly-elected Publications Officer, heads the group. Other members are Sally Greenberg as Web Site Editor and Electronic Mail List Coordinator, and the Editor of the *Biopharmaceutical Report*. One immediate result is that you should be seeing a steady stream of section news in *Amstat News* from now on.

Earlier this year I made a plea for volunteers to help with section activities both to provide manpower and to get new blood into our group. I am pleased to report that about 25 people contacted me and we have tried to put them to work. They have helped with round table luncheons, the Web site, award competitions, and chairing sessions. We maintain a volunteer list and will try to get all of them involved.

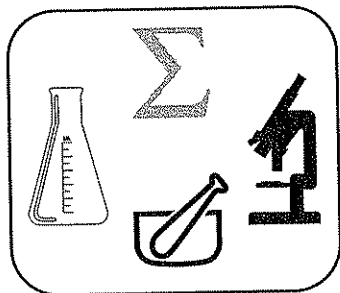
We have a large and growing membership and the luxury of a sizable treasury. I'm sure 1998 Chair Ken Koury will have an exciting list of Section accomplishments to report next year.

### Let's Hear from You!

If you have any comments or contributions, contact Editors William J. Huster, Eli Lilly and Company, Lilly Corporate Center, 2233, Indianapolis, IN 46285; phone: (317) 276-9802; fax: (317) 277-3220; E-mail: [huster@lilly.com](mailto:huster@lilly.com) or Curt Wiltse, Lilly Corporate Center, 2233, Indianapolis, IN 46285; phone: (317) 276-5773; Fax: (317) 277-3220; E-mail: [wiltse\\_curtis\\_g@lilly.com](mailto:wiltse_curtis_g@lilly.com); Anne Meibohm, Merck Research Laboratories, BL3-2, PO Box 4000, West Point, PA 19486; Phone: (610) 397-2545; Fax: (610) 397-2931; E-mail: [anne\\_meibohm@merck.com](mailto:anne_meibohm@merck.com).

The *Biopharmaceutical Report* is a publication of the *Biopharmaceutical Section of the American Statistical Association*.

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Printed in the United States of America



### Biopharmaceutical Report

c/o American Statistical Association  
1429 Duke Street  
Alexandria, VA 22314-3415  
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