Commonwealth Serum Laboratories

Operations and Capital Works Program

Report of the Independent Inquiry

APRIL 1978

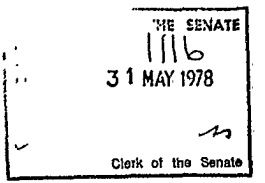
Commonwealth Serum Laboratories: Independent Inquiry

Commonwealth Serum Laboratories

Operations and Capital Works Program

Report of the Independent Inquiry

APRIL 1978



COMMONWEALTH SERUM LABORATORIES

REPORT OF AN INDEPENDENT INQUIRY INTO THE LABORATORIES' OPERATIONS AND CAPITAL WORKS PROGRAM

April 1978

Australian Government Publishing Service
Canberra 1978

ISBN 0 642 03685 3

Printed by Watson Ferguson & Co., Brisbane

INQUIRY
INTO THE OPERATIONS AND CAPITAL WORKS PROGRAMME OF THE COMMONWEALTH SERUM LABORATORIES

C/- Walter & Eliza Hall Institute of Medical Research
Royal Melbourne Hospital,
Parkville, Victoria, 3052 Telephone: 347 1511

14 April 1978

My dear Minister,

In your letters dated 27 October, 1977, you invited us to undertake an independent inquiry into the operations and capital works program of the Commonwealth Serum Laboratories. The terms of reference for the inquiry were:-

To inquire into and report on the Commonwealth Serum Laboratories internal operations and Capital Works Program and in particular:-

(1) the purposes, functions and organisational structure of the C.S.L.;

(2) the overall financial viability of C.S.L. in terms of the legislation under which C.S.L. operates;

(3) C.S.L.'s current research program and its future directions;

(4) the basis of the commercial aspects of C.S.L.'s operations;

(5) C.S.L.'s Capital Works Program as applied to the nature and direction of C.S.L.'s commercial research and public health activities and the impact of an appropriate Capital Works Program on C.S.L.'s financial viability;

and to make recommendations on the above matters.

Following discussions with you on 8 March, 1978, you subsequently wrote to us on 14 March, 1978, requesting us to explore the present practical relationship between the Commonwealth Serum Laboratories and Fawnmac, the possibilities for the future of an increase in co-ordination etc. and indeed a specific opinion as to whether the retention of Fawnmac is wise for the Government considering the whole Australian pharmaceutical scene.

We have conducted the inquiry and now have the honor of submitting the attached report.

Yours sincerely,

G.J.V. Nossal J.B. Reid

The Honourable Ralph J. Hunt, M.P.,
Minister for Health,
Room M125 Parliament House,
CANBERRA, ACT 2600

TABLE OF CONTENTS

Summary

This report reviews the role of biologicals in human and veterinary medicine in Australia and internationally. It concludes that biologicals are vital weapons, for some of which, the world supply situation is deeply worrying. The Inquiry concludes that C.S.L. should continue operation in its traditional field, and should not be artificially constrained by the word "biological", whose meaning is imprecise (Recommendations 1-3 and 17-20).

Segments of C.S.L.'s activities are undertaken because of the perceived national interest rather than for commercial reasons, and the Inquiry considers these to be C.S.L.'s most important function. Therefore, the national interest must be more precisely defined, and we see the Director-General of Health as being the focal point for the relevant advice to the Minister. Once the national interest has been defined, all activities associated with a national interest project should become part of the Department of Health's budget commitment (Recommendations 4-6).

The commercial and financial practices of C.S.L. have been examined in detail. Arising therefrom, a number of recommendations have been made (Recommendations 7-10).

The research and development programme of C.S.L. was reviewed. Whilst much of the effort is commendable, the Inquiry found that present salary ceilings posed problems for the recruitment and retention of first-class scientists; and also that C.S.L. would benefit from fuller relationships with outside research workers and organizations (Recommendations 11-15).

The Inquiry concluded that a useful check on the activities of private firms in the field of pharmaceuticals was the existence of two government-owned bodies in C.S.L. and Fawnmac. It feels that both bodies should continue to exist, and that Fawnmac should not be sold or merged into C.S.L. (Recommendations 22-24).

The Inquiry found that the proposed C.S.L. capital works programme had been well planned and was sorely needed, indeed frequently long overdue. Regretfully, the Inquiry concluded that the programme could not be financed from sales unless radical changes took place in C.S.L.'s pricing policies. Funding through the budget, following the appropriate definition of the national interest, will be necessary. Undue delay in completion of the C.S.L. master plan should be avoided (Recommendations 25-30).

The Inquiry noted with concern that an expensive new facility, the Australian National Animal Health Laboratory, was to be charged with the responsibility of manufacturing foot and mouth disease vaccine. As scaling up of virus production, packaging, storage and mass production technology generally demand specialized know-how and skills, the Inquiry urges strongly that C.S.L. take a leading part in the ANAHL exercise (Recommendation 32). In general, co-operation in planning of national laboratory facilities could be improved (Recommendation 25).

World supplies of poliomyelitis vaccine are going through a critical period. This situation needs to be studied more expertly than the Inquiry could do (Recommendation 33).

The Inquiry believes C.S.L. needs an enlarged Commission, and the Act under which it operates needs a number of reviews, both major and minor (Recommendations 3, 5(c), 35 and 36).

The Inquiry has concluded that C.S.L. represents a major and valuable national asset (Chapter 10) and that its staff should be allowed to pursue its prime objectives without any further diversions of time and talents into dealing with inquiries, of which there have been a number in recent years (Recommendation 34).

LIST OF RECOMMENDATIONS

	RECOMMENDATIONS	REFERENCE
1.	C.S.L. should continue operation in the field of biological manufacture.	2.4.1
2(a)	C.S.L. should collaborate with the World Health Organisation in its programme aimed at immunization against six common diseases of every child in the world by 1990 giving priority to the manufacture of bulk stocks of vaccine for purchase by W.H.O. or developing countries.	2.4.2
2(b)	The obtaining of a high price should not be the key element in negotiations with W.H.O. for the supply of vaccines. The national interest will, it is considered, be served by improving the health of the world's children.	2.4.2
2(c)	C.S.L. Commission should keep a close watching brief on world supplies of biologicals and consider local manufacture of such products as are deemed vital to the national interest and the supply of which is precarious.	2.4.3
3.	The Commonwealth Serum Laboratories Act be amended by removal of the word "biological" wherever it appears and particularly in Section 19 which specifies the functions of the Commission.	2.4.4
4.	The Director-General of Health, under the direction of the Minister, should be the focal point for advice to the Minister on the definition of the national interest from time to time. He should have access to all he may consider able to assist him reach that definition e.g. by convening Task Forces or Study Groups at appropriate occasions.	3.6.1 & 3.6.2
5(a)	When the national interest is defined all activities connected with viz:- Capital cost of buildings, plant and services; Raw materials and finished goods stocks; Operating costs including maintenance and depreciation; Research and development would become part of a national interest project.	3.6.3
5(b)	Activities referred to in Recommendation No. 5(a) should be reduced to an annual budgeting commitment within Department of Health under Section 19 of the Commonwealth Serum Laboratories Commission Act 1961-1973.	3.6.4

5(c)	As some areas of change require no legislative amendment they should be implemented as soon as possible. In areas where legislative changes are necessary e.g. products for sale, the Commonwealth Serum Laboratories Act 1961-1973 should be amended. Procedures for determining which current projects are in the national interest should be the matter for discussion between the Director-General of Health and the C.S.L. Commission.	3.6.5
6.	A facility for the manufacture of penicillin should be maintained in C.S.L. for the foreseeable future in the national interest.	3.6.6 7.4.3
7.	Depreciation at the proper rates be charged on all C.S.L. occupied buildings and that the cost of this be taken in account in budgets, capital expenditure projects, Section 19(b) applications and price applications.	4.2.9
8.	C.S.L. should re-examine its practices in respect of furlough.	4.3.3
9.	The number of "cottage" type industries undertaken by C.S.L. should be contained in number and extent as much as possible.	4.6.1
10.	The Department of Health in its assessment of C.S.L.'s requests for increases arising from, inter alia, raw materials and labour costs should not let the fact that there is a profit component militate against an increase.	4.6.3
11.	C.S.L. show more initiative in recognising and rewarding first class scientists. The fact that occasionally (not routinely) scientists of outstanding merit could be promoted to Research Scientist status should be made known internally and externally.	5.3.1
12.	Mechanisms recently instituted for outside "peer group" review of research be strengthened and formalised.	5.3.2
13.	Two research liaison committees be formally convened to strengthen collaborative and information links: one between C.S.L. and the relevant C.S.I.R.O. divisions and one between C.S.L. and the University-research institute sector.	5.3.3
14.	C.S.L. seek actively to sponsor exchange visits, where scientists from comparable overseas institutions could be invited to Australia and vice versa.	5.3.4
15.	The Research and Development Division not be reduced from its present size.	5.3.5

16(a)	Unless there is a useful and clearly definable reward, C & L should not commit itself to export orforeign investment activity.	6.1.4
(b)	Benefits gained from export sales should not be used as justification for the implementation of any capital expenditure programme unless the benefits are seen to extend to the long term.	6.4.2
17.	Further exploration of opportunities for foreign aid and W.H.O. projects should be undertaken.	6.3.1
18.	The tests described in Section 6.1 should be applied to all concepts of this kind before they are approved. If however C.S.L. is cleared to embark on aid or the like programs, then the cost should be treated in the same way as Section 19(b) policy decision described in Chapter 3, i.e. funded by special appropriation from the relevant Department having the carriage of Australia's involvement. In essence, let the user pay.	6.3.2
19.	Any other export activities should be judged by ordinary commercial standards so that C.S.L. will be seen to have succeeded or failed by its own efforts.	6.3.2
20.	Wherever C.S.L. is given a policy clearance to undertake other overseas national interest commitments, they should be treated in the same way as that proposed in Para. 6.3.2 (Recommendation No. 18).	6.3.3
21.	The conditions of C.S.L.'s production lines in the terms of the Code of Good Manufacturing Practice should be examined immediately and reported on.	6.4.2
22.	The Government retains ownership of the Fawnmac Companies: state unambiguously that this is its policy and confirm the present pattern of operations which is understood and accepted by the pharmaceutical industry and their suppliers and customers.	6.7.1
23.	The present independent corporate form of Fawnmac (if not precise structure) be maintained and preserved and the operation of its board and management continue substantially as at present.	6.7.2
24.	The present pattern of co-operation between Fawnmac and C.S.L. be encouraged and fostered, without limiting either in the exploration of opportunities for the common reduction of costs, enhancement of performances or pursuit of other sensible commercial options but no action whatever be taken to: (a) merge the two bodies; or (b) seek closer formal relations through the appointment of common Commissioners/Directors	6.7.3

25. N.B.S.L. should be consulted by C.S.L. on the design of major new production facilities at an early stage in the planning cycle. 6.8.7

26(a) The capital works program of C.S.L. as in the Commission's master plan be endorsed in principle. 7.5.1

(b) Major projects previously approved as evidenced by their inclusion in the Budget be completed as expeditiously as possible. 7.5.2

(c) Projects still in the planning stage be assessed for their consonance with national policy objectives as outlined in Chapter 3 and where they pass such assessment, be funded out of Consolidated Revenue. Through conjoint effort of the Commission and the Department of Health, the projects should be ranked in order of priority according to national interest and be completed in that order.

27. To the greatest degree consistent with Government and Department of Finance norms, advance notice of approvals and indications of likely future levels of funding should be given to the Commission, allowing strategy to be devised on a rolling triennial or quadrennial basis. 7.5.4

28. Capital works projects initiated primarily for commercial rather than national interest objectives should be funded on a strictly commercial basis. 7.5.5

29. In its planning for new plant and buildings, the Commission should pay heed to cost effectiveness and increases in productivity per employee. 7.5.6

30. The Commission should endeavour to maintain a policy of increased output with a stable work force and that one criterion in assessing a capital works project should be its ability to aid that goal. 7.5.7

31. The packaging-dispatch building at C.S.L. should be upgraded at the earliest opportunity according to the proposals embodied in C.S.L.'s capital works submissions but deferred because of budgetary considerations. 8.1.2

32. The proposed management structure of ANAHL should be re-evaluated with a view to - 8.2.10

(a) having C.S.L. involved in the research conducted within the laboratories should no exotic disease break out; and

(b) ensuring that C.S.L. be the lead agency should mass production of vaccine e.g. Foot and Mouth disease vaccine prove necessary.

33. Using the mechanisms outlined in Chapter 3, the C.S.L. Commission and the Director-General of Health should evaluate in detail and urgently whether it is in the national interest to develop a C.S.L. poliomyelitis vaccine and, with less urgency, measles and rubella vaccines. 8.3.4

34. On the assumption that this Inquiry's principal recommendations are adopted, that C.S.L. should not be subjected to further general inquiries but, once the Commission's role has been spelled out, C.S.L. should be encouraged to pursue its prime objectives without diversion of time and talent elsewhere. 8.4.7

35(a) In seeking replacement or additional commissioners, efforts should be made to provide a wider geographic representation. It is seen as important that members should come from several States to provide the appropriate national perspective. 9.1.5

(b) Section 8(1) of the Act be amended to read - "The Commission shall consit of not more than nine (9) commissioners viz..." 9.1.6

36(a) Action should be taken to have the Commonwealth Serum Laboratories Act amended to include certain proposed machinery amendments with the exception of the proposal to vary the provision that the Commission should meet at least once every five weeks. 9.2.6

(b) The Commonwealth Serum Laboratories Act should be amended to increase the amount shown in Section 20(2) to $250 000. A ceiling figure of $500 000 is recommended if it is determined that large contracts for raw materials etc. must be approved by the Minister. 9.3.3

LIST OF APPENDICES

CHAPTER 1 PREFACE

1.1. Method of Work

1.1.1 At the commencement of the Inquiry, it was decided that a full and informative data base was necessary. Accordingly a comprehensive list of questions concerning the Commonwealth Serum Laboratories Commission and its work was prepared and submitted to the Director of the Laboratories. A copy of the questionnaire is shown as Appendix 1.

1.1.2 The answers provided to this questionnaire became the basis of discussion with both the members of the Commonwealth Serum Laboratories Commission and the senior staff of the Laboratories.

1.1.3 The members of the Inquiry made detailed inspections of the facilities of the Laboratory both at Parkville and Woodend. As well, a visit was made to the Branch Offices of the Laboratories located in Adelaide, Perth, and Sydney.

1.1.4 In an endeavour to ascertain the attitude of overseas countries to the manufacture of biological products, letters were sent to the appropriate authorities in France, Canada, Sweden, United States of America, the Federal Rupublic of Germany and the United Kingdom. Information was also sought from several of the world's largest pharmaceutical manufacturers both in Australia and overseas.

1.1.5 Whilst overseas, Sir Gustav Nossal visited Connaught Laboratories in Willowdale, Ontario. Connaught, a manufacturer of biological products is a similar type organisation to the Commonwealth Serum Laboratories. Connaught are owned by the Canadian Development Corporation. Cutter Laboratories, a commercial manufacturer of biologicals and a subsidiary of Bayer were visited in Berkeley, U.S.A. During these visits, discussion took place on profitability, capital works programs and research and development programs.

1.1.6 Following reports of the Inquiry in the Press, unsolicited submissions were received from private individuals and organisations engaged in the pharmaceutical sphere. These were all considered by the Inquiry in the course of its investigation.

1.2 Acknowledgements

1.2.1 The Inquiry wishes to acknowledge the assistance given to it by the C.S.L. Commission, the Director Dr. N. McCarthy and staff of the Commonwealth Serum Laboratories. Any request for information and assistance was willingly and expeditiously attended to and comprehensive information provided. Discussions were open and frank and the staff of C.S.L. endeavoured in every possible way to assist the Inquiry. The assistance provided was extremely helpful.

1.2.2 The Director-General of Health and the officers of his Department, in particular the C.S.L. Secretariat, were most helpful in providing information and details required by the Inquiry.

1.2.3 Submissions and information were received from overseas Governments, commercial organisations and private individuals. All the information supplied assisted the Inquiry in carrying out its examination.

1.2.4 Mr. V. Warbey, the Acting Managing-Director of Fawns & McAllan Pty. Ltd., provided a most helpful overview of the operations of the Fawnmac group of companies and was of great assistance.

1.2.5 Dr. Leigh Dodson, the Director of the National Biological Standards Laboratory, provided the Inquiry with a most lucid explanation of the role of N.B.S.L. and its relationship to C.S.L.

1.2.6 The Inquiry was serviced by the Victorian Divisional Office of the Department of Health. The considerable assistance provided is appreciated. In particular, the Inquiry acknowledges its great debt to Mr. Kevin Delaney who acted as the Inquiry's highly efficient Secretary.

CHAPTER 2 FUNCTIONS & PURPOSES OF C.S.L.

2.1 HISTORY OF THE COMMONWEALTH SERUM LABORATORIES

2.1.1 Following the outbreak of the Great War in 1914, serious difficulties were experienced in obtaining supplies of antitoxins from European or American sources to meet Australian requirements. As a result of these difficulties, representations were made to the Government of the day urging the establishment of a Federal Institute for the production of antitoxins, sera and vaccines to meet Australia's needs and requirements.

2.1.2 In September 1915, the Metropolitan Hospital Board of Supplies, Melbourne, supported these representations and urged that there should be one Institute for the whole of Australia in order:-

(a) to meet any sudden demand which might be made in any part of Australia;

(b) that Australia might have an ample supply at the least cost;

(c) that products might be standardised throughout Australia and

(d) that supplies should be regularly available at all important points.

2.1.3 The establishment of the Commonwealth Serum Laboratories was approved by the Government of the day and steps were taken for the erection of the buildings and engagement of staff. The Laboratories were established under the administration of the Quarantine Branch of the Department of Trade and Customs which function was transferred to the Department of Health on the establishment of the Department in 1921.

2.1.4 The first Director of the Laboratories, Dr. W.J. Penfold, arrived from England in November 1916 and commenced work in the Walter and Eliza Hall Institute at the Melbourne Hospital.

2.1.5 During this period, the erection of permanent buildings for the Laboratories was proceeding at Royal Park and these premises were first occupied in July 1918.

2.1.6 In 1923, the Laboratories were one of the four original Laboratories entrusted with the task of preparing insulin on a large scale shortly after its isolation by Dr. Banting at the Toronto University in Canada.

2.1.7 The first issue of a handbook of instructions and price list for veterinary products was made in 1926 although developments had been taking place previously. Australia was previously largely dependent on imported products many of which were arriving in poor condition. In addition, they were not made from strains of bacteria isolated from local outbreaks and little attention was paid by overseas manufacturers to the need for local investigation of animal enzootics and, consequently, specific agents for their prevention or treatment had not been devised.

2.1.8 The activities of the Laboratories continued to develop and expand and in 1936, a farm of 325 acres was purchased at Broadmeadows, 9 miles from Melbourne.

2.1.9 The outbreak of the Second World War in 1939 saw the beginning of an additional and unprecedented demand for biological products. The demand had been largely foreseen in that much of the developmental work connected with Defence Force requirements was pressed forward at the Laboratories before both the commencement of hostilities and the Munich crisis. For example, Tetanus prophylactic was being developed and tested in 1938 and prepared in quantity in 1939. During the same years, large stocks of sera and vaccines were being accumulated for use in serious emergency. Extensive new buildings were planned and completed from 1937 to 1942.

2.1.10 A major land mark in the history of medicine and the later development of the Laboratories was the discovery and practical preparation of penicillin. Penicillin was first made experimentally at the Laboratories in 1943 and was supplied first to the combatant services and, when sufficient supplies became available, to the civilian population. Australia was the first country in the world to make penicillin commercially available for civilian use.

2.1.11 At the same time the blood transfusion service received a great impetus. Firstly, pooled human serum was produced and later, in 1952, serum fractionation commenced for the production of albumin, fibrinogen and gamma globulin and, later again, antihaemophiliac factor.

2.1.12 Another highlight in the Laboratories' history occurred in 1956 with the successful production of Salk inactivated poliomyelitis vaccine. This vaccine was used in large scale antipoliomyelitis campaigns conducted throughout Australia.

2.1.13 Because additional land was not available at the site of the Broadmeadows farm, it was necessary for a farm of 1361 acres to be purchased at Woodend in Victoria in 1959. This farm was needed for the breeding of horses required for serum production and their resting from production processes as necessary. In addition the area was to be utilized for the decentralization of certain production processes and the breeding of other livestock required for the Laboratories activities.

2.1.14 By 1961, the wide area of activity of the Laboratories had involved substantial capital investment and development. The Laboratories occupied a 23 acre site at Parkville, Melbourne, and operated a 325 acre farm at Broadmeadows and a 1361 acre farm at Woodend. The capital invested in the Laboratories exceeded $12 million, the annual turnover was approximately $4.8 million and the staff employed was approximately 1,000.

2.1.15 The continued development and operation of the Laboratories was considered by the Government and it was decided that the control of the Laboratories should be transferred to a Commission.

2.1.16 The Commonwealth Serum Laboratories Act, giving effect to this decision was assented to on 2nd June, 1961, and was proclaimed to come into operation on 2nd November, 1961. The control of the Laboratories accordingly passed from the Department of Health to the Commonwealth Serum Laboratories Commission on 2nd November, 1961.

2.1.17 Since 1961, the Laboratories under the direction of the Commission continued to expand and by early 1963 had opened sales offices in all capital cities.

2.1.18 In planning the expansion of facilities, the Laboratories have provided a reserve capacity over and above current foreseen needs to meet possible defence and national emergency type situations for important key products. The need for a defence capability was emphasised during the Vietnam war when C.S.L. provided large amounts of appropriate immunising vaccines such as cholera, typhoid and plague vaccines.

2.1.19 In 1974, Stage 1 of a new virus vaccine building was completed, the first in a major laboratory building program aimed at revolutionising C.S.L.'s vaccine production capacity. New buildings included in the program include Stage 2 of the Virus Vaccines building, a veterinary vaccines building, a maximum security Laboratory, a special pathogen free animal facility and a new building for the production of insulin. The human vaccines (bacterial) building to replace the old East Block which had been approved by the Government in 1959, still features on the list and awaits funding.

2.1.20 Each of these building projects has been a result of investigation and planning over a long period to ensure that C.S.L. would have facilities not only to produce increasing quantities of human and veterinary vaccines but also to meet the quality control standards that are now required and to have fail proof security conditions for future production and testing should an outbreak of exotic disease in Australia make them necessary.

2.2 THE INTERNATIONAL SCENE IN THE MANUFACTURE OF BIOLOGICALS

2.2.1 Biologicals including antibiotics and vaccines are the most powerful and cost-effective tools known to medical science. Yet, their production is fraught with many difficulties and it is widely recognized that biologicals represent a less profitable segment of pharmaceutical manufacture than synthetic drugs manufactured through organic chemistry. In order to place the Australian position into perspective, we undertook study of international policies and practices with regard to the manufacture of biologicals. This was approached through a reading of available literature; solicitation of submissions from Governments, the World Health Organization and leading international commercial manufacturers of biologicals; and a visit made by one of us to Canada and the United States, made possible through prior lecturing commitments in U.S.A.

2.2.2 The Inquiry is impressed by the "two-way squeeze" on profits felt by the manufacturers of biologicals. On the one hand, the chief purchasers of biologicals (particularly vaccines) are governmental agencies and instrumentalities, which, naturally and properly, seek to negotiate the lowest possible price. On the other hand, different governmental regulatory agencies, charged with certifying the safety and efficacy of biologicals, drive up the costs of research, quality control and production. One leading manufacturer told us that the increased demands of the regulatory agencies had driven costs up by a factor of 100% over the last several years. The result is that only "the first into a field" makes substantial profits out of biologicals; the second manufacturer provides sufficient competition to drive prices down considerably; and the third and fourth into a field "barely manage to break even".

2.2.3 Limiting the profits made by manufacturers may be, of course, in the public interest, as is an insistence on high standards. There is the possibility, however, of the trend progressing too far. Dr. Harry M. Meyer, Director of the Bureau of Biologics of the U.S. Food and Drug Administration, and thus himself the most important regulator in this field in U.S.A., put this position well in a paper in 1976 which he entitled "Are vaccines an endangered species?" He claims that vaccines were never a particularly profitable line for industry, and that "for more than 20 years, all but the largest companies have been frozen out and now even these companies regard investment in the area as increasingly risky". Referring to "third generation" vaccines such as those against poliomyelitis and measles, Meyer states that: "the only serious players in this new game were those who could and would gamble millions of R and D dollars". While 7 companies chose to gear up to produce polio vaccine in the mid 1950's, only one of these is still producing it. Similarly, measles vaccine was originally manufactured by 6 companies but now one remains. Even for older vaccines such as diphtheria-pertussis-tetanus, the current test standards are so tough that even the experienced manufacturers sometimes run into technical problems that put them out of production for months. Meyer concludes: "If Jenner and Pasteur and Walter Reed had to set up their clinical trials today to comply with Food and Drug Administration investigation of new drug regulations, I suspect that Jenner might stick to general practice, Pasteur to soil microbiology and Walter Reed to selling mosquito repellent".

2.2.4 A similar conclusion was reached by the National Immunization Work Group which submitted its report on March 15, 1977 to the Assistant Secretary for Health in U.S.A. Stressing the need for governmental support of development and production of certain vaccines, the report states: "A relatively low profit margin, high production risks, increasing costs of research and development, difficulties in clinical testing and increasingly stringent governmental standards of safety and efficacy are all formidable constraints to private investment". The report cited as one of the limitations of the present system, the delicate balance existing between industry and government. "The system is dependent upon mutual respect and delicate interactions between government and industry. Vagaries in the quality of leadership might seriously unbalance a system that requires competence and stability."

2.2.5 The flight of major firms in the U.S.A. from vaccine manufacture is documented in Table 1.

2.2.6 The Chief of Biologicals of The World Health Organization in a letter to the Department of Health makes a number of interesting points. Amongst these are:

(a) Poliomyelitis vaccine manufacturers made profits between 1955 to 1965, but as availability of vaccines increased and competition sharpened, these frequently turned to losses.

(b) Litigation has driven some companies from the field.

(c) If C.S.L. were to cease manufacture, Australia would be competing with many other countries for limited vaccine supplies, and might find itself in an embarrassing situation.

(d) The potential world needs for vaccines are enormous. W.H.O. has pledged vaccination for all children by 1990, and if this is to be achieved there will have to be 180 million extra doses per year of diphtheria-pertussis-tetanus and poliomyelitis vaccines and 60 million extra doses per year of measles and BCG vaccines manufactured.

(e) With this in mind, "any country with a secure supply of vaccines is in a very fortunate position and should think very seriously before passing this over to private enterprise".

(f) W.H.O. positively wishes governments to continue to support vaccine production facilities.

(g) In the opinion of W.H.O.: "C.S.L. are a fine organization. They are held in high esteem in the world and Australia should be proud of them..... they should receive financial support from the Government which should include a research component to allow them to keep abreast of developments".

2.2.7 The visit to Connaught Laboratories, Toronto, Canada was of special interest. (Appendix No.2) This organization, previously owned by the University of Toronto but now owned by the Canada Development Corporation as part of its Connlab health care group, is similar to C.S.L. in many respects. It manufactures a wide range of biologicals, has a sales volume and staff establishment comparable to that of C.S.L., and occupies a group of buildings many of which are nearing the end of their life-span.

2.2.8 Connaught's profit performance has been essentially comparable to or worse than that of C.S.L. over the last few years. The mechanism for paying for research is different, there being no Section 19b equivalent but the capacity to seek research grants, which currently run around $1 million per year.

2.2.9 A major difference is in how Connaught proposes to fund its building programme. Having no access to taxpayer's funds, Connaught hopes to finance a $40 million rebuilding programme entirely on commercial principles. However, it recognises

Table 1. Major Firms Producing Specified Vaccines (1977)

UNITED STATES OF AMERICA

TYPE OF VACCINE	DURING PAST 15 YEARS	CURRENTLY**
Live Poliovirus vaccine	Lederle Wyeth Pfizer, Ltd.	Lederle
Live measles virus vaccine	Merck Dow Lilly Charles-Pfizer Philips-Roxane Lederle	Merck
Live rubella virus vaccine	Merck Philips-Roxane Recherche et Industrie Therapeutiques S.A. (R.I.T.) Dow	Merck
Live mumps virus vaccine	Merck Dow	Merck
Yellow fever vaccine	Merrell-National	Merrell-National
Inactivated rabies virus vaccine (duck embryo type)	Lilly	Lilly
Inactivated influenza virus vaccine	Merck Merrell-National Parke, Davis Wyeth Lilly Lederle Philips-Duphar Dow	Merck Merrell-National Parke, Davis Wyeth
Diphtheria toxoid* Tetanus toxoid Pertussis vaccine (commonly combined as DPT)	Parke, Davis Wyeth Merrell-National Lilly Lederle Dow Merck	Parke, Davis Wyeth Merrell-National Lilly Lederle
Meningococcal Group A and C vaccine	Merck Merrell-National	Merck Merrell-National

* List does not include three state health laboratories producing DPT for intrastate distribution.

** Does not include firms still holding licences but no longer in active production for distribution in the United States.

Since this list was compiled, Merrell-National has ceased operations and is presently being investigated by Connaught (Canada) as a production facility. Lilly have withdrawn from the DPT vaccines and with the introduction in the near future of rabies vaccine made from human tissue culture by Wyeth, their duck embryo type rabies vaccine will be obsolete and they will be completely out of biologicals.

that this will involve charging premium prices for certain of its products, which it hopes the provincial governments will pay out of "national pride". As the building programme has not yet started, it remains to be seen how successful Connaught will prove in this regard.

2.2.10 Connaught also hopes to use the capacity for automation which new buildings and plants will provide for a further reduction of staff numbers and hence costs. Over recent years, staff numbers have already decreased from 815 to 737. Containment of labour costs is a key corporate strategy.

2.2.11 Connaught looks to export markets for considerable growth. Currently, 40 per cent of sales are foreign. The proximity of the U.S.A. offers certain advantages here which C.S.L. does not enjoy.

2.2.12 A submission from one of the leading British manufacturers of biologicals, attesting to their inherent lower profitability, envisages a role for governments in the manufacture of products not enjoying a certain critical volume of sales. This submission saw the government as a "manufacturer of last resort". The contrary view was also put to the enquiry, namely that even highly specialized, low-volume sales products could be manufactured by the private sector, provided an adequate price could be agreed on. An example was the manufacture by a U.S. subsidiary of a German multinational firm of plague vaccine through a "cost plus" contract with the U.S. Army.

2.2.13 In many countries, a situation similar to that in Australia pertains, namely governmental instrumentalities and commercial firms being engaged in manufacture of biologicals.

2.2.14 Conclusions

The Inquiry was reassured to note the consistency of most of the information gathered from the international scene. The contribution to human health and welfare, past, present and future, by biologicals is enormous. It would be tragic and short-sighted if all future decisions concerning research and development, production, testing and distribution of biologicals, were made on strictly commercial grounds. The case for government support for manufacture of "limited use" biologicals seems clear. The need for government intervention in respect of mass-produced biologicals is not as obvious, but projections of present trends suggest that the private sector may not be in a position optimally to service mankind in this vital area indefinitely. For example, the existence of only two manufacturers within North America for live, attenuated poliomyelitis (Sabin-type) vaccine is surely frightening. These trends suggest that the withdrawal of Australia and C.S.L. from biological manufacture would be against the tide of history and against the interest of Australia and the world community.

2.3 THE BIOLOGICAL CONSTRAINT.

2.3.1 The Commonwealth Serum Laboratories Act, 1961-1973, states in Section 19 and elsewhere that the functions of the Commission relate to the production or import and sale of biological products of therapeutic use. For the greater part of the life of the Commission, the inclusion within the legislation of the adjective "Biological" has been seen as a constraint. In particular, C.S.L. has felt itself to be at a competitive disadvantage with respect to private manufacturers who have a completely free choice of entry to all segments of the pharmaceutical market, subject only to patent and tariff considerations.

2.3.2 In evidence, C.S.L. stated that immediate removal of the "biological constraint" would not lead to substantial immediate changes in C.S.L.'s product strategy. In particular, it would not intend immediately to manufacture synthetic drugs. This attitude could change, were the Government to dispose of its ownership of the Fawnmac group of companies.

2.3.3 In the longer term however, C.S.L. believes that to survive as a healthy, independent organization, it must be given the incentive of pursuing profits wherever it can find them, thus reducing the drain on the public purse. Further, C.S.L. believes that removal of the constraint will facilitate access by C.S.L. to licenses for manufacture or importation of new products of which it may become aware.

2.3.4 In the veterinary area, C.S.L. feels disadvantaged from a marketing point of view against companies that market non-biological products such as veterinary products including dips and drenches.

2.3.5 In seeking removal of the constraint, C.S.L. is fully aware of its special responsibilities with respect to biologicals. Should an opportunity arise for non-biological products, C.S.L. would initially seek access to products which could be manufactured and/or distributed within existing facilities and infrastructure, and with the potential for a profit contribution of at least $50,000 per annum.

2.3.6 At present, there is very little conflict of interest in the market place between Fawnmac and C.S.L. If the constraint were removed, there would have to be consultation between the two companies as to which could produce and market the new product more effectively.

2.3.7 The Independent Inquiry believes there is a different and more compelling reason to avoid the restricting adjective in legislation. This relates to its lack of scientific precision. Historically, biological products cover substances present in, extracted from or made by living organisms. However, the giant strides made recently in molecular biology are blurring the traditional distinction between biological products and synthetic drugs. Hormones, for example, are traditionally extracted from tissues, such as insulin from pancreas glands. Now many hormones can be made by synthetic chemistry from the component amino acids, and the costs of such procedures

are coming down rapidly. Legalistically, it becomes open to debate whether such a synthetic hormone is a biological product. The day of synthetic vaccines is still some distance away, but much current research is being directed at the point. Many of the penicillins sold by C.S.L. are already "semi-synthetic" derivatives, the original biological extract being altered through sophisticated organic chemistry. Finally, there are numerous examples where a biological product and a synthetic drug subserve very similar thereapeutic goals (penicillins and sulfonamides; ACTH and cortisone; thyroid extract and thyroxine). It seems illogical to perpetuate in legislation, the capacity of a company to make and market the one but not the other.

2.3.8 There will however, be a continuing need for a general surveillance by the Minister, the Director-General and C.S.L. to ensure that C.S.L. does not embark on the manufacture of non biologicals

(a) at undue cost to the taxpayer and

(b) to the detriment of its national interest role.

2.4 Recommendations

2.4.1 The Independent Inquiry recommends that C.S.L. continue operation in the field of biological manufacture. (Recommendation No.1)

2.4.2 The Inquiry recommends that C.S.L. continues to collaborate with the World Health Organization in its programme aimed at the immunization against six common diseases of every child in the world by the year 1990, giving high priority to the manufacture of bulk stocks of vaccines for purchase by W.H.O. or developing countries. The Inquiry recommends further that the obtaining of a high price not be the key element in negotiations with W.H.O. for the supply of vaccines. The national interest, it is considered, will be served by improving the health of the world's children, thus adding to global welfare and stability. Any loss would be handled by the procedure set out in paragraph 3.5.2 (Chapter 3). (Recommendation Nos. 2(a) and 2(b)).

2.4.3 The Inquiry recommends that the C.S.L. Commission keep a close watching brief on world supplies of biologicals, and consider local manufacture of such products as are deemed vital to the national interest and the supply of which is precarious. (Recommendation No.2(c)).

2.4.4 The Independent Inquiry recommends that the Commonwealth Serum Laboratories Act, 1961-1973 be amended by removal of the word "biological" wherever it appears and particularly in Section 19 which specifies the function of the Commission. (Recommendation No.3)

CHAPTER 3 THE C.S.L. DILEMMA - NATIONAL INTEREST OR COMMERCIAL PROFIT

3.1 NATIONAL INTEREST

3.1.1 During our Inquiry two propositions were frequently encountered:-

(a) C.S.L. has a number of functions which it carries out because they are in the "national interest", and therefore, by inference, they can not be subject to the commercial standards of efficiency, cost benefit analysis or even profitability.

(b) Attempts have been made to distinguish between commercial and non-commercial activities but without success. The former would be susceptible to commercial standards of return on investment, and other commercial judgements; the latter would somehow remain immune.

3.1.2 The Inquiry did not find either of these propositions acceptable and, in fairness, neither did the Commission nor senior officers of the Commission.

3.1.3 External assessment of what C.S.L. does is difficult because no standards of measurement have been defined. These in turn could not be set since no definitive set of policy objectives has been spelled out and no practical mechanism created or operated to ensure that they reflect the needs of the times. This is not only a very unsatisfactory state of affairs, but the fact that it has remained so for so long has resulted in C.S.L., both as a Commission and as part of the Department of Health before that time, drawing its own set of definitions and defining its own policy objectives. On many occasions C.S.L.'s view has been completely justified. On some occasions, a second view might have been better with the wisdom of hindsight.

3.1.4 Equally, however, this condition should not continue as a large capital investment and pressing annual budget claims are involved.

3.1.5 National interest is not defined anywhere in the legislation, but may be inferred from the powers conferred upon the Minister. It is frequently referred to (sometimes in other words) in writings relating to the Commission and its work.

3.1.6 It has been defined by implication in those relatively rare cases where the Minister of the day has made determinations under Section 19(b) (Appendix No. 3) or has amended the Regulations which list products to be produced by C.S.L.

3.1.7 The Public Accounts Committee in 1969 identified this dilemma and on P.63, Para 236 of its Report said "this dilemma will remain until it is made clear that the Commission is to be regarded either primarily as a part of the public health service of the community with a section devoted to commercial activities or is primarily a commercial activity with limited government responsibility."

3.1.8 The result of this has been that C.S.L. has drawn its own definition, which undoubtedly on many occasions has been completely justified.

3.1.9 Enquiries at C.S.L. ascertained that any new policy action proposed by C.S.L. has been notified to the C.S.L. Secretariat in the Department of Health (and therefore by definition to the Department Head and thence to the Minister).

3.1.10 The Inquiry would expect that any proposed course of action contemplated by C.S.L. would have been subjected to close enquiry and that answers to the following questions (inter alia) would have been obtained before action was taken.

(1) Who are all the interested parties; what do they say of the need (both qualitatively and quantitatively); how have their views been checked?

(2) Assuming that all are agreed, what are the relative advantages and disadvantages in terms of local manufacture versus imports?

(3) What are the non-financial arguments for and against local manufacture or importation.

(4) Assuming a decision in favour of local manufacture, what are the initial and subsequent capital and operating costs?

(5) In the light of the answers to 4, how does the answer to 2 now appear?

3.1.11 Such does not appear to have been the case and as a result no quantitative goals appear to have been set and consequently no satisfactory basis for judging C.S.L.'s performance.

3.1.12 It is noted with pleasure that one difficulty referred to by the Public Accounts Committee in its 1969 Report, namely the adequacy of the accounting practices, and particularly cost accounting no longer exists. No doubt there are points for criticism and opportunities for improvement, but in our view the present practices enable cost items to be identified and attributed to particular activities with sufficient precision as to enable financial judgements to be fairly made. It is on this assumption that the workability in practical terms of what we propose is predicated.

3.1.13 What ought to be the primary role of C.S.L. has been examined by the Inquiry. With the senior management of the Commission attempts were made to find some practical and workable distinction between commercial and non-commercial activities.

3.1.14 The Inquiry found fundamental and recurring difficulties in defining once and for all what activities in C.S.L. should be 'commercial' and what 'non-commercial', for these reasons:-

(a) Some undoubted national interest activities e.g. penicillin fermentation are clearly financially unprofitable and will in all probability remain so.

(b) Some undoubted national interest activities e.g. insulin production are profitable. Should they therefore cease to be treated as national interest activities because they are profitable? The Inquiry does not think so.

(c) Some commercial activities e.g. antibiotics are of low profitability, while

(d) Some are profitable by any test.

3.1.15 There are a number of other features which made such a distinction unworkable in the long term.

(a) A given product - vaccine, antibiotic or whatever, has an unpredictable life cycle -

(i) The malady which it was designed to combat fluctuates as to frequency, intensity and geographic location.

(ii) Research and development in Australia or abroad may induce product obsolescence.

(iii) History has shown that commercial competitors of C.S.L. move into and out of a product range for the reasons given in (i) and (ii) and opportunity, or otherwise, for profit, but on balance there has been a general withdrawal from the market through mergers and acquisitions or change of policy direction all of which has resulted in a substantial reduction of producers in most areas of concern to C.S.L.

(iv) For policy reasons, prices of human dispensed products manufactured by C.S.L. and its competitors (where they exist) for the range listed as Pharmaceutical Benefits under the National Health Scheme are controlled by the Department of Health. Approximately 60% of C.S.L.'s output in dollar value comes under this heading.

3.2 THE PENICILLIN STORY

3.2.1 As an illustration of how historically decisions on C.S.L.'s activities have been taken, we have had prepared a summary of the fluctuating fortunes of penicillin. (See Appendix No. 4).

3.2.2 This illustrates in one example the circumstances which have led to action and the consequences of that action, together with the impact of external influences on the project.

3.2.3 This example can be repeated elsewhere in C.S.L. e.g. poliomyelitis vaccine, and is cited not so much as a criticism of those who were involved in decision making or management, but rather to indicate the inherent features of so much that C.S.L. does.

3.2.4 The outcome, however, is that in 1978, we have a grossly underutilized plant of a low written down book value requiring an annual expenditure of $1.0 million to preserve it on a care and maintenance basis. To this must be added that the present area for the manufacture, preparation and testing of seed culture does not closely comply with the Code of Good Manufacturing Practice so that upgrading and associated costs are anticipated.

3.2.5 Nor is that the end of the story. While the argument runs that Australia needs this facility in case of national need, the fact is also that a substantial number of important penicillin products are partly manufactured by C.S.L. some of the raw materials for which are at present largely imported from overseas as the only source available. Other penicillins are fully imported and repacked by C.S.L. These are mainly synthetic and semi-synthetic penicillins.

3.2.6 In money terms these items represent sales of between $5.5m and $6.0m out of C.S.L.'s annual sales of $23.6m., but a much higher percentage of the total antibiotic sales.

3.3 BLUETONGUE PROGRAMME

3.3.1 In 1968 planning was undertaken for the construction of a high security area in which work could be undertaken on a number of developments and tests. A paper on this development prepared for this Inquiry by C.S.L. appears in Appendix No. 5.

3.3.2 With the passing of time in 1973, the basic objectives underwent modification particularly by the addition of work (and proposed facilities) for tests on large animals and the production of exotic animal disease vaccines.

3.3.3 In the process, the estimated cost had escalated from $70,000 to $800,000.

3.3.4 Although the potential of the Bazeley Maximum Security Laboratory was seen by C.S.L. to be readily extended to include large animal work on bluetongue, the Director General of the day directed that such work should not be undertaken therein and neither would there be any intention of producing foot & mouth disease vaccine at C.S.L. On the other hand there was a widely held view that C.S.L. should equip itself to be able to cope with an exotic disease emergency.

3.3.5 The Morgan Virus Production Building was also designed to upgrade and develop work in epidemic contagious diseases in humans such as influenza etc., and to produce more economical batches of vaccine, and as a nationally determined policy, will include special zones for bluetongue work.

3.3.6 Be this all as it may, the Morgan Virus Production Building Stages I and II and the Bazeley Maximum Security Building together with the necessary plant and services have cost almost $5.0m and $1.5m respectively.

3.3.7 Once again, this case illustrates the process by which policy decisions have been arrived at, including the changes of direction which emerged during their evolution. It also illustrates the almost inevitable cost escalation which results from such a chronology of events. And this only takes in initial capital costs. Those for maintenance and periodic replacement, not to mention extensions or modifications are left to the vagaries of the future.

3.4 DEFINING THE NATIONAL INTEREST

3.4.1 Returning to the Public Accounts Committee's statement of the dilemma of C.S.L. the Inquiry unhesitatingly came down on the side of the proposition that C.S.L. is "a part of the health service of the community with a section devoted to commercial activities." None the less, the Commonwealth Serum Laboratories Act 1961-1973 does not contain words or phrases which refer directly to public health activities and appears to place prime emphasis on commercial activities.

3.4.2 The need is then seen for an external review mechanism to be established which will regularly and consciously define where lies the national interest in respect of activities in which C.S.L. currently engages at the time of review; proposes to engage in; or could engage in given its capability and expertise.

3.4.3 The strong impression gained is that historically except in the rare cases where the Minister of the day has specifically given a direction of his own initiative, national interest has been defined, initially at least, by the Commission itself. This is not to be condemned. It is in the business of manufacturing and supplying vaccines, antibiotics etc. and has demonstrated a good feel for the conditions affecting supply of and demand for its products and, the necessary lead time before a product can be made available to those who need it.

3.4.4 Accordingly, it is considered that C.S.L. has a major contribution to make in the assessment.

3.4.5 Concern is felt as indicated that C.S.L.'s role has been dominant in the assessments made in the past although admittedly, the Inquiry believes, because there has been insufficient activity by others. There have not been adequate checks and balances to ensure and demonstrate sound judgement or to evaluate thoroughly the financial consequences for the taxpayer.

3.4.6 The Commission is jealous of its independence as a statutory corporation, operating under its own Act of Parliament, and is concerned at the prospect of constraints upon that independence. Under its Act the Commission has the right of direct access to the Minister; is accountable to him for its performance and it is to him that it puts its views on policy including, no doubt, its assessment of the national interest.

3.4.7 Two hundred years after, the Inquiry finds apposite Talleyrand's remark "War is much too serious a thing to be left to military men" - mutatis mutandis.

3.4.8 The reality of public administration is that on all matters relating to his portfolio, the Minister will seek the advice of the Director-General, including those on which C.S.L. come directly to him.

3.4.9 This applies to requests for funds under Section 19(b), and what we have proposed is an enlargement of not the authority of the Section but rather the practical application of it. See Section 3.5.

3.4.10 It is considered in the light of this, that the Director-General (under the direction of the Minister) should be the focal point for the collection of advice, opinions and facts which will enable him properly to advise the Minister on the definition of national interest from time to time.

3.4.11 The Director-General should (by Cabinet decision if that be deemed necessary) have access to all whom he may consider able to assist him reach that definition. These would include people from relevant Commonwealth and State Government departments and agencies, medical and veterinary organisations, public health, academic and the private commercial sector.

3.4.12 The Director-General would nominate from time to time, who would be appropriate in the determination of the National interest, bearing in mind the types of questions that should be asked and answered in para. 3.4.10

3.4.13 The Inquiry would emphasise that we do not contemplate an inter-Departmental Committee nor indeed, any permanent formal panel or committee. Quite the reverse. It may well be in some cases, the Director-General may wish to advise the Minister solely from information he has gathered himself. That would be his decision.

3.4.14 At all times the Commission's own views should not only be expressed as the examination proceeds, but very carefully listened to. That, it is expected, would be seen to be logical and reasonable by the Minister and the Director-General.

3.4.15 One specific consequence of this procedure would be that national interest projects requiring the construction of new buildings would be accepted as such in the budgeting process so that they could proceed over one, two or more budget years with certainty as to planning, ultimate cost and progress cash requirements. This should result in greater efficiency and speed in design, construction and cost and in better cash budgeting for both the Commission and the Department of Finance.

3.5 FUNDING ARRANGEMENTS - NATIONAL INTEREST PROJECTS

3.5.1 Once national interest is defined, then all activities associated with it would become part of the national interest project. These would include:

- capital cost of buildings, plant and services,
- raw materials and finished goods stocks,
- operating costs including maintenance and depreciation,
- research and development.

3.5.2 These would be reduced to an annual commitment in budgetary terms within the Department of Health under Section 19 of the Act.

3.5.3 The funds provided to C.S.L. under this proposal would be accounted for separately by C.S.L. as is their present practice.

3.5.4 It will be recalled that under Section 38 the Minister has the power to reimburse expenditure incurred in S.19(b) which cannot be funded from trading profit and which he has done each year since 1972-73 in varying amounts.

3.5.5 This is very much an annual accounting exercise, as is evident in 1975-76 and 1976-77 which resulted in a no profit/no loss situation after partial recognition of national interest. The Inquiry believes this to be much less satisfactory than a close examination of the Commonwealth's financial commitment before the event, the more so as it will result in planning on a rolling triennial or similar basis and can only be an improvement on the present fiscal arrangements. These are discussed elsewhere.

3.5.6 In view of the likely aggregate amount of the annual appropriation under Section 19(b), a much closer examination ensuing of what constitutes the national interest as set out in Section 3.4. is considered essential.

3.5.7 The Inquiry considers that this must be done.

3.5.8 It will be argued that following the cost relief to C.S.L. flowing from this recommendation, C.S.L. will be well placed to make substantial profits from its non-national interest activities and indeed, perhaps, from some of its national interest activities. It is hoped that will be the case.

3.5.9 There are, however, several existing practical constraints.

(a) The large part of C.S.L.'s output is subject to price control by the Department of Health and in other relevant cases by open market competition.

(b) If C.S.L. does make substantial profits, under its Act it is liable to pay income tax. (Section 42(1))

(c) Thereafter the Minister under Section 39(3) can apply the surplus as he determines, including a repayment to the Commonwealth.

3.5.10 In other words, assuming that in a given year the total activities of C.S.L. results in a trading profit after tax, the balance can be restored.

3.5.11 It is thought unnecessary to go further into the accounting for this procedure in this Report. It is predicated on the assumption (which is considered justified) that the Commission will carry out its part, as will the Auditor General and the Director-General as principal advisor to the Minister.

3.6 RECOMMENDATIONS

3.6.1 It is recommended that the Director-General of Health under the direction of the Minister should be the focal point for advice to the Minister on the definition of the national interest from time to time. (Recommendation No. 4.)

3.6.2 The Director-General should have access to all whom he may consider able to assist him reach that definition, for example, by convening Task Forces or Study Groups at appropriate occasions. (Recommendation No. 4).

3.6.3 When the national interest is defined all activities connected with it, viz. -

Capital cost of buildings, plant & services;
Raw materials and finished goods stocks;
Operating costs including maintenance and depreciation;
Research and development

would become part of the national interest project. (Recommendation No. 5(a)).

3.6.4 Activities referred to in Para. 3.6.3 be reduced to an annual budgeting commitment submitted by the Department of Health under Section 19 of the Act. (Recommendation No. 5(b)).

3.6.5 As some areas of change require no legislative amendment, they should be implemented as soon as possible. In areas where legislative changes are necessary e.g. products for immediate sale, the Commonwealth Serum Laboratories Act 1961-1973 should be amended. Procedures for determining which current projects are in the national interest should be the matter for discussion between the Director-General of Health and the C.S.L. Commission. (Recommendation No. 5(c)).

3.6.6 A facility for the manufacture of penicillin in C.S.L. should be retained for the foreseeable future in the national interest (also refer Para. 7.4.3). (Recommendation No. 6).

CHAPTER 4

Financial Implications of Legislation and Policy

4.1 Financial and Accounting System

4.1.1 As noted elsewhere, the Inquiry noted the Public Accounts Committee's concern in 1969 about the adequacy of C.S.L.'s accounting procedures and practice.

4.1.2 From documentation obtained from the Commission, from written and verbal answers from the Commission and from observation of some of C.S.L.'s operations, we believe the accounting procedures to be satisfactory.

4.1.3 We are reinforced in this view by the decision of the Auditor General to cease the practice of having audit staff permanently based at C.S.L.

4.2 DEPRECIATION

4.2.1 In the preparation of its accounts C.S.L. depreciates plant and machinery and equipment used by it.

4.2.2 C.S.L. pays rent to the Commonwealth for land and buildings taken over in 1961 and occupied by the Commission. However C.S.L. has not adopted a practice of amortising the cost of buildings erected since 1961.

4.2.3 The Auditor General in his certificate to the accounts has drawn attention to this as not being in conformity with the Statement of Accounting Procedure.

4.2.4 We share the Auditor General's concern but on more serious grounds.

4.2.5 While there may be opportunity for debate about depreciation in the accounts of an enterprise, or warehouses, or large city buildings, there surely can be none in the case of special purpose structures used in C.S.L.'s operations.

4.2.6 Lying as it does in a constant condition of technological change and obsolescence, C.S.L. ought to treat all its structures as it does its plant and equipment for depreciation purposes.

4.2.7 It is no answer to say that because they are not owned by the Commission therefore they are not subject to depreciation. In the unlikely event of the Department which has the legal ownership charging itself with depreciation this argument might have some force.

4.2.8 The Inquiry acknowledges that the consequence of C.S.L. bearing depreciation on its buildings will have a disastrous effect upon its profit and loss account. That may be so, but we cannot agree with the present practice which seeks to deny the reality of the situation.

4.2.9 It is recommended that depreciation at proper rates be charged on all C.S.L. occupied buildings and that the costs of this be taken into account in budgets, capital expenditure projects, section 19(b) applications and price applications. Not to take this course of action now will be to lament in the future the short honeymoon provided by the recent construction of new buildings and the relatively low maintenance charges associated with their early years. (Recommendation No.7).

4.3 ACCOUNTS - PROVISION FOR FURLOUGH RECREATION AND LONG SERVICE LEAVE

4.3.1 While these are properly accounted for on principles agreed with the Commonwealth Actuary, the Inquiry noted that this has now risen to $2 272 522 as at 30 June 1977.

4.3.2 This must not only raise questions on cash funding for the payment of these accounts but also whether annual leave and long service leave are being taken by C.S.L. officers at the time of entitlement. Not to do so imposes an additional financial burden on the Commission by the amount of money representing the difference between the value at entitlement and the value when the leave is actually taken.

4.3.3 In these circumstances it is recommended that the Commission re-examine its practices in respect to furlough. (Recommendation No.8)

4.4 THE MARKET

4.4.1 Important factors creating and affecting the market include:-

(a) Australia's substantial dependence upon overseas sources of raw materials.

(b) The fact that almost all manufacturers are overseas owned.

(c) The entry into and cessation of manufacture of some of the range of products from time to time by manufacturers.

(d) The progressive enlargement over time, of items included in the Pharmaceutical Benefits Scheme.

(e) The fact that market prices of P.S.B. items are set by the Department of Health.

(f) Whether a product is covered or not covered by patent.

(g) Impact of world supplies and prices.

4.4.2 All these make for a consistently fluid condition of the market and make its definition impossible in once and for all terms.

4.4.3 It does emerge, in our opinion, that the existence of C.S.L. and Fawnmac together with the pricing control mechanism operated by the Department of Health provide a reasonable

set of checks and balances to ensure that the Australian consumer is supplied with the products he needs at reasonable prices, bearing in mind his role as taxpayer in which he funds a significant proportion.

4.4.4 The procedures we have recommended, if followed consistently and with diligence should ensure a sensitive adjustment of national and private sector activity to needs from time to time taking into account the factors described in 4.3.1.

4.5 EFFICIENCY IN THE COMMISSION'S OPERATIONS

4.5.1 The Commission is under the three main constraints of:

(a) Price control by the Department of Health of its main volume products.

(b) Inability to make or import and sell non-biological products.

(c) The planning constraint of annual bids for Commonwealth funds, whether under sub-section 19(b) or otherwise. It has the capability to produce as efficiently as its private sector competitors or where that does not apply, to make a profit by its own standards of measurement.

4.5.2 As a buyer of raw materials and equipment, C.S.L., through quantum of money involved, is or ought to be able to buy as well as anyone else, or better, bearing in mind the leverage its position gives it.

4.5.3 The Inquiry does not see it as its function to go into the purchasing policy of C.S.L. in great detail. It is clearly the role of the Commission as guardian of the taxpayers' resources to maintain constant surveillance. Equally, it is the task of the Department of Health in considering applications for price increases by C.S.L. or its competitors in respect of national health items, to equip itself to be aware of ruling rates and world market patterns of costs which obviously have a serious implication for the funding of Pharmaceutical Benefits Scheme.

4.5.4 The phenomenon of the overseas manufacturer selling pharmaceutical products or raw materials to its own subsidiary and taking its profit in its own country rather than allowing its subsidiary to make the profit has been explained to the Inquiry. We are not able to assess in any definitive way the extent, frequency or cost impact of this on either sales to C.S.L. or the claims of profitability or loss by members of the pharmaceutical industry in Australia.

4.5.5 The Inquiry does indicate however, that the presence of C.S.L. in the market, albeit incompletely and unequally because of its national interest function, is most important as a monitor of these features and as a reminder to any tempted

to exploit a national disadvantage, that it has the potential to provide a counter-force, at the discretion of the Minister, should the need arise.

4.5.6 The continuation of CSL presence together with the Department and Commission vigilance should provide adequate safeguards.

4.5.7. Concern was felt that CSL should preserve good commercial efficiency, as our recommendations should ensure. As a result of isolating national interest functions, the Commission should examine closely the present rationale for some of CSL's present activities, in both human and veterinary products.

4.5.8. There are questions which should be asked - these include:

(a) Is there really a need for CSL to be making and selling some products at all? Have events overtaken or are they overtaking some of the original justifications?

(b) If there is a reasonable prospect of the commercial manufacturers fulfilling the market need, why should they not be allowed to? This is the reverse of the proposition we put for CSL remaining in production of certain items viz. insulin where C.S.L. supplies approximately 65% of the market.

(c) What risk is there that CSL will continue to undertake a further series of marginally economic projects which will result in inappropriate aggregate capital expenditure and fragmented Research and Development production energy?

(d) For any business, there is a prospective new activity that is simply too small for it sensibly to undertake. Has that minimum scale of activity been examined and has it been renewed regularly?

4.5.9 There is no merit trying to marry large scale national functions with a series of pharmaceutical "Cottage" industries.

4.5.10 This is then a basis for review to ensure commercial relevance. We were assisted also by a paper prepared by the Director of CSL entitled "An Approach to the Analysis of Section 19(a) and 19(b) (Appendix No. 6)", in which he examines the features to be considered in the review process. The further study of this paper by the Commission and by the Department is recommended particularly as it draws upon the reports of the National Immunisation Work Groups in March 1977 in the United States of America dealing with similar philosophical and practical problems to those discussed in this report.

4.5.11 The Inquiry examined the role of the Department of Health in respect to the control of prices. As indicated above, this is seen as necessary and important in the national budget area as well as keeping the costs of pharmaceutical products to the Australian population under review. An efficient C.S.L. should provide the Department with appropriate and much needed indicators. It is recommended, however, that, if in the Department's assessment of C.S.L.'s requests for increases arising from, inter alia, raw material and labour costs, the fact that C.S.L. indicates a profit component should not militate against an increase. It is seen as absolutely essential for morale and proper efficiency assessment that there should be a proper profit element. The achievement of a profit will encourage C.S.L. to do better and to seek other areas for improvement. In cash terms, it will provide surpluses for C.S.L. to embark upon innovations for improvement outside the ordinary constraints of Commonwealth budgets which are an essential part of good management. C.S.L. will then quite rightly feel that it has earned a greater right to be more master of its own destiny since it has displayed responsible stewardship.

4.5.12 The Inquiry from its reading of published reports on earlier enquiries involving C.S.L. as well as some correspondence and submissions, has noted a number of charges laid against C.S.L.

4.5.13 Included among these are inefficiency, under protectiveness resulting from its Commonwealth ownership, want of commercial acumen etc.

4.5.14 No doubt from time to time and in varying degree there is some substance in these claims and will continue to be the case while the Commission and C.S.L. are staffed and operated by fallible human beings.

4.5.15 As a general proposition, however, the Inquiry has the strong impression that criticism stems from the lack of clarity of objectives as seen by people outside. This has been discussed in Chapter 3.

4.5.16 In a number of cases complaints have contained some of the facts but not all of them and show a predictable and partisan point of view, particularly when expressed by competitors or would-be competitors.

4.5.17 The Inquiry would urge great caution and a need to probe further for additional information before accepting at face value many complaints of the type we have encountered.

4.6 RECOMMENDATION

4.6.1 The number of "Cottage" type industries undertaken by C.S.L. should be contained in number and extent as much as possible. (Recommendation No. 9).

4.6.2 The Department of Health, in its assessment of C.S.L.'s requests for increases arising from "inter alia" raw material and labour costs, should not let the fact that there is a profit component, militate against an increase. (Recommendation No. 10).

CHAPTER 5

RESEARCH AND DEVELOPMENT WITHIN C.S.L.

5.1 DESCRIPTION OF THE PRESENT R. & D. EFFORT

5.1.1 Research and development at C.S.L. is directed towards the development of new biological products, to the improvement of existing ones and to scientific "trouble shooting" within the organization. Furthermore, scientists within the R. & D. division contribute advice and assistance free of charge to medical and veterinary bodies and to individual practitioners. Also, C.S.L. runs W.H.O. Centres for influenza, blood group serology and brucellosis; and the National Rabies Diagnostic Centre. In general, research at C.S.L. is applied research with the fundamental research component presently less than 5 per cent.

5.1.2 The R. & D. Group numbers 111 employees, of which 51 are professional and 60 sub-professional. The R. & D. Group Budget (including indirect costs and medical consultants) is $3.35 million or 14.2% of budgeted sales. This is well above the pharmaceutical industry norm, but below the Connaught figure (20 per cent of sales) and probably represents an appropriate level of activity, particularly bearing in mind the inclusion of public interest work such as Section 19(b) research, W.H.O. centres and consultant advice to outsiders and reserve capacity/facilities.

5.1.3 The R. & D. Division is loosely organized into 7 groups. In decreasing order of size, these are virology (41 staff), bacteriology (19), bioengineering (17) biochemistry (14), immunology (10), blood research (6) and pharmacology (4), this last group being new with plans for expansion.

5.1.4 Physically, the research groups are scattered throughout a number of buildings, some of which are quite a few minutes walk from others, and the geographic situation is not conducive to optimal interdisciplinary interactions. Taken individually, the research laboratories are of adequate space and quality, and the scientific equipment available is good.

5.1.5 There are some advantages to having R. & D. staff located in reasonable proximity to the relevant production activities, but on the whole we believe the advantages of having the R. & D. division in one well designed location outweigh these. The R. & D. group would certainly benefit from a new central R. & D. building. However, the proposal seems less urgent than some other needs.

5.1.6 To ensure that the R. & D. effort is well balanced and relevant, a Research and Development Advisory Committee reviews the work, and makes recommendations for termination of projects and initiation of new ones. Inputs come not only from within R. & D., but also from the medical production, technical and marketing groups.

5.1.7 As the R. & D. division cannot stand aloof from the day to day requirements of C.S.L. significant fractions of staff time go into responding to urgent requests for help from production or technical divisions.

5.1.8 The concept of outside "peer group" review of research as practised in the academic sector has not been established practice within C.S.L. Unfortunately, this is true for many government research activities. Currently, the idea is being actively developed as instanced by the appointment of a distinguished, recently retired virologist as a part-time consultant. The appointment of a further consultant (a university professor) to the bacteriology group has recently been approved.

5.2 R. AND D. GROUP EMPLOYMENT POLICIES AND PRACTICES.

5.2.1 Professionals within the R. & D. division are mostly employed as Biochemists, Class 1 (salary range $10 059 - 14 064), Class 2 ($14 663 - 16 178), Class 3 ($16 895 - 18 667) or Class 4 ($19 405 - 20 599) per annum. There is a structured hierarchy of employment levels for the approved establishment. On occasion, however, outstanding workers can be promoted by way of special submission to the Minister via the C.S.L. Commission.

5.2.2 These salary levels create difficulties with respect to the recruitment and retention of first class scientific staff. For example, the salary ranges for Lecturers, Senior Lecturers and Readers in universities are, respectively $14 988 - $19 688; $20 108 - 23 438; and $26 508. Within C.S.I.R.O. the ranges for Scientific Officers, Research Scientists, Senior Research Scientists and Principal Research Scientists are: $10 834 - 13 288; $14 639 - 17 944; $18 577 - 21 267 and $22 066 - 25 029 (all figures quoted are current as at the 31 March 1978.

In both of the above cases, it is possible to promote scientists still further, in universities to professorships or personal professorships, and in C.S.I.R.O. to senior principal Research Scientist or (occasionally) Chief Research Scientist. On personal merit.

5.2.3 Public Service Board determination under Section 53 of the Public Service Act describes as a Research Scientist, a person possessing a Ph.D. degree, and with scientific research ability. The next three grades require in addition, only research ability "of a high order"; "of a very high order" and "of an exceptionally high order". A joint statement by the P.S.B., the C.S.I.R.O., the A.A.E.C. and the then Department of Supply, in defining the nature of a Research officer, and of Research Groups, lays down certain standards of originality and inventiveness which would apply to some of the individuals within the C.S.L. R. and D. division, though probably not to the division as a whole.

5.2.4 At present, there are only 10 Ph.D's in the Research and Development division. Individuals with medical, veterinary or engineering degrees are paid on separate scales appropriate to each. Were we to recommend a general upgrading of the Ph.D's to Research Scientist status, we fear the consequential creation of an elite within the organization and an unbalancing of internal relativities with respect to scientists and managers in the technical, manufacturing and other sections. Nevertheless, there are some long-term implications of this lack of upward mobility. For example, vacancies within the R. & D. group are usually advertised both internally and externally. The response to outside advertising is inversely proportional to the level involved, hundreds of applications being received for a Biochemist Class 1 but only one for a recent Biochemist Class 4 vacancy. C.S.L. has had some difficulty in attracting outstanding scientists and has had only mixed success in holding such workers. The poor salary levels are doubtless a contributory factor. If C.S.L. is to be ready to face the challenges of a future in which its products may play a still larger role in medicine and veterinary science, mechanisms must be devised to attract and hold at least a small number of true research leaders.

5.2.5 Whereas it is possible to give an individual within C.S.L., a promotion (or personal re-classification) solely on the basis of outstanding work performance, this happens relatively rarely. An inhibitory factor has been the amount of administrative work involved. The present Section 26(2) of the C.S.L. Act prevents the Commission from taking final action on any classification. Until this is amended, Public Service Board scrutiny and Ministerial approval of every case would be necessary. The contrast with C.S.I.R.O. is noteworthy, and a more flexible machinery using the existing classification standards would be welcomed. In particular, the limited adoption of Research Scientist classifications, for example, to attract or hold a particularly gifted worker, represents an option which the Commission should be free to exercise, and for which Public Service Board concurrence should be prompt.

5.2.6 However, the onus should then be on the Commission to ensure that an individual to whom this option might be applied has truly exceptional qualities.

5.2.7 Currently, C.S.L.'s research is very practically oriented, there being more emphasis on the "D" end of the "R. and D." spectrum. Indeed, a good deal of effort goes into solving short-term problems arising within the production or quality control sections. We agree with this broad thrust. Nevertheless, we are somewhat concerned that the amount of basic research is under 5 per cent of the total effort, and that only one of the seven groups is maintaining a steady output of scientific papers. A basic research component closer to 10 to 20 per cent of R. & D. effort would represent a better balance, positioning the organization to contribute to world knowledge as well as benefitting from it.

5.2.8 Apart from in-house research, C.S.L. has on occasions contracted out particular segments of its research, especially where highly specialized techniques are involved. We would encourage this option where it is appropriate, but do not see it as being a very big proportion of the whole R. & D. effort.

5.2.9 One of the impressive features of the R. & D. division is its participation in staff post-graduate education schemes. Outstanding younger graduates are identified and funded for further education, usually in Australia and occasionally overseas. A judicious mixture of such "home grown products" and senior researchers recruited from the outside will give C.S.L. the best type of research leadership.

5.2.10 Though regular lecture and seminar programmes exist, and though staff travel to national and international meetings to an appropriate extent, one still gets the impression that the research group as a whole is somewhat intellectually isolated. In part this is due to the fact that no specific "peer group" with closely similar interests exists within Australia, as no other pharmaceutical manufacturer in Australia has an R. and D. division of similar size and perspective. In the United States, for example, there exists a large and highly-trained group of pharmaceutical industry researchers, who stimulate one another through a variety of national scientific meetings and otherwise. Furthermore, a vigorous movement of staff from company to company occurs as people move to seek promotion. In Australia, the R. & D. divisions of drug companies are quite small, and are concerned either with the co-ordination of clinical trials, or with routine problems of drug formulation. Conscious of this problem, C.S.L. has recently sought to strengthen co-operation with C.S.I.R.O., the Universities and the Walter and Eliza Hall Institute.

5.2.11 The research staff feels (rightly or wrongly) that public and political lack of enthusiasm for C.S.L. as an entity has had an inhibiting effect on the development of a first class research team.

5.3 RECOMMENDATIONS CONCERNING THE RESEARCH DIVISION

5.3.1 The Independent Inquiry recommends that C.S.L. show more initiative in recognizing and rewarding first class scientists. The fact that occasionally (not routinely) scientists of outstanding merit could be promoted to Research Scientist status should be made known internally and externally. (Recommendation No. 11).

5.3.2 We recommend that the mechanisms recently instituted for outside "peer group" review of research be strengthened and formalized. (Recommendation No. 12).

5.3.3 We recommend that two research liaison committees be formally convened to strengthen collaborative and information links: one between C.S.L. and the relevant C.S.I.R.O. divisions; and one between C.S.L. and the university-research institute sector. (Recommendation No. 13).

5.3.4 We recommend that C.S.L. seek actively to sponsor exchange visits, where scientists from comparable overseas institutions could be invited to Australia, and vice-versa. (Recommendation No.14).

5.3.5 We recommend that the R. and D. Division as a whole not be reduced from its present size. (Recommendation No.15).

CHAPTER 6 STUDY OF C.S.L'S & FAWNMAC'S OPERATIONS & RELATIONS

6.1 C.S.L. & EXPORT

6.1.1 Over its long history, C.S.L. has sold its products overseas, sometimes for good financial reward. As a general proposition the Inquiry acknowledges the wisdom of this not merely for financial reasons but, if C.S.L. has an international role to play, then that can only be good for C.S.L., its people and Australia.

6.1.2 Some warnings are sounded, however.

6.1.3 In recent years particularly, Australian exports have become increasingly uncompetitive and C.S.L. cannot be immune to the same influence.

6.1.4 It is recommended: (Recommendation No. 16).

(a) That unless there is a useful minimum and clearly definable reward, C.S.L. should not commit itself to export or foreign investment activity.

The rewards which need to be identified are:

(i) *Additional money profit after charging full* appropriate costs against export sales; or

(ii) A reduction in overall cost arising from the fixed costs of an under-utilized plant being spread over a greater volume resulting from export activity.

(b) The Inquiry recommends that benefits gained from export sales should not be used as a justification for the implementation of a capital expenditure programme unless the benefits are seen to extend to the long term.

6.1.5 The foregoing is our view in commercial terms.

6.1.6 It must also be noted that C.S.L. enjoys a high reputation for its products and marketing efforts overseas. It has received two Export Awards which thus puts it into a relatively exclusive band of Australian enterprises. It would be a pity not to develop and capitalise on this skill.

6.2 C.S.L., FOREIGN AID & W.H.O. REFERENCE CENTRES

6.2.1 One aspect of national interest not discussed in Chapter 3 is that which is covered by Foreign Affairs and the Aid Programme and the W.H.O. Reference Centres.

6.2.2 There is room for further discussion between the Department of Health and C.S.L. on the one hand and the Department of Foreign Affairs on the other, to see what opportunities there are for combining the attributes and

products of C.S.L. with Australia's commitment to developing, or undeveloped nations in need under, inter alia, United Nations obligations.

6.2.3 Here is an instrument of domestic national policy with a prime obligation to meet Australia's domestic national interest which can, under the conditions proposed above, make a useful contribution in Australia's international interest from a position of existing experience and knowledge.

6.3 RECOMMENDATIONS

6.3.1 Further exploration of opportunities for Foreign Aid and W.H.O. Projects should be undertaken (Recommendation No. 17). The enthusiastic support by W.H.O. for C.S.L.'s continued involvement in vaccines has been noted.

6.3.2 The tests described in Section 6.1 should be applied to all concepts of this kind before they are approved. If, however, C.S.L. is cleared to embark on aid or other like programmes, then the cost should be treated in the same way as Section 19(b) policy decisions described in Chapter 3 i.e. funded by special appropriation from the relevant Department having the carriage of Australia's involvement. In *essence*, let the user pay. Any other export activities should be judged by ordinary commercial standards so that C.S.L. will be seen to have succeeded or failed by its own efforts. (Recommendations 18 & 19)

6.3.3 Wherever C.S.L. is given a policy clearance to undertake other overseas national interest commitments, they be treated in the same way as proposed in paragraph 6.3.2 (Recommendation No. 20)

6.4 CODE OF GOOD MANUFACTURING PRACTICE

6.4.1 This code is laid down by the Commonwealth Government and followed by State Governments to ensure that all pharmaceutical manufacture conforms to a minimum standard. The Inquiry was told that this approval is obtained at the same time as the approval for a new product is obtained, where it is to be manufactured in Australia. The Inquiry was concerned to learn that a number of production lines within C.S.L. do not conform closely to the Code because of antiquity of buildings, obsolescence of plant or layout and this appears to have been confirmed in some respects at least by the outbreak of two potentially very serious fires in recent times.

6.4.2 It is recommended that this condition be examined immediately and reported upon. (Recommendation No. 21)

6.4.3 If the Code is the desired standard to be followed and C.S.L. is in breach, wherein lies C.S.L.'s status as a national resource against need or emergency? Second, even in the absence of emergency, how can production at below acceptable standards be tolerated bearing in mind the essential nature of many of C.S.L.'s products?

6.4.4 If the Code is excessive in the demands it makes upon a manufacturer bound by it, then not only C.S.L. but other Australia located manufacturers have presumably been incurring unnecessary costs in meeting the Code.

6.4.5 This paradox should be solved quickly.

6.5 FAWNMAC

6.5.1 By additional terms of reference given to the Independent Inquiry, a visit was made to Fawns & McAllan Pty. Ltd., and Rotary Tableting Corporation Pty. Ltd., (referred to hereafter for convenience as "Fawnmac") to "explore the relationship between the Commonwealth Serum Laboratories and Fawnmac, the possibilities for the future of an increase in co-ordination etc., and indeed a specific opinion as to whether the retention is wise for the Government, considering the whole pharmaceutical scene."

6.5.2 Discussions were frank and open and, because of that, detailed reasons for our recommendations are forwarded separately as a separate confidential document, since they rely on such matters as cost and market dissections which the Inquiry considers confidential to Fawnmac.

6.6 CONCLUSIONS REACHED:

6.61 Fawnmac is a neat, well laid out and well organized operation.

6.6.2 It makes a true operating profit; pays dividends to its shareholder (the Commonwealth) and has not made, and is unlikely to make, in the near future, demands upon its shareholder for funds.

6.6.3 It provides a window on the pharmaceutical world for the Department of Health, which, bearing in mind that Departments' annual budgeting demands, is a useful and necessary adjunct to its information gathering process.

6.6.4 There are good personal relations between senior Fawnmac and C.S.L. personnel. This is aided by the fact that they operate in different fields but is manifest in such matters as -

(a) Fawnmac undertakes tableting and packaging of dry powder products for C.S.L. on an arms length contract basis.

(b) Where one or other has contemplated a change of premises in a State branch, discussions have taken place on the opportunities for sharing space and therefore costs.

(c) Where overseas Governments have called tenders for the products of both organisations, they co-operate on the response to these and have done so successfully.

6.6.5 All this is found to be sensible and healthy.

6.6.6 The removal of the biological constraint from C.S.L. could potentially put them into conflict with each other. It is hoped that the existence of the present relations would make that highly unlikely and, if all else fails, the Department of Health has the opportunity and the obligation to prevent an outbreak of folly.

6.6.7 While uncertainties of Government policy on the future of Fawnmac are unhelpful to morale in Fawnmac, this position is well held but should not be allowed to continue any longer.

6.7 RECOMMENDATIONS

6.7.1 The Government retain ownership of the Fawnmac Companies; state unambiguously that this is its policy and confirm its present pattern of operation which is understood and accepted by the pharmaceutical industry and their suppliers and customers. (Recommendation No. 22)

6.7.2 The present independent corporate form of Fawnmac (if not precise structure) be maintained and preserved and the operations of its board and management continue substantially as at present. (Recommendation No. 23)

6.7.3 The present pattern of co-operation between Fawnmac and C.S.L. be encouraged and fostered without limiting either in the exploration of opportunities for the common reduction of costs, enhancement of performance or pursuit of other sensible commercial options, but that no action whatever be taken (Recommendation No. 24) -

(a) to merge the two bodies; or

(b) to seek closer formal relations through the appointment of common Commissioners/Directors

6.8 THE ROLE OF THE NATIONAL BIOLOGICAL STANDARDS LABORATORY (NBSL).

6.8.1 NBSL is the Commonwealth Government Agency charged with testing pharmaceutical products and certifying their purity and efficacy. In the case of biologicals, products which are in many ways more complex than synthetic drugs, this national "watchdog" function is particularly important.

6.8.2 While testing of batches of C.S.L. products obviously must be done, the Inquiry believes a helpful function of NBSL is to ensure that quality is built into the product through all stages of the manufacturing process. Thus NBSL, must collaborate closely with C.S.L. and other producers of biologicals in ensuring that physical facilities and processes meet the Code of Good Manufacturing Practice.

6.8.3 Evidence taken from NBSL and C.S.L. revealed that the working relationship between the two was good. That is not to say that differences of opinion do not occur, but present policy is to hammer these out openly across the table. NBSL is understanding of the problems which C.S.L. has had in meeting the Code of Good Manufacturing Practice, because the chief hold-up has been availability of funds. NBSL provided useful independent confirmation of two of the Inquiry's conclusions, namely that much of the C.S.L. plant and buildings was shockingly out of date, and that there was no likelihood that C.S.L. could remedy these defects out of its own resources.

6.8.4 The Inquiry noted the importance of close collaboration between NBSL and C.S.L. in the planning of complex facilities. The expertise which NBSL has developed over the years in the design of specialised laboratories particularly microbiological containment facilities complements that at C.S.L. and future C.S.L. buildings should reflect this specialized input.

6.8.5 The Commonwealth Department of Construction has worked closely with NBSL on several projects in recent years and again valuable experience has been acquired. The Inquiry notes that the C.S.L. Commission also works closely with the Commonwealth Department of Construction and sees that this relationship further supports those benefits mentioned in 6.8.4.

6.8.6 NBSL itself has some difficulties in fulfilling its testing role for some C.S.L. products. In particular, it is not presently geared up for optimally testing human vaccines. The Inquiry noted that this is not due to any inherent complexity but to the lack of adequate laboratory facilities. NBSL plans for a major new building are at an advanced stage, and if funds become available, NBSL considers it will be fully able to meet its responsibilities by 1984. Given the present difficulties, the Inquiry has reinforced its view that NBSL with the advantage already of having facilities on the Parkville site, take every opportunity to establish standards for evaluation through participation in the testing procedures for product quality during the in-process and final product testing stages.

6.8.7 The Inquiry recommends that NBSL be consulted by C.S.L. on the design of major new production facilities at an early stage in the planning cycle. (Recommendation No. 25).

CHAPTER 7

THE C.S.L. CAPITAL WORKS PROGRAMME

7.1 BACKGROUND TO THE PRESENT BUILDING PROGRAMME.

7.1.1 C.S.L. moved to its present site in Parkville in 1918, and while many of the present buildings are not quite that old, the need for an extensive updating of buildings and plant was already apparent in 1961 when the C.S.L. Commission was formed. The policy pursued over the first decade of the Commission's existence was one of replacement of worn-out plant and slight expansion only, expenditure being limited to essential items.

7.1.2 When the Commission took over the assets of the Laboratories, much of the plant and equipment had already been written down to a nil book value, though much of this plant is still in use 16 years later. This brings with it several problems, including high maintenance costs and poor efficiency compared with that of modern day performance expectations. Indeed, some of the plant could be considered hazardous. The same applied to buildings. Two serious and one minor fire have occurred in old buildings in recent years.

7.1.3 A more aggressive approach to these problems has been adopted since 1972, and over the past few years, the planning for optimization of property has been a major pre-occupation of the Commission and senior staff. A review of assets indicated that in many cases neither buildings nor plant were compatible with present-day technology. In fact, it was not possible to comply with the Code of Good Manufacturing Practice in many instances. Accordingly, a master plan for building expansion and rearrangement of facilities was drawn up by the Commission, and is in the process of being implemented as funds become available. The master plan looks much further forward than the "New Capital Works Proposals" which go to the Government as a three-year cost projection. This master plan conceives that the present 27 acre site in Parkville will be adequate for the next 15 years provided no entirely new manufacturing approaches are opened up. Further-more, it is not expected that the property development plans will require an increase in the number of people employed.

7.1.4 Planning has centred on three major considerations. Production capacity should be sufficient to provide at least for domestic markets; manufacturing and testing facilities should be upgraded at least to the stage where compliance with the code of Good Manufacturing Practice is possible; and obsolescent or hazardous plant and equipment should be replaced.

7.1.5 The Inquiry has been impressed with the degree of national and international consultation and of imaginative thinking, that has gone into the planning for new buildings and plant. Modern, cost-effective buildings and plant have already resulted from this and there is every indication that the pattern will be continued. However, in a country such as Australia with its small population, it is imperative that

skills and expertise be shared as much as possible. The Inquiry is not convinced that, in the field of the construction of specialized laboratories, the degree of consultation and collaboration between agencies such as C.S.L., N.B.S.L., C.S.I.R.O., the private research institutes, the universities and the Department of Construction has been optimal.

This aspect deserves further study by the Commission.

7.2 CAPITAL WORKS - ACTUAL EXPENDITURES AND PLANS UNTIL 1987.

7.2.1 The capital works expenditure by C.S.L. since the creation of the Commission can be separated into two distinct phases:-

(a) 1961/62 to 1971/72 - a slight expansion and replacement policy was followed with expenditure on only essential items.

(b) 1972/73 onwards - a review of assets indicated that they were not applicable to current manufacturing technology and did not meet the Code of Good Manufacturing Practice issued by the Commonwealth Government and followed by the State Governments. A planned programme of reconstruction was commenced which will continue for a number of years to come.

7.2.2 Table 2 below shows the amounts expended on capital works from the creation of the Commission to 30 June 1977.

Table No. 2 - Capital Works Expenditure - 1961/62 to 1976/77

Financial Year	Amount
1961/62	400,000
1962/63	500,000
1963/64	1,000,000
1964/65	800,000
1965/66	1,000,000
1966/67	800,000
1967/68	300,000
1968/69	600,000
1969/70	700,000
1970/71	800,000
1971/72	1,100,000
1972/73	1,800,000
1973/74	700,000
1974/75	4,600,000
1975/76	7,700,000
1976/77	4,800,000
	$ 27,600,000

.B. An additional amount of $6,024,000 has been appropriated for expenditure in 1977/78 of which only $5,322,000 will be expended in 1977/78. (Refer Paragraph 7.2.4 for details).

7.2.3 Of the total amount of $27,600,000 to the end of June 1977, $3,300,000 has been provided by C.S.L. from funds generated by trading profits - the balance of $24,300,000 has been provided by the Commonwealth.

7.2.4 Items included in the 1977/78 Capital Works Programme for which Commonwealth funds have been approved are:

Project	Approved Cost Estimate	Balance of Funds Required to Complete Project	
		1977/78	1978/79
Virus Production Bdg	4,760,000	$ 187,000	Nil
Veterinary Vaccine Bdg	5,700,000	420,000	Nil
Container Preparation Area and Packaging Extensions	1,150,000	106,000	Nil
Insulin Bdg	4,800,000	2,202,000	1,345,000
Bluetongue Project	60,000	60,000	
Extension to Blood Fractionation Facilities	1,400,000	300,000	466,000
SPF Bdg - Stage 1 and Leucosis	2,000,000	1,100,000	282,000
Other Major Works		124,000	Nil
Minor Works C/F from 1976/77		273,000	
Minor Works - 1977/78		550,000	
	$ 1,987,000	$5,322,000	$2,093,000

7.2.5 The capital works programme is based on planning which takes into account three (3) major aspects viz:-

(a) that capacity should be maintained and, if necessary expanded to provide for the levels of demand which might reasonably be reached for domestic markets;

(b) that manufacturing and testing facilities should be upgraded where necessary to keep pace with rising standards for good manufacturing practice;

(c) that obsolescent or hazardous plant and equipment should be replaced.

7.2.6 *This planning is converted into a rolling three* year programme with the current triennium covering the years 1978/79 to 1980/81. Details of items included in the current triennium are shown as:-

Table 3 - Existing programme - ongoing projects.

Table 4 - New Capital Works - forward estimates.

The total funding requirement covered by the programme for the triennium is:-

	1978/79	1979/80	1980/81	Total
Ongoing projects	7,100,000	3,500,000	1,911,000	12,511,000
New projects	1,794,000	3,675,000	3,045,000	8,514,000
	$8,894,000	$7,175,000	$4,956,000	$21,025,000

7.2.7 Included in the list of new projects in Table 4 are a "Research and Development Building" and "New Blood Fractionation Building" for which expenditure for a feasibility study and design only have been included. Each project would require capital expenditure of the order of $5,000,000.

7.2.8 *Items for which a need is foreseen within the next ten* years are as follows:-

Distilled Water Plant	$250,000
Upgrading/extending reticulation of existing services -	
(a) Parkville	200,000
(b) Woodend	100,000
Major roadways	270,000
Total	$820,000

7.2.9 Assuming that all items included in 1978/79 to 1980/81 programme are undertaken, a considerable renewal of production plant will be brought about by the middle of the late 1980's. Therefore beyond those projects, further plans and funding for the renewal during the 1980's of existing unsafe or inefficient production plant will be of relatively modest proportions. Items such as the following would require funding in the 1982/87 period:-

Replacement of autoclaves and other pressure vessels	$ 300,000
Renewal of laminar flow and biohazard cabinet systems and absolute filters	100,000
Replacement/extension of internal telephone system	180,000
Effluent disposal system	200,000
Minor works (less than $40,000) at $500,000 per annum	3,000,000
Total	$3,780,000

7.2.10 The total anticipated capital works at current estimates to 1987 is made up of:-

Current Triennium Programme (Para. 7.2.6)	$21,025,000
Cost of Research and Development, Blood Fractionation Facility (Para. 7.2.7)	10,000,000
Items 1982 to 1987 (Para. 7.2.8)	820,000
Renewals etc. 1982 to 1987 (Para. 7.2.9)	3,780,000
Total	$35,625,000

TABLE NO. 3

CAPITAL WORKS PROGRAMME - ONGOING PROJECTS
1978/79 TO 1980/81

Project	1978/79 $	1979/80 $	1980/81 $	Total $
Packaging and product holding areas. Extensions to packaging building.	576,000			576,000
Marketing storage despatch and office facilities	1,500,000	500,000		2,000,000
Blood fractionation facility	466,000			466,000
Insulin project	1,345,000			1,345,000
S.P.F. Building Stage 1	282,000			282,000
Human vaccine building	1,835,000	3,000,000	1,911,000	6,746,000
Relocation cell culture laboratory	913,000			913,000
Minor works	183,000			183,000
	7,100,000	3,500,000	1,911,000	12,511,000

TABLE NO. 4

CAPITAL WORKS PROGRAMME - NEW CAPITAL WORKS
1978/79 TO 1980/81

Project	1978/79 $	1979/80 $	1980/81 $	Total $
Service & Facilities				
Pyrogen free water reticulation	44,000			44,000
Laundry facilities	60,000			60,000
Relocation of car parks	40,000			40,000
Widening of 4th Street			40,000	40,000
Fire detection and protection services	50,000			50,000
Quality Control Building				
Extensions	600,000	200,000	50,000	850,000
Computer interface			40,000	40,000
Digital instrumentation			55,000	55,000
S.P.F. Animals Stage 2				
Preliminary	50,000			50,000
Construction		2,000,000	950,000	2,950,000
Research & Development Bldg.				
Feasibility Study	50,000			50,000
Design		300,000		300,000
Temporary relocation/R&D			200,000	200,000
Blood Fractionation Bldg.				
Feasibility/Site preparation		100,000		100,000
Other Building Works				
General purpose building - Exotic Virus		100,000		100,000
Remodel Virus Laboratory		125,000		125,000
Test animal laboratory accommodation			100,000	100,000
Administration building extensions	150,000			150,000
Equipment Requirements				
Relocation of electron microscope		100,000		100,000
New packaging equipment			700,000	700,000
Pilot fermenters			40,000	40,000
Installation of vaccine plant			120,000	120,000
Minor Works				
Various minor projects	750,000	750,000	750,000	2,250,000
	1,794,000	3,675,000	3,045,000	8,514,000

7.3 THE NEED FOR FORWARD PLANNING

7.3.1 In part, the high cost of the present building programme reflects the sins of the past. Because of the continuing national uncertainty about the role of C.S.L. and the low level of funding available for plant and buildings during the first ten years of the Commission's operation, a backlog of problems accumulated. The present master plan is designed to repair these defects and to position the organization for a more efficient future. It is essential that staff be able to plan ahead and be given confidence in the Government's intention to progress the plan at a realistic rate.

7.3.2 We have discussed in Chapter 3, the strengthened advisory machinery recommended to allow the Minister to define national policy with respect to biologicals. We see this machinery as having great bearing on forward planning for new buildings. As mentioned in Chapter 3, many "national interest" projects will require new physical facilities, and once national policy objectives have been defined and agreed to, the relevant capital expenditures should become a normal part of the Commonwealth planning and forward estimate cycle.

7.4 SOURCE AND JUSTIFICATION OF FUNDS FOR C.S.L.'s CAPITAL WORKS PROGRAMME.

7.4.1 Following the question of definition of national policy and the national interest, the next most difficult question the Inquiry encountered was that of who should pay for the capital works programme.

7.4.2 Various extreme positions were put to the Inquiry. At one extreme, some (but by no means all) of the opinion gathered from the free enterprise sector argued that C.S.L. should receive no subsidy for capital works required for the mass production of high volume sales items. This, it was argued, placed C.S.L. at an unfair advantage by comparison with the private sector. On this view, C.S.L. would have to borrow the funds for its new buildings at commercial rates, and repay interest and capital from cash flow generated through sales. At the other extreme, C.S.L. itself argued, in the absence of other sources of funds, for a continuation of the present pattern where all major capital works are paid for out of taxpayers funds. The chief justification given was that biologicals were inherently rather unprofitable (see Section 2.2) and that as C.S.L. has to rely largely on the domestic market, it could not reap the benefit of the economies of scale that the larger American and European firms can make. Furthermore, reference was made to the high labour costs in Australia - it seems unlikely, for example, that Australia could ever make penicillin as cheaply as the People's Republic of China or the Republic of China (Taiwan).

7.4.3 In this connection, the Inquiry was impressed by evidence given by the Director-General of Health, on behalf both of his own Department and the Department of Defence. The Director-General stated that the disappearance of a penicillin-producing capacity from Australia could not be tolerated under any circumstances, for reasons of national security. In his view (against which the Inquiry has heard no dissenting voice), penicillin remains one of the three most valuable pharmaceutical products available to mankind, and one quite vital to the national interest.

7.4.4 Intermediate views were also put to the Inquiry. Of greatest interest was that of Connaught, C.S.L.'s Canadian counterpart. Canada's population is significantly greater than Australia's, and the proximity of U.S.A. presents certain advantages for the development of an export business - 40% of Connaught's sales are foreign. Nevertheless, Connaught also finds it difficult to produce at costs equal to those of larger competitors. It, too, faces a major re-building programme. Connaught, furthermore, is not under Ministerial direction, and functions completely within the private sector but with more protection in some of its major markets. As mentioned in Chapter 2, Connaught hopes to finance its building programme through sales. However, as Connaught up to date has not made a profit, it is obvious that this praiseworthy goal will only be achieved either if Connaught achieves major efficiencies and cost reductions as a result of the building programme, or if it raises its prices. Connaught is hopeful of persuading the Canadian governments to purchase its products even if at times their prices exceed those charged by competitors. Though not a government agency, it sees itself as a national asset with national responsibilities. In other words, Connaught's position is really between the two extremes. However, the absence of enabling legislation or a Section 19(b) equivalent means that Connaught can adopt a more free-wheeling attitude about its product range than C.S.L.

7.4.5 It is clear to the Inquiry that new plant and buildings, with increasing automation, can serve to lower unit production costs, especially labour costs. Indeed, C.S.L. has increased its units of production by a factor of 2.6 with a stable work force over the last decade. However, the quasi-public service framework in which C.S.L. operates would make significant reductions in absolute staff numbers difficult to achieve. A more feasible strategy would be to attempt to continue to increase productivity per unit employee. While this policy will increase profitability in the longer term, it would not solve the immediate problem of how to pay for new plant and buildings.

7.4.6 C.S.L. has been successful in achieving a commendable 14 per cent per annum increase in its export sales over the last decade and exports now account for 14 per cent of total sales value. Even if further growth in exports can be maintained, the domestic market will be the major factor in the financial health of C.S.L. for many years to come. This being the case, it becomes clear that in the last analysis it must be the Australian taxpayer who bears the costs of C.S.L.'s new buildings, whether directly through tax dollars or indirectly through higher prices. The alternatives to this would be either not to update the facilities (which would be inefficient and hazardous), or to cease manufacturing those items which can be made more cheaply overseas. This latter alternative we reject both on national security grounds and because it could materially drive up the costs of those items which must, of necessity, be made locally (as a higher sales volume helps to spread fixed overheads, etc.). If the conclusion is that the taxpayer must foot the bill for C.S.L., it seems more sensible to adhere to

the present practice, as amended in Chapter 3, than to go the Connaught route, which remains unproven as to feasibility.

7.4.7 In suggesting that the C.S.L. capital works programme be funded through tax dollars, it is well to keep relativities in perspective. For example, an average capital works grant of $5 million per year would represent 0.08 per cent of the nation's total health bill, and 1.86 per cent of the average annual cost of hospital construction in Australia over the past four years.

7.4.8 The question of costs for C.S.L.'s products is also placed in an interesting light if one asks the question of what portion of the total cost of, e.g., an immunization represents the payment to C.S.L. for the product. For example, the price which C.S.L. obtains for one dose of influenza vaccine is $1.78. The chemist retails that for $4.55 to $5.50 and if the doctor administering the vaccination, charges the recommended fee, the final cost to a patient for giving an injection is $10.65 to $11.60 (Victorian rate). We believe it is not generally realized how cheap vaccines in general are. For example, the total per child which C.S.L. receives for supplying the vaccines given as a primary course to (hopefully) each Australian child, protecting the child against diphtheria, whooping cough and tetanus, is $0.72. This presents an interesting contrast to, for example, the medical fee for an appendicectomy, say $142 specialist surgeon rate; or of an average confinement conducted in a hospital by a specialist obstetrician, say $150.

7.4.9 The general endorsement of the principle that C.S.L.'s major capital works should be financed out of taxation revenue in no sense negates the need, argued in Chapter 3, for an independent assessment of national policies and priorities, and, moreover, a searching review of each and every proposal so that its absolute and relative merits can be assessed. In fact, to the three key planning considerations listed in paragraph 6.1.4, we should like to add the fourth criterion that new projects should be assessed for their cost effectiveness and capacity to add to the organization's overall strength and independence.

7.4.10 The chief justification for using tax dollars for capital works at C.S.L. relates to our view (paragraph 3.9) that it is primarily a part of the nation's public health service and only secondarily a commercial venture. It follows that capital works for commercial projects undertaken by C.S.L. mainly for profit, and in competition with free enterprise (i.e. projects with a low national interest component) should not be so financed. In practice, it may be hard to draw the line, but we hope that the guidelines discussed in Chapter 3 will help. We are not, in principle, against C.S.L. expending capital funds for projects where it sees a chance to make a profit, or to offer worthwhile competition to an overseas manufacturer. It may be that future evolution of C.S.L. will permit such developments. If so, we feel strongly that these should be financed (capital works, overheads, and all) on strict commercial principles.

7.5 RECOMMENDATIONS

7.5.1 The Independent Inquiry recommends that the capital works programme of C.S.L. as outlined in the Commission's master plan be endorsed in principle. (Recommendation No. 26(a))

7.5.2 We recommend that major projects previously approved as evidenced in the Budget be completed as expeditiously as possible. (Recommendation No. 26(b))

7.5.3 We recommend that projects still in the planning stage be assessed for their consonance with national policy objectives as outlined in Chapter 3, and, where they pass such assessment, be funded out of Consolidated Revenue. Through conjoint effort of the Commission and the Department of Health, the projects should be ranked in order of priority according to the national interest, and be completed in that order. (Recommendation No. 26(c))

7.5.4 We recommend that, to the greatest degree consistent with government and Department of Finance planning norms, advance notice of approvals and indications of likely future levels of funding should be given to the Commission, allowing strategy to be devised on a rolling triennial or quadrennial basis. (Recommendation No. 27)

7.5.5 We recommend that capital works projects initiated primarily for commercial rather than national interest objectives be funded on a strictly commercial basis. (Recommendation No. 28)

7.5.6 We recommend that in its planning for new plant and buildings, the Commission pay heed to cost effectiveness and increases in productivity per employee. We recommend further that the Commission endeavour to maintain the policy of increased output with a stable work force, and that one criterion in assessing a capital works project be its ability to aid that goal. (Recommendation Nos. 29 & 30)

8. VARIOUS PROBLEMS OF SPECIAL CONCERN

8.1 THE PACKAGING-DISPATCH BUILDING

8.1.1 In our overview of future building plans, the Inquiry found a number of commendable projects, but the need to re-think and upgrade the present packaging-dispatch area is singled out for a special mention. Even a casual inspection of this facility reveals its entirely unsatisfactory nature. The building is crowded; there is insufficient demarcation between sub-sections; there is no likelihood of meeting the Code of Good Manufacturing Practice while penicillin is processed in the same facility as other products for human use.

8.1.2 The Inquiry therefore recommends that the packaging-dispatch building of C.S.L. be upgraded at the earliest opportunity according to the proposals embodied in C.S.L.'s 1977-78 capital works submission but deferred through budgetary considerations. (Recommendation No. 31)

8.2 RELATIONS WITH A.N.A.H.L.

8.2.1 The Inquiry noted that the Australian National Animal Health Laboratory (ANAHL) is about to be constructed at Geelong, Victoria. The likely cost of construction will be in the vicinity of $100 million.

8.2.2 The chief purpose of this laboratory will be to protect the Australian livestock industry from exotic diseases, particularly virus diseases. Maximum security laboratories with sophisticated facilities for microbiological containment will be required for, a) the establishment of the correct diagnosis of a suspected serious exotic animal disease; b) production of vaccines, especially foot and mouth disease vaccine, in the event of an established outbreak; c) safety and potency-testing of such vaccines; d) the training and maintenance of a permanent team of experienced virologists engaged in research on animal viruses; and e) the training of field and laboratory staff in the recognition and methods of control of particular diseases.

8.2.3 In the C.S.I.R.O. Submission to the Parliamentary Standing Committee on Public Works dealing with ANAHL (9/9/1974), the statement is made that C.S.L. will not have the capacity to manufacture foot and mouth disease vaccine because this "requires facilities with maximum microbiological security". The Inquiry find it extraordinary that this claim is not amplified by arguments, as C.S.L. currently deals with severe human pathogens such as yellow fever virus. The Inquiry finds it even more extraordinary that in the minutes of evidence of The Public Works Committee hearing relating to ANAHL, a document of 133 pages, including evidence from 19 witnesses, nowhere is the C.S.L. position put. After all, C.S.L. is the nation's only manufacturer of human and animal vaccines, and the taxpayer might reasonably have requested that its comments on a $100 million facility for (inter alia) vaccine production might have been sought.

8.2.4 The Department of Health presented evidence to the Standing Committee and two of its officers answered questions. Again, in none of the documentation could we find reasoned argument as to why C.S.L. should not itself be the organization responsible for foot and mouth disease vaccine production, should the need arise.

8.2.5 Brief reference is made in the C.S.I.R.O. submission to the C.S.L. building for the possible manufacture of a live attenuated bluetongue vaccine. This is described as a "high security facility", denoting a level of microbiological containment lower than that of the "maximum microbiological security" building required for foot and mouth disease work. Most unbelievably of all, no reference is made anywhere to the Bazeley maximum security laboratory at C.S.L. which has recently been completed and is designed to deal with highly pathogenic viruses like rabies. Is the Inquiry to believe that C.S.L. is competent to deal with rabies but not with foot and mouth disease?

8.2.6 The C.S.I.R.O. submission makes reference to the possible need for producing 200,000 doses of foot and mouth disease vaccine per month, should an epidemic break out. Nowhere, however, is reference made to the fact that the scaling up of a virus-growth programme to such high production levels, and the subsequent processing and packaging of material involves highly sophisticated knowledge, skills and experience that a research organization like C.S.I.R.O. does not (and should not) possess, but a commercial manufacturing organization like C.S.L. does (and should).

8.2.7 The Independent Inquiry came upon this extraordinary situation through its own reading and not through any officer of C.S.L. raising it with us. When specifically questioned on the matter, C.S.L. offered the opinion that, if requested, it could manufacture foot and mouth disease vaccine, and at a capital works cost significantly lower than those proposed for ANAHL. It confirmed that C.S.L. had not been consulted within recent years on the ANAHL proposal.

8.2.8 These unusual facts notwithstanding, the Independent Inquiry is not against the basic concept of ANAHL. We do question whether the degree of consultation between the two relevant government authorities, C.S.I.R.O. and C.S.L., has been adequate, and we do state that C.S.L. but not C.S.I.R.O. is experienced in mass production technology.

8.2.9 A further striking fact is that C.S.L. is this year embarking on the training of personnel who will acquire direct experience by manufacturing foot and mouth disease vaccine in Indonesia over the next 3 to 4 years.

8.2.10 The Inquiry therefore recommends that the proposed management structure for ANAHL be re-evaluated with a view a) to having C.S.L. involved in the research conducted within the laboratories should no exotic disease break out; and b) to ensuring that C.S.L. be the lead agency should mass production of vaccine, e.g. foot and mouth disease vaccine, prove necessary. (Recommendation No. 32)

8.3 POLIOMYELITIS AND OTHER HUMAN VIRUS VACCINES

8.3.1 The Independent Inquiry is greatly concerned about the world supply situation with regard to poliomyelitis vaccine. Currently, Australia buys the totality of its requirements from one of the two North American manufacturers. Should some production emergency occur within that firm, it is unlikely that Australia would a) be able to insist that its demands take priority over U.S. domestic requirements; or b) be able rapidly to acquire alternate supplies from the (only two) European manufacturers.

8.3.2 Because the physical facilities, technology and expertise are largely common to the production of a number of human virus vaccines, a proposal that C.S.L. should manufacture live attenuated poliomyelitis vaccine could facilitate the production of measles and rubella vaccines, and could even lay the foundation for an eventual production of hepatitis vaccine.

8.3.3 C.S.L. estimates that an initial capital expenditure (in addition to expenditures listed in chapter 7) of $570,000 would be required for it to be able to manufacture live attenuated human virus vaccines. Appendix 8.

8.3.4 The Independent Inquiry recommends that, using the mechanisms outlined in Chapter 3, the C.S.L. Commission and the Director-General of Health, should evaluate in detail and urgently whether it is in the national interest to develop a C.S.L. poliomyelitis vaccine and, with less urgency, measles and rubella vaccines. (Recommendation No. 33).

8.4 THE MULTIPLE INQUIRIES ON C.S.L.

8.4.1 The Independent Inquiry is concerned at the number of inquiries and reviews in which C.S.L. has been involved in recent years. The C.S.L. Commission functions as a board of directors and reports regularly to the Minister and Parliament, and this is as it should be. To ensure that it is functioning efficiently, C.S.L. has itself sponsored a number of internal reviews. As well as this self-generated activity in public accountability, C.S.L. finds itself involved in a large number of public service reviews and inquiries.

8.4.2 There thus appears to be double load of review and reporting work placed on senior management to further the concept of accountability. This work necessarily competes with staff time spent in more productive areas.

8.4.3 The C.S.L. - sponsored reviews over recent years have included:

Mr. V. Solomon Management Consultant	- Review of administrative procedures (1962)
Beckingsale & Co.	- Review of overall organization of C.S.L. (1964)
	- Survey or marketing activities (1964)

P.E. Consulting Services	- Survey of the penicillin plant (1965)
	- Production Division Review (1966)
	- Review of packaging procedures which led to construction of new Packaging Building (1966)
	- Production Control Assignment (1967)
P.A. Consulting Services	- Export Review (1967)
Audience Survey Inc.	- Review of doctors' attitude to C.S.L. (1974)
C.S.L. Working Parties	- Involving outside experts, Ministerial representatives and C.S.L. executives conducted a comprehensive review of internal working procedures and practices (1975/76).
Frank Small & Associates) Quantum)	- Review of customers' attitudes to C.S.L. (1976)
Residential Management Seminar	- Involving Commission members and senior executives to review performance in 1976/77 and to plan for 1977/78 (1977)
Engagement of outside experts (currently Dr. E. French and Professor S. Faine)	- Review of R. & D. projects (1977/78)

8.4.4 The External Reviews and Inquiries involving a formal C.S.L. input have included:

- Royal Commission on Australian Government Administration (1974)
- Senate Standing Committee on Trade and Commerce (1977)
- Senate Standing Committee on Finance and Government Operations (1977)
- Senate Standing Committee on Science and the Environment (1977)
- Senate Standing Committee on Health and Welfare (2 Inquiries - 1975 and 1976)
- Parliamentary Joint Committee on Publications (1977)
- Parliamentary Public Accounts Committee (3 Inquiries)
- House of Representatives Standing Committee on Environment and Conservation (1977)

- Establishment of Australian Purchasing Commission (1975)

- Department of the Prime Minister and Cabinet (1975), Inquiry concerning contacts with State Governments.

- Department of Urban and Regional Development (1973), Inquiry concerning relocation of Government offices.

- Inter-departmental Committee (1975), concerning relocation in Albury-Wodonga.

- Public Service Board (1977), Inquiry regarding relocation in Tasmania.

- National Disaster Relief (Health) Committee (1977).

- Inter-departmental Committee on Motor Transport (1977)

8.4.5 While several e.g. the Tariff Board and I.A.C. Inquiries have had specific ends in view, in the main, they have traversed much the same ground as we have done, with little variation in detailed findings of fact.

8.4.6 While understanding that public administration requires multiple checks and balances and a special degree of accountability, the Independent Inquiry nevertheless notes that C.S.L.'s competitors in the private sector do not carry an equivalent load, which must have a negative impact on productivity at C.S.L.

8.4.7 The Independent Inquiry therefore recommends that, on the assumption that this Inquiry's principal recommendations are adopted, that C.S.L. should not be subjected to further general inquiries, but once the Commission's role has been spelled out, C.S.L. should be encouraged to pursue its prime objectives without diversion of time and talent elsewhere. (Recommendation No. 34).

8.5 THE WOODEND PROPERTY

8.5.1 C.S.L. operates a farm of approximately 600 hectares which is used for the breeding and maintaining of horses and other animals required for serum production, etc.

8.5.2 On the visit to the C.S.L. farm at Woodend, the Inquiry noted that suburban type sub-division was taking place not very far from the farm.

8.5.3 Expansion of this sub-division activity could have serious effects on the farm both in relation to the work carried out there and also the possible future charges for rates and taxes. The question of further capital expenditure should be examined in the light of these developments.

8.5.4 As the farm would be worth approximately $3,000,000, C.S.L. therefore should pay particular attention to its activities.

CHAPTER 9 COMMONWEALTH SERUM LABORATORIES COMMISSION LEGISLATION

9.1 THE COMMISSION - PROPOSALS FOR LEGISLATIVE CHANGE

9.1.1 Section 9 of the Act states that the Commission shall consist of five members of which one shall be a registered medical practitioner representing the major customer group and one shall be the Director.

9.1.2 Since 1973, one member has been an officer of the Department of Health, although not acting in that capacity i.e. we were told that he has no involvement with C.S.L. in the performance of his duties in the Department.

9.1.3 Since 1975 a member of the Trade Union movement has been appointed a Commissioner. Like the officer of the Department of Health his normal duties do not involve him directly in C.S.L.'s operations, although his Union has a substantial number of members employed by C.S.L.

9.1.4 The Chairman of the Commission as well as filling the role of Chairman, can be seen as representing the point of view of business, which is an important talent to bring to bear on much of C.S.L.'s activity.

9.1.5 Given the possible need for enlarged expertise on given subjects within the Commission e.g. engineering; finance; marketing; science, etc. etc., the present composition and numerical strength limitations preclude that possibility given that the backgrounds of the present members provide valuable contributions to the affairs of C.S.L. In seeking replacement or additional members for the Commission, we recommend that efforts be made to provide a wider geographic representation. We see it as important that members should come from several states to provide the appropriate national perspective. (Recommendation No. 35(a)).

9.1.6 While the Inquiry has no great liking for large boards or their equivalent, bearing in mind that the Act will probably not be amended for many years ahead, it considers that the number of Commission positions should be increased to "not more than nine", at the discretion of the Minister. Accordingly it recommends that section 8 (1) of the Act be amended to read "The Commission shall consist of not more than nine Commissioners viz....." (Recommendation No. 35(b)). This would provide the flexibility which we consider to be lacking at present, while making it clear that there is no mandatory requirement that all positions must be filled. The decision to fill or not to fill would result from the Minister's assessment of the needs of the day.

9.2 LEGISLATIVE CHANGES PROPOSED

9.2.1 The Commonwealth Serum Laboratories are currently operating under the Commonwealth Serum Laboratories Act 1961-1973. (Copy is at Appendix 9). The current legislation is substantially the same as that enacted in 1961 to create the Commonwealth Serum Laboratories Commission.

9.2.2 It is proposed to amend the legislation to change the financial relationships between the Commonwealth and the Commission. Section 19(b) of the Commonwealth Serum Laboratories Act 1961-1973 provides that if the Minister determines, the Commission shall undertake research on products not prescribed for sale and install or maintain plant or equipment capable of being used for the production of biological products; and to produce and hold stocks of biological products for purposes other than immediate sale, e.g. research on new antivenenes, and the holding of influenza vaccine reserve of 3,000,000 doses. Under section 38 of the Act reimbursement to the Commission of losses incurred in conducting public health activities (under Section 19(b) determinations) is limited to the extent of the Commission's overall financial loss in any particular year. (Actual Section 19(b) determinations in 1976/77 were valued at $2.1 million - C.S.L. contributed $1.5 million from trading profits while the balancing loss figure of $0.6 million was reimbursed to C.S.L. by the Commonwealth).

9.2.2.1 The net effect of Sections 19(b) and 38 outlined above is that the Commission's commercial activities are called upon, in the first instance, to meet the cost of public health activities determined by the Minister. In a highly competitive market situation, this situation acts as a positive disincentive to more efficient C.S.L. operation.

9.2.2.2 It is proposed that the Act be amended to place the Commonwealth in a client position with respect to those public health activities which are carried out by the Commission under Ministerial determination. The Commonwealth would pay the Commission for its public health activities under Section 19(b) determinations irrespective of the Commission's financial result. This action was recommended in the 104th Report of the Joint Committee of Public Accounts.

9.2.2.3 It is further proposed that the Act be amended to provide for the Minister to determine, in respect of each year, the percentage return on capital to be made to the Commonwealth and for the Commission to pursue a policy directed towards making this return. In making this determination the Minister would have regard to such matters as the extent of the activities required of the Commission under Section 19(b).

9.2.3 The functions of the Commission are to be amended to provide:-

(a) an extension of the Commission's powers to authorise;

(i) the purchase, general sale, export and import of biological materials;

(ii) the production, purchase, sale import and export of unprocessed or partly processed materials;

(b) formal authorisation for the Commission to:-

(i) maintain W.H.O. Reference Centres;

(ii) provide technical assistance outside Australia.

9.2.3.1 At present, the importation of products for sale is prescribed as a function of the Commission only in relation to specified vaccines which may be provided by the Commonwealth under the National Health Act for human immunization purposes (Section 19(aa) of C.S.L. Act). The vaccines currently prescribed under the National Health Act - poliomyelitis, measles and rubella - are those used in mass immunisation campaigns.

9.2.3.2 However, for some years it has also been necessary for the Commission to buy and import for sale to the Commonwealth other products required for human and animal quarantine purposes, e.g. rabies vaccines. Such action has been necessary because the products concerned are either unavailable in Australia or cannot be economically produced by the Laboratories in the relatively small quantities required. It is extremely unlikely that other manufacturers would be willing to take on this role of holding and distributing essential (for public health reasons) but rarely used biological products since it is essentially not an economic proposition.

9.2.3.3 With regard to the export of products, the present legislation does refer to the exercising of the Commission's functions in relation to trade and commerce with other countries but no specific power to export is present. The Commission has an active export market and has twice received an Export Award. To clarify the matter and to provide the Commission with the necessary flexibility in relation to its activities, it is proposed that the prescribed functions be extended to authorise the purchase, general sale, import and export of prescribed biological products and the sale and distribution of any biological product imported on behalf of the Commonwealth.

9.2.3.4 Section 19(a) of the Commonwealth Serum Laboratories Act limits the Commission to the production and sale of products "of a kind used for therapeutic purposes". This section has restricted C.S.L. in the products it could sell and will continue to restrict sales opportunities in the future unless the legislation is suitably amended. It is therefore proposed that the Commission's prescribed functions be extended so that it may produce, purchase, sell, import and export unprocessed or partly processed materials from which biological products used for therapeutic purposes may be derived.

9.2.3.5 For some years, the Laboratories have functioned as a World Health Organization reference centre in relation to blood-grouping, influenza and brucellosis. This involves such activities as the holding of reference materials, the collection and dissemination of information, and research on specific problems. The performance of these functions as Reference Centres is a valuable service to world health and brings considerable credit to Australia.

9.2.3.6 Section 19 of the Act provides that the functions of the Commission prescribed by that section are exercisable "for or in relation to any purpose of the Commonwealth". As Australia is a member of W.H.O. by virtue of Commonwealth legislation, the Laboratories' operations as a W.H.O. Reference Centre are related to a "purpose of the Commonwealth". However, the specific function of operation as a Reference Centre is not at present prescribed by Section 19. Accordingly it is proposed that the Act be amended to permit the Commission to operate Reference Centres for the World Health Organisation for such purposes as the Minister, at the request of the Organisation, determines, and such other Reference Centres as the Minister determines.

9.2.3.7 It is further proposed that appropriate amendment be made to the Act to provide for the reimbursement each financial year by the Commonwealth of the cost of operating these Reference Centres which are presently funded by the Commission.

9.2.3.8 The Commission for many years has provided technical assistance outside Australia in relation to the production of biological products or related research.

9.2.3.9 There is no specific power in the present legislation to carry out this activity.

9.2.3.10 It is proposed that the functions of the Commission be expanded to authorise the Commission to provide technical assistance to Foreign Governments and overseas organisations where the Commission's assistance is sought through the Department of Foreign Affairs.

9.2.4 A number of minor machinery amendments are also proposed:-

(a) additional definitions;

(b) lease of land;

(c) pricing of Commission's products supplied direct to Governments;

(d) leave of absence for the Director;

(e) appointment of acting Director;

(f) application of Therapeutic Goods Act and Customs (Prohibited Imports) Regulations to the Commission;

(g) requirements for appointment of officers;

(h) terms and conditions for employment of staff;

(i) awards;

(j) Ministerial power of delegation;

(k) application of other Commonwealth legislation;

(l) capital to be repaid to the Commonwealth;

(m) capital of the Commission;

(n) borrowing by the Commission;

(o) banking account;

(p) investment of money;

(q) estimates of expenditure;

(r) the application of profits;

(s) adequate control of assets;

(t) amendment to audit provisions;

(u) taxation under the Laws of a State or Territory;

(v) Ministerial power of direction to the Commission.

9.2.4.1 Section 4 of the Act be amended to include additional definitions:-

(a) "approved bank" - to be included to support the proposed amendment requiring the Commission to open and maintain at least one bank account in a bank which has been approved by the Treasurer.

(b) "therapeutic purpose" - insert the definition appearing in the Therapeutic Goods Act so as to add a more precise meaning to the term which already appears in Section 19 of the Act in connection with the type of biological products the Commission can produce.

9.2.4.2 It is proposed to insert a new provision to provide that the Commission shall not enter into a lease of land for a period exceeding 10 years without the prior approval of the Minister.

9.2.4.3 Present legislation requires the Minister, after consulting the Commission, to determine the prices to be paid for products supplied by the Commission to the Commonwealth or a State or to a person on behalf of the Commonwealth or a State. It is considered that this section of the Act has not served any useful purpose in the past and it is proposed that it be deleted. Existing arrangements would be continued under which the Commission makes representation to the Department of Health, on behalf of the Commonwealth, when necessary to vary the price of individual products supplied (these being mass immunisation vaccines, blood products and reserve stocks of special products).

It is proposed to insert a new provision in the Act for -

(a) Commissioner appointments to state whether they are full-time or part-time; and

(b) the full-time Commissioner should retire on attaining his 65th birthday.

9.2.4.4 Current legislation provides that the Director shall hold office on such terms and conditions as the Governor-General determines. In accordance with this requirement the Governor-General has determined that the Minister may approve absences and the terms and conditions of such absences which involve the Director being absent from duty for more than 14 consecutive days in any one year or more than 28 days in any one year. It is now proposed that a specific clause be inserted in the Act providing that the Minister may grant leave of absence to the Director on such terms and conditions as to remuneration or otherwise as the Minister determines.

9.2.4.5 Under the provisions of the present Act and the Acts Interpretation Act there is no power for the appointment of a person to act as Director when the position of Director is vacant. It is therefore proposed that provision be made to authorise the Minister to appoint an Acting Director for a period of not more than 12 months when the position of Director is vacant or when the Director is absent from Australia or from duty, or for any other reason is unable to perform the duties of the office, and for the Minister to determine the terms and conditions of appointment including remuneration.

9.2.4.6 Section 6 of the C.S.L. Act provides that the Commission is bound by all laws of the Commonwealth except laws that do not bind the Crown in right of the Commonwealth. Generally speaking, there is a presumption that a law does not bind the Crown in the absence of an express provision or necessary implication to the contrary. The Therapeutic Goods Act and the Customs Act does not expressly bind the Crown and it is now proposed that the C.S.L. Act be amended to make the Commission subject to the provisions of the Therapeutic Goods Act and Customs (Prohibited Import) Regulations.

9.2.4.7 In line with other recent statutory authority legislation it is proposed to delete the requirement that only British subjects be appointed as officers of the Commission and the necessity for officers to make an oath or affirmation of allegiance.

9.2.4.8 Present legislation imposes a limit of $5,000 p.a. in relation to the Commission's powers to determine the salaries of its employees without Ministerial approval. It is proposed to amend the staffing provisions of the Act to provide that the terms and conditions of service will be determined by the Commission subject to the approval of the Public Service Board.

9.2.4.9 Existing legislation provides that the Public Service Arbitration Act does not apply to officers or employees of the Commission. It is proposed that this section be deleted thereby making the Commission's officers and employees subject to the determinations of the Public Service Arbitrator as the Commission is in fact bound by the decisions of the Arbitration Commission.

9.2.4.10 A new section giving the Minister the power of delegation is proposed (except the power of delegation itself). This will simplify Ministerial administrative arrangements arising from the various provisions of the Act.

9.2.4.11 It is proposed that appropriate amendments be made to the Act to reflect the provisions of the Superannuation Act, Remuneration Tribunal Act and the Compensation (Commonwealth Employees) Act.

9.2.4.12 Present legislation gives the power to the Treasurer, after consulting with the Minister, to determine what amounts of capital shall be repaid to the Commonwealth from profits each financial year.

It is proposed that the Minister now make this determination, after consultation with the Treasurer, since he has the prime responsibility for administering the Act. This proposed amendment has the concurrence of the Department of Finance.

9.2.4.13 Present legislation provides that all amounts paid to the Commission from moneys appropriated by the Parliament form part of the Commission's capital. This would lead to problems in the case of loss or damage to buildings by fire, etc., where the Commonwealth reimburses C.S.L. for the loss since the moneys appropriated for this purpose would result in an overstatement of the Commission's capital. To enable the separation of loan and reimbursement obligations it is proposed that only capital moneys appropriated by the Parliament and paid by the Treasurer form part of the Commission's Capital.

9.2.4.14 Under existing legislation, the Treasurer -

(a) must consent to the Commission borrowing any monies;

(b) may make advances to the Commission from funds appropriated by the Parliament.

It is proposed that Section 34 of the Act be amended so that -

(a) the Treasurer -

(i) will still approve borrowing;

(ii) may guarantee on behalf of the Commonwealth, the repayment of amounts borrowed privately, including interest;

(iii) may, from funds appropriated by the Parliament, lend to the Commission at such rates of interest and in such terms and conditions as the Treasurer determines, moneys which the Commission is authorised to borrow above.

(b) the Commission be empowered to give security over the whole or any part of the assets of the Commission for the repayment of any sums borrowed including interest.

9.2.4.15 At present the Commission is required to maintain an account with the Reserve Bank and maintain an account or accounts with such other bank or banks as the Treasurer approves. It is proposed to amend this legislation and insert a standard banking provision providing that the Commission shall maintain at least one account in an approved bank.

9.2.4.16 The existing Act provides for the investment of money, not immediately required for the purposes of the Commission, in the Reserve Bink or with any other bank approved by the Treasurer. It is proposed to amend the legislation to allow investment in fixed deposits in a bank approved by the Treasurer or in securities of the Commonwealth or in any other manner approved by the Treasurer.

9.2.4.17 With regard to the provision of estimates, the Commission is presently required to submit to the Minister not later than the thirty-first day of March, its estimates for the forthcoming financial year. It is proposed to amend this provision to allow for the estimates of receipts and expenditure to be submitted in such form and at such times as the Minister directs.

9.2.4.18 Under present legislation the Minister, with the concurrence of the Treasurer, determines how profits of the Commission shall be applied. It is proposed to amend this legislation to authorise the Minister to determine the application of profits.

9.2.4.19 Existing legislation requires the Commission to keep proper accounts and records. It is proposed to enlarge this requirement to include the keeping of proper accounts and records, on the transactions and affairs of the Commission and the keeping of adequate control of assets in the custody of the Commission

9.2.4.20 It is proposed to amend current legislation to the standard provisions for Commonwealth trading authorities.

9.2.4.21 At present the Commission is not subject to taxation under the laws of a State or Territory. It is proposed that this area of the Act be redrafted to conform with more recent legislation which provides that exemption from taxation will not apply if a regulation has been made making the Commission subject to taxation under a specific law of a State or Territory.

9.2.4.22 It is proposed to insert a new provision in the Act to give the Minister a general power of direction to the Commission.

9.2.4.23 The Act currently provides that the Commission shall meet at least once every five weeks. It is proposed that the Act be amended to allow the Commission to meet as and when required with a minimum of two meetings in each of the four quarters of the year. The Inquiry has considered this proposal and the recommendation from the 104th Report of the Public Accounts Committee. However, the Inquiry still believes that regular meetings are essential, particularly if the procedures recommended in this Report are adopted.

9.2.4.24 It is proposed to change the title of "Vice Chairman" to "Deputy Chairman". The reason behind this proposal is not understood.

9.2.5 The Inquiry has examined the proposed amendments and is of the opinion that they would in certain cases formalise current procedure and practice and in others would considerably assist the Commission in its operations.

9.2.6 The Inquiry recommends that action be taken to have the Commonwealth Serum Laboratories Act amended to include certain proposed amendments with the exception of the proposal to vary the provision that the Commission should meet at least once every five weeks. Our view is that the Commission should meet at least 10 times each year. (Recommendation No.36(a)).

9.3 LEGISLATIVE CHANGES - SPENDING LIMITS

9.3.1 At present the Commission is required to obtain Ministerial approval to the purchase or disposal of capital assets for a consideration exceeding $40,000. It is proposed that the provision be amended to reflect current money values by providing that the Commission shall not, without the approval of the Minister, enter into a contract involving the payment or receipt of capital assets by the Commission of an amount exceeding $250,000 or, if a higher amount is prescribed by Regulation, that higher amount. The Inquiry agrees with the proposal.

9.3.2 The Inquiry understands that advice has been received that Department of Finance has sought to have Section 20 (2) of the Act take into account all contracts exceeding $250,000 claiming that the Commission should not be exempted from Ministerial approval of those contracts relating to his main function.

9.3.3 If the view of Department of Finance prevails, then we recommend that a separate ceiling of $500,000 should apply to contracts for the purchase of raw or partly produced materials or the sale of finished or partly finished products. There are a number of occasions where C.S.L. has the opportunity to conclude commercially valuable contracts for which quick decisions are essential. (Recommendation No. 36(b)).

CHAPTER 10

General Conclusions

10.1 The Independent Inquiry is convinced that biologicals are a vital component in the armamenterium of human and veterinary medicine, and that C.S.L. is a competent, internationally recognized manufacturer of biologicals with a proven record of achievement.

10.2 As such, C.S.L. is a valuable national asset, not only for those products that it currently manufactures, but also as a reserve resource of knowledge and skills. C.S.L. thus has an important national insurance role, as it has already amply demonstrated during wars and epidemics.

10.3 The Inquiry has great confidence in the senior management of C.S.L. Furthermore, we have noted that personal relationships between the major interacting parties, namely the Minister for Health, the Chairman of the C.S.L. Commission, the Director-General of Health, the Director of C.S.L., the heads of involved operating divisions of the Department of Health and the C.S.L. Secretariat are very good. These bonds of confidence and trust are frequently more important than regulations and laws. It is fair to say that the above has not always been true in the 60-year old history of the Laboratories, and we believe that some of the question marks that surround C.S.L. in some government circles may reflect past problems rather than present realities.

10.4 We see C.S.L. as suffering from four interacting sets of problems. The first it shares with the whole of Australian manufacturing industry, namely it is difficult to be price-competitive given the size of the Australian domestic market and our labour cost structure, particularly in products that can readily be moved around the globe. Secondly, this disadvantage is increased in a field where manufacturing technology is innovation-intensive. C.S.L. has not been able to keep up because, until recently, there have not been the resources for a major restructuring of plant and buildings. Thirdly, there has been national uncertainty about whether C.S.L. should be primarily a profit-making commercial enterprise or a part of the nation's public health service. Fourthly, the fact that the permanent staff enjoys public service privileges makes control of labour costs more difficult than is the case in the free enterprise sector.

10.5 While the Inquiry clearly cannot solve these problems, it can offer the following commentary upon them.

10.6 It would be conceivable for C.S.L. to cease manufacturing of bulk stocks of biologicals altogether in which case nearly all biologicals would have to be imported into Australia, and C.S.L. could become simply a packaging and distribution organization, or could cease to exist as such. This option we reject on three grounds, namely: (a) national security, including the reserve value of the trained and dedicated staff and given the critical world supply situation of some biologicals; (b) the great expansion in regulatory agencies that would be required; and (c) unfairness to an organization with a proud

APPENDIX No.1

QUESTIONNAIRE FOR COMMONWEALTH SERUM LABORATORIES COMMISSION, MELBOURNE.

A. THE COMMISSION

1. Please list the names, qualifications, background, length of service and current term of the members of the Commission.

2. How frequently does the Commission meet?

3. What matters does the Commission deal with at their meetings? What is the division of duties and responsibilities between the Commission and the Management as defined or perceived by the Commission.

4. What is the role of the Chairman vis a vis the Commission and vis à vis the Management?

5. What are the duties and responsibilities of the Chief Executive?

6. What is the raison d'être for C.S.L. in 1978? How does it compare or contrast with that of, say, 1968 and 1998?

   Please provide a statement of corporate objectives. How often are they reviewed? To whom are they communicated?

7. What is the legislative authority for C.S.L?

8. What other directives, guidelines, authorities govern or impinge upon the operations of C.S.L.? e.g. from the Minister, Department of Health, Department of Finance, etc. etc.

   Give details. Note: The general matter of relationships can be covered in our discussions.

9. What are the sources of funds available to C.S.L?

10. For what purposes may funds from different sources be employed?

11. What procedures are followed in determining expenditures (a) within C.S.L., (b) with Government?

12. What particular procedures are laid down for identifying the correct expenditure of those funds as distinct from those applying to routine control of funds generated by C.S.L?

13. In what way should legislative authority, directives, etc. etc. be varied to reflect more truly C.S.L's role and to improve the operating performance, policy delivery and efficiency of C.S.L?

B. STAFF

1. Please supply an organisation chart of C.S.L.

2. Please give names, descriptions, qualifications, experience and length of service of the senior people.

3. List total staff numbers for the years 1970-71; 1971-72; 1972-73; 1973-74; 1974-75; 1975-76; 1976-77; 1977-78.

4. Please break these down into categories so as to give comparison of numbers by category.

e.g. Administration - general
Accounts - qualified and other
Administration - scientific

Scientists - research
Scientists - production, quality control, etc.
Administration - production
Production - supervision
- direct production, qualified and other
Maintenance - production and other
Administration - marketing
Marketing, Sales, etc. - describe function and qualifications.
Other

5. What are the conditions of employment ? How are they determined ? What is the procedure for variation ?

6. Who determines variations in staff numbers ? After what procedures ?

7. What happens to poor performers ?

C. OPERATIONS - GENERAL Note : These may be better covered more fully in discussion.

1. What budgets and forecasts are prepared ?

2. Who prepares them ?

3. Who is responsible for their achievement ?

4. How often is performance reviewed against budgets ?

5 What cost controls procedures are maintained ?

D. PRODUCTS

1. Please list the main products, distinguishing between those imported and repacked; those partly manufactured and those fully manufactured.

2. Please give the main groups of products produced and sold in volume or dollar value (so as to provide a valid basis for comparison) for the years 1970-71; 1971-72; 1972-73; 1973-74; 1974-75; 1975-76; 1976-77; 1977-78 and the budgets for those years.

3. In describing the main products, please indicate those which are manufactured and distributed (a) for normal commercial reasons, (b) as a result of national policy directed by the Minister or Department of Health, (c) other.

4. Please indicate procedures for determining unit and marginal costs for each main product.

5. Please indicate which products C.S.L. would not manufacture and market if commercial considerations were the only criteria.

6. Please indicate gross profit/loss contribution in dollar values of each of the main products listed in (1) above, and the percentage margin which that represents on total cost of production of each.

   In answering this, please indicate the main cost items included in cost of production.

E. PRODUCTION

1. Please describe the production processes in sufficient detail to enable identification of individual lines.

2. Please describe main items of plant and machinery, indicating life, efficiency, original cost, present book value, output capacity, etc.

3. Please indicate present loading on each main unit or line of production equipment - i.e. number of shifts worked per week, percentage capacity presently used, etc. etc.

4. Please indicate whether on (a) present (b) projected volume demand each unit has (a) adequate, (b) inadequate, (c) excess capacity for production demands required of it. Where production capacity is inadequate or excessive, indicate what corrective action is being taken or planned. If further capital expenditure or labour is required or savings contemplated, please comment on these.

5. Describe the principal raw materials, production requisites etc. used; then source and the method of their procurement. Indicate any constraints upon C.S.L.'s ability to reduce costs of these items.

F. MARKETING

1. Describe the marketing organisation in C.S.L.

2. Indicate what C.S.L. considers to be the marketing objectives.

3. Describe C.S.L.'s customers i.e. those to whom sales are made and who pay C.S.L. for goods purchased.

4. Describe the selling and distribution chain between C.S.L. and those in (3) above.

5. What is the renumeration e.g. salary, commission, added profit margin, etc. etc. at each stage in the distribution chain ?

6. Who are C.S.L.'s competitors ? How does C.S.L. compare with them in those areas where they are comparable ?

7. What additional products would C.S.L. like to market that it does not do so at present ? And why ?

8. Given approval for those products in (7) to be added to the range, what would be the effect upon (a) Costs of operation, (b) Profits, (c) C.S.L.'s position in the market ?

9. Question (7) referred to other products for sale. Would they need to be manufactured by C.S.L. ? If not what would be the source ? What would be the effect on costs and profits ?

10. How does C.S.L. see its position vis à vis the Fawnmac Companies ?

11. C.S.L. has a number of distribution centres of its own (vide Annual Report).

    What is the justification for these ?

    What is the costs of occupation, the number of people employed and their cost involved ?

    What other better and/or cheaper ways could be found for distribution to be undertaken ?

12. What publications does C.S.L. produce ? What are the annual costs for each of the last 5 years ? How often are they reviewed with a view to deleting those no longer needed ? What charges if any are made for publications ? If not, why not ?

G. PROPERTY

1. Please list all property occupied by C.S.L. and give details of title, size, improvements, book value, current market value, occupancy costs.

   What are the plans for the property in terms of present use, prospective use, adequacy for both, projected need for capital expenditure, additional or reduced numbers of people, etc. etc. ?

2. In the years 1971-1977 how much has been or will be expended and/or committed by C.S.L. ?

   (a) Please describe the overall philosophy against which this has been planned;

   (b) What does this expenditure represent expressed as a percentage of the total plan ?

(c) What does the total plan contemplate ?

(i) In terms of capital expenditure ?

(ii) " " " depreciation or amortization ?

(iii) " " " maintenance and repair costs ?

(iv) " " " additional direct and support staff and their cost ?

3. What has been and is expected to be the source of funds ?

What is the justification in terms of improved earnings and/or more secure national policy for Australia ? Can this be quantified ? If so, please do so.

4. Please describe the process by which expenditure on buildings and other works has been undertaken,

e.g. Who draws up the purpose of the programme and checks it out ?

Who appoints the architect and checks his qualifications ?

What consultants are used ?

Who decides who they shall be ?

Who checks out the cost estimates ?

Who calls tenders and awards them ?

On what basis ?

Who supervises construction, particularly with a view to cost containment ?

In summary, we are interested in examining the process by which this construction work is undertaken to ensure, that it meets the needs of C.S.L., has proper checks and safe-guards built into it and does not waste the taxpayer's money.

II. RESEARCH

1. Please provide an overview of C.S.L.'s research activities,

(a) Please describe the overall philosophy of the research programme;

(b) Has any attempt been made to fix research expenditures as a percentage of sales? If so, what percentage? If not, how is an appropriate research budget arrived at?

2. In the Annual Reports, research expenditure is divided into Section 19 a) and 19 b) portions. Please describe in detail how this division is achieved, with particular reference to the mechanisms of advice tendered to the Minister concerning the activation of Section 19 b) Ministerial Determinations.

3. What procedures exist to ensure that research projects are relevant to the aims of the Commission and to consumer needs? In particular,

(a) How and by whom are research projects initiated?

(b) What reporting procedures are used for research projects?

(c) How and by whom are research projects evaluated? Who decides about publication, and how?

(d) Is there any outside "peer group review" of research, either at the strategic level or at the individual project level?

(e) Who determines appropriate funding levels for individual projects, and for research allocations between major divisions; and how?

4. Please provide a description of research staff recruitment and promotions policies. In particular,

(a) Is staff recruitment always by advertisement, or is it possible to invite a particularly gifted worker? How successful has C.S.L.

been in attracting and holding outstanding scientists?

(b) Is promotion chiefly on the basis of qualifications and length of service, or is there scope for promotion on individual productivity and merit? Who makes such decisions and how?

(c) When vacancies occur, is it usually possible to fill them promptly with individuals chosen from numerous applicants, or do positions sometimes remain vacant for long periods? If the latter, why?

5. Please describe training and education schemes for research scientists. In particular,

(a) What lecture and seminar programmes exist?

(b) What staff-initiated discussions take place (journal club, inter-group discussions, etc.)?

(c) Are there possibilities of short or medium term secondment of research staff to university departments, C.S.I.R.O. divisions, research institutes or teaching hospitals?

(d) Can and do staff participate in national and (more particularly) international scientific meetings? If so, how often, with what financial help? Who decides, and how?

6. Is any active attempt made for cross-stimulation and fertilization,

(a) within C.S.L., between individual research groups?

(b) within Australia, through links, conjoint programmes, discussions, workshops, etc. involving universities and other research groups in related fields?

(c) at the global level, through "special relationships" with similar groups or institutes overseas?

7. Does the "public service framework" impose any serious constraints on the performance of first class research? If so, please explain. Are there any ways in which research could be improved through recommendations this inquiry might make?

APPENDIX No.2

INQUIRY
INTO THE OPERATIONS AND CAPITAL WORKS PROGRAMME OF THE COMMONWEALTH SERUM LABORATORIES

C/- Walter & Eliza Hall Institute of Medical Research
Royal Melbourne Hospital,
Parkville, Victoria, 3052 Telephone: 347 1511

MEMO TO : Mr. Kevin Delaney, Mr. John Reid and Dr. Neville McCarthy

FROM : Professor G. J. V. Nossal

DATE : March 8, 1978

VISIT BY G.J.V. NOSSAL TO CONNAUGHT LABORATORIES, WILLOWDALE, ONTARIO - FEBRUARY 10.

A productive visit involved discussions with Mr. Alun Davies, Executive Vice-President; Mr. A. Kim Aagaard, Director of Finance and Secretary-Treasurer; and a tour of the hundred acre campus with its many facilities.

Connaught is the leading manufacturer of biologicals in Canada, previously owned by the University of Toronto, but acquired in June 1972 by the Canadian Development Corporation. Connaught manufactures 200 products, occupies 65 buildings and employs 737 people to generate sales of $25 million Canadian. These sales are 3/5 domestic and 2/5 foreign. Connaught is in an essentially "break-even" situation at the moment and is hoping to generate a small profit next year.

Connaught is run completely on commercial principles and accounting procedures. It does not receive any subsidies or grants except those available to industry at large - for example it participates in Canada's industrial research grants scheme and research personnel can compete for grants from the Canadian National Research Council. These sources generate about $1 million of research funding.

When Connaught has to engage in capital expenditures, it must use the same principles as any free enterprise - namely it must raise equity finance (which would involve the issue of new shares to the Canadian Development Corporation) or (more likely) it would have to raise a loan. The only advantage over any other company that it might see is that the banks would regard Connaught, being an off-shoot of the National Development Corporation, and a "good-bet". It is hoped to finance the $40 million rebuilding programme

../2

in this way, and here we see a major difference in philosophy between Connaught and CSL.

For example, the master plan for the rebuilding programme - which is still in a stage of evolution - places a major emphasis on new buildings saving costs, and indeed planned staff reductions constitute a major element of corporate thinking. For example, over the last 6 years a planned reduction from 815 people to 737 has occurred, and as the new buildings come on stream and automation takes hold, a further reduction of 200 people is deemed "not impossible". Connaught has therefore taken a hard nosed attitude to the problem of staff numbers and considers that these must be controlled if its ambitions for new buildings are to be met. At the moment labour costs totalled $14 million per annum. Whether the staffing position at CSL is as tightly controlled is a matter for examination.

Connaught and government relationships

Connaught is not subject to ministerial directive, but there is still a general ethos within the Company that sees its reason for existence more in national interest terms than in profit-producing terms. Obviously, requests from governments for production of specific biologicals can and do occur from time to time. For example, during the "swine flu" scare, Connaught was approached to make the vaccine, but six months of "hard nosed negotiations" with the government in relation to prices went on, and Connaught is simply not prepared to be told that it must make a product if the manufacture of that product would involve it in a commercial loss. On the contrary, Connaught relies on its reputation and on the intrinsic nationalism of Canadians to (on occasion) charge non-competitive prices for its product. For example, recently a 250% increment in the price for triple antigen was negotiated with the Ontario government as part of a plan to upgrade the vaccine producing facility.

Research and development at Connaught

The research and development effort at Connaught is comprable in size to that of CSL. The research and development involves "120 men-year equivalence", the point being that some research staff are not full-time but spend a proportion of their time on research and a proportion of their time in quality control or production. The total research budget is $2.5 million in direct expenditures, leading to an "all in" research cost of $5 million. The equivalence of size of research staff highlights still more the discrepancy in size of other staff between Connaught and CSL - (617 versus 940). The quality of the research staff was described as "not that great" and in fact the new management has had to move some older researchers out through earlier retirement. Recruitment of really first-class younger staff continues to be a problem. Connaught emphasises that its basic skill is not in fundamental research but in developing discoveries coming from academia to the state of mass consumption, and

../3

management feels very strongly that the research and development effort should reflect this.

Broad problems in manufacture of biologicals.

The Connaught management feels very strongly that it is important to have self-sufficiency in the manufacture of biologicals within Canada. They have found that biologicals do not represent a particularly profitable segment of pharmaceutical manufacture. It is capital intensive, labour intensive and innovation intensive. Connaught is concerned at the number of commercial firms going out of the field, and attaches a high national insurance value to a corporation such as Connaught and CSL. They make the point that during the 1950's and 1960's, the price of biologicals was high and there was a reasonable return on invested funds. Now prices are well down, in part because of the special relationships between biologicals and government bureaucracies (the chief customers), the latter being very adept at squeezing prices down. A further concern in costs relates to the third world. UNICEF and WHO are pressuring the industry dangerously - the pressure is for bulk purchases from third world countries at rock bottom prices, certainly for socially desirable ends but it leads to a compounding of the problems of the biologicals industry.

Concomitant with this price squeeze, there has been a savage increase in regulatory influences which have driven costs up. Connaught feels that a free market no longer pertains with respect to biologicals, on the contrary it is a highly manipulated market with governments being both the regulators and the purchasers of the product.

They make the point that biologicals in their totality represent a tiny percentage of health care costs and it is a pity to see this valuable segment of the pharmaceutical industry under a very real threat.

To beat these problems, Connaught emphasises two major points: (i) discipline (ii) production technology. They believe it is very important that Connaught should become a disciplined company. This necessitates a change in orientation from the previous largely academic atmosphere in which Connaught found itself. The "holy scientist" attitude must be combated, as must the capacity of some workers to crawl into a quiet little corner as can happen in academia. Connaught believes that it is only the disciplined company capable of meeting the real commercial challenges which will survive in the future.

Production technology is important because of the high labour costs - if one can contain labour costs through efficiency and automation, one has a chance of survival. Needless to say, Connaught felt that its own modus operandi was found preferable in this regard than the quasi-public service set up of CSL.

where a planned run-down of staff numbers might present problems.

Connaught's building plans

It was emphasised that the $40 million building programme was still really in very embryonic form, and a lot of work was being done by senior staff towards the construction of a master plan. However, the decision had been taken very firmly to construct these buildings not through taxation dollars but through cash flow generated from the business, even if this meant premium payments on existing products and the development of new products.

Education gap concerning biologicals

Connaught feels strongly that there is a major education and public relations gap overshadowing the biologicals segment of the pharmaceutical industry. Considerable effort has been expended by senior staff on a public education campaign, and the services of a PR consultant firm have been engaged. As part of this, a small survey was run in which people were asked what they believed poliomyelitis vaccination cost, and what they would be prepared to pay for poliomyelitis immunisation if this were not available through free government schemes. The bulk of people interviewed were wildly astray in their conceptions of this, for example, they said they would be prepared to pay $50 when in fact the truth of the matter is less than 1% of that figure. Connaught feels strongly that biologicals have demonstrated their cost effectiveness and in fact constitute the best "insurance" in the world at the prices presently pertaining. In fact, mechanisms to increase prices will have to be found if producers of biologicals are not to be driven to the wall.

In widening our this discussion somewhat, Mr Davies made reference to particular manufacturers of biologicals. From his own personal experience in working for one large biological manufacturer, he knew that the human side of biologicals was really very unprofitable, though the veterinary side was profitable. In the case of a very large American manufacturer of biologicals, the product line is very limited and there is no dissipation of effort into products of marginal profitability. The biggest problem area in the whole field is vaccines, as vaccine manufacturers were leaving the field at a large rate. There was a very strong feeling expressed that if a country was fortunate enough to have a vaccine manufacturer of high-status, it should go to considerable lengths to preserve it.

Management of Connaught

Apart from having a strong board of directors to run the business, Connaught also has a scientific advisory board comprising scientists, epidemiologists, physicians etc. who make inputs into the direction of research and new lines

of biologicals in which Connaught ought to become involved. The scientific advisory board is paid a substantial fee.

The biological constraint

Connaught does not feel any constraint and could in fact make anything it wanted to. However, they feel strongly that the non-biological segment of the pharmaceutical industry is very different, requiring different facilities and different market and distribution networks. Therefore, they stick with biologicals as a matter of choice. However, there are associated companies within the Canadian Development Corporation that manufacture synthetic drugs. Chief amongst these are Dumex and Omnimedic. These are not integrated in any real way with Connaught, and despite much lip service given to collaboration, they really pretty much go their own way.

Relations with private industry

Connaught now is not only within the private sector but is also acting as though it were within it. For example, it is standing up against too much government regulations and it is spending money on building up a private corporate image. It has and seeks no special privileges from the government sector. This free enterprise environment has helped the research staff to take a more commercial view point, although Mr. Davies did not conceal that there was a proportion of the research staff that didi not go along with the concept.

Liability insurance

Connaught drew attention to a problem that has not yet arisen in a major way in Australia, but was acting as one further constraint driving manufacturers out of the biologicals area. This is the concept of product liability insurance. Currently, on the sales of $25 million, $0.5 million is spent per annum on product liability insurance. This is expected to grow.

Attention was drawn to a paper, copy of which is available in my office, written by a senior official (Dr. H. M. Meyer) of the American Bureau of Biologics, entitled "Are vaccines an endangered species?" This paper documents, amongst other things, the way in which the seven manufacturers of poliomyelitis vaccine of a few years ago have progressively withdrawn from the scene so much that there is now only one manufacturer in United States (Lederle). Attention was drawn to some of the disadvantages of an "oligopolosit" situation in something as vital as polio vaccine. A further helpful paper (copy also available in my office) dealt with the report and recommendations of a national immunisation work group in the United States, headed by Saul Krugman. This reaches the conclusion that governmental support is needed for the development and production of limited use vaccines which were deemed to be inherently unprofitable. The present delicate balance of industry and government in vaccine manufacture was also referred to.

APPENDIX NO. 3

COMMONWEALTH SERUM LABORATORIES ACT
DETERMINATIONS UNDER SECTION 19(b)

DATE	DETAILS
29.2.1963	(a) The Commission is authorised to produce and hold at the Laboratory 1,000,000 doses of smallpox vaccine. (b) 800,000 doses of smallpox vaccine held at the Laboratory on behalf of the Department of Health shall be included in the stock of 1,000,000 doses authorised in (a) above. As and when the 800,000 doses is reduced by the distructior of time expired stock, the Commission shall increase its proportion of stock holdings accordingly so that at all times, the authorised stock of 1,000,000 doses is held at the Laboratory. (c) Quarterly returns are to be submitted to Department of Health. (d) The stock of 1,000,000 doses of smallpox vaccines is to be turned over through commercial sales and issues for the purposes of the Department of Health to reduce the necessity for destruction of time expired products to a minimum.
8.9.1967	The Commission is authorised to undertake research on the projects set out below at a total cost of $332,000. Bacteriology (a) Investigation of nature of essential antigens of pathogenic organisms and effect of cultural conditions on pathogenicity and antigenicity. (b) Investigation of bacteriological problems associated with human and animal diseases in Papua/New Guinea. (c) Investigation of the kinetics of bacterial growth under conditions of controlled and continuous culture. (d) Development of new diagnostic agents for use in clinical bacteriology. Biological Chemistry (a) Investigation, identification and clinical evaluation of plasma fractions. (b) Investigation of biochemical factors concerned in or associated with antibiotic resistance, with particular reference to the genetic control of penicillinase production.

(c) Investigation of the properties of antibiotics produced by Australian strains of streptomyces and their mutant and recombinant forms.

(d) Characterization and investigation of biologically active substances and enzymes found in natural materials and venoms.

(e) Development of new types of prophylactic agents by chemical modification of antigens in simple and adjuvant forms.

Immunology and Serology

(a) Study of the immunoglobulins in health and disease.

(b) Investigation and establishment of improved immunological techniques for the study of normal and abnormal antibody responses.

(c) Blood grouping and population genetic studies. Evaluation of blood grouping sera and related diagnostic agents.

Virology

(a) Co-operative investigative projects with C.S.I.R.O., Universities and other organisations in the screening of biologically active compounds.

(b) Investigation of virological problems associated with human and animal diseases of Papua/New Guinea.

(c) Cultivation of an agent responsible for infectious hepatitis.

(d) Investigation of the factors influencing the immunological response to viral antigens.

28.6.1968 The Commission is authorised to undertake research on the projects specified when at a total cost of $345,000.

Bacteriology

The study of bacteria and their products with a view to producing new or improved vaccines, including an evaluation of their antigenicity in simple and adjuvent forms.

Biological Chemistry

The biological factors associated with antibiotic resistance, including a genetic study of penicillinese production.

Immunology

A study of normal and abnormal immunoglobulins, including their purification, preparation of specific antisers, and antibody labelling with fluorescent eyes.

Veterinary

A study of the value of animal blood products in veterinary medicine.

Virology

A study of viruses of major importance to human health, including the development of safe and effective vaccines.

Wewak

The ecology of pathogenic micro-organisms in the Territory of Papua and New Guinea.

8.8.1969 The Commission is authorised to undertake research on the projects specified below at a total cost of $350,000.

Bacteriology

BA.1/70

The study of bacteria and their products with a view to producing new or improved vaccines, including an evaluation of their antigenicity in simple and adjuvant forms.

Biological Chemistry

B1.1/70

The biochemical factors associated with antibiotic resistance including a genetic study of penicillinase production

Immunology

IM.1/70

A study of normal and abnormal immunoglobulins including their purification, preparation of specific antisera and antibody labelling studies.

Veterinary

VE.1/70

A study of animal blood products for diagnostic and therapeutic purposes.

Virology

VI.1/70

A study of viruses of major importance to human health, including the development of safe and effective vaccines.

Wewak

WE.1/70

The ecology of pathogenic micro-organisms in the Territory of Papua and New Guinea.

18.9.1969 The amounts determined in Determination of 18.9.1967 are amended to total $365.824.

31.8.1970 The Commission is authorised to undertake research on the projects specified below to a total cost of $382,000.

Bacteriology

The study of bacteria and their products with a view to producing new or improved vaccines, including an evaluation of their antigenicity in simple and adjuvant forms.

Biological Chemistry

The biochemical factors associated with antibiotic resistance including a genetic study of penicillinase production.

Immunology

A study of normal and abnormal immunoglobulins including their purification, preparation of specific antisera and antibody labelling studies.

Veterinary

A study of animal blood products for diagnostic and therapeutic purposes.

Virology

A study of viruses of major importance to human health, including the development of safe and effective vaccines.

6.10.1971 The Commission is authorised to hold and maintain at the Laboratories, a reserve stock holding of 500,000 doses of SABIN poliomyelite vaccine.

The stock of 500,000 doses of SABIN poliomyelites vaccine is to be turned over by sales to reduce to a minimum the necessity for destruction of time expired products.

26.1-.1971 The Commission is authorised to undertake research on projects specified below to a total cost of $469,000.

Dept. 511 - Bacteriology

Studies of the toxogenicity and immunogenicity of C.chauvoci; collection, identification and serotyping of strains of Pseudomonas; Development of human leptospirosis vaccine; Studies of the effectiveness and mode of action of adjuvants.

Dept. 512 - Biochemistry

Mechanisms of antibiotic resistance in bacteria, particularly S.aureus; Physiology and pharmacology of the venom of Australian venomous snakes etc., and of antivenenes against these venoms.

Dept. 513 - Immunology

Studies on caprine gamma globulin, and investigation of the possibility of developing therefrom an anti-lymphocytic globulin for human clinical use; studies of the effects of environmentation, using immunoelectrophoretic techniques; Studies of the use of fluorescent antibody staining in diagnosis of human and animal disease with particular reference to rabies.

Dept. 514 - Veterinary

Studies of bacteriological and immunological aspects of colibacillosis in calves; Adjuvants in Veterinary vaccines.

Dept. 515 - Virology

The growth of attenuated viruses in human diploid cell lines, and the development of vaccines derived therefrom; Studies of human viral hepatitis and of the nature and role of the Au antigen; Identification of - viruses causing human disease, including identification of referred specimens; Isolation and identification of the capsid proteins of viruses, and their role in the immune response to viral infections, with particular reference to the influenza virus.

14.6.1972 The Commission is authorised to undertake research on project: specified when to a total cost of $596.888.

Department 511 - Bacteriology

Studies on the immunogenicity of C. chauvoci; development of a human pseudomonas vaccine; development of a human leptospirosis vaccine; streptococcal throat survey; studies on the antimicrobial and antifungal properties of passiflora sp. extracts;

Department 512 - Biochemistry

Study of biochemical factors associated with antibiotic resistance; study of the effects of venoms and their specific antivenenes on tissue ultrastructure; study of the coagulant, anticoagulant, haemolytic and myolytic properties of Australian snake venoms and antivenenes; studies on the venom of the sea wasp chironex fleckeri particularly in respect of its immunogenicity; cross-protection studies with sea snake venoms; the long-term preservation of red cells; a detailed biochemical and biophysical study of human plasma protiens.

Department 513 - Immunology

Studies on caprine gamma globulin with specific activity; studies on the venom of the Sydney funnel web spider, Atrax Robustus;

Department 514 - Veterinary

Maintenance of the Rabies Diagnostic Centre; studies on feline panleucopoenia vaccine; develop Marek's disease vaccine; develop an inactivated adjuvanted vaccine for ovine footrot.

Department 515 - Virology

Study on the growth and altenuation of viruses grown in human diploid cells; studies on viral hepatitis and the nature and role of the hepatitis associated (AU) antigen; ecological studies on the distribution of pathogenic viruses.

12.7.1973 The amounts listed in Determination of 14.6.1972 are amended to total $597,000.

.8.1973 The Commission is authorised to undertake research on the projects specified below to a total cost of $705,000.

Studies on Venoms and Antivenenes

This will include studies on the biological and immunochemical properties and mode of action of various venoms so that clinically effective and safe methods of prophylaxis and treatment could be made available.

Biochemical and biophysical study of human plasma proteins

The aims being to develop new therapeutically useful fractions, to improve the purity of existing fractions and the efficacy of the current fractionation procedures.

The development of new bacterial and viral veterinary vaccines

This will include work on Feline panleucopenia vaccine, Marek's disease vaccine, Blue-tongue vaccine, Combined Erysipelas-leptospira vaccine for pigs, fowl cholera vaccine and Ovine foot-rot vaccine (terminal stages).

This project will also include work on adjuvants and one-dose vaccines.

Ecological studies on the distribution of pathogenic viruses

A continuing study of viruses received from throughout Australia, including antibody studies in both animals and man. Includes studies on cot-deaths.

Studies on viral hepatitis and on the nature and role of Australia Antigen

Includes the development of a highly sensitive test for the detection of Australia antigen.

Biochemical factors associated with antibiotic resistance

This is a continuing study to elucidate the mechanism of antibiotic resistance by bacteria and devise means of controlling this resistance or counteracting its effects. Seven papers have already been published and meaningful results are continuing to emerge.

The establishment and maintenance of cell lines

Includes the development of new cell lines, and their potential use as a substrate for vaccines.

The establishment of a specialist Fluorescent Antibody Unit

To assist in basic and applied immunological, bacteriological, virological and toxicological investigations.

Study of the essential antigens of Pseudomonas, Bordetella and Leptospiral organisms

The application of knowledge so gained in the development of new or improved prophylactic agents caused by such organisma.

Studies on A.L.G.

To explore the extraction of antigens from thymic tissue and their use in producing immunosuppressive A.L.G.

Study of pathogenic Mycoplasmas of livestock and other mycoplasmas which occur in tissue cultures

Mycoplasmas are a major cause of disease in pigs. The project would be aimed towards diagnostic and prophylactic agents.

Rabies Diagnostic Centre

At request of Health Department.

12.7.1974 The Determination made on 12 August, 1973, is amended to provide a total cost of $730,000.

The Commission is authorised to undertake research on projects specified below to a total cost of $1,116,100.

Laboratory and Field Assessment of the Clinical Efficacy of Current Human and Veterinary Biologicals

Includes a continuing study of reactions to human vaccines, antibody responses to vaccines, efficacy of antibiotic treatment, efficacy of current human and veterinary vaccines as determined in the field and in experimental animals, thus assisting in development of new products.

Diagnostic Agents

Continuing studies on improved methods of laboratory diagnosis of bacterial and viral infections in man and animals, and the development of appropriate diagnostics for this purpose.

Studies on Venoms and Antivenenes

This is a continuing study of the biological and immunochemical properties and mode of action of various venoms so that clinically effective and safe methods of prophylaxis and treatment could be made available.

Biochemical and Biophysical Study of Human Plasma Porteins

The aims being to develop new therapeutically useful fractions, to improve the purity of existing fractions, and the efficacy of the current fractionation procedures. A continuing project.

The Development of New Bacterial and Viral Veterinary Vaccines

This will include work on Marek's disease vaccine, and Combined Erysipelas-Leptospirosis vaccine for pigs. This project will also include work on adjuvants and one-dose vaccines, and the development of pure substrates (e.g. SPF eggs) for the production of veterinary viral vaccines.

Ecological Studies on the Distribution of Pathogenic Viruses

A continuing study of viruses received from throughout Australia, including antibody studies in both animals and man. Includes studies on the role of respiratory viruses in the sudden death of infants.

The Establishment and Maintenance of Cell Lines

Includes the development of new cell lines, and their potential use as a substrate for vaccines.

The Establishment of a Specialized Antibody Labelling Unit

The establishment of a specialist unit for labelling antibodies (e.g. fluorescent labelling, peroxidase labelling) to assist in basic and applied immunological, bacteriological, virological and toxicological investigations.
e.g. tracing the movement of venoms in animal tissues; locating specific viral and bacterial antigens; develop reagents for the rapid identification of pathogenic microbes; develop reagents for the serological diagnosis of certain infections by indirect F.A. techniques; canine distemper (differential diagnosis of canine brain specimens for rabies.)

Studies of the Essential Antigens of Pseudomonas, Bordetella V. cholerae, S. typhi and Lentospiral organisms

To apply the knowledge so gained in the development of new or improved prophylactic agents caused by these organisma.

Study of Pathogenic Mycoplasmas of Livestock

Mycoplasmas are a major cause of disease in pigs (pneumonia, arthritis etc). A mycoplasma has also been recently incriminated as the cause of enzootic pneumonia in sheep. This is a continuing project which is aimed towards diagnostic and prophylactic agents.

Rabies Diagnostic Centre

At request of Health Department.

12.1.1975

1. that Stocks of influenza vaccine produced in 1973 comprising

   (a) 350,000 dispensed doses of influenza vaccine each dose having a formulation of -
   12,000 H.A. units of A/England/42/72 strain, and
   6,000 H.A. units of B/Roma/67 strain - valued at - $100,865

   (b) bulk stocks of B/Roma/67 strain comprising 30 litres of bulk concentrate - valued at $21,207

   were produced and held for purposes other than the immediate sale of those products.

2. that stocks of incluenza vaccine produced in 1974 comprising

   (a) 200,000 dispensed doses of influenza vaccine each dose having a formulation of -
   16,000 H.A. units of A/England/42/72 strain and
   8,000 H.A. units of B/Hong Kong/8/73 strain - valued at $50,000

   (b) bulk stocks of A/England/42/72 strain comprising 200 litres of vaccine concentrate - valued at - $117,583

   (c) bulk blended stocks of A/England/42/72 and B/Hong Kong/8/73 strains comprising 119 litres of vaccine ready for dispensing - valued at - $25,704

   were produced and held for purposes other than the immediate sale of those products.

   Total $315,359

21.5.1975 The Commission is authorised in the financial year 1975/76 to maintain plant capable of being usef for the production of penicillin for purposes other than immediate sale of the product.

21.5.1975 The Commission is authorised in 1975/76 to maintain plant capable of being used for the production of blue tongue and influenza vaccines and other exotic vaccines for the purpose other than the immediate sale of those products.

9.7.1975 The Commission is authorized to undertake research on projects specified below to a total cost of $1,484,000.

Laboratory and Field Assessment of the Clinical Efficacy of Current Human and Veterinary Biologicals

Includes a continuing study of reactions to human vaccines, antibody responses to vaccines, efficacy of antibiotic treatment, efficacy of current human and veterinary vaccines as determined in the field and in experimental animals, this assisting in development of new products of a more efficacious and less reactive nature.

Development of New Type Bacterial and Viral Vaccines for Human and Veterinary Use

These continuing activities cover the development of new vaccines for human and veterinary use and/or the development of new type vaccines to replace existing vaccines.

Development of New and Improved Type Biological Products (other than Vaccines) for Human and Veterinary Use

These continuing activities cover the development of new biological products (other than vaccines) for human and veterinary use and/or the development of new type biological products to replace existing products.

Development of New and Improved Diagnostic Agents

Continuing studies on improved methods of laboratory diagnosis of bacterial and viral infections in man and animals and the development of appropriate diagnostics for this purpose.

The Establishment and Maintenance of Cell Lines

Includes the development of new cell line. nd their potential use as a substrate for vaccines.

Study of Pathogenic Mycoplasma of Livestock

This is a continuing project which is aimed towards diagnostic and prophylactic agents and includes mycoplasma infection of cell lines.

Biochemical and Biophysical Studies of Human Plasma Proteins

The aims being to develop new therapeutically useful functions, to improve the purity of existing fractions, and the efficacy of the current fractionation procedure. A continuing project

Studies on Venoms and Antivenenes

This is a continuing study of the biological and immuno-chemical properties and mode of action of various venoms so that clinically effective and safe methods of prophylanis and teatment could be made available.

Ecological Studies on the Distribution of Pathogenic Viruses

A continuing study of viruses received from within Australia, including antibody studies in both animals and man. Includes studies on the role of respiratory viruses in the sudden death of infants.

The Establishment of a Specialised Antibody Labelling Unit

The establishment and operation of a specialised unit for labelling antibodies, (e.g. fluorescent labelling, peroxidase labelling and radioactive labelling) to assist in basic and applied immunological, bacteriological, virological and toxicological investigations.

Development of New Techniques for Scaling-Up Procedures to assist in the Design of Approval Capital Projects

This is a continuing development to ensure the optimum performance of new and updated facilities.

30.1.1976 The functions of the Commission are hereby deemed to include the undertaking of research on the attenuation of blue tongue virus strains in the Republic of South Africa to enable the importation of these strains into Australia in a safe condition

9.2.1976 The functions of the Commission are deemed to include the production and holding of stocks of yellow fever virus for purposes other than the immediate sale of the product.

The establishment of those stocks will necessitate the preparation of a seed lot continuing 1600 ampoules which corresponds to approximately four (4) million doses of yellow fever vaccine.

23.8.1976 The Commission is authorised to undertake research on projects specified below to a total cost of $1,701,528.

Laboratory and Field Assessment of the Clinical Efficacy of Current Human and Veterinary Biologicals

This project involves a continuing study of reactions to human vaccines, antibody responses to vaccines, efficacy of antibiotic treatment, efficacy of current human and veterinary vaccines as determined in the field and in experimental animals, thus assisting in development of new products of a more efficacious and less reactive nature.

Development of New Type Bacterial and Viral Vaccine for Human and Veterinary Use

These continuing activities cover the development of new vaccines for human and veterinary use and/or the development of new type vaccines to replace existing vaccines.

Development of New and Improved Type Biological Products (other than vaccines) for Human and Veterinary Use

These continuing activities cover the development of new biological products (other than vaccines) for human and veterinary use and/or the development of new type biological products to replace existing products.

Development of New and Improved Diagnostic Agents

This project covers continuing studies on improved methods of laboratory diagnosis of bacterial and viral infections in man and animals and the development of appropriate diagnostics for this purpose.

The Establishment and Maintenance of Cell Lines

This project involves the continual development of new cell lines and their potential use as a substrate for vaccines.

Study of Pathogenic Mycoplasma of Livestock

This continuing project is aimed towards diagnostic and prophylactic agents and includes mycoplasma infection of cell lines.

Biochemical and Biophysical Studies of Human Plasma Proteins

The purpose of this continuing project is to develop new therapeutically useful functions to improve the purity of existing fractions, and the efficacy of the current fractionation procedure.

Studies of Venoms and Antivenenes

This is a continuing study of the biological and immunochemical properties and mode of action of various venoms so that clinically effective and safe methods of prophylanis and treatment could be made available.

Ecological Studies on the Distribution of Pathogenic Viruses

This project involves a continuing study of viruses, received from within Australia, including antibody studies in both animals and man and studies on the role of respiratory viruses in the sudden death of infants.

The Establishment of a Specialised Antibody Labelling Unit

The aim of this continuing project is the establishment and operation of a specialised unit for labelling antibodies, (e.g. fluorescent labelling, peroxidase labelling and radio-active labelling) to assist in basic and applied immunological, bacteriological, virological and toxicological investigations.

Development of New Techniques for Scaling-Up Procedures to Assist in the Design of Approved Capital Projects

This is a continuing development to ensure the optimum performance of new and updated facilities.

24.8.1976 The function of the Commission are deemed to include:-

(a) the undertaking of research on the production of a vaccine against the veterinary disease of blue tongue;

(b) the production and holding of 1000 ampoules (equivalent to approximately 4,000,000 doses) of yellow fever vaccine other than the immediate sale of this product.

28.10.76 The functions of the Commission are hereby deemed to include the production and holding of a bulk reserve of 3 000 000 doses of A/New Jersey/8/76 like influenza vaccine for purposes other than the immediate sale of this product.

Production and testing of this vaccine comprising this reserve is to be completed by the Commonwealth Serum Laboratories Commission in sufficient time to allow, if an emergency arises, for the dispensing and distribution of the vaccine prior to the commencement of the recommended vaccination period for the 1977 winter.

Any reimbursement to the Commission under Section 38 of the Commonwealth Serum Laboratories Act 1961-1974 in respect of this bulk reserve shall be limited to $450 000.

This determination shall continue in operation until the thirtieth day of June 1977.

2.11.1976 The functions of the Commonwealth Serum Laboratories Commission are deemed to include the maintenance of plant in the buildings known as the Virus Production Building Phases 1 and 11 and the Maximum Security Building capable of being used for the production of blue tongue vaccine and other vaccines against diseases not presently endemic to Australia for purposes other than the immediate sale of these products.

Any reimbursement to the Commonwealth Serum Laboratories Commission under section 38 of the Commonwealth Serum Laboratories Act 1961-1974 in respect of this determination shall be limited to $382 000 in the financial year 1976/77.

This determination shall continue in operation until the thirtieth day of June 1977.

The functions of the Commission are:-

(a) undertaking of research in the projects specified below to a total cost of $2 257 000;

(b) undertaking of research towards the production of a vaccine against the veterinary disease of blue tongue - cost $70,000;

(c) maintenance of plant in the buildings known as the Virus Production Building Phases I and II and the Maximum Security Building capable of being used for the production of blue tongue vaccine and other vaccines against diseases not presently endemic to Australia for purposes other than the immediate sale of these products - cost $400 000.

GROUP 1 - Laboratory and Field Assessment of the Clinical Efficacy of Current Human and Veterinary Biologicals

This project involves a continuing study of reactions to biological products, antibody responses to vaccines, and efficacy of biological products, as determined in the field and in experimental animals, thus assisting in the development of new and improved products of a more efficacious and less reactive nature.

GROUP II - Development of New and/or Improved Type Bacterial and Viral Vaccines for Human and Veterinary Use

These continuing activities cover the development of new vaccines for human and veterinary use and/or the development of new type vaccines to replace existing vaccines.

GROUP III - Development of New and/or Improved Type Biological Products (other than vaccines) for Human and Veterinary Use

These continuing activities cover the development of new biological products (other than vaccines) for human and veterinary use and/or the development of new type biological products to replace existing products.

GROUP IV - Development of New and Improved Diagnostic Agents

This project covers continuing studies on improved methods of laboratory diagnosis of bacterial and viral infections in man or animals and the development of appropriate diagnostics for this purpose.

GROUP V - The Establishment and Maintenance of Cell Lines

This project involves the continual development of new cell lines and their potential use as a substrate for vaccines and includes the development of testing for mycoplasma infections and methods for clearing lines of contamination.

GROUP VI - Development in "In Vitro" Testing

The purpose of this project is to reduce the use of animals in product testing, particularly for "in process" testing by the development of effective "in vitro" testing methods.

GROUP VII - Biochemical and Biophysical Studies of Human

The purpose of this continuing project is to develop new therapeutically useful plasma fractions, to improve the purity of existing fractions and to establish methods of testing for the efficacy and safety of plasma fractions. Also included is the preservation of rare bloods for the Australian Red Cross Society.

GROUP VIII - Studies of Venoms and Antivenoms

This is a continuing study of the biological and immuno-chemical properties and mode of action of venoms and antivenoms so that improvements in the clinical efficacy and safety of prophylaxis and treatment can be made.

GROUP IV - The Establishment of a specialised Pharmacological Unit

The aims of this unit are to provide a specialised facility for investigating the basis for reactivity of existing products with a view to decreasing such reactivity and also for the safety testing of new and improved products.

GROUP X - The Establishment of a Specialised Antibody Labelling Unit

The aim of this continuing project is the establishment and operation of a specialised unit for labelling antigens and antibodies (e.g. fluorescent, peroxidase, and radioactive labelling) to assist in basic and applied immunological bacteriological, virological and toxicological investigations.

GROUP XI - Development of New Techniques for Scaling-up Procedures to Assist in the Design of Approved Capital Projects

This is a continuing development to ensure the optimum performance of new and updated facilities.

APPENDIX No.4

PENICILLIN PRODUCTION

Item	Reference
1 HISTORY	
• C.S.L. was first manufacturer to undertake local production of penicillin in Australia. Fermentation of Penicillin G 1943 Fermentation of Penicillin V 1955	Industries Assistance Commission (I.A.C.) Report 2.8.76 Page 18
Phenethicillin	
• GLAXO commenced production of bulk penicillin G & V at Port Fairy 1955. Ceased fermentation April 1975.	
• ABBOTS commenced production of penicillin V at Kurnell in 1964.	
• Accumulation of substantial stocks resulting from lower sales due to increased competition from industry following the removal of import licencing controls in February 1960, the Laboratory suspended production of all penicillin on 1 January 1961, and did not resume production till late February 1962.	Public Accounts Committee (P.A.C.) - Report No. 104 - 1969 Page 20
• Introduction of improved methods of production, although a continuing process became apparent in 1960-1961.	
• In four months from late February 1962 by the use of some new equipment and high yielding strains of penicillin producing mould, productivity of plant was raised very considerably above previous levels.	
• While process improvement contributed materially to reduce production costs during 1961-62, full advantage could not be taken of these during the period because sales only warranted operation of the plant at half its capacity.	
• Tariff Board reported in March 1963, that the two Australian manufacturers had the combined capacity to produce the main types of primary penicillin in quantities exceeding the total demands.	P.A.C Report No. 104 Page 21
• During 1964-65, the commissioning of a new 25,000 gallon penicillin fermentation plant was completed - trial runs on a second 25,000 gallon tank commenced later in the same year.	
• 1965/66 marked increase in demand for formulated penicillin products overtaxed existing facilities and steps were taken to obtain additional production equipment.	

../2.

Item	Reference
• Large export orders for bulk penicillin were made by operating the plant at maximum capacity for several months.	
• The prime manufacture of bulk penicillins was maintained at approximately 80% of maximum capacity during the first half of year. With falling export sales, production during the second half was further reduced.	C.S.L. Annual Report 1971/72. Page 20
• Throughout the first half of the year 1972/73, the fermentation plant was closed down, stocks of penicillin being more than adequate to meet marketing demands. Fermentation was resumed in January 1973 and maintained for the rest of the year but at less than maximum capacity.	C.S.L. Annual Report 1972/73. Page 19
• Primary manufacture of penicillin was carried on continuously at maximum fermentation capacity for most of the year.	C.S.L. Annual Report 1973/74. Page 19
• Prime manufacture of penicillins was continuous throughout the year but at less than maximum capacity during the final quarter. The sudden and severe downturn in the world penicillin market caused us to review our programme and the opportunity was taken to build up stocks so that a carefully staged short-term shut-down of the fermentation plant could take place.	C.S.L. Annual Report 1974/75. Page 9
• Export market for penicillin continued to be severely depressed.	C.S.L. Annual Report 1975/76.
• Penicillin fermentation did not take place during 1976/77 and further steps were taken to arrive at on balance of costs and availability between imported penicillin salts and those of our own manufacture.	C.S.L. Annual Report 1976/77.
• Government had decided that a further examination on the grounds of maintaining local manufacture.	
• Reserves of bulk penicillin seriously depleted and so steps were taken to rehabilitate the penicillin plant so that stocks could be accumulated during 1977/78.	
2 POLICY STATEMENTS	
• Minister for Trade to Tariff Board 1963:- "Board to have due regard to the considerable importance attached by the Government to the continued production of antibiotics in Australia in assessing what assistance should be accorded the Australian industry.	I.A.C. Report 2.8.76 Page 5

../3.

Item	Reference
. Similar policy statement contained in reference of 1968.	Page 6
3 PRODUCTION	
. Shortage of penicillin 1963/65, 1965/69. World shortage 1972/75.	Background Brief - Department of Health Page 3
. 3 year period 1972/73 domestically produced penicillin and streptomycin declined by 40%.	I.A.C. Report 3.1.76 Page 24
. 1972/73 production was 70,000 kg valued at $3.2 Million. C.S.L. was largest producer. Annual domestic production is well in excess of 1972/73 but there were a number of voluntary curtailments. Output in 1973/74 well in excess of 1972/73.	
4 CAPACITY	
. 1968 Tariff Board report into penicillins and streptomycin stated the combined capacity of C.S.L., Glaxo and Abbots was far greater than their combined outputs on the estimated Australian demand for them. Industry had sufficient installed capacity to produce at least 4 times the Australian demand for penicillin V after satisfying the demand for penicillin G and streptomycin.	I.A.C. Report 2.8.76 Page 24
. Position has worsened since 1968 as the development of new antibiotics has reduced the share of locally produced autibiotics.	
. In recent years, the increases in yields from existing plants have exacerbated the already high levels of unused capacity both in Australia and overseas.	I.A.C. Report Page 27
. C.S.L. as well as providing the ability to participate in export markets, has extra capacity installed to provide the facility to respond to a national emergency as requested by its operating charter.	I.A.C. Report Page 24
5 COSTS OF PRODUCTION	
Glaxo advise that direct raw material accounts for 40/55% of total manufacturing costs in the British plant but for only 20% on average of total manufacturing costs in the Australian plant.	I.A.C. Report Page 25
. The industry does not incur major disadvantages on the prices paid for raw material.	I.A.C. Report Page 25

../4.

Item	Reference
6 I.A.C. CONCLUSIONS	
. Imports of bulk penicillin of the types manufactured locally have been small in recent years - 1974-75 valued at $355,000.	I.A.C. Report Page 27
. The Commission is aware of some relatively low prices overseas and on the basis of these prices, local disadvantage of up to 160% have been calculated.	
. There is also evidence which suggest that local industry is not economic	
. It is unlikely that local production has any prospect of operating profitably if protected only be moderate duty levels and on economic grounds there is no case for assisting the industry.	
. If the Government does desire to maintain a manufacturing capability, the I.A.C. will recommend that this be done by reducing the tariff on primary antibiotics to minimum rates and supporting the operations of C.S.L. through budgeting appropriation or Abbots through a subsidy	

APPENDIX No.5

BAZELEY LABORATORY (MAXIMUM SECURITY BUILDING) AND THE BLUETONGUE ZONES OF THE MORGAN LABORATORY

Bazeley Maximum Security Laboratory

In August 1968 planning was commenced at CSL for the construction of a high security area in which work could be done on:

1. Brucellosis - Safety testing of Strain 19, preparation of suspensions, preparation of antisera for brucella strains, animal passage for typing of virulent strains and developmental work on Brucella meletensis.
2. Animal passage work for the preparation of vaccine strains for typhoid, cholera and plague and of challenge strains.
3. Leptospirosis challenge and animal passage work.
4. Post-mortem examination of rats for the surveillance of plague.
5. Challenge potency tests for vaccines such as cholera and typhoid.
6. Rabies diagnostic procedures.

Planning continued through to 1973; there was early exchange of data undertaken with the National Biological Standards Laboratory in 1969 at the time when they were planning for their proposed brucella testing unit, and then detailed development of the plan with Bates, Smart and McCutcheon.

As discussions took place between CSL, the Commonwealth Department of Health, the Victorian Department of Agriculture and overseas organizations who had been involved in similar planning, the initial estimate of $70,000 for the base concept gradually grew to approximately $800,000 by July 1973.

The initial concept was based on CSL's own established activities but in subsequent discussion with Canberra the question of whether the facilities should only allow for challenge testing or other *in vivo* tests on a routine basis or also for tests in large animals associated with the production of exotic animal disease vaccines under secure conditions continued to be raised.

By August 1973 it appears to have been clearly established that the Maximum Security Laboratory was not to provide additional housing areas for direct challenge experiments on animals such as sheep. Furthermore, the Director General of Health virtually directed that the Maximum Security Laboratory was not to be designed as a production unit of Bluetongue Vaccine nor was there to be any intention of producing Foot and Mouth Disease Vaccine at CSL.

On a number of occasions when discussions took place with Commonwealth and State authorities on the production of Bluetongue Vaccine it was emphasized repeatedly that no *in vivo* testing should be done at CSL. CSL's view was that with relatively minor modifications the Maximum Security Laboratory was suitable for tests involving animals as large as sheep.

The Bazeley Maximum Security Laboratory is now ready for urgently required work on the Bluetongue virus. The originally planned functions will be delayed because of the Bluetongue programme and the *in vivo* tests on sheep will be done as the flexibility of the CSL planning allows sheep to be housed and used for *in vivo* work.

This project commenced as a predominantly 19(a) or "commercial" activity because most of the intended work would have been on products which were sold. One would, however, have no difficulty categorizing those products as being in the public interest and important to Australia. The total activity for the next year or so will be on Bluetongue which is a 19(b) project and 'non-commercial'.

Bluetongue Zones of the Morgan Laboratory

In mid 1969 at a time when CSL was planning the erection of the Morgan Virus Vaccine Laboratory, it developed a proposal which was presented to the Exotic Diseases Sub-Committee of the Commonwealth and States Veterinary Committee. CSL proposed that it should be planning a facility for the production of Bluetongue vaccine which would also be suitable for other exotic animal diseases such as Rift Valley Fever, Wesselbron Disease, and Rinderpest.

The Exotic Diseases Sub-Committee considered the CSL proposal and recommended:

1. That for quarantine reasons bluetongue vaccine should not be imported into Australia.
2. That there is need to be prepared for the manufacture of bluetongue vaccine in Australia in a laboratory facility so constructed as to be vector-proof and with the usual security arrangements for effluent treatment and the entry and exit of staff, as set out in the submission from CSL.
3. That when these facilities have been built, seed of each antigenic type of attenuated bluetongue virus should be imported and cloned a sufficient number of times to ensure freedom from contaminating viruses.
4. That, because of the number of antigenic types, no attempt should be made to manufacture bluetongue vaccine in advance of an outbreak.
5. That in the event of an outbreak the Consultative Committee should authorise vaccine production to commence as soon as the strain has been identified and should make suitable arrangements for its safety and potency testing.
6. That the locally produced vaccine should be released to Departments only and then only on the decision of the Consultative Committee.
7. That there is an immediate need for these facilities, irrespective of a decision on the maximum security virus laboratory.

The CSL Commission was informed in 1971 that in the event of an outbreak of an exotic animal disease in Australia the Department of Health would look to CSL for the production of the appropriate vaccine and that in the event of an outbreak of major importance, such as Bluetongue, it would be required of CSL to give absolute priority to this work and, if necessary, at the expense of other routine production procedures.

Because of the conflict of interest which CSL would have in attempting under its Act to observe such national policy directives whilst concurrently performing its duties under the Act it was obvious that a substantial building capable of producing a number of viral vaccines at the one time was required. Furthermore, the Commission was informed that at that time a joint submission by Health, Primary Industry and Education and Science was to go to Cabinet recommending that any exotic animal vaccine manufacture (with the exception of Foot and Mouth Disease) which becomes necessary in Australia should be carried out entirely at CSL. The Commission was informed, however, that requests for additional funds to achieve this end could delay the consideration of the joint submission and therefore it was unadvisable to seek funding at that time.

In subsequent development of the project detailed consideration took place with the State of Victoria to ensure that they were completely happy with the level of security and their concurrence was obtained for all stages. In late 1971 negotiations were undertaken with the Veterinary Research Institute, Onderstepoort, South Africa, and during 1972 two officers of CSL undertook preparation of master seed lots of the attenuated strain of each of the 15 antigenic types of Bluetongue virus then held at Onderstepoort.

The planning of the building through 1972 eventually reached the stage where two zones were required for Bluetongue work in the Morgan laboratory; one zone being for the cloning and purification of each antigenic strain and the conversion of the seed lots of virus suitable for vaccine production and the second zone for the production, dispensing and freeze-drying of such a vaccine.

After completion of the term at Onderstepoort of the two CSL officers it was expected that further work would be done by Onderstepoort scientists but due to staff changes and their own priorities this did not take place. CSL also became concerned in 1972 that expenses which it was incurring for this work were not gaining ready acceptnace as Section 19(b) activity due to economic restraint by Government.

With the progress of the building well advanced at the end of 1975 CSL expressed concern that it was time for further developmental work to be undertaken at Onderstepoort. As a result of numerous approaches to the involved parties, CSL was able to obtain by 29 November 1975 agreement that there should be a Ministerial submission for Section 19(b) determination to cover the projected work, and by mid 1976 agreement with and approval of the proposed purification programme was achieved with the representatives of the Commonwealth Department of Health, Animal Health Bureau, CSIRO and the Victorian Department of Agriculture. Officers of CSL then returned to Onderstepoort and by December 1976 14 purified strains were returned to Australia to be held in quarantine at CSL. The purification work was carried out to the limit of the facilities at Onderstepoort and in accordance with the agreed protocol laid down before the work commenced. However, since that time the work has been subject to considerable criticism and agreement has not yet been reached on what should be the next stages of the purification project to be undertaken at CSL. When this work does eventually start and is completed several years later there will be purified master seed lots available for Bluetongue vaccine production in the event of a national emergency.

The Bluetongue work requires a substantial laboratory of pure S. 19(b)/non-commercial classification but it is part of a larger building which produces products for sale, but those latter facilities had to be provided to allow the Commission to fulfil its obligations to Australia under the CSL Act whilst serving the Government directive that we would be able to produce Bluetongue vaccine as a top priority.

Both the Bluetongue area of the Morgan Laboratory and the Bazeley Maximum Security Laboratory have been built to standards far beyond those agreed on in discussions throughout the earlier years of planning with State and Federal authorities. However because of the changing state of the art, and perhaps the fact that full analysis of detail had not been attempted by some outside experts until the buildings were erected, work is still being undertaken to achieve the degree of security now deemed necessary.

APPENDIX No.6

AN APPROACH TO THE ANALYSIS OF SECTION 19(a) and 19(b)

ACTIVITIES OF CSL - FEBRUARY 1978

Previous attempts to segregate the 'commercial' and 'non-commercial' activities of CSL have not been particularly fruitful. Some of the difficulty has come from the absence of any accepted definition of 'commercial' and 'non-commercial'; and one of the problems has been that 'profitability' and 'non-profitability' do not coincide with 'commercial' and 'non-commercial'. Neither does the present breakdown into Section 19(a) and Section 19(b) activities provide a sufficient approach.

To briefly demonstrate the difficulties attending the attempts at analysis the following examples are listed.

1. Serum fractionation shows up as a profitable activity in the CSL department profitability analysis although there is no market price. After full absorption of all costs attributable to that department the efficiencies therein allow a reimbursement price to be struck which makes a worthwhile contribution to CSL's operating revenue whilst at the same time achieving price levels competitive to those charged in other countries.

   Furthermore although CSL is the only organization which undertakes serum fractionation in Australia and this activity is an expression of Government policy in the national interest, it is a Section 19(a) 'commercial activity' with no reserve of capacity or stocks under a Section 19(b) determination.

2. Penicillin fermentation capacity existed throughout 1976-77 in a reserve capacity role but was not accepted by Government as qualifying for S 19(b) reimbursement for shutdown fixed charges or maintenance.

Although available to the nation at all times during that year this plant-in-Reserve was carried by CSL as a cost against its S.19(a) trading operations. During the previous year the Minister had issued a S.19(b) determination for the inactive period; the bulk reserves produced during the productive months were funded through S.19(a) commercial activity and subsequently held during the shutdown period as S.19(a) i.e. commercial items.

3. The WHO Reference Laboratories for Influenza, Brucellosis and the National Blood Group Reference Laboratory although undoubtedly maintained by CSL for the national interest in the area of public health, as well as overseas standing, are supported by CSL as part of S.19(a) 'commercial' activities.

4. Influenza vaccine is not manufactured by any other organization in Australia and only on rare occasions is there vaccine available from overseas appropriate to Australian requirements. CSL believes that it grapples with this problem in the national interest as the availability of vaccine is always of great public health and political significance. CSL on occasions makes significant profits from influenza vaccine; and that is usually in those years when the public health/political significance is at its height and when there is no alternative ready source of supply elsewhere in the world. At all times however the fixed costs of the 'reserve capacity', both plant and expertise, and the losses resulting from obsolete production are borne by CSL as S.19(a) expenses.

   This short list is far from exhaustive of the number and diversity of complex examples.

At our discussions on 16 February we suggested that a different approach to such questions as

(a) why is CSL 'unprofitable'?

(b) where is the S.19(a), S.19(b) dividing line?

(c) where is 'profit' the yardstick, and what are the costs of 'public health'/'non-commercial' activities?

(d) what is the relevant level of R & D?

could be more useful than attempting to draw a 'chalk-line' through the present product/activity/plant and expertise mix. (Alternatively this latter complex could be regarded as a revenue/expense/capital asset mix).

The following approach, with its several options, requires that consideration be given to the implication of establishing a CSL *de novo*, or alternatively conducting it in some other fashion on the present site. Within these two streams several sub-levels of activity can be examined, e.g.

A. CSL to undertake only those activities for which there is no 'acceptable' overseas supply.

B. CSL to continue to manufacture those products for which it is the sole Australian manufacturer regardless of whether or not there may be overseas sources of supply.

C. In addition to A and B, CSL to continue with all its present full process manufacturing activities even though there may be other similar manufacturers in Australia.

D. Although several other stages could be proposed this last base of operation is that which CSL presently pursues and, for comparison, a S.19(a) product manufacturing organization operating for the Australian market only.

The following outline of option A1, A2

B1, B2

C1, C2

D1, D2

requires many assumptions, suffers from the absence of detailed costing based on deliberative inquiry, and is intended to demonstrate general conclusions only. However in each of the following propositions the staffing and activities have been estimated to ensure an integrated team with appropriate numbers in the functional areas which CSL presently recognizes as necessary for efficient performance.

A1			A2
		FUNCTIONS	
		Serum Fractionation Snake & Spider Antivenoms Allergens : Diagnostic Agents (limited range)	
		CAPITAL AND STAFF REQUIREMENTS	
10 acres & 100 acres	$0.3 m	Land	Parkville and Woodend Sites
	$14 m	Building & Services	Existing. N.B. New Serum Fractionation Plant Required 1985, $5 m.
	166	Staff	166
		OPERATING REVENUE AND COSTS	
	$3.4	Revenue	$3.4 m
	$3.0	Costs	$3.3 m Excess capacity of services etc. imposes penalty est. $0.3 m.

Comment:

The additional capital cost of establishing a new CSL for this limited function could be in the order of $14 - $15 million. Operating revenue and staffing can be assumed as equal for both propositions. Some plant/buildings on Parkville and Woodend site for A2 could be possibly sold or leased out; however a new serum fractionation plant should be planned for 1985, estimated cost $5-$6 million if established in a completely new building. Probably 1,000 acres could be sold at Woodend. At present pricing levels and policies the operation A1 could yield a net trading profit of $0.4 m compared with $0.1 m from carrying out the A2 activity. No national reserve or 'S.19(b)' functions are deliberately conducted in A1 or A2. Staffing would be, say, Production 80, Quality Control 20, Engineering and Maintenance 10, R & D 16, Animal Care 3, Finance and Supply 6, Personnel 14, Distribution 3, Administration and Professional 10.

B1			B2
		FUNCTIONS	
		A + Additional Allergens and Diagnostics e.g. Tuberculin Insulin, HGH etc. Influenza Vaccine, Tetanus Toxoid, Diphtheria, Pertussis, BCG, Smallpox, Typhoid, Cholera, Yellow Fever Vaccines. Antitoxins - human	
Australia only			Australia and Export
		CAPITAL AND STAFF REQUIREMENTS	
20 acres & 500 acres	$0.5 m	Land	Parkville and Woodend Sites.
	$40 m	Buildings & Services	Existing. N.B. New Serum Fractionation 1985, $5 m.
	330	Staff	357
		OPERATING REVENUE AND COSTS	
	$10 m	Revenue	$12 m
	$8.5 m	Costs	$10 m Excess capacity costs still incurred.

Comment:

The effect on sales and costs of operating in export markets becomes apparent at this level. Land requirements under the A1, B1, C1, D1 stream start to grow rapidly as more large animals are required for production and testing. The alternative of intensive housing of animals would be costly as inner areas of land would be then required and feed bills very high. No national reserve or S.19(b) functions are deliberately conducted in B1 or B2. The estimates of this analysis project a trading profit of $1.5 m from B1 and $2 m from B2. Staffing for B1 would be, say, Production 153, Quality Control 30, Engineering and Maintenance 20, R & D 40, Animal Care 5, Finance and Supply 20, Personnel 30, Distribution 5, Marketing 15, Administration and Professional 12. For B2 there would be an additional requirement of 25 in Production and an additional two people in Finance and Supply.

C1			C2
		FUNCTIONS	
Australia only		A + B + Veterinary Vaccines, Antisera & Diagnostics	Australia and Export
		CAPITAL AND STAFF REQUIREMENTS	
50 acres & 1000 acres	$1 m	Land	Parkville and Woodend Sites
	$50 m	Buildings and Services	Existing
570		Staff	600
		OPERATING REVENUE AND COSTS	
	$12.2 m	Revenue	$14.3 m
	$10.5 m	Costs	$12 m Excess capacity costs still being incurred.

Comment:

The addition of the veterinary vaccines, antisera and diagnostics whilst increasing considerable the land, building and staffing requirements and adding $2.2 m to revenue does little to increase profitability under present conditions. This is due to the depressed state of the many veterinary markets and the intense price-cutting being experienced in recent years. It is timely to note that CSL's presence in this market, as in others, serves to ensure some stability of supply at a time when irrational pricing policies are potentially disruptive to continuity of manufacture. The additional staffing for the C level would be Production 84, Quality Control 18, Engineering and Maintenance 16, R & D 12, Animal Care 30, Finance and Supply 15, Personnel 33, Distribution 5, Marketing 20, Administration and Professional 11.

D1			D2
		FUNCTIONS	
Australian Markets Only, No Penicillin Fermentation or Processing		Present Range	Australia + Export and Current National Reserve Functions
		CAPITAL AND STAFF REQUIREMENTS	
100 acres & 1500 acres		Land	Parkville and Woodend Sites.
?		Buildings and Services	Existing + Ten Year Capital Works Program.
1020		Staff	1160
		OPERATING REVENUE AND COSTS	
$21 m		Revenue	$24 m
$19 m		Costs	S.19(a) $22 m S.19(a) + (b) $24 m

Comment:

The present market range of products would be maintained in D1 but without a CSL plant for fermenting or processing penicillin. The benefits in terms of increased capacity, revenue from export sales, ability to support a larger number of trained staff and to undertake the S.19(b) functions, whilst having much more resources in the national interest S.19(a) functions, are demonstrated to be available under D2 without net financial disability. In reviewing the progression from A to D the important point is made that whilst the national estate is considerably increasing a significant operating income is still maintained and the D2 option provides an important contribution to non-revenue generating national policies. Previous papers have recorded CSL's contribution since the formation of the Commission of $8,015,000 towards a total 19(b) of $10,201,000. There is substantial argument that all R & D in the vaccine field should be funded by Government and it is timely to note that CSL's profit before R & D and national reserve function in 1975/76 was $2,252,788 and in 1976/77 $2,469,685.

Each of these options A1 and 2, B1 and 2, C1 and 2 show that on a limited base of operation there is

(i) a significant new capital expenditure requirement if completely new facilities, tailored to the level of activity, were to be set up,

(ii) but offsetting this there would be some economies of operation particularly in the cost of power, services and maintenance for A1, B1, and C1, over A2, B2 and C2.

(iii) but against this is the fact that C.S.L. is traditionally, when compared to either the public sector department or its private sector competitors, relatively poorly served in personnel and management development staffing, management support services and at a number of salary levels. Thus setting up CSL *de novo* could develop into a much more expensive exercise than indicated,

(iv) no national reserve capacity concept,

(v) no WHO centres.

Option D2 allows the continuation of CSL in its present form. This must not be construed as saying that CSL is at an ongoing optimal structure or should continue rigidly with its present mix of costs and functions. Rather, we are saying that the present *modus operandi* is the comparative organization for the other options proposed.

The ongoing costs of continuing CSL in its present structure have been outlined elsewhere in the projected estimates of new capital plant and services. Marginal profitability, inherent in biologicals,

demands that Government funding continue to be available, at the very least for S.19(b) activities, whilst CSL does its best to trade profitably. The benefits from this level of operation given present circumstances, are many, typical examples being:

(a) natural reserve capacity in plant, expertise and stocks

(b) savings of overseas funds (capital outflow)

(c) a greater day by day contribution to market vitality, public health and biological sciences

(d) continuation of WHO reference laboratories, national rabies diagnosis centre etc.

(e) additional contribution from export and some containment of prices from economies of scale.

This brief paper has not attempted to produce recommendations on the way in which the accounting and funding of CSL activities may be based. Rather it has attempted to increase understanding of the implications which have to be faced as one attempts to closely examine the operation of CSL. To that end it should not be read *in vacuo* but as part of the presentation of information which has been made.

If, in contraindication to the *ad hoc* judgements which have often been made on CSL's performance in attempting to serve obscure and unspecified goals, there is to be a well-based policy understood and agreed to by Government and CSL then we would be pleased to have the opportunity to prepare recommendations on an appropriate method of accounting for financial expenditure on the functions then undertaken. The Act amendments presently under consideration do not tackle this problem but represent a continuation of an *ad hoc* approach which will however recognize but not resolve, CSL's public health and other activities not particularly well encompassed by the current legislation.

The Reports and Recommendations of the National Immunization Work Groups submitted to The Office of the Assistant Secretary for Health of the U.S.A. Government highlights the extent to which that country has thought about the importance of ensuring, *inter alia*, production and supply of vaccines. Attached are two segments of the reports. In considering the vast amounts of public money which the U.S.A. has expended through numerous agencies in the human vaccine field alone one must keep well forward in mind that CSL operates in a much wider field of human and veterinary health.

REPORTS AND RECOMMENDATIONS

OF THE

NATIONAL IMMUNIZATION WORK GROUPS

MARCH 15, 1977

Submitted
to
The Office of the Assistant Secretary for Health

Under
Contract No. 263-77-s-0076

JRB Associates, Inc.
8400 Westpark Drive
McLean, Virginia

I. THE PROBLEM

1. The Threat to Production and Supply

Demand for vaccines* is of two general sorts: some are required for a substantial segment of the population (general use vaccines) while others are needed only for limited populations (special use vaccines). Private production of general use vaccines has been traditionally accomplished by industry in response to a significant demand which makes investment reasonable on a free market basis. Governmental support is needed, however, for development and production of limited use vaccines which are inherently unprofitable and cannot be expected to be undertaken spontaneously by private industry.

The availability of adequate supplies of general use vaccines and special use vaccines for both public and military use, while not yet an acute problem, is certainly a potential problem for several reasons:

- While the potential capability of American industry to supply vaccine requirements is unarguable, there has been a steady attrition of specific pharmaceutical manufacturers from the entire field of biologics, as shown in Table 1. A relatively low profit margin, high production risks, increasing costs of research and development, difficulties in clinical testing, and increasingly stringent governmental standards of safety and efficacy are all formidable constraints to private investment.

- Failure to solve the liability and informed consent problems and any marked change in the already delicate balance between the industry and the highly structured regulatory process in the direction of a more adversary position could drive the remaining few firms from a commitment to vaccine production under the present system.

*"Vaccines" will include for the purpose of this report specific antisera ("serums").

Table 1. Major Firms Producing Specified Vaccines (1977)

TYPE OF VACCINE	DURING PAST 15 YEARS	CURRENTLY**
Live poliovirus vaccine	Lederle Wyeth Pfizer, Ltd.	Lederle
Live measles virus vaccine	Merck Dow Lilly Charles-Pfizer Philips-Roxane Lederle	Merck
Live rubella virus vaccine	Merck Philips-Roxane Recherche et Industrie Therapeutiques S.A. (R.I.T.) Dow	Merck
Live mumps virus vaccine	Merck Dow	Merck
Yellow fever vaccine	Merrell-National	Merrell-National
Inactivated rabies virus vaccine (duck embryo type)	Lilly	Lilly
Inactivated influenza virus vaccine	Merck Merrell-National Parke, Davis Wyeth Lilly Lederle Philips-Duphar Dow	Merck Merrell-National Parke, Davis Wyeth
Diphtheria toxoid* Tetanus toxoid Pertussis vaccine (commonly combined as DPT)	Parke, Davis Wyeth Merrell-National Lilly Lederle Dow Merck	Parke, Davis Wyeth Merrell-National Lilly Lederle
Meningococcal Group A and C vaccine	Merck Merrell-National	Merck Merrell-National

*List does not include three state health laboratories producing DPT for intrastate distribution.
**Does not include firms still holding licenses but no longer in active production for distribution in the United States.

- A firm's desertion of the field of biologics manufacture means dissolution of an expert staff and removal of commitment to further activity in the biologics field. For example, whereas numerous firms of diverse size were recently committed to manufacturing viral vaccines and serums, there has been a notable attrition of pharmaceutical houses from the manufacture of viral vaccines, as shown in Table 1.

- Supply of vaccines involve both their availability and distribution on the one hand, and their acceptance by the public and the health professionals on the other. The problem of acceptance of vaccine by both the public and the health professionals has not been dealt with adequately and this issue will be addressed separately later in this report.

Thus, unless the above problems are dealt with effectively, production and supply as well as research and development of present and potential vaccines and serums could be threatened, despite the absence of a current crisis.

2. The Need for Planning and Coordination

No single agency in government has the authority to formulate, implement, or evaluate immunization policy. Many components of the federal government have various levels of responsibility. Among these are the Center for Disease Control (CDC), the Bureau of Biologics (BOB) of the Food and Drug Administration, the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health, and the Department of Defense (DOD). The interrelationships between these agencies have developed on an ad hoc basis and are heavily dependent upon good interpersonal relations among the leaders of these agencies.

No structured forum exists to debate policy questions and to assure input from many nonfederal groups that have legitimate concerns. Examples of such groups are professional organizations, state and local health departments, special interest consumer groups and voluntary health agencies, the pharmaceutical industry, the media, and the insurance carriers.

3. Specific Needs

Specific areas in which a need for planning and coordination are suggested include:

A. Special Use Vaccines and Serums

(1) Decisions regarding the magnitude, duration, and priority of production and supply of these vaccines and serums must be made by the appropriate agency.

(2) The conditions for contract, licensure, production, and stockpiling of these vaccines and serums must be determined.

(3) Alternatives for production must be assured if industrial firms discontinue manufacturing vaccines.

(4) Priorities must be established when competition develops for specific resources among these vaccines and serums (e.g., fertilized eggs, technical personnel animals) and between them and the general use vaccines.

B. General Use Vaccines and Serums

(1) Production plans must be adjusted to changing recommendations for usage.

(2) Unpredictable variations in large batch production by a single-source producer may result in delays in release of products. Stockpiling would keep supply from being threatened until correction of production problems could be made.

(3) Unexpected new regulations may be required by new scientific information and may result in increased cost of production.

(4) Strict regulations tend to generate pressure to maintain the status quo. To implement advances in science, a more flexible mechanism is required for innovation and improvement of vaccines.

C. Clinical Trials. The area of vaccine development is the most threatened of any clinical research field by the problems of liability, informed consent, and other proposed limitations on the use of human subjects in nontherapeutic research. None of the present agencies is clearly responsible for addressing problems which may arise over issues

such as on whom clinical trials should be done, by whom, with what budget, and with what priority.

D. Research and Development. It is particularly difficult to improve vaccines that have already met rigid standards of efficacy but may not be optimal. Past relative success may actually make further progress difficult.

II. LIMITATIONS OF THE EXISTING SYSTEM

1. Obstacles to Functions of Existing Agencies

The current system, although a loose one, has so far functioned remarkably well but the agencies which comprise it are encountering mounting obstacles, including underfunding, to their continued effective performance discussed above.

2. Delicate Balance of Industry and Government

The system is dependent upon mutual respect and delicate interactions between government and industry. Vagaries in the quality of leadership might seriously unbalance a system that requires competence and stability.

3. Under-representation of Industry

Industry is under tight constraints in its communication both among companies and with the government and feels the lack of opportunity to participate adequately in discussions of vaccine needs, problems of production, and research and development.

4. Interface with Social and Economic Issues and Forces

While the present system works well for decisions related to biomedical expertise, other concerned groups in the realm of law, economics, insurance, social issues, public education, and the general public are all under-represented.

The impact of vaccine policy has not been systematically assessed as it pertains to major social and economic issues such as informed consent, liability, the changing health care system, and the practice of medicine. There is no systematic approach by any one agency to interface with these forces.

The delivery of vaccines is dependent not only on its mechanics of distribution, but upon the provision of health care by health professionals in the public and private sector whose awareness, understanding, and acceptance of vaccination policy is critical to its implementation.

Finally, without adequate public acceptance and involvement, all issues of implementation of vaccination will be irrelevant. The present system lacks the means for adequately implementing public and professional acceptance as complementary requirements for production and supply.

5. Public Education and Publicity

The high visibility afforded immunization and the often controversial nature of the subject matter which must be handled by the communications media underscore the need for public education and the need for expert public relations concerning this emotionally charged subject. There are two special features of immunization policy and decision making which create particular difficulties in achieving optimal levels of public awareness and education. On the one hand, the factors influencing vaccine decisions are often highly technical and lose their impact in a nontechnical context. A different kind of communication difficulty arises from the fact that all immunization decisions are founded on an assessment of benefit versus risk--both of which are always finite--and the public is generally unfamiliar with benefit/risk ways of thinking about their individual health concerns. It will require a coherent coordinated response from a coalition of socially responsible forces with high credibility to offset public insecurity and confusion about immunization.

III. PROPOSED SOLUTIONS

1. Preservation of Effective Components of Present System

It is essential to preserve the effective components of the present system, particularly the excellent function of its governmental, advisory, and industrial components. Their current effectiveness stems mostly from the high concentration of expertise represented within each of these components. Any proposed solution to the broad newly perceived social and economic policies should not dilute or distort this expertise. However, the areas needing new approaches include liability, informed consent, public and professional acceptance, and clinical research.

2. Proposed National Immunization Commission

The unanimous concensus of this work group was for the establishment of a National Immunization Commission reporting to the Secretary DHEW and to the Congress.

A. *Functions*

(1) Augmentation of Communication. A leading function of the proposed Commission would be communication with the public, the media, the professions, industry, the Congress, government agencies, and the Department of Defense.

(2) Policy Development, Coordination, and Review. Policy development by the Commission should be distinct from expert recommendations by such advisory committees as the Advisory Committee for Immunization Practices and Bureau of Biologics panels except where such are in conflict. Implementation of policy should be placed in the context of national priorities and resources based on perceived national needs.

Anticipatory vigilance in interpreting the impact of current events upon vaccine usage and development would be a major policy role for the Commission. As major social and economic currents threaten stable vaccine production and supply, sufficient lead time could be assured to identify and activate alternatives. Coordinative functions would include the facilitation of the use of a new vaccine with activation and cooperation of public and private segments of the community involved. Also, its coordinating role would come into play

when one or more agencies faced apparent conflict of interest in certain aspects of production and supply or of research and development.

(3) The Commission should ensure that contracts be funded when necessary for vaccine production. This would be needed routinely in the case of special use vaccines. In addition, the Commission should recommend contracts for general use vaccines when free market conditions do not assure their continued availability and should, if necessary, provide for stockpiling.

(4) The Commission should help to establish priorities for vaccine research and development which could be implemented through various health agencies inside government and in academic or industrial sectors.

(5) The Commission should provide a forum for wide discussion and debate on vaccine issues to assure full participation from all diverse segments of society.

(6) The Commission should serve as a review or appeal group when conflict of opinion exists for the implementation of expert recommendations.

B. Structure

(1) The Commission should be as small as can be designed to present a broad coalition of interests. Additional expertise and representation can be obtained by consultation and ex officio representation.

(2) The membership should include one or more representatives from the following categories:

Academia

State and local health departments

Industry

Insurance/law

Physicians involved in patient care

Government-industrial relations expert

Members of the general public

The public media

Ex officio representation from the following agencies: NIH/NIAID, BOB/FDA, CDC, and DOD.

C. Operations

(1) Members should be part time except for an executive secretary and a small staff.

(2) The chairman should be chosen and appointed by the Secretary DHEW.

(3) The chairman should have technical biomedical expertise.

(4) The Commission should have defined powers, particularly for assessment of contract needs and priorities.

(5) The Commission should consider that present sentiment is strongly in favor of preserving the efficiency, expertise, and cost control advantages of private industry. To accomplish this objective, the Commission should be thoroughly familiar with the problems and exigencies of commercial vaccine research, development, production, marketing, and distribution. It should engage in long-term planning to assure the continued viability of these functions within private industry with special emphasis on new, rare, and improved vaccines. Such planning should specifically include contract support for research, development, and production of important vaccines. In any case, the Commission must be responsible for ensuring the production and supply of the nation's needed vaccines, including the obligation to consider in depth the pros and cons of a national production facility should it appear that private production sources may disappear.

D. Implementation

(1) Legality. The legal status of the Commission should be established by congressional action.

(2) Authority. The Commission should report both to the Secretary DHEW and to appropriate congressional committees.

(3) Budget. The Commission should advise the Secretary DHEW on comprehensive budgetary needs for immunization. In particular, the Commission should assist in obtaining earmarked funds that would ensure the following activities by the Secretary DHEW:

(a) Contracting for stockpiling and distribution of vaccines whenever such action is necessary to protect production and supply

(b) Contracting for the further development and improvement of existing vaccines

(c) Promoting a program of immunization promotion and awareness

(d) Assistance in approaches to the resolution of liability issues

(e) Assistance in approaches to the resolution of informed consent

(f) Setting recommended funding levels for the Vaccine Assistance Act.

From Transcript of Proceedings, National Immunization Conference
November 14, 1976, William S. Jordan, M.D.

THE ROLE OF GOVERNMENT IN VACCINE RESEARCH AND DEVELOPMENT

Immunization is one of the most effective preventive measures employed on behalf of the health of the public. As such, it has long been recognized as an essential component of medical practice and as an appropriate concern of government health agencies at local, state, and national levels. These agencies share responsibility for three major aspects of immunization: (1) availability and administration of existing vaccines; (2) improvement in the safety and efficacy of existing vaccines; (3) development of new vaccines. Federal effort and expenditure on behalf of the second and third of these responsibilities, particularly new vaccines, is the subject of this presentation.

There are many precursors to successful immunization (see Table 1). The first step is identification of a clinical entity which can be segregated from similar syndromes by specific diagnostic procedures. These tests usually depend on isolation of the etiologic agent and the measurement of antibodies induced by it. With identification of all infections, from those which are subclinical to those which are lethal, the full clinical spectrum can be described, and the risk to the individual assessed.

The disease in question may prove to be important for any of several reasons. If the incidence is low but the case fatality high, it may be necessary to immunize hundreds of people to prevent a single death. If the incidence is high but the case fatality low, immunization of the same number of individuals would prevent the same number of deaths. The disease may rarely be fatal, yet result in symptoms which are sufficiently troublesome to cause significant time lost from school or work. In this case, prevention is directed at reducing transient misery and the socioeconomic impact of morbidity.

The next step toward prevention and, indeed, toward rational treatment is an understanding of the pathological physiology of the particular infectious process (see Table 2). How and where does the bacterium, virus or other pathogenic organism inflict its damage? What host defenses lead to recovery? Is recovery followed by immunity? If so, how long does it last? These are obvious questions, but they are questions to which investigators must seek answers before embarking in search of a vaccine. It is just possible that other preventive measures may be more effective and/or offer prospects of earlier control.

To learn what has been outlined about the host response, it is necessary to identify and to characterize the causative agent (see Table 3). If the

pathogen can be grown in the laboratory or in readily available small animals, prospects for the development of diagnostic reagents and elucidation of pathogenesis are bright. If cultivation is impossible and infection of animals limited to costly or rare species--as, for example, with the leprosy bacillus, treponema pallidum, and the hepatitus virus--vaccine prospects are greatly diminished.

Although growth of the agent is a necessary step--except perhaps in the case of hepatitis B virus--success at this point is only the beginning. The nature of the disease, as with superficial viral infection of the respiratory tract, may forecast limitations of systemic immunization. The existence of multiple serotypes, as in the case of rhinoviruses, or of the capacity to undergo antigenic variation, as in the case of influenza virus, compounds the difficulty.

The next step is selection of the type of vaccine that might be developed, given current knowledge of the disease, the nature of the pathogen, and the existing technology (see Table 4). Time does not permit an elaboration of the many other steps between this choice and production of the first pilot lots of vaccine. Sometimes this production is undertaken in the investigator's own government or university laboratory; sometimes it is undertaken by an industrial laboratory. If commercial prospects are limited, this industrial participation is usually supported by federal funds.

When the absence of extraneous agents has been assured and protocol approval granted by appropriate review committees, the vaccine is tested in a small number of volunteers (see Table 5). Success at this step is followed by more limited testing, and then mass production. Those familiar with industrial processes are acutely aware that the transition from experimental lots to large-scale manufacture is not always an easy one. Understandably, such an undertaking requires either good marketing prospects or a cost-plus subsidy.

Once the vaccine is available for administration to the population for which it was developed, large-scale field trials are designed to test its acceptability, safety and efficacy. Should it live up to the dreams and hopes of its proponents, the new vaccine will find its place in practice, providing both the medical profession and the public are educated as to its benefits and limitations.

A number of federal agencies play interrelated roles in the steps from disease recognition to vaccine utilization (see Table 6). The National Institute of Allergy and Infectious Diseases funds most of the basic research essential to the early steps. Other agencies also undertake basic studies in their own laboratories or fund such studies in extramural laboratories. In the case of the Department of Defense, such studies now are restricted to problems peculiar to the military.

The NIAID also funds the greatest proportion of the developmental effort, including volunteer studies and early field trials. Here again, the other agencies undertake clinical trials of particular relevance to their

responsibilities. Before a vaccine can be used in such trials, it is approved for limited testing by the Bureau of Biologics, the regulatory agency responsible for the safety and efficacy of licensed vaccines. In this connection, it is noted that six panels appointed by the Commissioner of the Food and Drug Administration will soon complete extensive reviews of all currently licensed biologic products.

Recommendations for the use of licensed vaccines are developed and periodically revised by a Committee on Immunization Practices, chaired by the Director of the Center for Disease Control (see Table 7). The CDC coordinates the activities of state health departments in the use of federal funds for immunization programs. This is the fourth year that it has joined with various professional groups, including the American Medical Association, to make October "immunization action month." Surveillance by CDC identifies gaps in the utilization of existing vaccines as well as indicating the potential utility of new vaccines.

The Department of Defense is required to protect military populations in special environments ranging from recruit camp to jungle. Scientists in military laboratories have a long tradition of research on vaccines. Most recently, Army research was largely responsible for the development of meningococcal types A and C polysaccharide vaccines. The availability of live enteric adenovirus vaccines reflects fruitful collaboration between the armed forces, investigators at NIAID, and the pharmaceutical industry. Its use has reduced the incidence of acute respiratory disease at basic combat training posts. Of equal importance, epidemiological studies in civilian groups indicated that the types in the vaccine were not appropriate for the control of adenovirus infections in the general population.

These examples and the background material considered to this point are familiar to many in this audience. Hopefully, the review will provide a useful introduction to a summary of recent and current federal investment in vaccine research and development. The data to be presented were assembled rather hurriedly through the kindness of officials in the various agencies, and should be considered approximations of the number of vaccines under study and of the total dollars expended.

As exemplified by hepatitis B, it is impossible to predict where basic research will lead, so the classification of basic research as "vaccine related" is arbitrary (see Table 8). With this caveat, NIAID grants funded in the last 12 years were so classified, indicating that nearly $45 million were invested in early steps to immunization.

At NIAID, intramural and extramural research on bacterial vaccines totaled $15 million between 1965 and 1975, and $2 million this year (see Table 9).

In search of vaccines for 11 viral deseases, NIAID spent $32 million. About equal amounts were spent on rhinoviruses and rubella (see Table 10). Vaccines for the latter became a reality and support was discontinued. Support was also discontinued for rhinoviruses as increasing knowledge of multiple serotypes dimmed the prospects of control through immunization.

Research continues on Rocky Mountain Spotted Fever, Q-Fever, and Mycoplasma pneumoniae vaccines (see Table 11). Applied research expenditures by NIAID since 1965 totaled over $51 million and is now approximately $9.5 million annually. It is worth noting that it now takes $1.75 to buy what one dollar bought in 1965.

Research supported by the Army is summarized on Tables 12-14. As previously noted, we are indebted to Army scientists for Groups A and C meningococcal vaccines; Groups B and Y remain a problem.

Fifteen viruses or viral families are being studied by the Army, with an emphasis on encephalitis viruses (see Table 13).

The Army, too, is interested in rickettsial vaccines (see Table 14). An improved Rocky Mountain Spotted Fever vaccine progressed to limited clinical testing in volunteers this year, but then all studies had to be terminated 1 October 1976 because the House-Senate Appropriations Committee--in rather rigid interpretation of the Mansfield Amendment--reduced monies in this specific area. Pertinent to this Conference is the question of who will continue development of this promising vaccine. Despite such recent restrictions, the expenditure totals indicate that the Army has funded vaccine research and development in an amount exceeding 50% of the NIAID support.

The Navy's portfolio is summarized on Table 15.

The Navy is continuing to support work on 7 of the 14 agents of interest to it during recent years (see Table 16).

The last of the expenditures to be listed are those of the Bureau of Biologics (see Table 17). This year it will spend two million on product related research, such as test improvement and clinical trials, and $5.4 million on its regulatory mission. At present it is awaiting results of trials of 41 experimental vaccines authorized for testing in humans.

Adding all figures from $45 million for basic research to $23 million for applied research and licensing, yields a total investment for the current year of $68 million (see Table 18). Is this too much or too little? Is the public getting its money's worth? Should this extensive effort be better coordinated? If so, how will this be done, and who will set priorities? Those to whom this task is assigned will need better data on the incidence, medical and socio-economic impact of infectious diseases.

Another issue is the proper role of industry in this effort (see Table 19). How much of its profit is industry prepared to invest in vaccine R&D? Should development continue on a vaccine by vaccine contract basis between government and industry, or should a national production facility be established to meet the public need? How are public and private interests best served as we move from government supported R&D to industrial licensing and production?

Finally, there is a need for the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, or its successor, to address the issue of a National Volunteer Policy. The public must understand and support the necessity for testing experimental vaccines in human subjects, and be willing to provide appropriate protection for both the volunteer and the investigator.

There are many steps to successful immunization. I share your hope that this conference will hasten our progress toward this goal.

William S. Jordan, Jr., M.D.
Director
Microbiology and Infectious Diseases Program
National Institute of Allergy
and Infectious Diseases
National Institutes of Health
Bethesda, Maryland

Table 8. DHEW-NIH-NIAID
Basic Research--Vaccine Related

Category	Period	Expenditure (000's)
Bacterial	1967-1976	$16,828
Fungal	1971-1976	449
Viral	1965-1976	24,454
Parasitic	1965-1976	2,884
Total		$44,615

Table 9. DHEW-NIH-NIAID
Applied Research--Bacterial Vaccines

Agent or Disease	Expenditure (000's) 1965-1975	1976
Cholera	$ 2,749	$ 349
Gonorrhea	371	96
Meningitis (Hemophilus, Neisseria)	1,610	453
Pertussis	1,400	320
Pneumococcus	6,380	621
Streptococcus	681	11
Syphilis	573	152
Tuberculosis	1,306	32
TOTAL	$15,070	$2,034

Table 10. DHEW-NIH-NIAID
Applied Research--Viral Vaccines

Agent or Disease	Expenditure (000's) 1965-1975	1976
Adenovirus	$ 6,137	$ 84
Colorado Tick Fever	200	--
Hepatitis	5,235	2,190
Influenza	6,628	3,600
Gastroenteritis	500	100
Parainfluenza	1,770	311
Rabies	899	56
Respiratory Syncytial Virus	1,256	720
Rhinoviruses	4,334	--
Rubella	4,361	--
Smallpox	762	--
TOTAL	$32,082	$7,061

Table 11. DHEW-NIH-NIAID
Applied Research--Other Infectious Disease Vaccines

Agent or Disease	Expenditure (000's) 1965-1975	1976
Rickettsia		
Rocky Mountain Spotted Fever	$ 300	$ 80
Q-Fever	750	160
Mycoplasma pneumoniae	2,868	196
Total	$ 3,918	$ 436
GRAND TOTAL	$51,070	$9,531

Table 12. DOD-Army
Bacterial Vaccines

Agent or Disease	Expenditure (000's) 1965-1975	1976
Meningococcal Meningitis	$ 9,000	$ NG*
Plague	3,117	150
Shigella	NG	250
Staphylococcus (Enterotoxin)	1,490	150
Tularemia	3,340	--
Typhoid	NG	250
Total	$16,947	$ 800

*Not given.

Table 13. DOD-Army
Viral Vaccines

Agent or Disease	Expenditure (000's) 1965-1975	1976
Adenovirus	$ 4,300	$ 600
Bolivian Hemorrhagic Fever	55	150
California Encephalomyelitis	25	5
Chikungunya	990	200
Dengue	1,500	1,193
Eastern Equine Encephalitis	1,209	290
Influenza	--	550
Japanese Encephalitis	35	5
Langat	35	5
O'Nyong-nyong	35	5
Rift Valley Fever	1,628	50
Sindbis	35	5
St. Louis Encephalitis	25	5
Venezuelan Equine Encephalitis	5,597	250
Western Equine Encephalitis	787	255
Total	$16,256	$3,568

Table 14. DOD-Army
Other Infectious Disease Vaccines

Agent or Disease	Expenditures (000's) 1965-1975	1976
Rickettsia		
Rocky Mountain Spotted Fever	$ 654	$ 450
Q-Fever	2,457	150
Typhus	350	--
Trypanosomiasis	500	200
Total	$ 3,961	$ 800
GRAND TOTAL	$36,964	$5,168

Table 15. DOD-Navy

Agent or Disease	1965-1975	1976
Bacterial		
Meningitis (Neisseria)	X	X
Syphilis	X	X
Plague	X	
Fungal		
Coccidioidomycosis	X	
Mycoplasmal		
Mycoplasma Pneumoniae	X	
Rickettsial		
Epidemic Typhus	X	X
Scrub Typhus	X	X

Table 16. DOD-Navy (continued)

Agent or Disease	1965-1975	1976
Viral		
Adenovirus	X	
Hepatitis	X	X
Japanese Encephalitis	X	
Small Pox	X	
Parasitic		
Chagas Disease	X	
Malaria	X	X
Schistosomiasis	X	X
Total Expenditures (000's)	$4,660	$1,255

Table 17. DHEW-FDA-BOB
FY 1977

Function	Expenditure (000's)
Product Related Research	$2,100
Control and Regulation	5,400
Total	$7,500

Table 18. Issues Relative to National Policy

Coordination of Federal Programs

- Selection of target diseases
  - For general population
  - For special populations
- Establishment of priorities
  - On basis of need--desirability
  - On basis of technology--feasibility
  - On basis of anticipated cost effectiveness

Table 19. Issues Relative to National Policy (continued)

Need for a National Production Facility

- For developmental research.
- To improve existing vaccines
- To produce pilot lots of new vaccines
- To manufacture selected vaccines
  - For special groups without commercial market
  - As "standby" reserve for all biologics

Need for a National Volunteer Policy

- To protect human rights and safety
- To indemnify for unsuspected injury
- To facilitate testing of experimental vaccines
- To limit harassment of investigators

APPENDIX No.7.

E740-3

Experimental Officer

EXPERIMENTAL OFFICERS—JOINT POLICY STATEMENT BY PUBLIC SERVICE BOARD, DEPARTMENT OF SUPPLY, COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANIZATION and AUSTRALIAN ATOMIC ENERGY COMMISSION

Introduction

1. The Respondents after full consideration of the staffing and management needs of their respective research establishments and of the nature of the work required to be performed have concluded that it is essential to maintain an organization structure based on the use of research groups which include three classes of individuals, viz. Research Officers, Experimental Officers and Technical Grades.

2. The functions of each of these classes are interdependent and their retention as functional entities is essential to the effective and efficient conduct of such research establishments.

3. The reviews have clearly established that the Research Officer and Experimental Officer groups constitute coherent classes with separate specific functions in the research field; they are distinguishable one from the other and from normal professional groups by the nature of their work, their special characteristics, and the environment in which they work.

4. In these circumstances it is the considered view of the Respondents that the determination of pay rates for each necessary organization level can validly only be approached on the basis of the necessary qualifications, individual merit and ability, work requirements and responsibility of each of these classes as a functional entity.

5. Put another way it is not possible or practicable to consider as a separate entity a group of Research Officers or Experimental Officers qualified in the one professional discipline. Rather it is necessary to consider, inter alia, the whole spectrum of professional qualifications necessarily required in each of these functional classes. Conceptually this involves a necessary departure from normal practice of considering "trade" or "one profession" groups, but in the special circumstances of employment of these classes it is the logical and inevitable course to be followed. Basically, it involves a furthering of the approach followed by Mr. Arbitrator Casteau in Determination Nos. 51 and 52 of 1954 having regard to all the circumstances now existing.

Research Groups

6. The purpose of a research group, in the establishment of the Respondents, is to carry out systematic scientific investigation and experimentation directed towards making new discoveries; originating, proving or disproving scientific theories; finding applications of the theories or discoveries to new or existing devices or processes; or simply towards the advancement of human knowledge.

7. The spectrum of scientific activities of the Respondents extends from the pursuit of abstract fundamental truth to the ad hoc investigation of industrial problems. Through the whole spectrum between these two extremes there is a common range of activities, the principal stages of which are:

   (a) Recognition of the existence and nature of a problem, or of a need for new knowledge in a particular area.

   (b) Interpretation and analysis of scientific requirements in order to design experiments or formulate theoretical analysis.

   (c) Specification and design of experiments or planning of theoretical analysis.

   (d) Setting up the equipment, getting it to function satisfactorily and calibrating the instrumentation; programming of work.

   (e) Carrying out the experimental and/or theoretical programme of work.

   (f) Analysis of results and definition of further research, or its application.

   (g) Reporting and publication.

8. Participating in this work are the functional classes which go to make up the personnel of a research group, and the necessary allied or ancillary services which are further described in Paragraph 21 et seq.

Research Group and Other Personnel

Research Officers

9. The function of the Research Officer is to produce original ideas, to plan the broad lines of attack on the problem in hand, and to assume overall scientific responsibility for it. He is the initiating, directing, inventive, and interpretive brain of the research group. He also directs and participates in the experimental and theoretical work. For appointment he must possess academic qualifications of a high order (at least a 1st or 2nd Class Honours Degree or, in A.A.E.C. and C.S.I.R.O., now normally a Ph.D.) and he must then prove his ability to carry out research. In his work he will be concerned with the establishment of new principles and their application to new or existing processes or devices, rather than with the solving of day to day professional problems. This is a special distinguishing feature between this group and a normal professional group.

10. A good research man therefore will be characterised by intellectual integrity combined with the ability to think creatively and logically; considerable initiative and resourcefulness, pertinacity and high academic qualifications; the ability to think in terms of fundamentals rather than the application of known scientific principles; capacity and depth to assess the progress of experimentation and the possibilities of the difficult and often very devious routes necessary to reach their goals; the ability to fulfil the requirement of preparing the results of his research for publication. In this connection it must be emphasised that the reputation of an Establishment in the scientific world depends inter alia on the established reputation of individual staff members, it being generally recognised that in bearing the scientific responsibility for the research programme, they set the standards. In this instance the principle of anonymity does not apply.

11. Research officers constitute a composite functional group, the preservation of which on both scientific and management grounds is essential to the efficient and effective operation of research establishments.

12. The functions listed in paragraph 8 above constitute the broad role of the Research Officer, but he is particularly concerned with items (a), (b), (e), (f) and (g).

Experimental Officers

(a) General Qualifications and Broad Functions

13. The function of the Experimental Officer Class is broadly to collaborate with the Research Officer, to assist with detailed planning, to provide professional help in the experimental and theoretical work, and to carry the work on in its more practical aspects. He is usually responsible for work in which, although it is of an original nature, the scientific principles have been broadly defined by the Research Officer. The Experimental Officer must possess a recognised degree or diploma in an appropriate field and potential for, or proven ability in, the type of work described in paragraph 15 below.

14. Functions (c), (d) and (e) in paragraph 7 above are the main responsibility of the Experimental Officer although he will take part in (f) and (g) under the supervision of the Research Officer.

(b) Definition

15. Typically the Experimental Officer is required to apply scientific method to —
    (i) the conception and bringing into being of new experimental equipment and methods essential to advance the programme of the group, and
    (ii) the carrying out of tests or experiments to try out new ideas or to obtain new data.

(c) General Features of Duties

16. Under the direction of research staff, an Experimental Officer —
    (i) Assumes responsibility for the carrying out of some part of an experimental programme. This includes —
        (a) Selection, testing and adaptation of existing experimental techniques (theoretical or practical) and establishment of new techniques where necessary.
        (b) Designing, specifying and testing experimental equipment.
        (c) Liaison with design and service groups.
        (d) Carrying out experiments to evaluate new ideas or to provide new data.
        (e) From results obtained, recognising inadequacies of equipment or technique, and modifying accordingly.
        (f) Collation of results and assistance to Research Officer in evaluation and presentation.
    (ii) Assists in scientific or patent publication and may publish independently.
    (iii) Instructs and trains professional and/or technical staff and supervises their work as may be required.
    (iv) May be required to use specialised knowledge gained in his experimental work to assist in or advise on its external application.
    (v) May be permitted to follow independent lines of enquiry into research problems, either as part of training in research, or as an incidental to normal experimental functions.

(d) Characteristics

17. The Experimental Officer carries out his duties in a research situation and the varying work which he performs is such that it is usually necessary for him to go in direction and at times in depth beyond the normal limits of the discipline in which he was originally trained. This may involve him, on the one hand, in entering a completely different area of science, e.g. the physicist becoming involved in biology, and on the other hand in developing a specialised part of his training to an unusual extent.

    There is also a necessary lack of stability of function as he follows the trend of the experimental work in which he is engaged. It is thus not possible to define the work of an Experimental Officer as lying permanently within the confines of any accepted academic discipline, and in some cases he may operate in a borderline area for which there is no accepted description. For these reasons it is impossible to limit the definition of the duties of an Experimental Officer wholly and continuously to any one accepted academic discipline.

    He performs work of a high standard and responsible nature in this wider scientific area under the direction and guidance of more senior officers. As he gains in experience in the base grade the amount of direction normally lessens, and as he is able to accept more independence in discharging his functions and responsibilities, he may proceed by promotion to the higher grades.

(e) The Experimental Officer Class as a Functional Entity

18. While the duties of Experimental Officers require a basic training in one or more of the specific disciplines, e.g. Chemistry, Biology, Engineering, etc., it has been concluded by the Respondents, because —
    (i) research problems do not recognise the boundaries of any one academic discipline;
    (ii) most experimental officer functions require a broader basis of knowledge and experience than is covered by any one specific discipline;
    (iii) experimental officers are expected to have and develop special aptitude for work of a novel and original nature;
    (iv) experimental officers work as a part of a research team under the guidance of Research Officers;
    (v) of the frequent impossibility of making distinctions between the disciplines in experimental work (see paragraph 17);
    (vi) of the necessity for such a general yet descriptive designation in the flexible utilisation of staff and in recruitment; and
    (vii) of the clear functional distinctions between this class and other occupations,

    that the efficient conduct of a research establishment and the attainment of its objectives requires the flexibility deriving from the retention of the single Experimental Officer designation.

19. In this sense there is a natural relationship between the Research Officer and Experimental Officer groups even though in terms of requirement, functions and responsibilities, one is quite distinct from the other.

Technical Grades

20. The Technical Grades provide skilled assistance in the experimental programme. The occupants of such positions are not required to possess professional qualifications but must have relevant aptitudes. Their backgrounds vary: persons with Intermediate or Leaving Certificate, trade qualifications or part completion of a University Degree or Technical College Diploma are found amongst those employed. Their duty is to provide assistance to professional officers in the development and setting up of experimental equipment and methods, and in the carrying out of tests or experiments: it will range from the carrying out of such tests and experiments under direction and/or supervision to assistance in the collection, collation and analysis of data.

Other Personnel

21. These persons or groups do not form a direct part of the research group. They have been referred to in paragraph 8 above as the allied or ancillary services. These services may include professional and technical staff. Most research organisations include units or groups, including uni-discipline professional officers, whose task it is to provide some form of service to the research group, e.g. the design in detail and manufacture of equipment to requirements laid down by the Research Officer and/or Experimental Officer. Such a unit or group is normally also responsible for maintenance of, and installation of, services. Other services include library services, clerical and stores staff, etc.

Experimental Officer

Conclusion

22. All managerial considerations which led to the formation of the Experimental Officer class have been confirmed by experience. The retention of the designation is therefore administratively essential. Its nature is such that it should be considered for classification purposes as a distinct entity, and not as a collection of persons qualified in various disciplines.

October 1968

APPENDIX NO. 8

PLANNING FOR THE NATIONAL INTEREST

SABIN POLIOMYELITIS VACCINE

Production of Salk Poliomyelitis Vaccine at CSL ceased in the early 1960's and pilot batches only of the Sabin Vaccine were made at that time. In 1971, when CSL proposed to produce Sabin Poliomyelitis Vaccine and Rubella Vaccine, using human diploid cells, the correspondence which passed between the Department of Health and CSL suggested that there was no significant weight put on the national interest as a reason for CSL undertaking those activities. Whether the situation is different today is one of conjecture but there is evidence that continuity of supply of Sabin Poliomyelitis Vaccine is less than previously.

Because the physical facilities, technology and expertise are largely common to the production of a number of human vaccines from tissue culture a proposal to enter into manufacture in Australia for Sabin Poliomyelitis Vaccine could serve also the production of measles and rubella vaccine and lay a foundation for possible later manufacture of hepatitis vaccine.

In summary, capital costs additional to those in 1978/79 - 1980 Triennial Program which includes the relocation of the Cell Culture Laboratory and SPF Phase II, are estimated to be of the order of, say,

1.	Refurbishing of old polio area	$400,000
2.	Extensions to Quality Control	$100,000
3.	Up-grading of monkey holding facilities	$50,000
4.	Additional R & D equipment	$20,000
	TOTAL	$570,000

This list assumes the completion of SPF Phase I (imminent) and release of other animal breeding facilities for testing purposes; and as a consequence of the old polio area being allocated for polio vaccine manufacture the dispensing of sterile penicillin powders would have to be rescheduled to outside contractors. Finally there might be need for NBSL to provide a testing unit.

Although the initial capital expenditure involved in such a project is considerable, it should be pointed out that the capacity of the facility can be extended fairly readily, i.e. by increasing the number of runs, and one would have the technology to prepare other live attenuated human viral vaccines, e.g. measles and rubella. There would be several advantages both to CSL and to the nation in undertaking such a programme:

(i) independence from overseas sources of supply

(ii) the possibility of exporting these vaccines

(iii) the capacity to explore and introduce new technological advances in this area, e.g. coat protein vaccines for herpes viruses

(iv) provision of training facilities under the W.H.O. biomecical Research and Development programme for Asian and Pacific countries.

Other projects considered worthy of similar consideration are:

(a) The production of new bacterial vaccines, for example, meningococcal and pneumococcal purified polysaccharide vaccines.

(b) The investment of considerably more funds and personnel in developing a centre of excellence in blood fractions research. Although this is a stated CSL objective the limitation on growth of R & D has not permitted early development of this concept.

(b) The purification, fractionation and standardization of allergens peculiar to Australia.

COMMONWEALTH SERUM LABORATORIES ACT 1961-1973

TABLE OF PROVISIONS

17053/73—Recommended retail price 20c

Published 1 November 1974

TABLE OF PROVISIONS—*continued*

COMMONWEALTH SERUM LABORATORIES ACT 1961-1973*

An Act relating to the Commonwealth Serum Laboratories.

BE it enacted by the Queen's Most Excellent Majesty, the Senate, and the House of Representatives of the Commonwealth of Australia, as follows:—

PART I—PRELIMINARY

Short title.

1. This Act may be cited as the *Commonwealth Serum Laboratories Act* 1961-1973.*

Short title amended: No. 32, 1918, s. 2.

Commencement.

2. This Act shall come into operation on a date to be fixed by Proclamation.†

* * * * * * * *

Section 3 repealed by No. 216, 1973, s. 3 and Schedule 1.

Definitions.

4. In this Act, unless the contrary intention appears—

"Commissioner" means a member of the Commission and includes an Acting Commissioner;

"the Auditor-General" means the Auditor-General for the Commonwealth;

"the Chairman" means the Chairman of the Commission, and includes a Commissioner acting as Chairman under section eleven of this Act;

"the Commission" means the Commonwealth Serum Laboratories Commission established by this Act;

* The *Commonwealth Serum Laboratories Act* 1961-1973 comprises the *Commonwealth Serum Laboratories Act* 1961 as amended by the other Acts specified in the following table:

Act	Number and Year	Date of Assent	Date of Commencement
Commonwealth Serum Laboratories Act 1961	No. 38, 1961	2 June 1961	2 November 1961
Statute Law Revision (Decimal Currency) Act 1966	No. 93, 1966	29 October 1966	1 December 1966
Commonwealth Serum Laboratories Act 1970	No. 42, 1970	24 June 1970	24 June 1970
Statute Law Revision Act 1973-1974	No. 216, 1973	19 December 1973	31 December 1973
	No. 20, 1974	25 July 1974	31 December 1973

† The date fixed was 2 November 1961; *see Gazette* 1961, p. 3729.

"the Director" means the person appointed under section twenty-three of this Act to be the Director of the undertaking known as the Commonwealth Serum Laboratories, and includes a person for the time being performing the duties of the Director;

"the Vice-Chairman" means the Vice-Chairman of the Commission, and includes a Commissioner appointed under section eleven of this Act to act as Vice-Chairman.

Determinations by Minister to be in writing.

5. A determination by the Minister or the Treasurer for the purposes of this Act shall be by instrument in writing.

Application of Commonwealth Acts.

6. Subject to this Act, the Commission is bound by all laws of the Commonwealth except laws that do not bind the Crown in right of the Commonwealth.

PART II—THE COMMONWEALTH SERUM LABORATORIES COMMISSION

Division 1—Establishment and Constitution of the Commission

Establishment of Commission.

7. (1) There shall be a Commission by the name of the Commonwealth Serum Laboratories Commission.

(2) The Commission—

(a) is a body corporate, with perpetual succession;

(b) shall have a seal;

(c) has power to acquire, hold and dispose of real and personal property; and

(d) may sue and be sued in its corporate name.

(3) All courts, judges and persons acting judicially shall take judicial notice of the seal of the Commission affixed to a document and shall presume that it was duly affixed.

Constitution of Commission.

Sub-section (1) amended by No. 216, 1973, s. 3 and Schedule 1.

8. (1) The Commission shall consist of—

(a) four Commissioners, one of whom is a medical practitioner registered under a law of a State or a Territory providing for the registration of medical practitioners; and

(b) the Director.

(2) The Commissioners referred to in paragraph (a) of the last preceding sub-section shall be appointed by the Governor-General.

(3) The Governor-General shall appoint one of the Commissioners appointed by the Governor-General to be the Chairman, and another of the Commissioners appointed by the Governor-General to be the Vice-Chairman, of the Commission.

Substituted by No. 216, 1973, s. 3 and Schedule 1.

(4) A Commissioner appointed by the Governor-General shall, subject to this section, be appointed for a period of 4 years.

Sub-section (5) omitted by No. 216, 1973, s. 3 and Schedule 1.

* * * * * * * *

(6) In the event of a Commissioner appointed by the Governor-General ceasing to hold office before the termination of the period of his appointment, another Commissioner may be appointed in his place for the remainder of that period.

(7) A Commissioner appointed by the Governor-General is eligible for re-appointment.

(8) A person who—

(a) has a financial interest, whether direct or indirect, in a company that is engaged in, or a business enterprise that is carried on wholly or partly for the purpose of, the production or wholesale distribution of pharmaceutical products (including biological products of a kind used for therapeutic purposes); or

(b) is a director, officer or employee of a company that is so engaged,

shall not be appointed under this section as a Commissioner.

(9) The exercise or performance of the powers or functions of the Commission is not affected by reason only of there being a vacancy in the office of a Commissioner.

Oath or affirmation of allegiance.

9. A Commissioner shall, before entering on his duties or exercising any power under this Act, make, before a Justice of the Peace or a Commissioner for taking Affidavits, an oath or affirmation of allegiance in accordance with the form in the Schedule to the Constitution.

Leave of absence.

10. The Minister may grant leave of absence to a Commissioner appointed by the Governor-General upon such terms and conditions as to remuneration or otherwise as the Minister determines.

Absence of Commissioners.

11. (1) Where the Minister grants leave of absence under the last preceding section to a Commissioner appointed by the Governor-General, the Minister may appoint a person to act as a Commissioner during that absence, and a person so appointed has all the powers and functions of a Commissioner.

(2) Where the Minister grants leave of absence under the last preceding section to the Chairman of the Commission, the Vice-Chairman shall act as Chairman during the absence.

(3) Where the Minister grants leave of absence under the last preceding section to the Vice-Chairman of the Commission or where the Vice-Chairman is or will be acting as Chairman, the Commission may appoint a Commissioner (other than the Director or an Acting Commissioner) to act as Vice-Chairman during the absence, or during the period for which the Vice-Chairman acts as Chairman, as the case may be.

Remuneration and allowances.

12. A Commissioner appointed by the Governor-General shall be paid such remuneration (if any) and such allowances (if any) as the Governor-General determines.

Dismissal of Commissioner.

13. The Governor-General may terminate the appointment of a Commissioner appointed by the Governor-General for inability, inefficiency or misbehaviour.

Resignation of Commissioners.

14. A Commissioner appointed by the Governor-General or an Acting Commissioner may resign his office by writing under his hand addressed to the Governor-General or the Minister, as the case may be.

Vacation of office.

15. (1) If a Commissioner appointed by the Governor-General—

(a) becomes bankrupt, applies to take the benefit of any law for the relief of bankrupt or insolvent debtors, compounds with his creditors or makes an assignment of his remuneration for their benefit;

(b) becomes a person referred to in sub-section (8) of section eight of this Act;

(c) is absent, except on leave granted by the Minister, from three consecutive meetings of the Commission; or

(d) fails to comply with his obligations under the next succeeding sub-section,

the Governor-General shall, by notice published in the *Gazette*, declare that the office of the Commissioner is vacant, and, upon the publication of the notice, the office shall be deemed to be vacant.

(2) A Commissioner who is directly or indirectly interested in a contract made or proposed to be made by the Commission, otherwise than as a member, and in common with the other members, of an incorporated company consisting of not less than twenty-five persons, shall, as soon as possible after the relevant facts have come to his knowledge, disclose the nature of his interest at a meeting of the Commission.

(3) A disclosure under the last preceding sub-section shall be recorded in the minutes of the Commission, and the Commissioner—

(a) shall not take part after the disclosure in any deliberation or decision of the Commission with respect to that contract; and

(b) shall be disregarded for the purpose of constituting a quorum of the Commission for any such deliberation or decision.

Meetings of Commission.

16. (1) Subject to this section, the Chairman shall convene such meetings of the Commission as, in his opinion, are necessary for the efficient conduct of its affairs.

(2) The Chairman shall not permit a period exceeding five weeks to elapse between a meeting of the Commission and the next meeting of the Commission.

(3) The Chairman shall, on receipt of a written request signed by a Commissioner, convene a meeting of the Commission.

(4) The Minister may at any time convene a meeting of the Commission.

(5) The Chairman shall preside at all meetings of the Commission at which he is present.

(6) In the event of the absence of the Chairman from a meeting of the Commission, the Vice-Chairman shall preside at that meeting.

(7) In the event of the absence of both the Chairman and the Vice-Chairman from a meeting of the Commission, the Commissioners present shall appoint one of their number to preside at that meeting.

(8) At a meeting of the Commission, three Commissioners other than the Director constitute a quorum.

(9) A question arising at a meeting of the Commission shall be decided by a majority of the votes of the Commissioners present.

(10) The Commissioner presiding at a meeting of the Commission has a deliberative vote and, in the event of an equality of votes, also has a casting vote.

Delegation.

17. (1) The Commission may, either generally or in relation to a matter or class of matters and either in relation to the whole of the Commonwealth or to a State or part of the Commonwealth, by writing under its seal, delegate all or any of its powers under this Act (except this power of delegation).

(2) A power so delegated may be exercised by the delegate in accordance with the instrument of delegation.

(3) A delegation under this section is revocable at will and does not prevent the exercise of a power by the Commission.

Interpretation.

18. In this Division, a reference to a Commissioner appointed by the Governor-General does not include a reference to the Director.

Division 2—Functions, Powers and Duties of the Commission

Functions of Commission.

Amended by No. 42, 1970, s. 3; and No. 216, 1973, s. 3 and Schedule 1.

19. The functions of the Commission are—

(a) to produce and sell such biological products of a kind used for therapeutic purposes as are prescribed and to undertake research in connexion with any such prescribed product;

(aa) to import into Australia and sell to the Commonwealth any vaccine referred to in section nine B of the *National Health Act* 1953-1970;

(b) if the Minister so determines—

(i) to undertake research towards the production of biological products of a kind used for therapeutic purposes, being products other than products prescribed for the purpose of paragraph (a) of this section; and

(ii) to install or maintain plant or equipment capable of being used for the production of biological products, and to produce and hold stocks of biological products, for purposes other than the immediate sale of those products,

in accordance with the determination; and

(c) subject to the last three preceding paragraphs, to carry on the undertaking known as the Commonwealth Serum Laboratories,

and are exercisable for or in relation to any purpose of the Commonwealth including any of the following purposes:—

(d) the defence of the Commonwealth;

(e) external affairs;

(f) trade and commerce with other countries or among the States;

(g) the provision by the Commonwealth of pharmaceutical, sickness or hospital benefits or of medical or dental services;

(h) quarantine; and

(i) a Territory.

Powers of Commission.

Amended by No. 93, 1966, s. 3 and First Schedule.

20. (1) Subject to the next succeeding sub-section, the Commission has power to do all things necessary or convenient to be done for or in connexion with the performance of its functions.

(2) The Commission shall not, except with the approval of the Minister, purchase or dispose of capital assets for a consideration exceeding Forty thousand dollars.

Duties of Commission.

21. The Commission shall, in relation to biological products prescribed for the purpose of paragraph (a) of section nineteen of this Act, pursue a policy directed towards securing revenue from the sale of those products sufficient to meet all its expenditure (including expenditure in undertaking research) in connexion with those products that is properly chargeable to revenue, and to permit the payment to the Commonwealth of a reasonable return on the capital of the Commission.

Prices to be determined by Minister.

22. The Minister shall, after consulting the Commission, determine the prices to be paid for products supplied by the Commission directly to the Commonwealth or a State or to a person on behalf of the Commonwealth or a State.

Division 3—The Director

Director of Commonwealth Serum Laboratories.

23. (1) The Governor-General shall appoint a person to be the Director of the undertaking known as the Commonwealth Serum Laboratories.

(2) The Director shall be appointed for such period, not exceeding five years, as the Governor-General specifies in the instrument of appointment but is eligible for re-appointment.

(3) The Director shall hold office on such terms and conditions as the Governor-General determines.

(4) A person referred to in sub-section (8) of section eight of this Act shall not be appointed as the Director.

(5) The provisions of sub-section (1) of section fifteen of this Act apply to the Director and the office of the Director in like manner as they apply to a Commissioner referred to in that sub-section and the office of such a Commissioner.

(6) The Director shall be the chief executive officer of the Commission.

Division 4—Staff

Appointment of officers.

24. The Commission may appoint such officers as it thinks necessary for the purposes of this Act.

Requirements for appointment.

25. (1) Subject to the next succeeding sub-section, a person shall not be appointed as an officer of the Commission unless—

(a) he is a British subject;

(b) the Commission is satisfied as to his health and physical fitness; and

(c) he makes and subscribes, before a Justice of the peace or a Commissioner for taking Affidavits, an oath or affirmation of allegiance in accordance with the form in the Schedule to the Constitution.

(2) The Commission may appoint, to such positions or to positions of such classes as are approved by the Minister, persons who do not comply with all the provisions of the last preceding sub-section.

Terms and conditions of employment.

26. (1) Subject to this section, the terms and conditions of employment of officers appointed by the Commission shall be such as are determined by the Commission.

Amended by No. 93, 1956, s. 3 and First Schedule.

(2) The Commission shall not, except with the approval of the Minister, determine the salary of a position at a rate exceeding Five thousand dollars per annum.

(3) Before giving or refusing his approval for the purposes of the last preceding sub-section, the Minister shall consult the Public Service Board.

Amended by No. 216, 1973, s. 3 and Schedule 1.

(4) Where a Commissioner, the Director or an officer appointed in pursuance of this Act was, immediately before his appointment, an officer of the Public Service of the Commonwealth—

(a) he retains his existing and accruing rights; and

(b) for the purpose of determining those rights, his service as a Commissioner, as the Director or as an officer of the Commission shall be taken into account as if it were service in the Public Service of the Commonwealth.

Temporary and casual employees.

27. The Commission may employ such temporary or casual employees as it thinks fit, on such terms and conditions as the Commission determines.

Public Service Arbitration Act not to apply.

28. The *Public Service Arbitration Act* 1920-1960 does not apply in relation to the employment of officers or employees of the Commission.

Preservation of certain awards.

29. Nothing in this Act prevents the making of an industrial award order, determination or agreement under any Act (other than the *Public Service Arbitration Act* 1920-1960) in relation to persons appointed or employed under this Act or affects the operation of any such award, order, determination or agreement in relation to persons so appointed or employed.

Section 30 repealed by No. 216, 1973, s. 3 and Schedule 1, as amended by No. 20, 1974, s. 3 and Schedule 1.

* * * * * * * *

Division 5—Finances of the Commission

Transfer to Commission of assets, and assumption by Commission of liabilities, of Commonwealth Serum Laboratories.

31. (1) Upon the commencement of this Act—

(a) the Minister shall transfer or cause to be transferred to the Commission the assets owned by the Commonwealth and held or used in connexion with, or arising from the business of, the undertaking known as the Commonwealth Serum Laboratories; and

(b) the Commission is, by force of this section, liable to pay, satisfy, observe, perform and discharge the debts, liabilities and obligations of the Commonwealth in connexion with, or arising from the business of, that undertaking.

(2) The Commission shall indemnify the Commonwealth, and keep the Commonwealth indemnified, from and against all actions, claims, demands, proceedings, suits, damages, expenses and costs that may be brought against, or incurred by, the Commonwealth at any time for or in respect of a debt, liability or obligation that the Commission is liable to pay, satisfy, observe perform or discharge under paragraph (b) of the last preceding sub-section.

(3) In this section, "assets" includes—

(a) plant, machinery, equipment, office furniture, fittings, motor vehicles and stock in trade;

(b) book and other debts due to the Commonwealth and the benefit of any securities for those debts;

(c) the benefit that is capable of assignment of all pending contracts;

(d) the amount standing to the credit of the Commonwealth Serum Laboratories Trust Account at the commencement of this Act;

(e) all other property, rights or interests to which the Commonwealth is entitled and which it may assign; and

(f) all appropriate records maintained by the Commonwealth,

but does not include—

(g) land (including buildings on land); and

(h) stocks of biological products that are not prescribed for the purpose of paragraph (a) of section nineteen of this Act.

Capital of the Commission.

32. The capital of the Commission at any time is an amount equal to the sum of—

(a) the value, as determined by the Treasurer and notified to him to the Commission, of the assets transferred to the Commission under the last preceding section; and

(b) such amounts as have been paid to the Commission by the Treasurer out of moneys appropriated by the Parliament for the purposes of the Commission,

less any amounts of capital that have been repaid to the Commonwealth by the Commission.

Payments to Commonwealth by Commission.

33. (1) Interest is not payable to the Commonwealth on the capital of the Commission but the Commission shall pay to the Commonwealth, out of the profits of the Commission for a financial year, such amount as the Treasurer, after consulting the Minister, determines.

(2) The capital of the Commission is repayable to the Commonwealth at such times and in such amounts as the Treasurer, after consulting the Minister, determines.

(3) In the making of a determination under either of the last two preceding sub-sections, the Treasurer shall have regard to any advice that the Commission has furnished to the Minister in relation to the financial affairs of the Commission.

Borrowing by the Commission.

34. (1) The Commission may, with the consent of the Treasurer, borrow moneys for temporary purposes on overdraft from the Reserve Bank of Australia or from such other bank as the Treasurer approves.

(2) The Treasurer may, out of moneys appropriated by the Parliament for the purposes of this Act, make advances to the Commission of such amounts, and on such terms, as he thinks fit.

(3) The Commission may, with the consent of the Treasury, borrow moneys, whether for a temporary purpose or not, otherwise than in accordance with the preceding provisions of this section.

(4) The Commission shall not borrow moneys otherwise than in accordance with this section.

Bank accounts.

35. (1) The Commission shall open and maintain an account or accounts with the Reserve Bank of Australia and may open and maintain an account or accounts with such other bank or banks as the Treasurer approves.

(2) The Commission shall pay all moneys received by it into an account referred to in this section.

Application of moneys by Commission.

36. (1) Subject to this section, the moneys of the Commission shall be applied only—

(a) in payment or discharge of the expenses, charges and obligations incurred or undertaken by the Commission in the performance of its functions under this Act;

(b) in payment of the remuneration and allowances of Commissioners; and

(c) in making any other payments that the Commission is authorized or required to make under this Act.

(2) Moneys of the Commission not immediately required for the purposes of the Commission may be invested on fixed deposit with the Reserve Bank of Australia or with any other bank approved by the Treasurer, or in securities of the Commonwealth.

Estimates of receipts and expenditure.

37. The Commission shall, not later than the thirty-first day of March in each year, prepare and submit to the Minister estimates, in accordance with such form as the Minister directs, of its receipts and expenditure for the financial year commencing on the following first day of July.

Loss resulting from compliance with Minister's determination.

38. Where—

(a) the Commission undertakes research, installs or maintains plant or equipment or produces or holds stocks of a biological product in accordance with a determination by the Minister under section nineteen of this Act;

(b) the Commission satisfies the Minister that the operations (including the undertaking of research) carried on by the Commission in accordance with the determination have been so carried on at a loss in a financial year; and

(c) a loss results in that financial year from the whole of the operations of the Commission,

the Commission is entitled to be reimbursed by the Commonwealth to the extent of the first-mentioned loss or to the extent of the second-mentioned loss, whichever is the less.

Profits of the Commission.

39. (1) For the purposes of this Act, the amount of the profits of the Commission for a financial year is the amount (if any) remaining after deducting from the revenue received or receivable in respect of that financial year the expenditure properly chargeable against that revenue.

(2) For the purpose of the last preceding sub-section, the expenditure of the Commission properly chargeable against the revenue received or receivable in respect of a financial year includes—

(a) charges and expenses accrued in that year but not paid;

(b) provision made in that year for obsolescence and depreciation of assets;

(c) provision made in that year in lieu of insurance;

(d) provision made in that year for staff superannuation; and

(e) provision made in that year for income tax,

but does not include expenditure charged against amounts provided out of revenue of a previous year or expenditure in payment of charges and expenses accrued in a previous year.

(3) The profits of the Commission for a financial year shall be applied in the first place in payment of such sums as have been determined by the Treasurer under sub-section (1) of section thirty-three of this Act and the balance (if any) shall be applied in such manner as the Minister, with the concurrence of the Treasurer, determines.

(4) In the making of a determination under the last preceding sub-section, the Minister and the Treasurer shall have regard to any advice that the Commission has furnished to the Minister in relation to the financial affairs of the Commission.

Proper accounts to be kept.

40. The Commission shall keep proper accounts and records in accordance with the accounting principles generally applied in commercial practice and shall do all things necessary to ensure that all payments out of its moneys are correctly made and properly authorized and that adequate control is maintained over its assets and the incurring by it of liabilities.

Audit.

41. (1) The Auditor-General shall inspect and audit the accounts and records of financial transactions of the Commission, and shall forthwith draw the Minister's attention to any irregularity disclosed by the inspection and audit that, in the opinion of the Auditor-General, is of sufficient importance to justify his so doing.

(2) The Auditor-General shall, at least once in each year, report to the Minister the result of the inspection and audit carried out under the last preceding sub-section.

(3) The Auditor-General or an officer authorized by him is entitled at all reasonable times to full and free access to all accounts, records, documents and papers of the Commission relating directly or indirectly to the receipt or payment of moneys by the Commission or to the acquisition, receipt, custody or disposal of assets of the Commission.

(4) The Auditor-General or an officer authorized by him may make copies of or take extracts from any such accounts, records, documents or papers.

(5) The Auditor-General or an officer authorized by him may require a Commissioner or an officer of the Commission to furnish him with such information in the possession of the Commissioner or officer or to which the Commissioner or officer has access as the Auditor-General or authorized officer considers necessary for the purposes of an inspection or audit under this Act, and the Commissioner or officer of the Commission shall comply with the requirement.

Liability to taxation.

Sub-section (1) amended by No. 216, 1973, s. 3 and Schedule 1.

42. (1) Subject to this section, the Commission is subject to taxation under the laws of the Commonwealth, but is not subject to taxation under a law of a State or Territory to which the Commonwealth is not subject.

Amended by No. 216, 1973, s. 3 and Schedule 1.

(2) The Commission is not a public authority for the purposes of paragraph (d) of section twenty-three of the *Income Tax Assessment Act* 1936-1973.

Amended by No. 216, 1973, s. 3 and Schedule 1.

(3) For the purposes of the *Income Tax Assessment Act* 1936-1973, the cost to the Commission of any asset transferred to the Commission under section thirty-one of this Act shall be deemed to be the value of that asset as determined by the Treasurer under section thirty-two of this Act.

Division 6—Reports

Commission to keep Minister informed.

43. (1) The Commission shall from time to time inform the Minister concerning the general conduct of its business.

(2) The Commission shall furnish to the Minister such information relating to its operations as the Minister requires.

Annual Report of Commission.

44. (1) The Commission shall, as soon as practicable after each thirtieth day of June, prepare and furnish to the Minister a report of its operations during the year ended on that date, together with financial statements in respect of that year in such form as the Treasurer approves.

(2) The report shall deal specifically with any operations of the Commission in respect of which a determination by the Minister under section nineteen of this Act was in force during the year and the financial statement shall show separately the financial results of any such operations.

(3) Before furnishing the financial statements to the Minister, the Commission shall submit them to the Auditor-General, who shall report to the Minister—

(a) whether the statements are based on proper accounts and records;

(b) whether the statements are in agreement with the accounts and records and show fairly the financial operations and the state of the affairs of the Commission;

(c) whether the receipt, expenditure and investment of moneys, and the acquisition and disposal of assets, by the Commission during the year have been in accordance with this Act;

(d) as to the adequacy of provision in the nature of reserves made in the accounts of the Commission; and

(e) as to such other matters arising out of the statements as the Auditor-General considers should be reported to the Minister.

(4) The Minister shall lay the report and financial statements of the Commission, together with the report of the Auditor-General, before each House of the Parliament within fifteen sitting days of that House after their receipt by the Minister.

PART III—MISCELLANEOUS

Regulations.

45. The Governor-General may make regulations, not inconsistent with this Act, prescribing all matters required or permitted by this Act to be prescribed, or necessary or convenient to be prescribed for carrying out or giving effect to this Act.

INDUSTRIES
COMMISSIO

THE MU
INDUST

TABLED PAPER
31.5.78

15 February 1

No. 162