Appendix D

Congressional Access to Proprietary Pharmaceutical Industry Data

In the past, numerous congressional committees have expressed an interest in the research, development, and marketing costs of the pharmaceutical industry. While the industry is quite willing to disclose its own estimates, it guards the financial information that is used to derive these estimates, especially the data needed to determine overall industry profitability and profitability per product.

Without voluntary disclosure, Congress must resort to compulsory processes. Congress' auditing body, the U.S. General Accounting Office (GAO), which investigates "all matters relating to the receipt, disbursement, and application of public funds,"[1] is probably best equipped to do a financial analysis of the pharmaceutical industry, In addition, GAO is afforded special power to audit the expenditure of public funds through government contracts. Since 1951, almost all government contracts must contain a clause authorizing GAO to:

> ...examine any directly pertinent books, documents, papers, and records of the contractor or any of his subcontractors engaged in the performance of and involving transactions related to such contracts or subcontracts.2

However, the pharmaceutical industry successfully battled GAO for a decade to prevent GAO from using these "access to records" clauses to obtain information about individual companies' research, development, and marketing costs. The following discussion outlines GAO's unsuccessful attempt to obtain research, development, marketing, and promotional costs from the industry, demonstrating the industry's willingness to fight disclosure.

Another avenue for obtaining this data would be through a congressional subpoena. It is clearly within congressional powers to subpoena this data; however, it appears that Congress has been reluctant to use this power against the pharmaceutical industry. The broad scope of congressional subpoena power summarized in this appendix demonstrates that legal constraints have not prevented Congress from obtaining proprietary data.

GAO and the Pharmaceutical Industry

The controversy between GAO and several of the largest U.S. pharmaceutical companies began in 1967 when the Senate Select Committee on Small Business, Subcommittee on Monopoly, held a series of hearings on all aspects of the pharmaceutical industry, including its profitability and the amount of competition in the industry.[3] The intent of these hearings was to establish

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[1] *31* U.S.C. Sec. 712.

[2] See, e.g., 41 U.S.C. Sec. 254 (1992) (civilian contracts); 22 U.S.C. Sec. 2586 (1992) (arms control and disarmament); 22 U.S.C. Sec. 2206 (1992) (atomic energy); 50 U.S.C. Sees. 1431, 1433 (1992) (military/national defense). Harvard Law Review, "The Controller General's Authority To Examine the Private Business Records of Government Contractors: ***Eli Lilly & Co. v. Staats*, *Harvard Law Review 92:*** 1148-1159 (1979).

[3] "Competitive Problems in the Drug Industry: Hearings before the Subcommittee on Monopoly of the Senate Select Committee on Small Business (pt. I) 90th Cong., 1st Sess. passim (1967), cited in note, "The General Accounting Office's Access to Government Contractor's Records," ***University of*** *Chicago Law Review'* 49:1050- *1075 (1982).*

a record in preparation for possible legislative action.[4] In 1971, the Comptroller General of the United States, the head of GAO, testified at one of these hearings.[5] The Subcommittee Chairman, Senator Gaylord Nelson, suggested that GAO use the 'access-to- records' clause, found in a number of government contracts with the pharmaceutical companies, to ''take a look at the costs" of the pharmaceutical industry.[6] After the hearings Senator Nelson's staff continued to urge GAO to use its powers under these clauses to obtain cost records ''without any strings attached so that the high profits' of the drug industry could be made public by product and firm.[7]

Following the hearings, in 1972 GAO approached the Pharmaceutical Manufacturers Association (PMA) about doing a comprehensive study on the industry, including production process, efficiency, costs, and profits. PMA-member companies rejected GAO's request because the confidentiality of their cost and other data could not be protected.[8] GAO revised its plan and proposed a Phase I study that would examine the characteristics and methods of the industry. Six companies voluntarily cooperated with this initial phase: SmithKline Corporation, Bristol Laboratories, division of Bristol-Myers Company, Abbott Laboratories, Eli Lilly & Company, Merck& Company, Inc., and Hoffman La Roche.

In 1974, GAO published its Phase I findings[9] and proposed a second part to gather data that would illuminate ''salient economic and operational aspects of the industry. "[10] GAO originally proposed that the cost data from individual companies or drugs be kept confidential; however, Senators Nelson's and Edward Kennedy's staff insisted that the Committee's objectives could only be met if the data were made public.11 The drug companies refused to cooperate, and in 1974 GAO decided to use its authority under the access to records clause to obtain the data.

Each of the six pharmaceutical companies GAO studied in Phase I had government contracts with the U.S. Defense Department and the U.S. Veteran's Administration. Relying on the access to records clauses in these contracts, GAO sent a letter to each company requesting:

> . . . all books, documents, papers, and other records directly pertinent to the contracts, which include, but are not limited to (1) records of experienced costs including costs of direct materials, direct labor, overhead, and other pertinent corporate costs, (2) support for other information as may be necessary for use to review the reasonableness of the contract prices and the adequacy of the protections accorded the Government interests.[12]

As would later become apparent, GAO was seeking financial data that would allow it to estimate research, development, marketing, promotion, and distribution costs for individual products.

Each of the pharmaceutical companies' contracts was negotiated freed price and the prices were therefore based on catalog prices, often with volume

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4 'Competitive Problems in the Drug Industry: Hearings before the Subcommittee on Monopoly of the Senate Select Committee on Small Business (pt. 1) 90th Cong , 1st Sess passim (1967) (remarks of Senator Gaylord Nelson) cited in note, ''The General Accounting Office's Access to Government Contractor's Records, *University of Chicago Law Review* 49: 1050-1075 (1982).

5 ''Hearings on Competitive Problems in the Drug Industry before the Senate Subcommittee on Monopoly of the Senate Select Committee on Small Business, ' 92d Cong., 1st Sess., 8020 (1971) cited in note, ''The General Accounting Office's Access to Government Contractor's Records, " *University of Chicago Law Review* 49: 1050-1075 (1982).

6 *Bowsher v. Merck & Co , Inc., 103* S. Ct. 1587, 1591 n.4 (1983).

7 *Bowsher* v. *Merck & Co , Inc , 103* S. Ct. **1587, 1591** n.4 **(1983).**

8 *Eli Lilly & Co* , v. *Staats, 574* F.2d. 904, 923 (7th Cir. 1978), *cert. denied*, 439 U.S. 959, 99 S. Ct. 362 (1978).

9 *Eli Lilly & Co. v. Staats, 574* F.2d. 904, 923 (7th Cir. 1978), *cert. denied, 439* U.S. 959, 99 S. Ct. 362 (1978).

10 *Bowsher* v. *Merck & Co., Inc.*, **103 S. Ct. 1587,** 1591n.4 **(1983).**

11 GAO later asserted that i, report to **Congress** would not identify particular companies or products, but rather it would be an industrywide report. *Eli Lilly & Co,* v. *Staats, 574* F.2d 904 (7th Cir.1978), *cert. denied, 439 U.S. 959, 99* S. Ct. 362 (1978).

12 Harvard Law Review, ' 'The Controller General's Authority To Examine the Private Business Records of Government Contractors: *Eli Lilly & Co. Staats*'', *Harvard Law Review 92:* 1148-1159 (1979).

discounts. When the contracts were negotiated, the reasonableness of the prices was assessed on the basis of the contractor's established catalog or market price; no attempt was made to demand the manufacturer's actual costs.[13] A number of the companies believed any data relating to costs of the products were irrelevant to a fixed price contract, and to the extent any financial data were relevant, only direct costs (e.g., materials and labor) apply. Furthermore, the companies believed GAO was not authorized under the statute to conduct an audit for the sole purpose of doing a congressional study. They argued that the access-to-records clause was meant only to prevent fraud and abuse in government contracting and could not be used unless there was a reasonable basis for GAO to suspect fraud and abuse in pricing. Since the contract prices were at or below the catalog prices and were not negotiated, the companies claimed GAO should not be allowed to investigate their prices. Therefore, in answer to GAO's request, five of the six companies filed suit to prevent GAO from enforcing its demand.[14]

The fact that the catalog prices were not questioned during the contractual negotiations did not prevent GAO from auditing the prices paid. A previous case involving a fixed-price defense industry contractor had already established that GAO was not strictly limited in its investigation of government contracts to those items specifically negotiated. The word 'contract, ' as used in the access-to-records statute, was interpreted to not only include the specific terms, but also the general subject matter of the contract which includes the business arrangements of the contract.[15] Faced with this precedent, the courts in the pharmaceutical cases were unwilling to narrowly limit GAO's ability to use access-to-records clauses to gather information on prices even when the price was not specifically negotiated and was less than a catalog price. Moreover, although the courts recognized that GAO's request was motivated largely by the Senate Subcommittee on Monopoly's desire for a study on the pharmaceutical industry, the courts concluded that such mixed motivations did not limit GAO's stated statutory powers.[16]

After quickly disposing of these issues, the courts struggled with what became the main issue: what documents could GAO properly request? The only precedent, *Hewlett Packard v. United States,* had given GAO access to books and records related to the direct cost of materials, labor, and overhead but had not addressed the question of whether GAO's access extended beyond direct costs.[17]

The scope of GAO's power turned on the phrase "directly pertinent" in the statute authorizing GAO access to documents under government contracts. Interpreting the applicability of these two words became the subject of litigation for nearly a decade. No other court had interpreted this language, and the legislative history was ambiguous.[18] The original proposed bill allowed GAO access to all records that were 'pertinent. '' The adjective "directly' was added at the end of legislative debate to limit snooping' that may be carried out."[19] This amendment revealed that although Congress sought to give GAO broad enough powers to obtain data that would enable it to evaluate the reasonableness of Federal Government contracts and deter impropriety and wastefulness, certain Members also expressed concern about giving GAO overly broad access to private data.[20]

Between 1977 to 1983, 10 separate Federal court decisions were handed down in the cases between

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13 S.S. Garner, ''GAO Right of Access and the pharmaceutical Industry: *Bowsher v. Merck," Air Force Law Review* 24(2): *125-156* (1984).

14 Hoffmann LaRoche chose to settle with GAO. Letter from Thornas G. Stayton to the *Harvard Law Review* (Jan. 3, 1979) cited in "The Controller General's Authority To Examine the Private Business Records of Government Contractors: *Eli Lilly& Co. v. Staats*'', *Harvard Law Review 92:* 1148-1159 **(1979).** The terms of that settlement and the amount of information obtained from Hoffman La Roche do not appear to have been made public.

15 *Hewlett Packard Company* v. *United States,* 385 F. 2d, 1013 (9th Cir. 1967), *cert.* denied, 390 U.S. 988, 88 S.Ct. 1184 (1968).

16 See e.g., *SmithKline* v. *Staats,* 668 F.2d 201 (3rd Cir. 1981), *cert.* denied, *Bowsher v. SmithKline Corp.*, 461 U.S. 913, 103 S. Ct. 1891 (1983). For a more complete discussion of this issue, see Case Comments, "The Comptroller General's Authority To Examine the Private Business Records of Government Contractors: *Eli Lilly & Co. v. Staats, Harvard Law Review 92: 1148-1159 (1979).*

17 *Hewlett Packard* v. *United States,* 383 F.2d *1013* (9th Cir. 1967), *cert. denied,* 390 *U.S.* 988, 88 S.Ct. 1184 (1%8).

18 NO@ ''The General Accounting Office's Access to Contractor's Records,' *University of Chicago Law Review* 49:1050-1075 *(1982).*

1997 *Congressional Record* 13377 (1951) cited in *Merck* v. *Bowsher,* at 1602. The complete quote of Congressman Hoffman, who supported the amendment, was that [t]he purpose is to limit 'snooping' that may be carried out under this bill which we do not have the votes to defeat." 115 *Congressional Record* 25800 (U.S. Senate - Sept. 17, 1969).

20 *Bowsher* v. *Merck & Co. Inc., 460* U.S. *824, 103* S.Ct. *1587 (1983).*

GAO and the pharmaceutical companies.[21] All of the courts agreed that GAO had the authority to see cost data even if the prices were not negotiated. The courts also agreed that direct costs, such as manufacturing costs, royalty costs, and delivery costs were relevant to the contract and were therefore subject to GAO review.[22] But, the courts were split on GAO's right of access to indirect costs (research and development (R&D), marketing, promotion, distribution, and administration costs). In most cases, the companies successfully argued that indirect cost data were not *directly pertinent* because only a small portion of indirect costs could be allocated to the Federal Government's contracts, and GAO would have to examine a large amount of data not related to the Government's contracts in order to discern this small amount.[23] The Government unsuccessfully argued that GAO would not have to go on a fishing expedition through all the company's unallocated costs, because the companies allocate costs to products and perform profitability studies for their own purposes.[24] That argument fell on deaf ears, and GAO was given access only to direct cost data that the industry was willing to provide.[25] From a practical point of view, these decisions left GAO with little meaningful data, since direct costs amounted to only about 9 percent of the cost of a particular pharmaceutical product. The access granted by these courts was, therefore, virtually useless as an auditing tool.

GAO did find a sympathetic ear in one judicial circuit. In *Eli Lilly & Co. v. Staats*,[26] the Seventh Circuit concluded that because R&D, marketing, and promotion costs constituted a major portion of the total price of the contracts, they were directly pertinent under both "common and legal understandings."[27] The court concluded that records were "directly pertinent" to a contract if it is "a significant input in the cost of the product purchased in the contract."[28]

The conflict between the courts was finally resolved by the U.S. Supreme Court, in Bowsher *v. Merck & Co. Inc.*[29] The Federal Government again argued that GAO had the right to examine records pertaining to every cost that the company used the Government's payments to defray.[30] The decision to make such a broad assertion of power may have been a strategic mistake because it gave no apparent recognition to the statutory limits imposed by the word "directly," and the Government's interpretation, "carried to its logical extreme. . . would dictate that few, if any, of private contractor's business records would be immune from GAO scrutiny."[31] Moreover, the Supreme Court cited GAO internal decisions and a memorandum to Con-

21 *Bristol Laboratories Div. of Bristol-Myers Co.* v. *Staats*, *428* F. Supp. 1388 (1977), *aff'd per curium,* 620 F. *2d* 17 *(2d* Cir. 1980), *aff'd mem. by evenly divided court*, *451* U.S. 400 (198 1); *SmithKline Corp. v. Smuts, 483* F. Supp. 712 (E.D. Pa. 1980), *aff'ds 668* F.2d 201 (3d Cir. 1981), *cert. denied, Bowsher* v. *SmithKline Corp.*, 461 U.S. 913 (1983); *Eli Lilly & Co. v. Staats*, *574* F.2d. 904 (7th Cir. 1977), cert. *denied, 439* U.S. 959,99 S. Ct. 362 (1978); *U.S. v. Abbott*, *597* F.2d 672 (7th Cir. 1979). *Merck& Co. v. Staats*, 529 F. Supp. 1 (D.C.C. 1977); *aff'd*, 665 F.2d 1236 (D.C.Cir. 1981), *aff'd.*, *Bowsher v. Merck & Co.*, *460* U.S. 824, 103 S. Ct. 1587 (1983).

22 In one of the first cases decided, the Bristol-Myers Company offered to provide GAO with data on direct costs. This compromise position proved to be a useful strategy because the courts concluded that the company's offer reflected 'a responsible and reasonable effort to distinguish 'directly pertinent' matter. " *Bristol Lab. Div. of Bristol-Myers Co. v. Staats*, at 1391.

23 *Bristol Lab. Div. of Bristol-Myers Co. v. Staats*, at 1391.

24 *SmithKline Corp. v. Staats*, *668* F.2d 201 (1981), *cert. denied, Bowsher v. SmithKline Corp.*, 461 U.S. 913, 103 S. Ct. 1891 (1983) "we therefore adopt the standard formulated in *Bristol*, which for the most part relies on the distinction between direct and indirect costs' *Merck & Co. v. Staats*, 665 F.2d 1236 (D.C. Cir. 1981), *aff'd*, **Bowsher v.** *Merck & Co., 460* U.S. 824, 103 S. Ct. 1587 (1983).

25 *Merck v. Staats*, at 1247 (Mikva, J., concurring in part, dissenting in part).

26 574 F.2d 904 (7th Cir. 1978), *cert. denied, 439* U.S. 959 (1978).

27 574 F.2d 904 (7th Cir. 1978), *cert. denied, 439* U.S. 959 (1978).

28 574 F.2d 904 (7th Cir. 1978), *cert. denied, 439* U.S. 959 (1978).

29 460 U.S. 824, 103 S. Ct. 1587 (1983).

30 *Bowsher* V, *Merck & Co. Inc.*, *460* U.S. 824, 843, 103 S. Ct. 1587,1598 (1983).

31 *Bowsher* V. *Merck & Co. Inc.*, *460* U.S. 824, 103 S. Ct. 1587 (1983).

32 In a 1969 memorandum responding t. Congress' interest in performing a profitability study of the defense industry, 'AO wrote that ''While GAO's legal authority would permit it to perform some to the work necessary in making a profit study. . . . to do a meaningful study of profitability. . . . legislation should be enacted broadening [GAO'S] right of access to record. ." Part of GAO's concern was that without specific **authority it would be drawn into protracted** litigation. *Memorandum on the Adequacy of the LegalAuthority of the General Accounting Office To Conduct a Comprehensive Study of Profitability in the Pharmaceutical Industry,* reprinted 115 *Congressional Record 25,801* (Senate 1969).

gress in which GAO appeared to acknowledge more limited authority .32

The Court followed the majority of the lower courts and drew the line between direct and indirect costs. The Court held that since Congress had drafted the limiting language (''directly pertinent"), arguments for change should be directed to Congress. The Court also noted that in the past Congress had found it necessary to pass legislation expanding GAO's powers to conduct a profit study of the defense industry .33 In that case, Congress expressed its reservations about providing GAO with the authority to conduct a "fishing expedition" and limited this expansion of GAO's authority to a single study .34 This past congressional action weakened the Government's argument that GAO had such broad powers under the access-to-records clauses.

The Availability of Congressional Subpoena Power

Although the Federal Government was willing to fight five separate cases through to the Supreme Court, Congress was not willing to use its subpoena power to obtain the data. A brief review of the scope of congressional subpoena power demonstrates that since the hearings were being carried out in anticipation of legislation, a congressional subpoena would have been a legal alternative, although perhaps not politically feasible.

Congress' power to legislate includes the power to investigate, to compel witnesses to testify, and to demand the production of documents. The power to investigate and issue subpoenas is, however, limited to the congressional committees.[35] There are few' limitations on the scope of a congressional subpoena, provided it is carried out in the course of legitimate congressional powers. As the Supreme Court cases in this area demonstrate, legitimate congressional powers are quite extensive and congressional subpoenas are virtually immune from judicial challenge.[36]

The courts give congressional subpoenas deference because they fall within the protections of the Speech and Debate clause of the Constitution.[37] The Speech and Debate clause *literally* protects all Senators and Representatives from "questioning in any other Place for *any* Speech or Debate in either House. " As interpreted, this protects members of Congress from judicial interference in legislative matters.

In *Eastland v. United States Servicemen's Fund,*[38] *the* Supreme Court reviewed a congressional subpoena issued during the course of an investigation of the United States Servicemen's Fund, Inc. (USSF). The USSF challenged the subpoena alleging it infringed upon the USSF's First Amendment rights.[39] The Court rejected the USSF claim, stating that since the congressional subpoena fell within the "sphere of legitimate legislative activity," the Committee's actions could not be questioned by the courts because the "prohibi-

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33 Military Appropriations &t of 1970, Public Law 91-121, Sec. 408, 83 Stat, 204, cited in *Merck* v. *Bowsher,* at 1595, n.12.

34 115 Congressional Record 25795,25793 (statements of Senator Ribicoff and Senator Proxmire, respectively), cited in *Merck v. Bowsher,* at 1595, n. 12.

35 The power to investigate using compulsory process is derived from theU.S. Constitution, but Congress itself has limited subpoena power to the committees. Since 1946, each standing Senate Committee has had the power to issue subpoenas without obtaining specific permission from the Senate. See The Legislative Reorganization Act of 1946 (Public Law 79-901), cited in Congressional Quarterly, *Guide to Congress* (3rd Ed.) (Washington, DC: Congressional Quarterly Inc., 1982). In 1974, House Committees were given general subpoena power; however, each subpoena must be approved by the majority of the Committee or Subcommittee and can only be enforced by action of the full House. Congressional Quarterly, *Guide to Congress* (3rd Ed.) (Washington, DC: Congressional Quarterly Inc., 1982).

36 *McGrain* v. *Daugherty,* 273 U.S. 135 (1927) *(establishing* that Congress must be able to obtain information to fulfill its legislative duties and may compel such disclosure). *Watkins v. United States, 354* U.S. 178 (1957).

37 U.S. Constitution, Art.I, Sec. 6, clause 1.

38 421 U.S. 491, 95 S. Ct. 1813 (1975).

39 The USSF published an underground newspaper for American military persons and established coffeehouses near domestic military installations which were admittedly a' 'focus of dissent and expressions of opposition within the military toward the war in [Southeast Asia].' Congress was concerned that the activities of the USSF were undermining the moral of American servicepersons and issued a subpoena requesting all USSF documents and records to the bank in which USSF kept its account. The USSF protested that Congress was attempting to force the disclosureof4'beliefs, opinions, expressions and associations of private citizens which may be unorthodox or unpopular,' and that the sole purpose of the subpoena was to ''harass, chill, punish, and deter [USSF and its members] in their exercise of their" First Amendment rights, particularly freedom of the press and freedom of association. ***Eastland v. United States Servicemen's Fund, 421*** U.S. 491 (1974).

tions of the Speech and Debate Clause are absolute."[40] Even valid constitutional objections are overridden by the absolute nature of the Speech and Debate clause.[41] To be within the protections of the Speech and Debate clause, the subpoena must be issued in ''a session of the House by one of its members in relation to the business before it."[42] In addition, a court will not examine the motives for the subpoena, provided it can be related to possible legislative actions;[43] "the wisdom of congressional approach or methodology is not open to judicial veto."[44] The Supreme Court has stated that a legislative inquiry is valid even if there is ''no predictable end result. ''[45]

Given this broad subpoena power, it is likely that a congressional committee could devise a legitimate subpoena to obtain R&D costs from the pharmaceutical industry. For example, Congress might investigate whether discounts should be required for pharmaceuticals purchased for Medicaid, Medicare, or other government programs, or look into whether current tax subsidies for R&D costs are warranted. The industry has cited its research costs in testimony during 1987 hearings on the consequences of the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and, therefore, has arguably made it a legitimate target for investigation.

Any subpoena directed at such data is likely to be met by protests about the proprietary nature of the data. Although business confidentiality arguments are not sufficient to block the subpoena,[46] such arguments can result in protracted negotiations over whether the information will be kept confidential and the scope of the documents that must be turned over.

In summary, Congress has the power to request R&D and marketing cost data from the industry. But, given the past history of litigation on the issue it is safe to predict that pharmaceutical companies are not likely to make such a request easy, and Congress has so far been unwilling to exercise this power.

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40 *Eastland* v. *United States Servicemen's Fund*, *421* U.S. 491, *95* S.Ct. 1813 (1975) **(additional cites Omitted).**

41 *Eastland* v. *United States Servicemen's* Fund, 421 U.S. 491 (1975) (additional cites omitted). However, three Justices wrote that in certain cases the constitutionality of a congressional subpoena may be reviewed by the Court, even if the subpoena is within the sphere of legitimate legislative activity. ***Id.*** (concurrence of Justice Marshall, with whom Justices Brennan and White joined).

42 *Kilbourn* v. *Thompson*, 103 U.S. 168 (1881), *cited* in *Eastland* ***v.*** *United States Servicemen's Fund*, 421 U.S. 491 *(1975).*

43 *Eastland* v. *United States Servicemen's Fund*, 421 U.S. 491 (1974); *Watkins* v. *United States*, 354 U.S. 178, 200, 93 S. Ct. 2018 (1957).

44 Doe v. *McMillan*, **412 U.S. 306, 313, 93 S. Ct.** 2018 **(1973).**

45 *Eastland* v. **United** *States Servicemen's Fund, 421* U.S. 491 (1974) (additional cites omitted).

46 *Conversation* with Charles Tlefer, Office of the General Counsel, House of Representatives, U.S. Congress (September 4, 1991).