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- 19. Blair, et al., "Biological Availability of Oxytetracycline HCl Capsules," 215 J.A.M.A. 251-254 (1971); Brice & Hammer, "Therapeutic Nonequivalency of Oxytetracycline Capsules," <u>Drug Information Bulletin</u>, January/June 1969, pp. 112-114.
- 20. OTA Report, p. 12.
- OTA Report, p. 13. Among the studies relied upon by the Panel to demonstrate the link between bioinequivalence and therapeutic inequivalence are Lindenbaum, et al., supra, and Catz, et al., "Chemically Inactive Thyroid, U.S.F. A Preliminary Report," 266 N. Eng. J. Med., 136-137 (1962).
- 22. OTA Report, p. 14.
- 23. "Critical Issues/Maximum Allowable Cost: Edwards -- on the MAC Regs," Chain Store Age - Drug Edition, January, 1975, pp. 32, 34, 38.
- 24. Section 19.3(b), (39 FR 40304), November 15, 1974.
- 25. PMA Analysis "MAC/AAC Proposed Regulations."
- 26. IMS/America, Ambler, Pennsylvania, Letter to PMA, October 7, 1974.
- 27. Requiring states to describe the methods and procedures which are to be used to assure that payments for drugs do not exceed levels consistent with efficiency, economy and quality of care was not intended to "authorize price fixing of drugs by the Secretary ..." See Conference Rep. No. 1030, 90th Cong., 1st Sess., in 1967 U. S. Code, Cong. & Admin. News 3179, 3213.