

Erill S (2008). Louis Lasagna (1923-2003).



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In 1955, Louis Lasagna, one of the pioneers of clinical pharmacology in the United States, published an article on the theory and practice of clinical trials ([Lasagna 1955](#)). This is featured on *The James Lind Library* because it is an important early example of the 'codification' of clinical trial methodology which was occurring during the 1950s. The paper is based on a presentation Lasagna had made the previous year to a 4th year Therapeutic Conference at the Johns Hopkins University School of Medicine. The paper begins by stressing the need for clinicians and statisticians to collaborate in designing and conducting clinical trials, and it has sections on treatment allocation, blinding and placebos, analysis, and the need for caution in generalising from the trial results. Indeed, the paper shows Lasagna's insights into many of the problems that we continue to face today in evaluating the effects of treatments.

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Louis Lasagna was born in Queens, New York, in 1923. He graduated at Rutgers University and qualified in medicine at Columbia University College of Physicians and Surgeons. The years that had most impact on his future career were those spent as a clinical research fellow in anaesthesia at Harvard University. He met Henry K Beecher there and became interested in the study of subjective responses to treatments, in particular in the evaluation of analgesics. As Lasagna was to write many years later, "in the pre-Beecher era, a subjective response such as pain was generally considered unsusceptible to quantification. We now know better" (Lasagna 1980).

Lasagna joined the faculty of Johns Hopkins School of Medicine in 1954 and promptly created a pioneering division of clinical pharmacology. He spent 16 years at Johns Hopkins and then moved to the University of Rochester where he chaired the department of pharmacology and toxicology. It was there that he founded the Center for the Study of Drug Development, which moved with him to Tufts University when he became dean of the Sackler School of Graduate Medical Sciences there in 1976.

The contributions of Louis Lasagna to pharmacology and medical therapeutics were impressive. In addition to his papers on subjective responses, in particular, his study of the placebo response (Lasagna et al. 1954), he wrote about adverse effects (Lasagna 1964a), on many other aspects of clinical pharmacology (e.g. Lasagna 1967; 1974), and on the value of informed consent (Epstein and Lasagna 1969). Lasagna also made many influential contributions to drug regulatory reform in the United States. Among these, his contributions during the Kefauver hearings on the 1962 amendments to the Food, Drug and Cosmetic Act helped to formulate a drug law specifying criteria for demonstrating effectiveness.

Reminiscing during an address delivered in 1975 (Lasagna 1975), he recalled that he had spent a lot of time in his early career trying to persuade others of the merits of the controlled clinical trial, but that he had later had to warn that "caution, critique, and restraint are constantly needed"... (Lasagna 1960) and that "the physician must be aware of the temptation to come down on easily measured parameters which are not necessarily relevant to our ultimate aims" (Lasagna 1964a). He pointed out how difficult it can be to weigh up the relative advantages and disadvantages of drugs: "How is one to say whether an agent is more or less desirable than another, when the side-effects generated by the two agents are not only quantitatively different but qualitatively different?" (Lasagna 1964b). And he also noted that, as a price always has to be paid for progress, the challenge was to see that the price is not too high (Lasagna 1964a).

Louis Lasagna was never dogmatic, but he felt unrestrained in criticising whatever he deemed outrageous, be it the prescribing habits of some physicians (Lasagna 1964a; Stolley and Lasagna 1969), the misuse of statistics (Lasagna 1955), and "the pathetic faith in the ability of animal toxicity and premarketing clinical trials to predict good and bad effects of drugs in man" (Lasagna 1975). Indeed, he went on to state that "the adverse drug reaction problem continues to create havoc by repeated mouthings of poor data egregiously extrapolated and finagled to produce scare headlines that, not surprisingly, strike terror into the hearts of the public" (Lasagna 1975).

Louis Lasagna was a wise man. In his book *Life, Death and the Doctor* (Lasagna 1968), he draws on John Locke, Bernard Shaw, Peter Medawar, Berthold Brecht, and Rostand who made substantial contributions to our understanding

of how to test treatments rigorously. He died in Newton, Massachusetts, on 6 August 2003.

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