testimony that it is beneficial to the patient and the medical profession to reduce the number of infections, when balancing this with the tragic occurrence in the case at bar and perhaps several other cases, the reduction of injections argument pales into insignificance.

[4] Accordingly, it is my opinion that the defendant has breached its warranty of merchantability to the plaintiff. In view of this discussion, the issues involving liability for breach of the warranty of fitness for a particular purpose need not be considered.

Negligence

[15–16] The finding of implied warranty liability does not preclude this Court from finding the defendant liable in negligence. *Stromsodt* v. *Parks-Davis & Co.*, supra, 257 F.supp. at 995. However, it is fundamental law that plaintiffs will be limited to one recovery.

[17] Defendant herein is chargeable with negligence in failing to adequately test its product, for thereafter releasing the product for commercial distribution in the face of certain danger signs emanating from the test results, and in failing to adequately warn the medical profession of the risks inherent in its use.

[18] It is established law that where a drug manufacturer develops a new drug subsequently found to produce harmful side effects which the manufacturer failed to discover in the course of testing the product, the manufacturer is liable in negligence where it appears that the drug in fact was inadequately tested or that the manufacturer failed to exercise due care in the development of the product prior to its release on the market for commercial distribution. 3 Frumer & Friedman § 33.01[2]; *Roginsky* v. *Richardson-Merrell, Inc.*, 378 F.2d 832 (2d Cir. 1967); *Stromsodt* v. *Parke-Davis & Co.*, supra.

The tests which the various lots of vaccine had to undergo prior to their release on the market were generally biological and/or clinical in nature. Not only was it required that each lot fall within the acceptable standards of potency and toxicity established by DBS, but also the reports from the doctors in the field as well as those testing the vaccine under clinical conditions had to indicate that the drug was safe for use and that it produced no untoward adverse reactions in the recipients.

Both the potency and toxicity tests were first performed in the laboratories of the manufacturer. Once satisfactory results were achieved, the manufacturer would send the lot to DBS which, in turn, would conduct its own independent study. If the DBS test results confirmed the manufacturer's report or protocol, the lot would be approved for release on the market. If, on the other hand, the DBS results conflicted with the results set forth in the manufacturer's protocol, the lot would be returned to the manufacturer for re-testing.

As hereinbefore stated, the potency test was performed by injecting groups of mice with varying dilutions of vaccine, and, after a period of time, challenging the mice with virulent organisms. The protective activity of the vaccine was judged by the number of mice which survived the challenge at the various dilution levels. In addition, it was required that the pertussis vaccine component have no greater potency than 12 protective units per total human immunizing dose (THD).[11] Because a standard deviation is inherent on a test of this nature, a vaccine would be deemed satisfactory if the result of one test or an average of the combined results of two or more tests indicated that the calculated protective activity of the vaccine fell within the allowable range of 8 to 36 protective units. Any result falling outside this range indicated that the particular lot was not fit for public use and consequently was unacceptable for distribution.

The standard toxicity text was preformed by weighing a group of ten mice, injecting them with a test dose of vaccine and weighing them again at the end of periods of 72 hours and 7 days. A vaccine was accepted as being free from toxicity if at the end of 72 hours the group weight of the mice was no less than it had been at the initial weighing, and at the end of 7 days was greater than it had been initially. A lot automatically failed the test if it was determined that a mouse had died from the vaccine.

Although Parke-Davis found no problem in meeting the potency requirements in the testing of its triple antigen vaccine, Triogen, it is apparent from the

[11] "THD" is the total dose of vaccine, administered in a series of three separate inoculations, that any one individual is required to be given in order to insure full immunizing protectivity. The "12 protective units" standard represents the number of bacteria within a total human dose which successfully immunizes the recipient from the disease without itself causing harmful side effects.