ISSN 1081-4140

SAFETY BULLETIN

June 1996 Volume 3, No. 4

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Consultants in Safety Philosophy and Technology

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Defect Free Medical Devices

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ABSTRACT

The FDA appproval process cannot assure that medical devices are defect free. The major responsibility for safety and efficacy remains with the medical device manufacturer.

DISCUSSION

Medical devices much like consumer products are accompanied by instructions for use. The objective is the same for both; provide the user with the information necessary to use the product correctly.

In the case of medical devices these instructions are called label copy. This is a vestigial term, more appropriate for drugs which actually do have labels and which have been regulated by the FDA long before medical devices were amended in 1976.

The term, now applicable to all medical devices, refers to all materials which serve to instruct and inform the medical community about the correct use of the product.

Medical device label copy which comes in the form of product inserts, labels, instruction books, videotapes and to some extent in-service training sessions for medical staff, includes performance limitations, contraindications for use, adverse reactions if applicable, and other precautions as are known from the clinical studies, premarket evaluations, or medical history.

Inaccuracies, omissions, or misleading statements in this material are called misbranding, a condition that renders the label copy defective.

Defective medical devices are subject to varying degrees of recall depending on the criticality of the device. Label copy is treated as a device component, an element of the device itself. Defective label copy causes the device to be a defective and, therefore, violative medical product subject to recall.

Label copy is submitted, along with other evidence to support the safety and efficacy of the device, to the FDA in the form of a 510 k which is the regulatory process which notifies the FDA of the intention to market the device.

The FDA treats the information submitted in the 510 k process as a complete and accurate account of the manufacturers claims of safety and efficacy. In some cases the product involved may be unique and perhaps on the cusp of experimental technology. Such circumstances usually cause greater attention to be given to the data offered by the manufacturer to support their claims about the product.

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In this process there is no sure test by which the FDA can measure the accuracy of the information supplied to them by a manufacturer. The argument in some courts that the FDA approval of a critical (Class III) medical device removes it from further criticism is therefore inappropriate.

Medical device manufacturers are motivated to present their products in the most favorable manner. Obviously adverse reactions are not favorable. Unlike drugs, where adverse reactions are considered to be an acceptable trade off against the benefits they provide, a medical device reaction may raise questions of design adequacy.

A full disclosure of the adverse reaction which is useful to the medical community and to the patient, now becomes a marketing liability to be exploited by the competition.

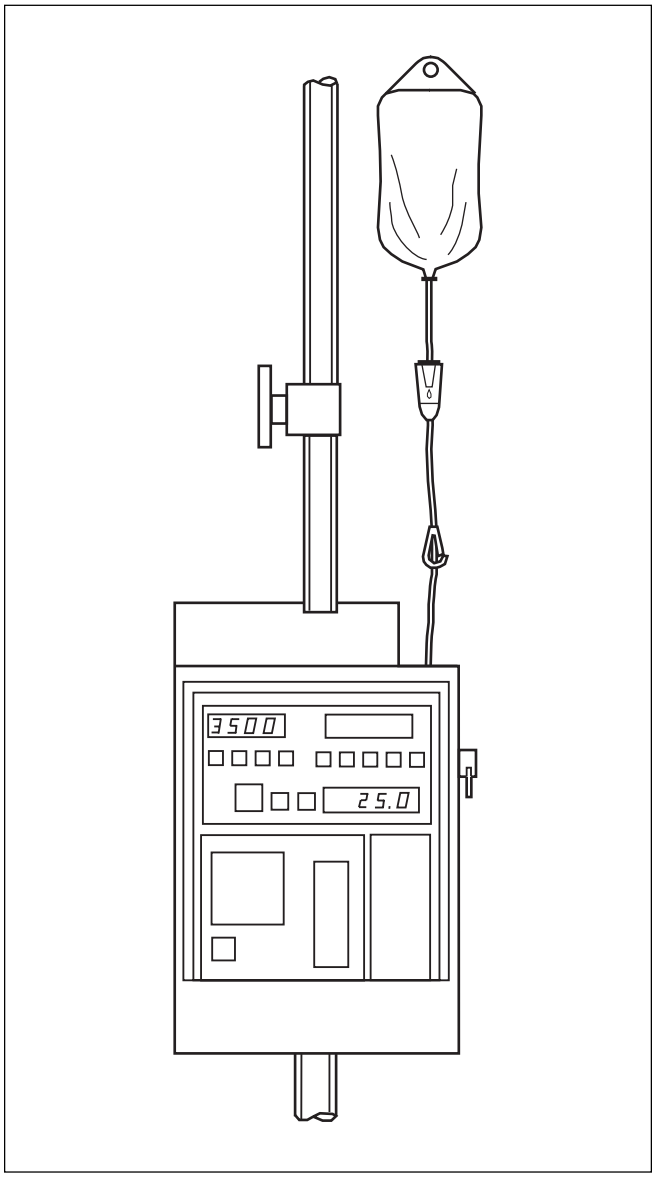

Fig. 1 IV Infusion Pump

Similarly, the FDA does not verify the accuracy of performance data. The desire of a manufacturer to present marginal data in a favorable way and yet not to be untruthful, may still be misleading.

The accuracy of an IV infusion pump for example depends on two things; the inherent ability of the pump to operate at the set rate and manufacturing parameters for the tubing such as luminal diameter, wall thickness, and material elasticity. To report the accuracy data for the perfect pump and tubing combination may be advantageous and truthful, but if it does not account for process control variations in tubing production it is misleading. The laboratory is not the hospital.

Another example involves the use of stainless steel rods which are surgically implanted next to the spinal column to correct a medical condition called scoliosis. In one case a patient who had been healing well during the first year was found to have a broken rod during a follow up examination. There was also a further complication because a condition called pseudo arthrosis had developed necessitating more surgery.

The surgeon had no explanation as to causes. The manufacturer had two. One was that the pseudo arthrosis caused the rod to break, and the second, that the rods are not intended to remain implanted; sooner or later stresses imposed by normal activity could cause a rod to break.

The surgeon had different expectations. Implanting the rods was major surgery and the technique of aligning the spine with the rods and fixing the two together with fine wires was a delicate and intricate process. He did not calculate the undoing of any of this.

Of course, there was no discussion of any of the explanations advanced by the manufacturer in the label copy for this instrumentation. It is certainly reasonable to expect that when a manufacturer develops a medical device in mutual cooperation with the medical community, both are in agreement about the conditions of use.

Both distraction rods and IV infusion pumps are critical devices and have been long approved for use by the FDA. As important as this approval process is, it does not alone insure safety and efficacy in any absolute sense. The medical device manufacturer has the greater responsibility in this regard.