



Division of Dockets Management (HFA-305)  
Food and Drug Administration  
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**Comments of Patient & Consumer Coalition  
to the U.S. Food and Drug Administration  
Agency Information Collection Activities;  
Proposed Collection;  
Comment Request;  
Medical Devices; Device Tracking  
Docket No. FDA—2008—N-0050**

The undersigned members of the Patient & Consumer Coalition write to comment on the proposed collection of medical device tracking information by the agency. We believe that thorough medical device tracking is necessary for the FDA to fulfill its mission of “protecting the public health by assuring the safety, efficacy, and security of...medical devices...”<sup>1</sup>

Every American relies on medical devices. Whether they use band-aids, contact lenses, hearing aids or pacemakers, medical devices are part of our daily lives. Increasingly, baby boomers rely on medical devices such as artificial hips, heart valves, and wrinkle fillers.

More than 5,000 medical devices were approved by the FDA in 2006. Almost all (98%) were cleared through the less than rigorous 510(k) process. This process usually does not require clinical trials to prove that the devices are either safe or effective. As a result, some devices are neither safe nor effective, which underscores the need for a strong medical device tracking system.

If a patient experiences a problem with a medical device, his or her life could depend on knowing whether the problems are specific to a particular batch of products, to a certain

manufacturing facilities, or a failure of the device design. A system to collect medical device tracking information will help assist this patient and similarly situated Americans relying on medical devices. Medical device tracking will also help ensure the safety, efficacy, and security of devices that are increasingly made in foreign facilities that are infrequently inspected. Even devices made in the United States are manufactured in facilities that have been inadequately inspected.

The Code of Federal Regulations (CFR) states: “[R]egulations are intended to ensure that tracked devices can be traced from the device manufacturing facility to the person for whom the device is indicated, that is, the patient. Effective tracking of devices from the manufacturing facility, through the distributor network (including distributors, retailers, rental firms and other commercial enterprises, device user facilities, and licensed practitioners) and, ultimately, to the patient is necessary for the effectiveness of remedies prescribed by the act, such as patient notification (section 518(a) of the act) or device recall (section 518(e) of the act)...the legal responsibility for complying with this part rests with manufacturers who are subject to tracking orders, and that responsibility cannot be altered, modified, or in any way abrogated by contracts or other agreements.”<sup>2</sup>

In Docket No. FDA—2008—N-0050, the FDA invites comments on four topics:

1. Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility;
2. The accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Ways to enhance the quality, utility, and clarity of the information to be collected;
4. Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

The Patient and Consumer Coalition’s comments focus on topics 1 and 3.

On topic 1, we are specifically examining the sections of the CFR referenced in Table 1.—‘Estimated Annual Reporting Burden’ and Table 2.—‘Estimated Average Annual Recordkeeping Burden.’

According to Table 1, complying with 21 CFR Section 821.30(a) and (b) requires the most ‘Total Hours’ on the ‘Estimated Annual Reporting Burden.’ Nevertheless, this is necessary information to protect patients from serious adverse health consequences from defective devices. This section deals with tracking obligations of persons other than device manufacturers, such as distributors of medical devices. This reporting request provides basic information with practical utility such as the name and address of distributors, the lot number, batch number model number or serial number of the medical device. If necessary, further critical tracking information is required: the date the device was explanted and contact information for the explanting physician; the date of the patient's death, or the date the device was returned to the manufacturer, permanently retired from use, or otherwise permanently disposed of. All information requested is vital

to patient safety and each piece of critical public health data should continue to be a part of the medical device tracking system.

21 CFR Section 821.25 deals with the device tracking system and content requirements for manufacturers and mirrors many of the requirements for distributors of medical devices (see Section 821.30(a) and (b) above. Again, this is practical information that is a necessary part of the medical device tracking system designed to protect patients from defective devices.

21 CFR Section 821.2 deals with ‘exemptions and variances’ and requires manufacturers and distributors to give reasons why compliance with tracking requirements are unnecessary and to describe alternative steps to ensure that an effective tracking system is in place. This section rightfully puts the burden on manufacturers and distributors to justify an exemption or variance. In fact, exemptions should be exceedingly rare.

As the FDA notes in this ‘Comment Request,’ “Manufacturers and FDA (where necessary), use the data to: (1) Expedite the recall of distributed medical devices that are dangerous or defective; and (2) facilitate the timely notifications of patients or licensed practitioners of the risks associated with the medical device.”<sup>3</sup>

Notifying patients of recalls of defective devices in a timely manner is essential to patients’ good health, and sometimes is a matter of life and death. Problems with medical devices are not uncommon. In a recent three-month span, federal regulators responded to more than 100 safety problems regarding medical devices.<sup>4</sup>

Too many unsafe devices have reached the market. Examples include<sup>5</sup>:

- Jaw implants (TMJ implants): The Teflon from the Vitek implants broke off into particles that caused bone degeneration in the jaw joint and skull. Some patients can no longer eat, others have holes in their skulls, and chronic pain is a common problem.
- Bladder slings: Boston Scientific’s ProteGen bladder sling caused vaginal erosion.
- Pacemakers and defibrillators: Tens of thousands of pacemakers and defibrillators have been recalled in recent years. When these products are defective, patients can die.
- Contact lens solution: Bausch & Lomb’s ReNu with MoistureLoc contact lens solution turned out to be a breeding ground for fungus that caused severe eye infections. One-third of consumers who developed the eye infections needed to have their eyesight restored with corneal transplant surgery.
- Heart valves and other implants: In April 2007, the FDA seized all implantable medical devices from Shelhigh, Inc. after finding deficiencies in manufacturing. The devices are used in open heart surgery in adults, children, and infants.

More unsafe medical devices will likely reach the market due to the overuse of the 510 (k) process, the speed of the device review process, the lack of inspections, and the use of non-FDA “third party” inspections of manufacturing facilities.

Since third-party inspection companies are paid and selected by device companies, the current third party inspection process creates an incentive for third party inspection companies to please their customers, if they want to stay in business. A stronger medical device tracking system is necessary to balance these inherently conflicted device approval procedures.

On topic 3, the Patient & Consumer Coalition believes that the FDA can enhance the quality and utility of device information collected by immediately implementing the unique identification system for medical devices, which was mandated by the Food and Drug Administration Amendments Act of 2007.<sup>6</sup> PL 110-85 states: "Secretary shall promulgate regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number."<sup>7</sup>

FDA products, such as spinach and peanut butter, can be traced back to their growers or processors. Without a unique medical device numbering system, the FDA, however, is unable to efficiently track medical devices, which could potentially put thousands of patients' lives at risk.

The FDA should also enhance product safety and the quality and utility of information by ensuring that device manufacturing facilities are inspected in a timely manner. FDA officials estimate that U.S. makers of the highest-risk medical devices are examined, on average, every three years, and moderate-risk devices every five years. These facilities should be examined every two years. Examination of overseas medical device makers is even worse. In fact, foreign facilities are examined every six years for the riskiest products. Approximately 27 years can lapse between FDA inspections for moderate-risk products.<sup>8</sup>

The Patient & Consumer Coalition believes the risk of untracked medical devices is too high for public health. The FDA should strengthen its medical device tracking system and utilize a unique identifications system. Any changes to the tracking process should ensure that patients' health is the first priority.

Sincerely,

Consumers Union  
Government Accountability Project  
National Research Center for Women & Families  
National Women's Health Network  
Our Bodies Ourselves  
Title II Community AIDS National Network  
The TMJ Association, LTD

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<sup>1</sup> Food and Drug Administration's Mission Statement,  
<http://www.fda.gov/opacom/morechoices/mission.html>

<sup>2</sup> Code of Federal Regulations, 21 CFR 821.1

<sup>3</sup> Federal Register/Vol. 73, No. 24/Tuesday, February 5, 2008/Noticespage 6730.

<sup>4</sup> "U.S. Supreme Court shields makers of medical devices, *Associated Press*, February 21, 2008.

<sup>5</sup> National Research Center for Women & Families, "The Medical Device User Fee Act (MDUFA) and Patient Safety," Issue Brief, June 2007, <http://www.center4research.org/i-brief-mdufa.html>

<sup>6</sup> Maureen McKinney, "Coalition calls on FDA to act on medical-device ID scheme," Government HealthIT, <http://www.govhealthit.com/online/news/350295-1.html>

<sup>7</sup> PL 110-85, Sec. 226 "Unique Device Identification System."

<sup>8</sup> Anna Wilde Mathews, "FDA Faulted for Scrutiny of Medical-Device Makers," *The Wall Street Journal*, January 29, 2008.