DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Mr. Ivan Bland
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This responds to your petition dated July 27, 2004 (filed by the Food and Drug Administration (FDA) on August 9, 2004) requesting a determination that an advisory opinion or exemption from preemption is not necessary for certain ordinances regarding automated external defibrillators (AEDs) that the City of Arlington is considering. Because FDA cannot respond to your petition without determining whether the ordinances would be expressly preempted by section 521(a) of the Federal Food, Drug, and Cosmetic Act (the act), we are considering your petition as a request for an advisory opinion under 21 CFR § 808.5.

Medical Device Preemption Under the Federal Food, Drug, and Cosmetic Act

Section 521 of the act, 21 U.S.C. § 360k, states that, except as provided in section 521(b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement which is different from, or in addition to, any Federal requirement applicable to the device, and which relates to the safety or effectiveness of the device or to any other matter included in a Federal requirement applicable to the device. Section 521(b) sets forth the requirements if a State or a political subdivision thereof applies for an exemption from preemption. The Secretary may issue an exemption regulation if the state requirement is (1) more stringent than the Federal requirement which would be applicable to the device if an exemption were not in effect, or (2) the requirement is required by compelling local conditions, and compliance with the requirement would not cause the device to be in violation of any applicable Federal requirement under the act.

The Supreme Court addressed the scope of section 521 in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). That case arose out of Medtronic's marketing of a cardiac pacemaker that was subject to the premarket notification requirements of section 510(k) of the act (21 U.S.C. § 360(k)). The decision generally is interpreted to mean that FDA clearance of a device under the premarket notification requirements of section 510(k) does not, by itself, create federal "requirements" for the device that would support express preemption of State or local requirements under section 521 of the act. *Lohr* did not address the scope of section 521 with respect to devices for which FDA has approved a premarket approval application (PMA) under section 515 of the act.

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FDA Regulation of AEDs

An automated external defibrillator (AED) is a low-energy device with a rhythm recognition detection system that delivers into a 50 ohm test load an electrical shock of a maximum of 360 joules of energy intended for use in defibrillating (restoring normal heart rhythm to) the atria or ventricles of the heart. An AED analyzes the patient's electrocardiogram, interprets the cardiac rhythm, and automatically delivers an electrical shock (fully automated AED), or advises the user to deliver the shock (semi-automated AED) to treat ventricular fibrillation or pulseless ventricular tachycardia. 21 CFR 870.5310(a). The only AEDs lawfully on the market in the United States are in commercial distribution pursuant to premarket notification submissions cleared by FDA under section 510(k). FDA has approved no premarket approval applications (PMAs) for AEDs.

The Ordinances

1. 102.10 Emergency Medical Provisions Regarding Automatic External Defibrillators (AEDs)

This ordinance would require that the owner/occupant of a health (exercise) facility make an AED readily accessible and available in the facility for site employees and the general public. The ordinance would also require that the owner/occupant maintain the AED and provide training to designated employees on the proper use of the AED. Based on review of this ordinance, FDA concludes that the proposed ordinance would not establish any requirements with respect to the device itself, including its design, labeling, manufacture, or use. Thus, if enacted, the ordinance would not establish any requirement with respect to a device that is different from, or in addition to, any FDA requirement with respect to that device. FDA, therefore, has determined that this ordinance, if enacted as proposed, would not be preempted by section 521 of the act.

2. 102.10 Emergency Medical Provisions Regarding Automatic External Defibrillators

The second measure would require that the owner or occupant of a building that can accommodate more than 1,000 occupants, other than a church or hospital, make an AED readily accessible and immediately available, when needed, for building employees and the general public. The ordinance would also require that the owner or occupant maintain the AED and provide training to employees on the proper use of the AED. As with the proposed ordinance summarized above, this proposed ordinance would not establish any requirements with respect to the device itself, including its design, labeling, manufacture, or use. If enacted, this ordinance would, therefore, not establish any requirement with respect to a device that is different from, or in addition to, any FDA requirement with respect to that device. FDA, therefore, has determined that this ordinance, if enacted as proposed, would not be preempted by section 521 of the act.

3. Section 3.01 Duties of Owner

Section 3.01 would provide that any person who owns or acquires an AED, other than a person who owns or acquires it strictly for resale, shall:

a. Register the AED with the Arlington Fire Department;

b. Inspect, test, store, maintain, and service the AED in accordance with all federal and state laws and regulations;

c. Require all persons reasonably expected to operate the AED to complete training on the use of the AED;

d. Notify the Arlington Fire Department as soon as possible, but no later than 24 hours after the use of the AED of certain information relevant to the incident; and

e. Receive and maintain records regarding information required to be reported under the ordinance.

FDA has not imposed any requirements on AEDs that are counterparts to the requirements that the ordinance summarized above would impose. If enacted, this ordinance would, therefore, not establish any requirement with respect to a device that is different from, or in addition to, any FDA requirement with respect to that device. FDA, therefore, has determined that this ordinance, if enacted as proposed, would not be preempted by section 521 of the act.

4. Section 4.01 Emergency Contact Following AED Use

Section 4.01 would require any person who uses an AED outside a hospital setting to call 911. This proposed ordinance would not establish any requirements with respect to the device itself, including its design, labeling, manufacture, or use. If enacted, this ordinance would, therefore, not establish any requirement with respect to a device that is different from, or in addition to, any FDA requirement with respect to that device. FDA, therefore, has determined that this ordinance, if enacted as proposed, would not be preempted by section 521 of the act.

5. Section 5.01 Sales of AEDs

Section 5.01 would require all persons selling an AED within the city to report the sale of the AED to the fire department and require that the purchaser provide proof that it will comply with other requirements of the ordinance. This proposed ordinance would not establish any requirements with respect to the device itself, including its design, labeling, manufacture, or use. If enacted, this ordinance would, therefore, not establish any requirement with respect to a device that is different from, or in addition to, any FDA requirement with respect to that device. FDA, therefore, has determined that this ordinance, if enacted as proposed, would not be preempted by section 521 of the act.

6. Section 6.01 Fire Department

Section 6.01 would permit the fire department to establish standards for training, testing, maintenance, servicing and inspection of AEDs and to maintain records regarding AEDs. FDA has not imposed any requirements on AEDs that are counterparts to the requirements that this ordinance would impose. If enacted, this ordinance would, therefore, not establish any requirement with respect to a device that is different from, or in addition to, any FDA requirement with respect to that device. FDA, therefore, has determined that this ordinance, if enacted as proposed, would not be preempted by section 521 of the act.

Conclusion

In sum, FDA has concluded that the City of Arlington's proposed ordinances regulating use of AEDs, if enacted as proposed, would not establish any requirements with respect to AEDs that are different from or in addition to any FDA requirement with respect to AEDs. As a result, the City of Arlington's proposed ordinances would not be preempted by section 521 of the act. Please note that this opinion is based upon the proposed ordinances enclosed with your submission. This opinion may not apply if the legislation is changed significantly upon enactment.

If you have any questions about this response, please contact Myrna Hanna at (301) 827-2971.

Sincerely,

Linda S Kahan

Linda S. Kahan
Deputy Director
Center for Devices
and Radiological Health