Testimony Before the FDA's Circulatory System Devices Panel of the Medical Devices Advisory Committee

Proposed Classification of External Cardiac Compressor (ECC) Devices

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Thank you and good morning.

I am Sarah Sorscher, a researcher at Public Citizen's Health Research Group (HRG), testifying on behalf of myself and the organization. We have no financial conflicts of interest.

Public Citizen opposes to the reclassification of External Cardiac Compressor (ECC) devices, because the best-designed study of these devices, the ASPIRE study, provided strong evidence that death and neurological injury are more common with use of this device compared to manual CPR.

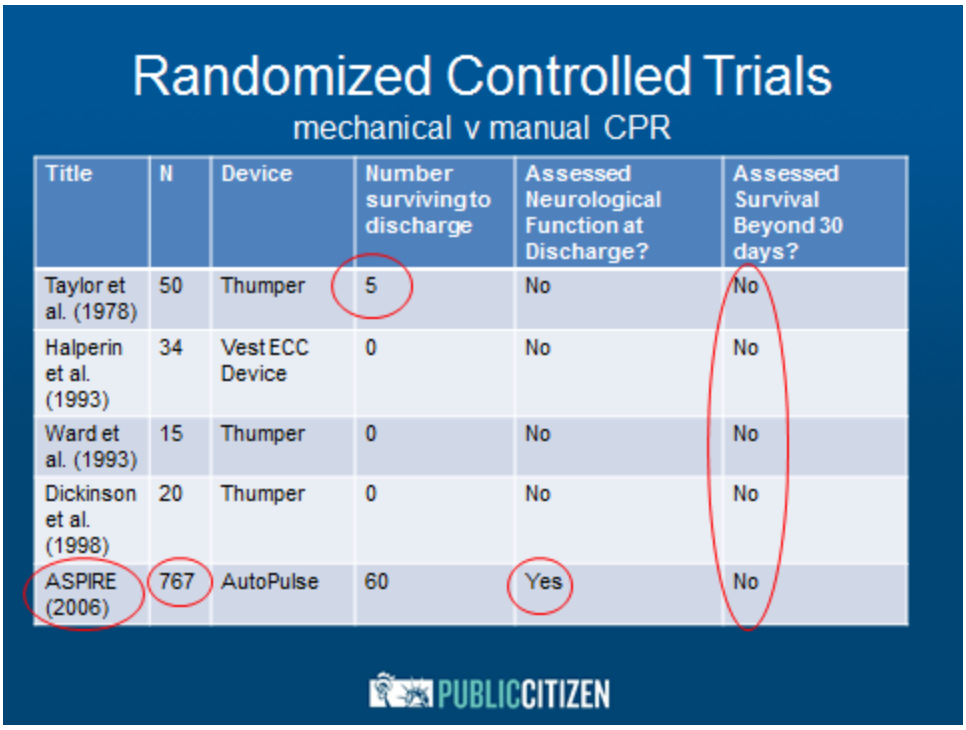
Moreover, the FDA's proposal for limiting the use of the device to situations where fatigue or insufficient personnel render manual CPR ineffective is not a workable solution.

I will not discuss CPR Aid devices.

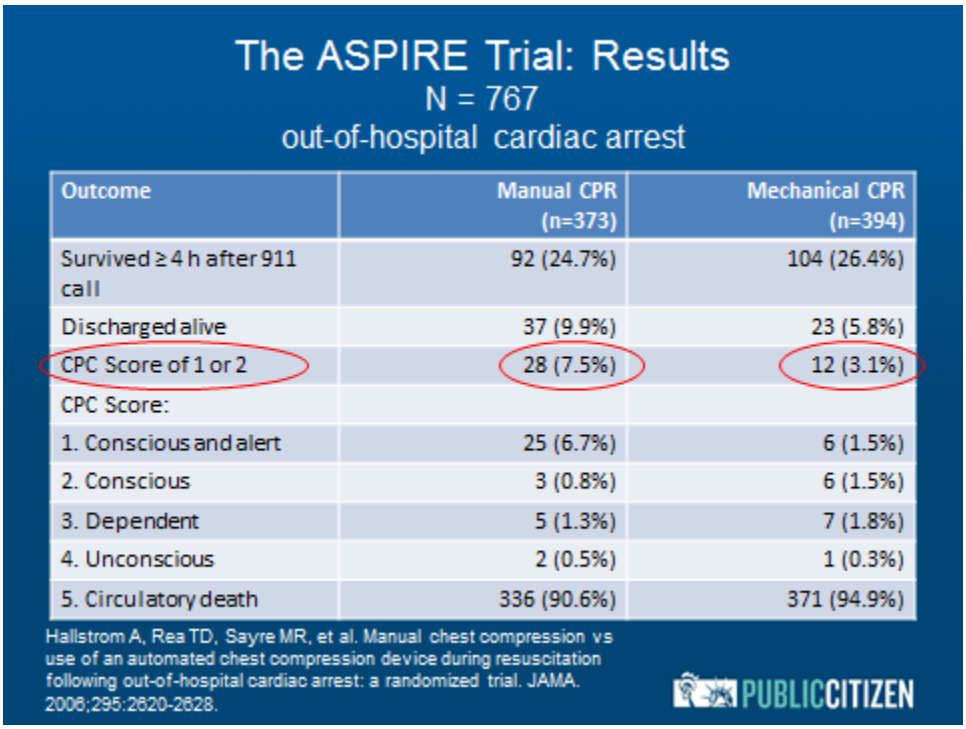
The FDA has acknowledged that "[Available evidence] cannot provide reasonable assurance that the devices are safe and effective when used *in place of* standard manual CPR."[1]

Indeed, only five randomized controlled clinical trials have ever compared mechanical to manual CPR. Only one trial, the ASPIRE study, was sufficiently powered to detect a difference between groups. That trial was also the only trial that studied survival and neurological status at discharge. In fact, of the four other randomized controlled studies, only five patients total even survived to discharge. No trials assessed long-term survival beyond 30 days.

[1] FDA Executive Summary. Prepared for the September 11, 2013 meeting of the Circulatory System Devices Panel. Classification of the External Cardiac Compressor (including CPR Aid Devices) [21 CFR 870.5200]. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM367601.pdf. Accessed September 10, 2013.



The most striking finding of the ASPIRE study was that subjects in the mechanical compression group were significantly more likely to have worse neurological outcomes at hospital discharge, with only 3.1% of subjects in the device-treated group leaving the hospital in a state of consciousness (CPC score 1 or 2) versus 7.5% of subjects in the manual CPR group (P=0.006).



There have been criticisms of the ASPIRE study, there remains debate over whether that study showed conclusive evidence of harm, and additional studies have been proposed that may address these issues.

None of this critique addresses the main point, which is that neither the ASPIRE trial, nor any randomized controlled study, has shown that the device is safe and effective when used in clinical practice, under any conditions.

The FDA has attempted to avoid this problem by stating that the device will only be used under specific conditions:

- During transport,
- Extended CPR when fatigue may prohibit the delivery of effective/consistent compressions to the victim, or
- When insufficient EMS personnel are available to provide effective CPR.[2]

The FDA's argument is that if manual CPR is truly "unavailable," mechanical chest compressions are better than nothing.

But *imagining* that this scenario exists is not enough: the FDA must have evidence to establish that such conditions can be identified in clinical practice and effectively guide treatment decisions.

In practice, EMS teams using this device will arrive at the scene and hopefully initiate manual CPR as soon as possible. If circulation does not return, they must decide: do we continue manual CPR? Or position the patient in a mechanical compression device?

FDA's proposed special control is, in effect, an instruction to EMS personnel to balance the safety and efficacy of two possible treatment options themselves, on an ad hoc basis.

Perhaps there is some point at which the team becomes so "fatigued" that the quality of manual compressions suffers, and the scales tip in favor of mechanical compressions. But how tired does the team have to be before mechanical compressions are a good idea? Will using the device to allow easier prolonged transport lead to better outcomes, or worse? No randomized studies have addressed these questions, and the ASPIRE trial, which involved situations of out-of-hospital cardiac arrest, demonstrated harm.

I will close with a quote from the authors of the ASPIRE study:

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[2] FDA Executive Summary. Prepared for the September 11, 2013 meeting of the Circulatory System Devices Panel. Classification of the External Cardiac Compressor (including CPR Aid Devices) [21 CFR 870.5200]. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM367601.pdf. Accessed September 10, 2013.

> The evidence from [the ASPIRE study] is that the AutoPulse has no survival advantage and may be harmful. For now, the AutoPulse should be used only in the context of clinical research until evidence can sufficiently explain the ASPIRE results and provide assurance of survival advantage.[3]

Public Citizen agrees. Until survival advantage can be demonstrated, under the FDA's proposed indication or otherwise, death and neurological impairment remain a probable health risk, safety and effectiveness are not assured, and the probable benefits of the device do not outweigh the risks.

We urge this panel to recommend retaining the device in Class III, so that further testing can be conducted before additional members of the public are exposed to the device.

Thank you for your time.

[3] Hallstrom A, Sayre MR, Christenson J, et al. The AutoPulse Assisted Prehospital International Resuscitation (ASPIRE) trial investigators respond to inhomogeneity and temporal effects assertions. *Am J Emerg Med.* 2010;28(8):973-976.