

News Release

A Good Cigar May Be A Smoke, But A Gun Is Not A Medical Device, FDA Says In Response To Gunmaker

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Contact Communications:
(202) 898-0792



Washington, DC - The headlines were attention-grabbing. **Discovery News** wrote "FDA Approves Handgun for the Handicapped." The website **NowPublic** wrote "FDA Certifies Handgun as 'Medical Device.'" **Medgadget**, which calls itself "the internet journal of emerging medical technologies," wrote "Medicare to Cover Prescription Handguns?"

The **New Zealand Herald** wrote "A U.S. gun company will market a pistol to elderly Americans that will be subsidi[z]ed by the government in the same way as a wheelchair or walking frame." **FOX News** wrote the gun's manufacturer "says it's had it certified by the FDA as a 'Class I Medical Device.' That means doctors could prescribe the handgun to qualified patients, who would then have some or all of the cost reimbursed by Medicare or private insurance."

The U.S. Food & Drug Administration says otherwise.

After a flurry of calls generated by the manufacturer of the Palm Pistol, a single-shot 9mm handgun that rests in the palm and fires when squeezed, **the FDA told the Brady Campaign to Prevent Gun Violence on Monday that it certainly had not approved the device.** Shortly after the Brady organization contacted FDA, the agency issued a statement saying "the U.S. Food and Drug Administration has determined that the Palm Pistol, manufactured by Constitution Arms, is not a medical device under the Federal Food, Drugs, and Cosmetic Act. The manufacturer registered and listed the product in the FDA's electronic database on Dec. 2, 2008. Because the FDA has determined the product is not a medical device under section 201(h) of the Act, FDA is canceling the registration and will return its registration fee."

Matt Carmel, CEO of Constitution Arms in Maplewood, New Jersey and inventor of the device, may be confused by this. Before the FDA's announcement, he was quoted on gun blog [SnowflakesinHell.com](http://www.snowflakesinhell.com) as saying: "All the "experts" said the Palm Pistol would never be classified as a medical device by FDA and I proved them wrong. Now all the experts are saying there is no way this will be reimbursable under Medicare. Well, we shall see about that!" And the gun blogger, who calls himself Sebastian, responded "the progressives created this system, and now we have hijacked it to help people buy guns! Matt has hoisted them on their own petard." (<http://www.snowflakesinhell.com/2008/12/03/hoisted-on-their-own-petard/>)

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