

Bureaucracy, Red Tape, and Anti-Gunners:

What You Fight to Bring a New and Unique Firearm to Market

■ BY BRIAN McCOMBIE

It was early December 2008, and shooting instructor Matthew Carmel was feeling pretty good. Carmel, something of a tinkerer and inventor, had come up with a single-shot, 9mm pistol. It fit in the palm of a person's hand with the trigger actuated by the thumb. Dubbed "The Palm Pistol," Carmel's invention was created with disabled shooters in mind.

Prior to December, the Food and Drug Administration (FDA) was performing a "Device/Not a Device" determination for the Palm Pistol, and Carmel was all but told the Palm Pistol would be listed as a Class I Medical Device. He would still have to jump through a number of other administrative hoops. The FDA's indication that the unique handgun would receive medical device status meant that one day physicians could essentially "prescribe" the Palm Pistol to patients who lacked the physical ability to use a standard firearm. Patients could then get partial (or in some cases, full) reimbursement through Medicare and other health insurance policies.

As word of the FDA determination made its way to the media, the Palm Pistol was written about and blogged about. It received a fair amount of television coverage, too, including a few jokes by Jay Leno, host of NBC's *Tonight Show*.

That's when the FDA reversed its position and told Carmel the Palm Pistol no longer qualified as a medical device. Carmel believed the reversal was ultimately political in nature, and the result of pressure applied by the nation's largest anti-gun group.

A resident of Maplewood, New Jersey, Carmel is 52 years old. He's also an environmental health engineer, who, until a couple years ago had not shot a firearm since summer camp when he was 12.

"I always believed in the Second Amendment," Carmel said. "But I never took any direct action to get involved."

Yet the September 11, 2001, attacks on this nation gave Carmel a different perspective on self-defense. A few years later Hurricane Katrina hit New Orleans, and hundreds of law-abiding people had their firearms confiscated by the New Orleans police.

"Then it became clear in my mind where this whole thing was going," said Carmel, and he knew it was time for him to take some of that "direct action."

So in 2005, Carmel founded Constitution Arms. He became an NRA-certified instructor in rifle, pistol, and shotgun, and also became certified as a range safety officer. He applied for and received federal firearms licenses, both for retail and manufacturing. Then he dedicated himself to his new life's work as a firearms instructor. His current specialty is teaching handgun self-defense.

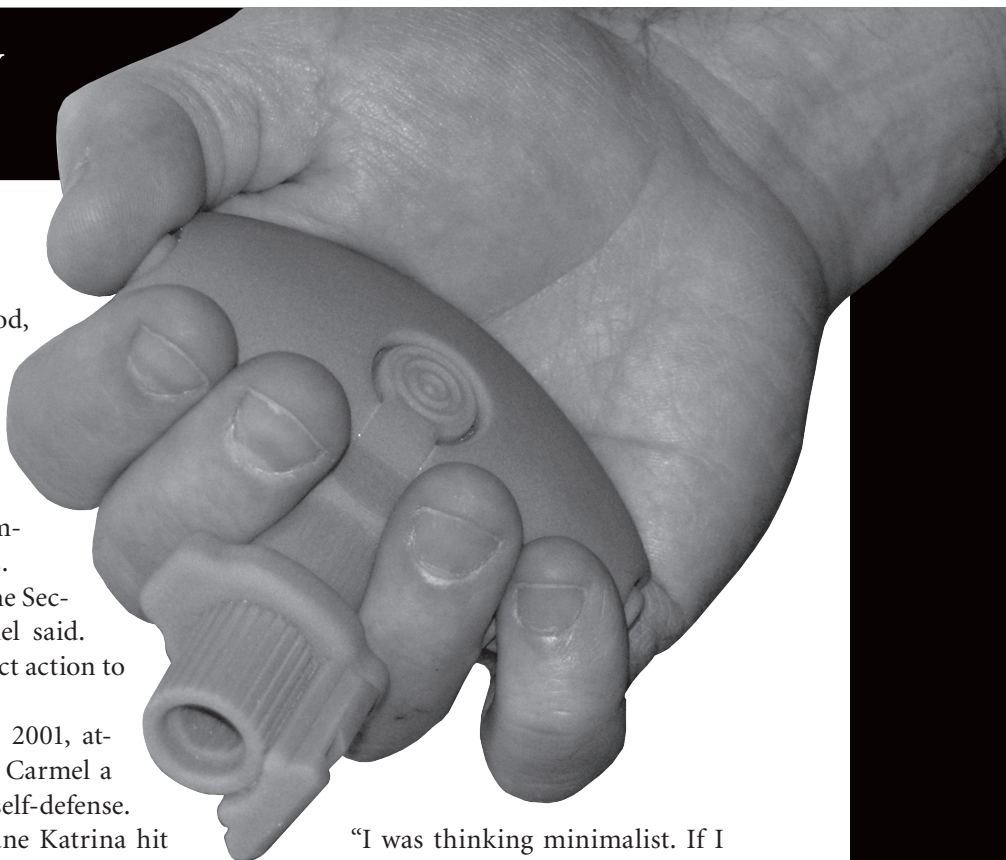
"I was sitting in my workshop one day, playing around with a T-handled screwdriver," Carmel remembered. "And I was thinking about the recurring problem I have with the seniors I teach — loading cartridges and locking slides, and hand weakness.

"I was thinking minimalist. If I start with just a cartridge, what is the minimal thing I have to put around it in order to ignite the primer and send this projectile downrange? What's the least amount of 'thing' I need to do that?"

The T-handled screwdriver in Carmel's hand suggested the answer. The minimal "thing" needed was a barrel, a breech, and a short butt or handle. The pistol would fit the palm, and be fired by the thumb.

Carmel created some sketches, and talked the idea over with friends and people knowledgeable about handguns. One potential problem Carmel kept hearing was his pistol might be considered an "AOW" or Any Other Weapon, under the National Firearms Act. An AOW designation would mean additional red tape and bureaucratic hurdles, not to mention an extra tax on the firearm — all of which could make the Palm Pistol too problematic to bring to market.

Carmel consulted with attorney Stephen Halbrook, who specialized in firearms law.



Halbrook felt that the Palm Pistol would qualify as a Standard Pistol, the much-preferred legal designation.

Carmel and Halbrook submitted the necessary paperwork to the Bureau of Alcohol, Tobacco, Firearms and Explosives (BATFE). About 18 months later, BATFE informed Carmel that the Palm Pistol qualified as a Standard Pistol. “That was the first big hurdle,” Carmel said.

Next up, the FDA. Between the time he applied to BATFE and actually heard back from the agency, Carmel was working on Palm Pistol drawings and mock-ups using computers and standard CAD software. During this time, it was beginning to dawn on Carmel what a help the Palm Pistol might be to the disabled and the elderly — people who were very susceptible to attack, yet were the least able to fight off attackers.

Having received the blessing of the BATFE, Carmel contacted the FDA. Under FDA guidelines, for example, things like crutches and canes are considered medical devices, because they allowed people with disabilities or various conditions to operate at a normal day-to-day level.

“That’s what my device does — it mitigates an existing medical condition,” Carmel said. “Just like a walker or a cane or a hearing aid or any number of things which the government already approves for reimbursement. My Palm Pistol does the same exact thing.

“So I called FDA,” Carmel said. “I explained to them [what the Palm Pistol was, and who might benefit from its use]. They said, ‘You may have a medical device there.’ They told me that I may have a medical device.”

Carmel submitted a request for an FDA “Device/Not a Device” determination. About a month and a half later, Carmel heard from an FDA employee who said the Palm Pistol would very likely be ruled a medical device. The FDA employee explained the next administrative steps Carmel should take.

“Get yourself registered as a medical device establishment,” Carmel remembered being told. “Get the Palm Pistol listed as a medical device. He walked me through the process,” said Carmel of the FDA employee. “Very helpful guy. Walked me through the process personally, the day after Thanksgiving 2008, on the phone, while I was on the computer.”

All of which was done by Carmel to get the Palm Pistol registered as a “Daily Activity Assist Device.”

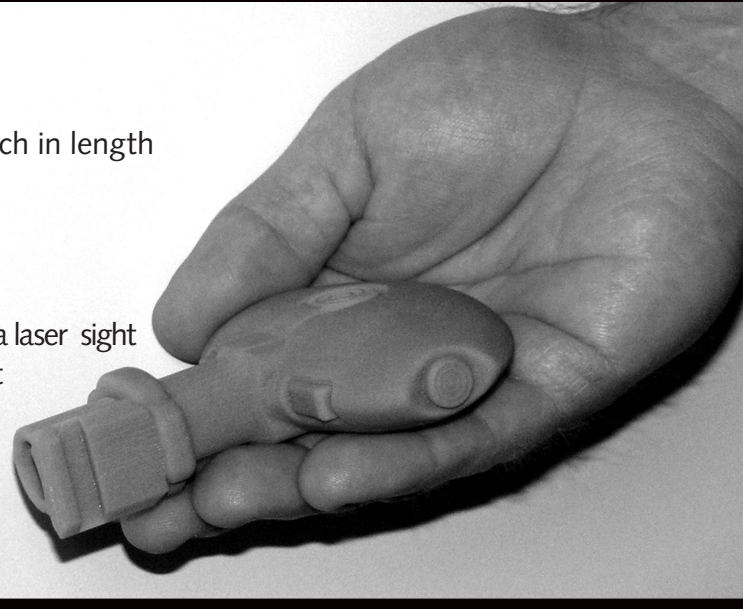
“He gave me the product code under which it would be listed,” Carmel said. “I said to him, ‘Once I have my ‘establishment registered,’ and my ‘device listed’ — phrases that are very critical — I’m not yet ‘approved’ by the FDA but I’m ‘registered’ and ‘listed’ — I said, ‘Once I have that, may I enter commerce with this device?’”

“He said, ‘You are good to go.’”

Believing he was “good to go,” Carmel sent out press releases, emailed firearm websites, and contact-

PALM PISTOL SPECS:

- Rifled, 9mm barrel, just under one-inch in length
- Adjustable trigger pull
- Grip safeties
- Chamber access latch
- Weight: to be determined
- Optional Picatinny rail for accessories like a laser sight
- Range: estimated at three to five feet
- Estimated price: \$300



ed a medical equipment website.

“I told people, ‘The FDA has listed the Palm Pistol as a medical device.’ And this hit the fan — the phone wouldn’t stop ringing. Unbelievable. Jay Leno did two jokes on it. I was interviewed by Bill Hemmer on [the Fox News program] “The Strategy Room.” The New York Post did an editorial — the writer was a friend of mine, actually. He found what I was doing was very interesting.

“Ultimately, this made such national and international news that the Brady Campaign, I was told, brought political pressure to bear on the FDA, and forced them to cancel my registration listing.”

Carmel’s assertion of political pressure by Brady was at least partially backed up by a press release from the Brady Campaign to End Gun Violence. Dated December 8, 2008, the release read, in part:

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. (All bold is in the original)

Notice the timeline the Brady press release itself referenced: The Palm Pistol was generating considerable press; so Brady then contacted the FDA — and it’s clear that Brady’s purpose was to voice its displeasure to the FDA; the FDA told Brady it had not approved the device; after Brady’s contact, FDA issued a statement to that effect.

“A week later, I got a curt email from the FDA saying, ‘Your device has been listed in error — they didn’t say whose error — and we are canceling your registration and are refunding your fees,’” Carmel said.

Carmel could appeal that FDA decision. But doing so, he estimated, would cost in the neighborhood of \$50,000. He simply does not have the money to pursue that type of legal action.

Financing is Carmel’s biggest problem right now. He figured it would cost \$150,000 just to get a handful of working prototypes built, plus the accompanying legal fees, testing, and initial marketing.

“I’m probably going to have to do an equity partnership or some sort of licensing agreement, with an established firm,” he explained. “I don’t have the financial or the infrastructure resources to make this happen. For example, if I build one gun, the manufacturing liability insurance is a minimum of \$15,000, a year, every year.”

The good news is the firearms manufacturing community has shown some interest in the gun. In fact, he had several meetings with potentially interested companies at the SHOT Show in mid-January. Carmel said the meetings went well, and he left SHOT feeling the Palm Pistol could be a reality one day in the not too distant future.

When GDTM talked with him, Carmel had just received the first actual prototype model of the Palm Pistol. Shown in the photos with this article.

The situation with the FDA still rankled Carmel, though, and he said if he ever made money with the Palm Pistol, he might just fund an appeal on the FDA’s decision.

“The only people the FDA’s hurting are the seniors and the disabled, people who might not otherwise be able to afford a device to defend themselves,” Carmel said. “I’ve gotten emails from all over, from seniors and disabled people, saying, ‘No one ever thinks of us, and thanking me for coming up with this idea.’”