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How the Food and Drug Administration Could Use the Power of Publicity to Minimize Harm and Maximize Safety of Regulated Products

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HOW THE FOOD AND DRUG ADMINISTRATION COULD USE THE POWER OF PUBLICITY TO MINIMIZE HARM AND MAXIMIZE SAFETY OF REGULATED PRODUCTS

*Katelen Walsh**

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INTRODUCTION

Throughout the course of its existence, the Food and Drug Administration (FDA) has been a somewhat overlooked entity. That is, until the FDA proclaims that something on the American market available to consumers or doctors is unsafe or dangerous. The FDA is responsible for regulating almost all foods consumed by humans, domestic animals, and livestock.¹ In addition, the FDA regulates drugs, medical devices, biologics, cosmetics, and radiation-emitting devices. In 2015, the FDA issued an average of 12.5 press releases each month.² In contrast, the U.S. Department of Health and Human Services, which has similar goals of American consumer health and protection, issues an average of 7.5 press releases each month.³

Press releases containing adverse publicity, e.g., that products or classes of products carry even the possibility of harm to the public, can be extremely harmful to the products' manufacturers occasionally compelling the manufacturers to voluntarily withdrawing the product.⁴ Traditionally, the FDA has enforced its statutory mandate by halting production or seizing tainted items before they reach the consumer market.⁵ However, the FDA may be increasing its impact by relying more on press releases that warn the public that products might carry some harm, whether it is proven or unproven.⁶ And in today's world of breaking news stories getting through to the general public through social media platforms like Twitter (which limits each post to 140 characters or less), FDA press releases on the internet can create more misinformation and panic for consumers and manufactures alike with every re-tweet.⁷

In addition, the FDA may use negative press releases as a threat, to effectively pressure manufacturers to comply with regulations or voluntarily recall products. Manufacturers may decide to incur the costs of voluntary compliance, instead of seeing their brands harmed. In 1959, the FDA broadly announced that cranberries harvested in Washington State and Oregon might be hazardous, because they had been treated with pesticides that caused cancer in laboratory rats.⁸ While the FDA warning may have had some

¹ 21 U.S.C. §§ 332, 334, 375 (2014) (outlining the FDA's role); *but see* §§ 607(d) and 457(c) (delegating the U.S. Food Safety and Inspection Service (FSIS) to regulate the U.S. commercial supply of meat, poultry, and egg products).

² *Press Announcements*, FDA, <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2015/default.htm>.

³ HHS, *2015 News Releases* (June 30, 2015), <http://www.hhs.gov/news/press/2015pres/2015.html>.

⁴ Ernest Gellorn, *Adverse Publicity by Administrative Agencies*, 86 HARV. L. REV. 1380 (1973) (arguing that the FDA has made inaccurate statements that have adversely affected the regulated entities).

⁵ *Id.*

⁶ *Id.*

⁷ Michael Barthel et al., *The Evolving Role of News on Twitter and Facebook*, PEW RESEARCH CENTER (July 16, 2015), <http://www.journalism.org/2015/07/14/the-evolving-role-of-news-on-twitter-and-facebook/> (explaining that social media users across demographics increasingly use social media platforms as their main source of news, especially news events as the events are happening which can lead to misinformation).

⁸ Lisa M. Willis, Third-Year Paper, *No Cranberries for Thanksgiving: The Impact of FDA Adverse Publicity* (2005), LEGAL ELECTRONIC DOCUMENT ARCHIVE, <http://dash.harvard.edu/bitstream/handle/1/8889457/Willis05.html?sequence=2>.

positive effect, it failed to mention that only 1 percent of the cranberries grown in that region were contaminated.⁹ As a result, many perfectly good cranberries went unsold and producers were unduly harmed.¹⁰ This example demonstrates the significant impact of one public statement from the FDA.¹¹

In the hyper-connected modern age, an FDA press release can impact manufacturers and consumers in a matter of minutes. In recent years, the FDA, recognizing that press releases are influential and cost-effective, has used them more and more often to regulate products, particularly medical devices.¹² Overall, the numbers of FDA injunctions and seizures have increased proportionally with the amount of recall events within the press releases. However, these numbers are steadily increasing each year.¹³ Unfortunately, thus far, the FDA's press releases have not been wholly accurate.¹⁴ Quite often, the press releases contain *alleged* violations, which the internet can inflate, misreport, and spread incredibly fast. The FDA has failed to use their power of publicity in a way that best guides consumers and manufacturers alike. In order to better this unfortunate use of power, the FDA must recognize that when adverse publicity is made available to the public, the effects of such publicity go beyond the product or good at issue. Once that is recognized, the solution is another obstacle the agency must face in the modern internet age of irrevocable statements. Through an in-depth look at the handling of one medical device, the issues of the FDA's use of publicity will be assessed, possible solutions to the overall problem observed. Such solutions will then be addressed, hypothetically, to the problem at issue in order to demonstrate how the FDA could potentially reign in its abuse of publicity in such a fashion that would benefit all parties.

I. THE PROBLEM

Publicity has many benefits because it can quickly alert consumers of hazardous products. However, adverse publicity can cause undue harm on the manufacturers, that may outweigh the benefit to consumers. Adverse publicity may be viewed as the deprivation of a private person or firm's right to engage in commerce and free enterprise, without the due process of law normally associated with government action.¹⁵ In other words, if the government makes a negative statement about a private actor or its product, the private actor has no recourse, even if the statement is false.¹⁶ The private actor can only

⁹ *Id.* at 6.

¹⁰ *Id.*

¹¹ 21 U.S.C. § 375 (2014).

¹² *FDA Enforcement Statistics Summary Fiscal Year 2012*, FDA (2013), <http://www.fda.gov/downloads/ICECI/EnforcementActions/UCM346964.%20pdf>.

¹³ *Id.*

¹⁴ See *infra* notes 20-23 and accompanying text (arguing that the FDA wrongly banned importation of all fruits grown in Chile, after receiving warning that grapes grown in Chile had been poisoned and finding two punctured grapes in the U.S. market).

¹⁵ Shannon E. Johnson, Third-Year Paper, *Publicity and the FDA, An Update* (1997), DIGITAL ACCESS TO SCHOLARSHIP AT HARVARD, <http://dash.harvard.edu/bitstream/handle/1/8846783/sjohnson.pdf?sequence=1>.

¹⁶ *Id.*

hope the government uses common sense and does not abuse its discretion.¹⁷ Moreover, judicial review and potential monetary compensation for market losses cannot undo the widespread effects of erroneous adverse publicity because, with sovereign immunity, such judicial review is unavailable to those injured.¹⁸ A negative FDA press release can have lasting harm to a particular product's marketing or to a manufacturer's overall reputation, even if the press release is later proved to be true only in part.¹⁹ For example, in the mid-1990s, the U.S. Embassy in Chile received two anonymous tips that grapes grown in Chile and shipped to the United States had been contaminated with cyanide.²⁰ The FDA then found puncture marks in two Chilean grapes, quickly concluded the anonymous tips must be true, and banned *all* Chilean fruits from entering the United States.²¹ The FDA took this broad action even though it found no signs of contamination whatsoever in a second batch of Chilean grapes.²² Unsurprisingly, Chilean fruit suffered economically in the American marketplace as a result of the scare generated from the FDA's press release regarding possible contamination.²³

FDA press releases that mislead American consumers and the general marketplace have dramatic and widespread effects. Unfortunately, broad, initial negative statements about products attract more attention than subsequent corrections or retractions. In one study, 160 newspapers reported negative information about a product — but only half of those newspapers published a retraction.²⁴ Even when a statement is not an outright press release from the FDA, statements from sources viewed by the general public as associated with the FDA can still have negative consequences for those whom are concerned with the subject material.²⁵ Even though the FDA does not intentionally create this misunderstanding, it still causes great harm to the manufacturers and producers at issue.²⁶ For example, in summer 2014, FDA branch chief Monica Metz claimed, in the form of a constituent update posted on FDA's website, that the agency planned to ban the traditional technique of aging artisan cheeses on wooden shelves, citing the risk of bacteria growth.²⁷ It was not an official press release but still scared many American cheesemakers and cheese lovers.

¹⁷ *Id.*

¹⁸ Federal Tort Claims Act (FTCA), 28 U.S.C. § 2680 (2014) (granting sovereign immunity to the government regarding “any claim based upon an act or omission of an employee of the Government, exercising due care, in the execution of a statute or regulation—or based upon the exercise or performance—on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused.”).

¹⁹ Willis *supra* note 8, at 5 (writing that a press release can lead to product liability suits, brand rejection, and decreased stock market value).

²⁰ *Fisher Bros. Sales, Inc. v. U.S.*, 46 F.3d 279, 282 (3rd Cir. 1995).

²¹ *Id.* at 287.

²² *Id.*

²³ *Id.*

²⁴ James T. O'Reilly, *Federal Information Disclosure*, § 25.01 (2015).

²⁵ *Clarification on Using Wood Shelving in Artisanal Cheesemaking*, FDA (June 11, 2014) <http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm400808.htm>.

²⁶ *Id.*

²⁷ *Id.*

Considering the FDA's influence, it must exercise greater caution before issuing negative information about consumer products. If the FDA reasonably believes, but has not confirmed, that a product will threaten American consumers' lives, it may need to disseminate a warning immediately. In a situation like this, an immediate and effective press release can be a great exception to the need for caution and careful steps. Unfortunately, the FDA has not created any procedure for this kind of exceptional situation, which would probably require consultation with outside experts and an immediate recall of the product.²⁸ The FDA would benefit from such a procedure: for example, it would have been extremely helpful in early 2014, when the FDA first encountered a crisis centering on power morcellators.²⁹ This crisis has continued for months and has even prompted the U.S. House of Representatives to call for an investigation of the FDA's regulation of medical devices.³⁰

Another growing concern is that the FDA fails to perform the investigations and audits that may help regulated entities to comply voluntarily and avoid adverse publicity.³¹ In 2011, the FDA failed to perform its own audits of facilities associated with food preparation in one-third of U.S. states; instead, it relied on state entities' inspections of those facilities.³² The FDA has also reduced its staff and conducted fewer food product safety tests, even as manufacturers have initiated a greater number of food recalls, over the past fifteen years.³³ Instead, the FDA has used broadly worded and inexpensive press releases to compel manufacturers to voluntarily recall their products.³⁴ If the FDA continues to use press releases to enforce its regulations, it must try to decrease the chance of undue alarm and misinformation, and not harm companies that are in full compliance with the FDCA.

²⁸ *Power Morcellator Activist Protests FDA Failure to Ban Uterine Morcellation*, BERNSTEIN LIEBHARD LLP (Nov. 11, 2014), <http://www.prnewswire.com/news-releases/power-morcellator-activist-protests-fda-failure-to-ban-uterine-morcellation-bernstein-liebhard-llp-reports-281323621.html> (discussing Dr. Amy Reed, doctor and cancer patient who underwent surgery with the device at issue, campaigning for the outright recall of the laparoscopic power morcellator, a medical device used in minimally invasive surgeries, and furiously upset with the lack of action and several months of time the FDA spent considering an outright recall of the medical device that possibly causes uterine cancer).

²⁹ *Id.*

³⁰ Jennifer Levitz, *House Passes Bill to Improve Safety Monitoring of Medical Devices*, WALL ST. J. (July 12, 2015) available at <http://www.wsj.com/articles/house-passes-bill-to-improve-safety-monitoring-of-medical-devices-1436736213>.

³¹ *Vulnerabilities in FDA's Oversight of State Food Facility Inspections*, HHS OFFICE OF INSPECTOR GENERAL (2011), <http://oig.hhs.gov/oei/reports/oei-02-09-00430.pdf>.

³² *Id.*

³³ David Morgan, *Despite Food Scares, FDA Cuts Inspections*, CBS (Feb. 26, 2007), <http://www.cbsnews.com/news/despite-food-scares-fda-cuts-inspections/>.

³⁴ FDA Enforcement Statistics Summary Fiscal Year 2013, *supra* note 12.

II. UNDERSTANDING THE OBSTACLE

A manufacturer unduly harmed by an inaccurate or overblown press release has little recourse, largely because the FDA has broad discretion to act against *potentially* harmful products.³⁵ Furthermore, the Federal Tort Claims Act (FTCA) generally protects federal government entities from liability.³⁶ As a result, the FDA can only be found liable for breaching its duty of care.³⁷ However, since Congress has declared that the FDA alone has the expertise to ensure that foods, drugs, and medical devices are safe for public use, courts are unlikely to second-guess the FDA's decisions.³⁸ This discretion is reflected in the Administrative Procedures Act ("APA"), which directs courts to defer to most decisions by the FDA and other administrative agencies.³⁹ Consequently, it is quite unlikely that a court will find that the FDA erred when the agency issued a precautionary press release.⁴⁰ Upon creating the FDA, Congress primarily intended to do away with Sinclairian producers and manufacturers.⁴¹ Congress simply assumed that the FDA would exercise good reasoning while seeking to improve health and safety in the American marketplace.

When adverse publicity results in a company's demise, it is difficult to build each necessary part of the case against the FDA. First, a plaintiff must exhaust all available agency remedies and fulfill other difficult requirements to overcome the FTCA's general grant of sovereign immunity.⁴² Even then, the plaintiff must demonstrate that the FDA's negative press release caused its economic harm.⁴³ It will be difficult to establish that the FDA's statements about a company's alleged violations of the FDCA proximately caused consumers to abandon the company's products. It is possible that consumers simply preferred competing products and the market worked as it should. Even if the plaintiff can prove causation, the plaintiff must then prove its harms. These hurdles may dissuade some plaintiffs for even seeking judicial redress.

³⁵ 28 U.S.C. § 2680 (2012) (granting discretion to the FDA and limiting judicial review of the FDA's actions).

³⁶ *Id.*

³⁷ Mark Niles, *Nothing but Mischief: The Federal Tort Claims Act and the Scope of Discretionary Immunity*, 54 ADMIN. L. REV. 1275 (2002).

³⁸ 21 U.S.C. § 393(b)(2)(A) (2012).

³⁹ Administrative Procedure Act, 5 U.S.C. § 706 (2012) (providing that judicial review is only warranted when administrative agencies act contrary to, or in excess of, statutory or constitutional authority).

⁴⁰ See Lars Noah, *Governance by the Backdoor: Administrative Law(Lessness?) at the FDA*, 93 NEB. L. REV. 89, 128 (2014) (suggesting that adverse publicity is a form of a procedural short cut that the FDA uses to avoid judicial proceedings).

⁴¹ See generally UPTON SINCLAIR, *THE JUNGLE* (See Sharp Press 2003) (1906) (exposing hazardous conditions and health code violations of workplaces within the meat-packing industry).

⁴² See 5 U.S.C. § 704 (outlining administrative exhaustion requirement).

⁴³ *Mizokami v. United States*, 414 F.2d 1375, 1376-77, 1381 (Ct. Cl. 1969) (obtaining a private bill from Congress to waive FDA's sovereign immunity and determining that "sufficient connection had been proven between the [FDA]'s actions and the alleged losses"). In *Mizokami*, a private law allowed plaintiff vegetable growers who claimed that their spinach crops were contaminated with pesticides to file suit against FDA. *Id.* at 1376-77. Along with waiving FDA's immunity, the bill also outright conceded to FDA's liability for the actions and left it to the court to decide damages for growers. *Id.* at 1379.

A negative press release has lasting effects on manufacturers and consumers. Adverse publicity lingers even after the information is found to be untrue.⁴⁴ Unfortunately, the FDA rarely issues corrections and retractions; when the FDA does, it receives much less attention, and it might create even more confusion about whether the products are safe.⁴⁵ Specifically, the FDA only revisits a negative statement after determining that everything possible to improve or completely remove the product from the market has been done, and after several FDA offices coordinate in writing with one another.⁴⁶ Therefore, it is difficult for manufacturers to recover from adverse publicity.

A. Internet Pains and Not Enough Gains

The FDA's failings in issuing press releases, which potentially cause undue recalls and consumer misinformation, are compounded by the nature of the World Wide Web. Most unfortunately, the "Internet serves as a content multiplier, and when capital markets seize information without verifying the details, the velocity and severity of the fallout can be even greater."⁴⁷ The FDA and other government agencies particularly struggle to communicate accurately over social media sites like Twitter, which call for a brief statement and a link to a formal press release. The FDA's recent social media campaign through the FDA Adverse Event Reporting System (FAERS) is a perfect example.⁴⁸ This proposed system would search the Internet for adverse events involving regulated products, which have not yet been reported to the FDA.⁴⁹ The FDA's guidance document on the proposed system focuses on how food and drug manufacturers should be properly labeling and marketing their products on social media outlets.⁵⁰ It even discusses how to address Twitter's 140-character limit.⁵¹ The system would empower consumers to report perceived violations of the FDCA directly

⁴⁴ See Nathan Cortez, *Adverse Publicity by Administrative Agencies in the Internet Era*, 2011 BYU L. REV. 1371, 1403 (2011) (suggesting that the FDA often acts on "limited information and scientific uncertainty").

⁴⁵ See 21 C.F.R. § 7.55(a) (2015) (outlining the steps for terminating an FDA recall).

⁴⁶ *Id.* A recall will be terminated when the Food and Drug Administration determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product. Written notification that a recall is terminated will be issued by the appropriate Food and Drug Administration district office to the recalling firm.

⁴⁷ Cortez, *supra* note 44 at 1401.

⁴⁸ *Mining Social Media for Adverse Event Surveillance*, FDA, <http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm455305.htm>.

⁴⁹ *Id.*

⁵⁰ Thomas Abrams, *FDA Issues Draft Guidances for Industry on Social Media and Internet Communications About Medical Products: Designed with Patients in Mind*, FDA VOICE BLOG (June 17, 2014), <http://blogs.fda.gov/fdavoice/index.php/2014/06/fda-issues-draft-guidances-for-industry-on-social-media-and-internet-communications-about-medical-products-designed-with-patients-in-mind/>.

⁵¹ *Guidance for Industry Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices (Draft Guidance)*, FDA (2014), <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401087.pdf>

to the FDA.⁵² However, many commentators, including physicians, were quite dubious that the FDA would be able to process and analyze these reports.⁵³ It could simply be seen as the FDA trying to keep up with the times.

In general, consumer panic about a particular product could prevent the manufacturer from telling its side of the story and might lead to the collapse of that manufacturer or the entire industry. As long as the internet remains an unfiltered and unregulated world of bloggers and news watchdogs, the FDA must attempt to issue accurate statements and discourage the public from overreacting and furthering unfounded allegations.⁵⁴

The FDA's use of the internet has only intensified its ability to create adverse publicity. There is a grave possibility that FDA statements will spread too quickly and become distorted before manufacturers can properly respond.⁵⁵ Furthermore, the FDA is not required to give advanced notice to manufacturers before issuing press releases.⁵⁶ Manufacturers may be caught entirely off-guard and may struggle to respond accurately and effectively to the public and to government regulators.

The FDA's broad communication can reach consumers in numerous ways. In print alone, agency publications like the FDA Consumer reach a circulation of more than 25,000 paid subscribers.⁵⁷ Furthermore, an individual may sign up for multiple FDA mailing lists, which can add up to 4 emails a day. This high number of original communications from the FDA can then become twisted and misconstrued on the internet as they are removed and become indirect communications, in ways that even the most sensationalist newspapers of the FDA's early days could not imagine because of the multiple levels between the actual source and what the audiences consumes.⁵⁸ So when an initial press release is inaccurate or incomplete, it is even more likely that the press release's dissemination on the internet will create panic.

While the FDA cannot control everything that is said on the Internet or in the press, the FDA should maintain better control, self-restraint, and due diligence in making sure that its press releases are as factually sound and clear as possible.⁵⁹ Such control could include consulting with experts outside of the agency when necessary and investigating matters further before releasing negative press releases, especially when there are no members of the FDA specialized and duly prepared to assess a particular product.

⁵² See Abrams, *supra* note 50 (emphasizing that the focus of the social media project is safety for the consumer).

⁵³ Lena J. Weiner, *FDA's Social Media Gambit 'A Long Shot,' Says Patient Advocate*, HEALTH LEADERS MEDIA (August 13, 2014 6:45 AM) <http://www.healthleadersmedia.com/page-1/QUA-307343/FDA-Social-Media-Gambit-A-Long-Shot-Says-Patient-Advocate##>.

⁵⁴ See Cortez, *supra* note 44, at 1395 (discussing the likelihood of data being misinterpreted through social media).

⁵⁵ *Id.*

⁵⁶ Johnson, *supra* note 15, at 10.

⁵⁷ *Id.* at 13.

⁵⁸ Cortez, *supra* note 44, at 1371.

⁵⁹ *Id.* at 1376.

B. What the FDA World Needs Now

Consumers, manufacturers, and retailers alike deserve a better process through which they can learn about truly dangerous or unsafe products. The FDA should only communicate reliable, factual, and timely information about investigations of products and manufacturers, including whether those investigations are pending or completed. In addition, the FDA must consider the public's likely reaction before making any announcement, to minimize the possibility of harm and maximize the potential of protecting consumers. In other words, the FDA should inform consumers about dangerous products, but should not push consumers to become hostile towards any brand or industry. By striking this balance, the FDA can ensure consumer safety without creating undue consumer panic.

III. THE PROBLEM AS FOUND IN TODAY'S HEADLINES

A. The Tragedy

The FDA demonstrated its ability to create chaos and confusion in its recent treatment of the laparoscopic power morcellator (LPM). An LPM is used to perform hysterectomies (surgical removal of the uterus) and myomectomy (surgical removal of uterine fibroids).⁶⁰ FDA regulation of the LPM began, like its regulation of many products, with tragedy. Specifically, the FDA took notice of Dr. Amy Reed's campaign to demonstrate how a common procedure used to remove otherwise benign uterine fibroids from women could actually lead to cancer.⁶¹ Fibroids are common, benign uterine growths that can be easily removed and most of the time are recommended to be removed, as the growths could later become cancerous.⁶² However, the LPM was found, in certain cases, to leave behind portions of the fibroid within the woman's uterus and become malignant some months, or sometimes sooner, after the procedure.⁶³ After this occurred to Dr. Reed, she resolved to publicize the procedure's risks.

The LPM's use in myomectomies has been and continues to be praised by some.⁶⁴ In April 2014, the FDA estimated that this surgery is performed at least 50,000 times in the United States each year.⁶⁵ It is minimally invasive, requires very little recovery time, and generally succeeds at removing uterine fibroids from a place where they would be too small to develop samples to test for cancer prior to the fibroids removal.⁶⁶ The LPM's spinning blade slices fibroid tissue into smaller pieces and removes those pieces

⁶⁰ *FDA Discourages Use of Laparoscopic Power Morcellation for Removal of Uterus or Uterine Fibroids*, FDA (April 17, 2014), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm393689.htm> (hereinafter FDA, *April 2014 Press Release*).

⁶¹ JENNIFER LEVITZ & JON KAMP, *DEADLY MEDICINE: A COMMON SURGERY FOR WOMEN AND THE CANCER IT LEAVES BEHIND* 34, 53, 67 (Wall St. J. ed. 2014).

⁶² *Id.* at 9-12.

⁶³ FDA, *April 2014 Press Release*, *supra* note 60.

⁶⁴ LEVITZ & KAMP, *supra* note 61, at 49-50, 56.

⁶⁵ *Id.* at 23.

⁶⁶ *Id.* at 9-10, 12-13.

through small incisions.⁶⁷ This procedure may be performed with a bag to catch spare pieces of the fibroids that can spread into the uterus.⁶⁸ Unless the gynecologist uses a bag with the LPM, some of the fibroid fragments may spread and be left behind in the uterus after surgery.⁶⁹ However, gynecologists routinely used the LPM device without a bag in removing uterine fibroids.⁷⁰

Dr. Reed, an anesthesiologist and mother of six, is attempting to use her own experience to push the FDA to regulate the LPM. She had the basic surgery to remove uterine fibroid tumors using the LPM, but eight days later, she learned it had worsened her prognosis by spreading cancer from the remaining uterine fibroids.⁷¹ The shredding of the fibroid inadvertently spread the undetected cancer because the fragments were uncontained.⁷² Throughout fall 2014, while Dr. Reed's cancer had progressed to stage four, her husband focused on writing letters to the FDA, questioning its failure to act about the potentially deadly medical device.⁷³ While many agree with Dr. Reed's calls for action, others argue that the device is safe and that the FDA created a mountain out of a few exaggerated facts.⁷⁴

At the time of this writing, Dr. Reed had a recurrence of her cancer, a tumor in her spine, but that has not stopped her avid fight for justice.⁷⁵ She is now involved in an FBI investigation about whether the device's manufacturer, Johnson & Johnson, knew about the risks as early as 2006.⁷⁶ Dr. Reed argues that she and other patients should have been better protected and this story involves "a violation of federal law that has led to the loss of life."⁷⁷

⁶⁷ Jon Kamp, *More Health Insurers Take Action to Curb Morcellator Use*, WALL ST. J. (Apr. 2, 2015), available at <http://www.wsj.com/articles/more-health-insurers-take-action-to-limit-morcellator-use-1428009386>.

⁶⁸ *Id.*

⁶⁹ LEVITZ & KAMP, *supra* note 61, at 24.

⁷⁰ *Id.* at 24-25.

⁷¹ *Id.* at 13-15.

⁷² *Doctor with Cancer Raises Alarm about Medical Device*, CBS NEWS (June 4, 2015), <http://www.cbsnews.com/news/doctor-with-cancer-morcellator-medical-device/>.

⁷³ BERNSTEIN LIEBHARD LLP, *supra* note 28.

⁷⁴ Jennifer Levitz & Jon Kamp, *Gynecologists Resist FDA Over Popular Surgical Tool*, WALL ST. J. (Sept. 21, 2014), available at <http://www.wsj.com/articles/gynecologists-push-back-on-fdas-caution-about-cancer-when-using-morcellation-in-hysterectomies-1411358341> (reporting that obstetrics and gynecologists alike were split over the use of LPMs in myomectomies, even after the FDA discouraged their use); see also Jon Kamp, *J&J's Exit from Morcellator Sales Leaves Opportunities for Others*, WALL ST. J. (Sept. 23, 2014), <http://blogs.wsj.com/corporate-intelligence/2014/09/23/jjs-exit-from-morcellator-sales-leaves-opportunities-for-others/>.

⁷⁵ CBS NEWS, *supra* note 72.

⁷⁶ *Id.*

⁷⁷ *Id.*; see also BERNSTEIN LIEBHARD LLP, *supra* note 28.

B. The First Press Release

In April 2014, the FDA issued its first press release regarding the LPM.⁷⁸ However, the press release simply asked doctors to *reconsider* the possibilities of harm posed by use of the LPM: a less than useful recommendation. With separate statements of caution, warning, and urging of doubt regarding the procedure's benefits and risks, the FDA's press release revealed that the benefits of the device may be limited due to the potential development after surgery, of uterine sarcoma, that had not been found or realized prior to surgery.⁷⁹ The release itself was extremely limited and offered little research data or clarity about the device's use in the future.⁸⁰ However, the press release did claim that the LPM causes cancer in 1 in 350 women and further stated:

There is a risk that the procedure will spread the cancerous tissue within the abdomen and pelvis, significantly worsening the patient's likelihood of long-term survival. For this reason, and because there is no reliable method for predicting whether a woman with fibroids may have a uterine sarcoma, the FDA discourages the use of laparoscopic power morcellation during hysterectomy or myomectomy for uterine fibroids.⁸¹

The FDA admitted that this reasoning was based on only a survey of the small amount of information on the dangers of the medical device available at the time.⁸² While the concern for the medical device had been slowly growing since approximately 2006, available information and studies about the device had unfortunately not increased. In the April 2014 press release, the FDA also promised that an advisory committee would review the device's risks in more detail that July.⁸³ Unfortunately, that committee only conducted a general review of nine studies (one of which was only in abstract form).⁸⁴

For the next five months, the FDA did not take any further actions regarding this potentially cancer-inducing surgical device. During the FDA's period of silence, individual and institutional providers offered their opinions about whether the device should remain on the market.⁸⁵ Many also criticized the FDA for discouraging use of the device but not actually recalling the device or offering any conclusive answers.⁸⁶

⁷⁸ FDA, *April 2014 Press Release*, *supra* note 60.

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² LEVITZ & KAMP, *supra* note 61, at 56.

⁸³ Jennifer Levitz, *FBI Eyes Hysterectomy Device Found to Spread Uterine Cancer*, WALL ST. J. (May 28, 2015), available at <http://www.wsj.com/articles/fbi-is-investigating-surgical-device-1432746641>; *Quantitative Assessment of the Prevalence of Unsuspected Uterine Sarcoma in Women Undergoing Treatment of Uterine Fibroids: Summary and Key Findings* (2014), FDA, available at <http://www.fda.gov/downloads/MedicalDevices/Safety/AlertsandNotices/UCM393589.pdf> (explaining limited studies conducted over the past 30 years) (hereinafter FDA, *Quantitative Assessment*); FDA, *April 2014 Press Release*, *supra* note 60.

⁸⁴ FDA, *Quantitative Assessment*, *supra* note 83.

⁸⁵ LEVITZ & KAMP, *supra* note 61, at 55, 77.

⁸⁶ *Id.* at 55.

C. The Reaction

Following the FDA advisory committee's July 2014 meeting on the LPM numerous U.S. doctors and hospitals, citing years of mistrust of the LPM, asked the FDA to announce a complete recall.⁸⁷ The leading LPM manufacturer, Johnson & Johnson, announced that it would keep its version from the market until the FDA made a conclusion about the LPM's safety.⁸⁸ BlueCross/BlueShield, Highmark, and other health insurance providers quickly followed suit by discontinuing reimbursement for procedures that used the LPM.⁸⁹

However, this was not a one-sided debate. Other patients, doctors, hospitals, and manufacturers argued that the FDA was making a mountain out of a perfectly fine and functional molehill.⁹⁰ Many wondered whether the FDA had overstepped its boundaries by declaring that 1 in 350 women treated with the LPM would develop cancer, without offering conclusive support for that statement.⁹¹ Some doctors proposed that the FDA's risk analysis was incorrect and that the actual risk of undetected sarcoma developing after the surgery was more likely to be 1 in 300.⁹² Some commentators suggested that the FDA should have considered patients' ages, history of other cancers, and other traits that might have affect the benefits and risks of using the LPM to remove fibroids.⁹³ While manufacturers and healthcare providers had varying opinions about the LPM, it became clear that those opinions could have helped FDA earlier in the process.

D. The Second Press Release

On November 24, 2014, the FDA issued a second press release that further discouraged use of the LPM to remove uterine fibroids.⁹⁴ The FDA then suggested that "immediately in effect," LPM packaging should include two additional safety warnings.⁹⁵ First, the packaging should display a "black box warning"⁹⁶ disclosing that the operation could increase the risk of spreading cancer throughout the body and worsen the patient's likelihood of long-term survival.⁹⁷ Second, the packaging must list contraindications for

⁸⁷ See *id.* at 55-56; BERNSTEIN LIEBHARD LLP, *supra* note 28.

⁸⁸ LEVITZ & KAMP, *supra* note 61, at 54.

⁸⁹ Roopal Luhanna, *Blue Cross/Blue Shield Ends Coverage for Power Morcellation in 3 States*, LEGAL EXAMINER (Sept. 12, 2014), <http://newyork.legalexaminer.com/defective-dangerous-products/blue-crossblue-shield-ends-coverage-for-power-morcellation-in-3-states/>; Kamp, *supra* note 67.

⁹⁰ Levitz & Kamp, *supra* note 74.

⁹¹ *Id.*; see also LEVITZ & KAMP, *supra* note 61.

⁹² LEVITZ & KAMP, *supra* note 61.

⁹³ *Id.* at 54, 63-64; FDA, *Quantitative Assessment*, *supra* note 83.

⁹⁴ *FDA Warns Against Using Laparoscopic Power Morcellators to Treat Uterine Fibroids*, FDA (Nov. 24, 2014), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm424435.htm> (hereinafter FDA, *Nov. 2014 Press Release*).

⁹⁵ *Id.*

⁹⁶ 21 C.F.R. § 201.57 (2015) (providing that a black box warning is the strongest warning manufacturers may be required to display on their products).

⁹⁷ FDA, *Nov. 2014 Press Release*, *supra* note 94.

use of the LPM.⁹⁸ Overall, the second FDA press release encouraged doctors to have more discussion of the LPM's risks and benefits with their patients.⁹⁹ The FDA further promised that it would continue monitoring adverse event reports and information as it became available on the medical device to protect public health.¹⁰⁰ However, the FDA's assurance could be viewed as insufficient given the delayed warning.

E. The Silver Lining

Before the FDA's advisory committee convened and issued its conclusions in its second press release, other stakeholders — manufacturers, doctors, hospitals, and insurers—conducted their own fruitful discussion. However, one group above all clearly benefited from the FDA's final conclusion: women considering procedures using the LPM. Following the FDA's second press release, those women and their providers better knew what to consider before choosing to use the LPM. The FDA was most useful when it organized and disclosed all of the stakeholders' competing arguments and helped patients to make their own informed decisions.

The FDA's actions prompted each patient and her doctor to engage in a more sustained dialogue about whether to use the LPM. The FDA has also prompted doctors to ask patients to sign informed consent forms before undergoing procedures, to share videos of the LPM's use with other doctors, and to keep asking whether the LPM surgery is the best option for each patient.¹⁰¹ So while the FDA took almost five months to issue its much-needed second press release, the FDA did help to initiate conversations between patients and doctors. Admittedly, during the delay, patients and other stakeholders may have begun to rely on the FDA's inaction and may have concluded on their own that the FDA would not issue a recall of LPMs. However, either way, the process was beneficial because patients began reviewing their options and making more educated decisions.

Despite this eventual success, the FDA has been criticized for its handling of the LPM device. For example, a majority of doctors surveyed by the Wall Street Journal agreed that the FDA should update its methods of regulating medical devices such as the LPM.¹⁰² Other government agencies are reviewing the FDA's actions and trying to ensure that this does not happen again. The FBI is currently considering the FDA's ability to effectively regulate medical devices, specifically since it initially approved the LPM, which clearly carries some risks.¹⁰³ The FBI is conducting a second, separate investigation centering on the LPM itself.¹⁰⁴ While the FBI acknowledges that the FDA made the right moves toward resolving the issue with the medical device by requiring

⁹⁸ *Id.*; *Contraindication*, MERRIAM-WEBSTER DICTIONARY, <http://www.merriam-webster.com/dictionary/contraindication> (defining contraindication as "something (as a symptom or condition) that makes a particular treatment or procedure inadvisable.").

⁹⁹ FDA, *Nov. 2014 Press Release*, *supra* note 94.

¹⁰⁰ *Id.*

¹⁰¹ LEVITZ & KAMP, *supra* note 61, at 12.

¹⁰² Thomas M. Burton, *Do the FDA's Regulations Governing Medical Devices Need to Be Overhauled?*, WALL ST. J. (Mar. 23, 2015), <http://www.wsj.com/articles/do-the-fdas-regulations-of-medical-devices-need-to-be-overhauled-1427079649>.

¹⁰³ Levitz, *supra* note 83.

¹⁰⁴ *Id.*

new warning labels on the product, the FBI is still seeking to find what information should have come to light before even the first FDA press release back in July 2014.¹⁰⁵ Finally, members of the U.S. House of Representatives, in response to the LPM crisis, have proposed an amendment to the “21st Century Cures” Act that would require more Congressional oversight on the FDA’s methodologies in determining whether a device is “generally recognized as safe” for use in the marketplace.¹⁰⁶

IV. RECOMMENDED SOLUTIONS

With some reforms, the FDA can better inform American consumers about medical devices and other consumer products. The FDA should ensure that the information in each press release is thorough and well-supported by sufficient facts.¹⁰⁷ The FDA should offer a notice and comment period to experts and stakeholders or should resolve all material questions before issuing a press release, whenever it is possible to do so.¹⁰⁸ The FDA should also consider the public’s knowledge of a product and the potential for confusion, before rushing to issue a press release.¹⁰⁹ The FDA must also become more effective at retracting and correcting negative statements, to effectively inform the public and minimize undue harm to manufacturers.¹¹⁰ In addition to FDA reforms, private actors harmed by adverse publicity should be able to seek compensation when they are harmed by inappropriate FDA action.¹¹¹

The LPM crisis demonstrates that the FDA should also find some way to address emergency situations involving products that are already on the market. The FDA should establish a taskforce that will respond to tips received through the new FAERS system.¹¹² Finally, the FDA must amend and retract flawed statements more effectively.¹¹³ This solution to the abuse and misuse of the FDA’s power of publicity could come in the form of an adjustment to the Administrative Procedure Act (APA) or the FDCA itself, through the possible creation of an amendment to the FDCA. No matter where this amendment occurs, it should include a higher standard of proof and research behind each press release, notice to companies and industries prior to release, proper termination of recalls and the mandate of corrective press releases, increased overall self-restraint by the FDA,

¹⁰⁵ *Id.*

¹⁰⁶ Levitz *supra* note 30.

¹⁰⁷ Richard S. Morey, *FDA Publicity Against Consumer Products—Time for Statutory Revitalization?* 30 BUS. LAW. 165-67 (1975) (explaining because of the large number of products regulated by FDA, manufacturers are particularly vulnerable to the adverse effects of recalls or the threat of recalls whether or not the recall is appropriate or the manufacturer feels it justified).

¹⁰⁸ *See* Gellhorn, *supra* note 4, at 1431.

¹⁰⁹ *Id.* at 1425-27, 1429 (comparing the reliability of an overflow of information on which agencies rely and exploring the effects of press releases across different agencies which can reduce agency credibility and benumb the public).

¹¹⁰ *See* Johnson, *supra* note 15.

¹¹¹ *See* Cortez, *supra* note 44, at 1406, 1408 (recommending less dependency by the FDA on the protections of the APA and opening themselves up to more judicial review when there is actual harm).

¹¹² *See* FDA, *Mining Social Media for Adverse Event Surveillance*, *supra* note 48

¹¹³ *See* Gellhorn, *supra* note 4.

and the creation of a task force that can quickly respond when there is a legitimate threat of seriously harmful products.¹¹⁴

A. Better Research

If the FDA is required to be more thorough and careful when drafting a press release, it will be less likely to cause harm.¹¹⁵ Instead, the resulting press release will be more reliable and beneficial to the public.¹¹⁶ Also, by always making sure that there is some level of outside, specialized expert opinion involved in a press release regarding the specific product and its functions, adverse publicity will be less likely to have misleading or incorrect information in it.¹¹⁷ By mandating a minimum amount of time and research on a product prior to the press release, this amendment could occur without too much extra cost and time to the FDA. This higher standard could also decrease the amount of allegations that the FDA included in their press releases and further dispel the opportunity for misinformation as the information trickled through social media. The FDA could ban allegations in press releases altogether. Alternatively, in cases of more significant risk or substantial harm, when the FDA needs to issue press releases, it should require expert opinions and caveat the release by indicating the case is currently an allegation, or that it lacks complete information.¹¹⁸

B. Due Notice

Furthermore, the FDA should be required to offer some warning to manufacturers before suggesting publicly that the manufacturers have not complied with the FDCA. Due notice could mean that the FDA was required to give a reasonable amount of time for manufacturers and producers to be able to comment or even correct the issue that FDA found with the product, much like the standard voluntary recalls of the FDA.¹¹⁹ Such a notice and comment period would protect manufacturers from undue adverse publicity.¹²⁰ It might allow manufacturers to voluntarily recall potentially harmful products while maintaining public goodwill. Reasonable notice could even be limited to when the pending press release contains significant risk to either public health or (and possibly one leading to the other) significant economic risk to the manufacturer upon disclosure of the press release.¹²¹ More than likely, if the FDA were more susceptible to tort liability, the agency might be more willing to provide reasonable notice.

¹¹⁴ See Cortez, *supra* note 44, at 1409 (arguing for a higher standard of proof); Gellhorn, *supra* note 4 (arguing for greater self-restraint by the FDA); Johnson, *supra* note 15; Willis, *supra* note 8, at 2 (arguing for faster and more attention-grabbing corrective press releases).

¹¹⁵ See Gellhorn, *supra* note 4.

¹¹⁶ *Id.*

¹¹⁷ See Johnson, *supra* note 15.

¹¹⁸ *Id.*

¹¹⁹ 21 C.F.R. § 810 (2012) (granting the FDA the alternative method of regulation by recalling products when there is a defect in the produce by itself or in the labeling of the product).

¹²⁰ Gellhorn, *supra* note 4, at 1431.

¹²¹ Johnson, *supra* note 15.

C. Proper Terminations & Corrective Statements

The FDA could also further the public health by becoming more willing and effective at amending or correcting press releases. The FDA should pay attention to new information and public response to its press releases, and respond when necessary. These back-end fixes to adverse publicity would provide some aid to manufacturers injured by misleading or misinformed press releases.¹²² Corrective press releases would also considerably aid confused American consumers. Such follow-up press releases could report the final outcome of FDA investigations and summarize the underlying research and evidence.¹²³

Given that the internet is a large cause of confusion and misinterpretation, the FDA could arguably try to oversee all internet commentary on FDA regulatory action.¹²⁴ Because the use of social media has become so prolific, the FDA should incorporate social media into FAERS to monitor the public's reaction to press releases and to seek out adverse events to address.¹²⁵ Through the FDA's acceptance of an additional medium to communicate with the public, it could effectively decrease the amount of misinterpretation of FDA press releases, especially those leading to adverse publicity. Integrating social media with FAERS will allow the FDA to promptly offer a corrective follow up press release to cease confusion through its FAERS operator.¹²⁶ Twitter's one hundred and forty characters will be feared no more.

D. Self-Restraint and Addressing Emergency Situations

Considering that the FDA's ability to create adverse publicity for manufacturers greatly predated the Internet, the FDA should exercise more self-restraint overall.¹²⁷ The FDA is responsible for regulating a great number of products, many of which are potentially harmful or misleading to the public. However, the FDA does not need to issue public press releases about each one of those violations unless they are emergency situations. By exercising some self-restraint, the FDA would demonstrate that it is truly dedicated to public health and would also improve its relationships with manufacturers.¹²⁸ Self-restraint by the FDA could also generate public support for a task force that will respond quickly to those products already on the market that pose imminent, serious threats to public health, but only when such a task force is completely necessary. With dedicated time and effort to study whatever available research exists and offer a recall or other advisement on the product as soon as trouble is found, such a task force would effectively guide the FDA to fulfilling its public service duty.

¹²² See generally Willis, *supra* note 8 (giving the example of the 1956 "cranberry crisis").

¹²³ See Gellhorn, *supra* note 4.

¹²⁴ See generally Barthel et al., *supra* note 7 (studying the rise of Twitter and Facebook as new sources).

¹²⁵ See FDA, *Mining Social Media for Adverse Event Surveillance*, *supra* note 48.

¹²⁶ See *id.*; see also, e.g., FDA, *Clarification on Using Wood Shelving in Artisanal Cheesemaking*, *supra* note 25 (withdrawing previous informal statements that the FDA would prohibit longstanding practice of aging cheese on wooden boards).

¹²⁷ Cortez, *supra* note 44, at 1376.

¹²⁸ *Id.* at 1376, 1428.

E. Emergency Taskforce

An emergency task force will be extremely helpful at quickly responding to products like the LPM, which are already on the market and potentially harming the public. In such cases, the FDA cannot take five months or more to reach a conclusion.¹²⁹ Adverse publicity here is simply not enough, even if it may scare up conversation between patients and their healthcare providers. Because the FDA is the leading regulator of such products, it should also be the leader in the conversation as to how to approach the products.¹³⁰ As Dr. Reed pointed out in the LPM case, if the FDA fails to offer answers, it violates its duty to protect the public from potentially harmful and unsafe products.¹³¹ An emergency taskforce can aid in the FDA's protection of the public by utilizing available information and conducting additional field research to determine whether an immediate response for a recall is required.

V. APPLICATION OF THESE RECOMMENDATIONS TO THE LPM CRISIS

In lieu of the second press release's resolution, the recommended amendments to FDA's use of publicity can be applied to the LPM crisis. The recommendations offer more effective and possibly less panic arousing public health communication methods to an agency committed to protecting consumers through the regulation of food, drugs, cosmetics, and medical devices.

A. Research

The FDA's first press release regarding the LPM did not offer any definitive conclusions, but merely suggested the LPM posed a "risk" that could worsen patients' survival.¹³² The harmful effects of LPM became more apparent after testimony surfaced in the FDA committee meetings with the Obstetrics and Gynecology Devices Panel and the subsequent FBI investigation.¹³³

The FDA admitted that there was little research on whether the LPM caused the later development of uterine sarcomas. The FDA should have thought further, and recognized that eight studies and one abstract were not conclusive enough to announce that 1 in 350 women relying on the LPM would later develop cancer.¹³⁴ Relying on a small number of studies and issuing a press release about a substantial public health issue may indicate that the lack of substantiation by the FDA caused the FDA to breach its duty to the public, or at least that there was a great deal of information left unturned.¹³⁵ By increasing the minimum threshold requirement for research studies cited, the FDA could have had the support of more doctors and hospitals to support its position and

¹²⁹ See Levitz, *supra* note 74.

¹³⁰ 21 U.S.C. § 353 (2014); Levitz, *supra* note 74.

¹³¹ Levitz, *supra* note 74 (highlighting the FDA's duty to support and protect the American consumer by diligently approving products that are healthy and safe to use but also providing professional users of such devices with due instructions on best performance practices).

¹³² FDA, *April 2014 Press Release*, *supra* note 60.

¹³³ *Id.*; Levitz, *supra* note 83.

¹³⁴ FDA, *April 2014 Press Release*, *supra* note 60.

¹³⁵ *Id.*

dissuade the use of the medical device. If the FDA utilized dissemination channels with direct access to patients: doctors, hospitals, and manufacturers, consumers would have been immediately informed and dissuaded against the use of the medical device.

B. Due Notice

Notice would be a more difficult concept to tackle here simply because the medical device industry under the regulation of the FDA is quite unlike the other consumer products regulated by the FDA in that the product is not available to the everyday consumer. However, if the FDA had given notice to both the manufacturers of the surgical medical device and the hospitals and doctors who used them, then there might have been a greater consolidation of the opinions regarding the medical device and furthermore, a better understanding of how to properly treat patients with or without it. There currently exists too much lag time between when information is available about when a device is unsafe and when the FDA issues a public determination that a device is unsafe.¹³⁶ Had the FDA notified device manufacturers, doctors, and hospitals earlier that it was committed to further researching ill health effects, there could have been a greater collaboration amongst everyone instead of the blowback the FDA received after issuing the press release. Although LPM was life-threatening, in a less dangerous context, both notification of industry personnel and consultation with experts provide stronger basis for the FDA to release adverse publicity. By collaborating its efforts, the FDA not only decreases the hostility the industry feels toward the agency, but it also increases the likelihood for voluntary participation in its device program effectiveness efforts.

C. Emergency Taskforce

The LPM is also a prime example of products already on the market potentially causing harm, which the FDA should investigate quickly. The FDA should not have taken nearly five months to report its advisory committee's findings in its second press release. The delay justifies distrust of the FDA as it currently operates and questions about whether the FDA is truly doing its best to protect the public welfare. If the FDA had an emergency taskforce when this crisis arose, it could have acted more quickly.

CONCLUSION

While the FDA is tasked with protecting the health of consumers by regulating products in the marketplace, its authority for use of publicity should be limited.¹³⁷ At the very least, the FDA must exercise care and minimize unnecessary harm to manufacturers and consumers.¹³⁸ This is particularly important as the FDA increasingly relies on adverse publicity to warn the public of *potentially* harmful products and threaten manufacturers to recall those products voluntarily.¹³⁹

¹³⁶ See Levitz, *supra* note 83.

¹³⁷ 21 U.S.C. §§ 379f-j62 (2012) (extending user-fee programs for prescription and medical devices, establishing user-fee programs for generic drugs and biosimilars, but that requiring inspection of drug manufacturing facilities, domestically and abroad based on risk assessment factors).

¹³⁸ See Gellhorn, *supra* note 4.

¹³⁹ FDA Enforcement Statistics, *supra* note 12.

Adverse publicity often creates the burden of stress for consumers, especially when a press release is later proven untrue or misrepresented. When consumers panic or fail to adequately understand FDA warnings, manufacturers suffer economically. Therefore, the FDA must gather adequate data and provide notice to manufacturers before issuing a press release containing adverse publicity. The FDA should also exhibit self-restraint on what to put into the media stream and be prepared to issue corrective statements and retractions in the case of false or misleading information. Congress can mandate these improvements by amending the FDCA or the APA, or the FDA can voluntarily implement these improvements.

Combined, these changes would improve the FDA's ability to make public statements that effectively protect consumers from dangerous products without unduly punishing manufacturers with unreasoned adverse publicity. If the FDA conducts proper research and utilizes its resources, the next time a product raises immediate concern, the FDA will be able to expeditiously address the issue, keep consumers informed, and strengthen its relationship with regulated entities.