A “Phantom Recall” Does Not Comport with FDA’s Regulatory Practice—Or Does It?: The Need for More Stringent Mandatory Reporting in FDA Matters

Eleanor G. Tennyson

ABSTRACT: This Note examines the regulatory and enforcement authority of the Food and Drug Administration (“FDA”) in light of the recent rash of recalls of pediatric over-the-counter medicines by The McNeil Consumer Healthcare Company (“McNeil”), a subsidiary of Johnson & Johnson. After detailing the controversy surrounding McNeil’s quality-control and recall procedures, the analysis focuses on proposed legislation that would give the FDA mandatory recall authority. The analysis proposes that, without requiring mandatory reporting of unexpected events associated with drugs, such legislation may only equip the FDA with phantom authority. As such, it concludes with a proposed methodology of co-reporting that would ensure the FDA has both the knowledge and power necessary to force drug manufacturers and distributors to comply with the FDA’s regulations.

I. INTRODUCTION

II. THE FDA’S RECALL POWERS AND THE MCNEIL “PHANTOM RECALL” CONTROVERSY

A. VOLUNTARY AND INVOLUNTARY RECALLS: THE (IN)ABILITY OF THE FDA TO MANDATE RECALL OF PHARMACEUTICAL AGENTS

B. THE HEADACHES OF TYLENOL AND MOTRIN: MCNEIL’S TWO-YEAR BATTLE WITH SYSTEMIC RECALLS

C. A CONGRESSIONAL HEARING DISCOVERS LAPSES IN QUALITY CONTROL AND DISTURBING REMEDIAL MEASURES UNDERTAKEN BY MCNEIL

D. THE HEADACHE CONTINUES: A SECOND CONGRESSIONAL HEARING DETERMINED TO FULLY INVESTIGATE THE “PHANTOM RECALL”

* J.D., The University of Iowa College of Law, 2012; M.S., Clemson University, 2009; B.A., Grinnell College, 2007. I would like to thank the student writers and editors of Volumes 96 and 97 of the Iowa Law Review for their work on this Note—notably Andrew Tran and Anthony Tucci. I would also like to thank my family—MTR, GET, AGT and GTT—as well as SEP for constant encouragement and support.
III. USING THE "PHANTOM RECALL" TO ARM THE FDA WITH MORE TANGIBLE ENFORCEMENT POWERS .......................................................... 1852
A. WHY DOESN'T THE FDA HAVE THE AUTHORITY TO MANDATE A RECALL FOR DRUGS IN VIOLATION OF THE FDCA? ............................. 1852
B. AN ATTEMPT TO GIVE THE FDA MANDATORY RECALL POWER: H.R. 5740 AND S. 1584 ................................................................. 1853
C. DOES THE PROPOSED LEGISLATION GIVE THE FDA PHANTOM AUTHORITY? ............................................................ 1856
D. ENSURING PROPER NOTICE BEGINS WITH MANDATORY FDA NOTIFICATION .......................................................... 1858
   1. Reporting Unexpected Drug Events to the FDA: The Who, Where, How, and Why ................................................................. 1859
   2. The FDA Should Be Notified of All Unexpected Events Related to Drugs and Medical Devices .......................... 1860

IV. CONCLUSION ................................................................................. 1862
The Food and Drug Administration (“FDA”) is charged with the important responsibility of ensuring that food and drug products are safe for consumption and that manufacturers comply with its regulations. However, this regulatory agency that oversees the safe and effective manufacture, distribution, advertisement, and recall of drugs has little formal enforcement authority to ensure quality products. Consider the example of the now infamous Fen-Phen, the diet drug that caused valvular heart disease1 in a significant number of consumers: had the manufacturer not complied with the FDA’s request to voluntarily withdraw the drug,2 the FDA would have needed to exercise its court-ordered injunction and seizure authority to cease distribution of Fen-Phen on the market.3 Moreover, it is not entirely clear that the FDA would have succeeded in halting production and distribution of the drug, despite its potentially serious side effects on consumer health. The lackluster and often confusing enforcement power of the FDA has troubled its employees, the courts, and consumers throughout its existence.

A quick survey of the news related to pharmaceuticals in the past few months reveals numerous stories of drug companies recalling products, often because of unexpected odors and unpleasant side effects not usually associated with the product.4 Are the recent problems localized to a small number of manufacturers and distributors in violation of the FDA’s regulations? Or is the problem more widespread with consumers left unaware? More importantly, is the FDA aware?

This Note attempts to at least raise these questions and examine possible answers. In doing so, this Note focuses on the history of lax safety measures by Johnson & Johnson and its subsidiary McNeil Consumer Healthcare Company (“McNeil”), against the backdrop of Representative


3. See infra note 18 and accompanying text.

4. See, e.g., 38,000 More Bottles of Lipitor Recalled over Odor Complaints, CNN.COM (Oct. 30, 2010, 8:06 AM), http://www.cnn.com/2010/HEALTH/10/30/lipitor.recall/index.html?hpt=T2 (providing a very timely example of another voluntary recall). This latest recall, at the time of this analysis, is in fear of contamination with 2,4,6-tribromoanisole—the very same contaminant involved in the Children’s Motrin recall by McNeil earlier this year. Id. The increasing prevalence of problems with this chemical agent seem to suggest some reform in the drug manufacturing and processing procedure is necessary, but such an analysis is outside the scope of this Note.
Edolphus “Ed” Towns’s proposed legislation, H.R. 5740, and its successor, S. 1584, which aim to provide the FDA with mandatory recall authority. Part II describes the power vested in the FDA to deal with matters related to unsafe or ineffective drugs on the market and then examines the rash of safety violations and recalls plagued by the McNeil Company and its pediatric products such as Motrin and Tylenol. Of particular concern to this analysis is a “phantom recall,” a term coined by Chairman Towns, whereby McNeil sent independent contractors into the field to secretly purchase problematic Motrin without ever informing the FDA or consumers. Part III presents important proposed legislation, H.R. 5740 and its successor S. 1584, and examines how each modifies the current recall powers vested in the FDA. This Note ultimately argues that, while the amendments contained in the proposed legislation certainly promise some improvement in FDA regulation, more emphasis on mandatory reporting is necessary to ensure total and transparent compliance with the FDA. In doing so, this analysis suggests that mandatory reporting of all unexpected events may be a necessary counterpart to the proposed legislation to ensure that mandatory recall power is not simply a “phantom” authority given to the FDA.

II. THE FDA’S RECALL POWERS AND THE MCNEIL “PHANTOM RECALL” CONTROVERSY

Consumers are now somewhat hesitant to trust the Tylenol and Motrin products on the market and may be opting instead for off-brand, over-the-counter (“OTC”) medications. McNeil, slammed for unacceptable quality standards, has repeatedly apologized to consumers. The FDA, though aware on some level of the safety problems, did little to expedite the removal of affected OTC products from the market. The FDA stressed that its lack of proactive steps stem not from its disinterest, but rather from its inability to require a manufacturer to recall products.

This Part begins by detailing the recall authority available to the FDA in order to highlight the fact that the FDA generally cannot compel a manufacturer to recall drugs or medical devices. Against this backdrop, this
Part then describes the recalls that McNeil issued for its Tylenol and Motrin products.

A. VOLUNTARY AND INVOLUNTARY RECALLS: THE (IN)ABILITY OF THE FDA TO MANDATE RECALL OF PHARMACEUTICAL AGENTS

The Federal Food, Drug, and Cosmetic Act ("FDCA" or "Act")\(^\text{11}\) established the FDA to ensure public safety with respect to food, drugs, and cosmetic materials that are marketed and sold in interstate commerce.\(^\text{12}\) Acting under the authority of the federal government, the Commissioner of the FDA and the Secretary of Health and Human Services ("Secretary") implement policies that provide the public with safe access to products covered by the Act.\(^\text{13}\) Moreover, the Secretary is vested with the authority to promulgate regulations in accordance with the FDCA and FDA regulation policies.\(^\text{14}\) The Commissioner of the FDA has equivalent authority because the Secretary delegates it accordingly.\(^\text{15}\) Therefore, the FDA is equipped with the power to devise and enforce its own rules and regulations.\(^\text{16}\)

However, even with the FDCA's authority, the FDA has few formal enforcement powers.\(^\text{17}\) This Act provides the FDA with the ability to seize products, obtain injunctions against manufacturers, and even criminally prosecute those in violation of the FDCA.\(^\text{18}\) The surprising and anomalous feature is that the FDA generally does not have the authority to order a recall.\(^\text{19}\) "Except for infant formulas, and medical devices since 1990, [the]


\(^\text{12}\). 21 U.S.C. § 393(b).

\(^\text{13}\). Id. § 393(d) (2006 & Supp. IV 2010).

\(^\text{14}\). Id. § 371(a).

\(^\text{15}\). PARKER, supra note 11, at 2.

\(^\text{16}\). I. Scott Bass, FDA Enforcement Powers, in FOOD AND DRUG LAW AND REGULATION 635, 636 (David G. Adams et al. eds., 2008).

\(^\text{17}\). Id.; see also 21 U.S.C. § 332 (injunctions); 21 U.S.C. § 333 (2006 & Supp. IV 2010) (criminal penalties); 21 U.S.C. § 334 (2006 & Supp. IV 2010) (seizures). Though rare, the FDA's criminal division will become involved if there is egregious noncompliance with the FDCA; the events surrounding the McNeil Company's lax safety measures and pattern of concealment have risen to the level to invoke criminal investigation.

\(^\text{18}\). "Recall means a firm’s removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action .... Recall does not include a market withdrawal or a stock recovery." 21 C.F.R. § 7.3(g) (2011).
FDA has no authority to require a recall of products. Yet, the recall is one of [the] FDA’s most potent enforcement tools, and provides the greatest measure of public protection.”

It is more common that a drug is subject to a voluntary recall, whether suggested by the FDA or the manufacturer’s own internal policies. Drug manufacturers prefer not to label problems with products as a recall because such connotation requires a public report in the FDA Enforcement Reports. The FDA will request a recall if it deems there to be a sufficient hazard to the public because of the manufacturer’s violation, but this request often carries little weight and does not compel removal of the product from the market. For example, in 2007, the FDA requested that the manufacturer of contaminated heart valves and other medical devices recall its products, but the company simply refused. The company finally consented to the recall after another six weeks passed and after the FDA petitioned for a court-ordered injunction. The problem with this procedure is that seeking court approval for injunctions and seizures can be time-intensive, sometimes further endangering the public while the violative product is still on the market.

Perhaps more worrisome is that when a manufacturer decides to conduct a recall without request from the FDA, the manufacturer is not required to notify the FDA, though it is strongly encouraged. When a recall is issued, the FDA has a classification system that it uses in order to characterize the nature of the recall and notify the public of the problem(s)

20. Bass, supra note 17, at 658 (footnotes omitted); see also 21 C.F.R. § 810.13 (detailing the procedures by which the FDA may order a manufacturer of a violative device to cease distribution and begin recall steps).
21. Bass, supra note 17, at 658; see also 21 C.F.R. § 7.50.
22. Bass, supra note 17, at 658. It is at least possible that the manufacturer understands further action will be taken by way of court-ordered remedies if the threat does not subside and the manufacturer continues to violate the FDCA. Id. at 659.
24. Shelhigh Responds to FDA Recall Request, PRWEB (May 3, 2007), http://www.prweb.com/releases/FDA/Shelhigh/prweb523767.htm. This recall request and refusal is especially illustrative of the weak FDA enforcement power since the FDA had already obtained and performed a court-authorized seizure of violative medical devices from Shelhigh’s manufacturing facility. See FDA Requests Recall of All Shelhigh Medical Devices, supra note 23.
26. 21 C.F.R. § 7.46(a) (“A firm that [conducts a recall without FDA request] because it believes the product to be violative is requested to notify immediately the appropriate Food and Drug Administration district office . . . .” (emphasis added)). Notice that there is no requirement that the manufacturer notify the FDA of recalls or recall-like behavior. There is one exception: a firm is required to notify the FDA of “serious adverse events” related to a drug when it receives the report. See infra note 127 and accompanying text.
associated with the product.\textsuperscript{27} The import of involving the FDA is that it provides an efficient method of removing potentially unsafe products, ensures the FDA understands the manufacturer’s commitment to public safety, and allows effective dissemination of recall information to the public.\textsuperscript{28} It is noteworthy that the number of recalls, with the FDA’s knowledge and support, has increased steadily in recent years.\textsuperscript{29} One of the most publicized recalls in the past few years was that of Tylenol and Motrin products manufactured by Johnson & Johnson’s subsidiary, McNeil Consumer Healthcare.

\textbf{B. The Headaches of Tylenol and Motrin: McNeil’s Two-Year Battle with Systemic Recalls}

The story of the McNeil Company’s now infamous “phantom recall” cannot be told without first examining the rash of recalls by McNeil in the past few years. Though the recent recalls by McNeil have been for various and sometimes seemingly unrelated reasons, understanding the prevalence of problems with its OTC products demonstrates a shortcoming of the current FDA notification and recall practices.\textsuperscript{30} The string of problems related to McNeil’s various recalls led to two separate congressional hearings on the company’s quality-control practices before the House Oversight and Government Reform Committee (“the Committee”). These hearings, with their accompanying fact-finding procedures, brought to the surface the story of the “phantom recall” of sub-potent Motrin products in early 2009.\textsuperscript{31}

The controversy around the McNeil Company began in September 2009 when the company recalled infant and children’s Tylenol products.\textsuperscript{32} The company feared that certain lots of these products were contaminated

\begin{itemize}
\item \textsuperscript{27} Bass, \textit{supra} note \textsuperscript{17}, at 660; \textit{see also} 21 C.F.R. § 7.3(m)(1) (defining class I recall as involving a “reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death”); 21 C.F.R. § 7.3(m)(2) (defining class II recall as involving “temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote” with the use of the violative product); 21 C.F.R. § 7.3(m)(3) (defining class III recall as a situation in which the “use of, or exposure to, a violative product is not likely to cause adverse health consequences”).
\item \textsuperscript{28} One can imagine that if the FDA learned of a manufacturer’s recall-type behavior, without notifying the FDA, the Administration would seriously scrutinize the manufacturing and distribution processes in the (possibly indefinite) future.
\item \textsuperscript{29} Bass, \textit{supra} note \textsuperscript{17}, at 658.
\item \textsuperscript{30} There is also the problem of when a manufacturer must notify the FDA of certain adverse events related to its drug. Analysis of this element of the recall process will be addressed below.
\item \textsuperscript{31} \textit{See discussion infra} Parts \textit{II.C–D}.
with the bacteria \textit{B. cepacia}\footnote{\textit{Burkholderia cepacia} (\textit{B. cepacia}) is a bacteria commonly found in nature. \textit{Burkholderia Cepacia in Healthcare Settings}, CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/HAI/organisms/bCepacia.html (last updated Nov. 24, 2010). This bacteria does not pose a significant risk to healthy individuals but can adversely affect people with compromised immune systems. Id. It is at least arguable that infants and children have weaker immune systems than healthy adults, especially those who are sick and thus require medicine such as children’s Tylenol or Motrin.} but stressed that the presence of this bacterial agent posed minimal health risks to consumers.\footnote{Letter from Edwin K. Kuffner, MD, Vice President, Medical Affairs, McNeil Consumer Healthcare, to Healthcare Professionals (Sept. 18, 2009), available at http://www.tylenolprofessional.com/assets/TYLENOL_Letter_091809.pdf.} Shortly thereafter, in December 2009, McNeil issued another voluntary recall of its Tylenol Arthritis caplets after receiving complaints of a musty odor associated with the OTC pain-reliever.\footnote{Yuliya Talmazan, \textit{Tylenol Recall 2009: Tylenol Arthritis Pain Caplet 100 Count}, NOWPUBLIC (Dec. 29, 2009, 8:46 AM), http://www.nowpublic.com/health/tylenol-recall-2009-tylenol-arthritis-pain-caplet-100-count.} Though the company was not entirely sure as to the source of the odor, McNeil suspected that the pain-reliever was contaminated with 2,4,6-tribromoanisole (“TBA”).\footnote{Id. TBA is a compound that can be readily obtained by conversion of 2,4,6-tribromophenol (“TBP”), a common wood-treatment agent, into TBA. \textit{What Do We Know About the Chemical Associated with the Tylenol Recall?}, ONLYSCIENCE (Dec. 29, 2009, 6:34 PM), http://onlyscience.net/2009/12/29/tylenol-recall/. The chemical TBP is used to treat wood that will be used for processing food and pharmaceutical agents but can be metabolized into TBA by naturally occurring fungi. Frank B. Whitfield, Jodie L. Hill & Kevin J. Shaw, \textit{2,4,6-Tribromoanisole: A Potential Cause of Mustiness in Packaged Food}, 15 J. AGRIC. & FOOD CHEMISTRY 894 (1997). For a good discussion on the natural synthesis of TBA from TBP and the hallmark signs of TBA contamination, see \textit{id}.} McNeil further expanded the odor-related recall less than a month later to Motrin, Benadryl Allergy Ultratab, Rolaids Antacid Tablets, Simply Sleep, and St. Joseph products.\footnote{Scott Wu, \textit{Tylenol Recall 2010: List of Expanded Tylenol Recall Lot Numbers}, NOWPUBLIC (Jan. 15, 2010, 9:30 AM), http://www.nowpublic.com/health/tylenol-recall-2010-list-expanded-tylenol-recall-lot-numbers.} Both the December and January recalls related to TBA-contamination came with reports of somewhat adverse health events—namely nausea, vomiting, and diarrhea.\footnote{Id.} 

Early in 2010, McNeil formally recalled large amounts of its Children’s Motrin, Benadryl, and other allergy and cold products.\footnote{Children’s Cold, Allergy Medicine Recalled, CNN.COM (May 1, 2010, 5:23 PM), http://www.cnn.com/2010/HEALTH/05/01/drug.recall/index.html?iref=allsearch.} The company stressed that the recall was not related to any adverse medical reaction,\footnote{Id.} but rather due to an uncommon—and unsettling—odor emanating from these products.\footnote{The odor was initially described as a musty one that reminded consumers of mold. Wu, \textit{supra} note 37.} This recall was further expanded in June 2010 to include
Benadryl Ultratab and Tylenol Rapid Release Gels\(^{42}\) and then again in July to include even more products.\(^{43}\) These events were again related to musty and moldy odors coming from the product, and were also suspectedly associated with TBA-contamination.\(^{44}\) And though McNeil had been seriously chastised by the FDA and shut down one of its plants for not being up to code,\(^{45}\) the McNeil Company issued yet another recall for similar problems in October 2010.\(^{46}\)

Examining the aforementioned laundry list of problems plaguing the McNeil Company, one cannot help but ask what is going on here? Why were there so many recalls within such a short period of time? Exactly these questions drew congressional interest to the matter, leading Chairman Towns to call for a formal investigation into the major recall of McNeil’s pediatric medications.\(^{47}\) The first congressional hearing was held in late May 2010 in an attempt to uncover any possible deficiencies in McNeil’s manufacturing and packaging processes that could have led to product contamination.\(^{48}\) After discovering McNeil had conducted a “phantom recall” in 2009, a second congressional hearing was held in late September of 2010.\(^{49}\)


\(^{44}\) Drug Recall, supra note 42; Pepitone, supra note 43.

\(^{45}\) See discussion infra Parts II.C–D.


\(^{48}\) Johnson & Johnson’s Recall of Children’s Tylenol and Other Children’s Medicines: Hearing Before the H. Comm. on Oversight & Gov’t Reform, 111th Cong. 1–2 (2010) [hereinafter McNeil Hearing I]. In the May and the later September hearings, the Committee uses the name Johnson & Johnson instead of McNeil but intends for it to mean McNeil. See id. at 8 (statement of Rep. Darrell E. Issa) (“Johnson & Johnson has owned the McNeil Consumer Healthcare Division since 1959, so for, one, from this day forward, I will say Johnson & Johnson and not talk about a subsidiary that has been owned by a company for so long.”).

C. A CONGRESSIONAL HEARING DISCOVERS LAPSES IN QUALITY CONTROL AND DISTURBING REMEDIAL MEASURES UNDERTAKEN BY MCNEIL

In late May 2010, Chairman Towns called for a hearing before his Committee that was solely intended to understand why the McNeil Company had been plagued by so many drug recalls, to determine the reasons for the safety breakdown, and to find methods to prevent future recalls from the same problem.50 In this Hearing, Representatives extensively questioned Dr. Joshua Sharfstein, Principal Deputy Commissioner of the FDA, and Colleen Goggins, worldwide chairman of the Consumer Group of Johnson & Johnson, on the facts surrounding the recall of the pediatric products.51

This Hearing primarily focused on the B. cepacia and TBA-contamination present in many of the children’s products that McNeil manufactured and introduced to the market. Despite some reports to the contrary, Goggins stressed that no deaths or “serious adverse medical event[s]”52 had been linked to either contamination.53 One of the most troubling findings was that McNeil received complaints of a musty odor and some related side effects, such as gastrointestinal issues, nearly a year before any recall action was taken.54 Goggins acknowledged that conditions at one of McNeil’s manufacturing facilities had been gravely subpar and promised that significant changes in quality control had been implemented.55

During the investigation of the various recalls, Chairman Towns introduced evidence that McNeil hired independent contractors in 2009 to go into various stores to assess whether any ineffective Motrin still remained in the market.56 At the time of assessing the inventory, these contractors actually purchased any remaining Motrin.57 Dr. Sharfstein testified that the FDA did not condone the McNeil Company’s actions, even though the product posed no health risk to consumers.58 He even suggested that the FDA was not entirely sure what McNeil was doing out in the field with

50. At the time of this analysis, it is clear that the hearing, and any subsequent action undertaken by the FDA or McNeil, did little to remedy the problem. See Pierson, supra note 46 (reporting yet another TBA-related recall of McNeil’s OTC pain-reliever Tylenol).
51. See discussion supra Part II.B.
54. Id. at 15.
55. The manufacturing plant in question was the one in Fort Washington, Pennsylvania. Id. at 72–73.
56. Id. at 71. The problem with the Motrin product involved was that it did not dissolve properly, so consumers were getting less-than-effective doses to alleviate their problems. Id. at 73. However, both the FDA and McNeil stressed that this issue did not pose any sort of health risk to the general public. Id. Moreover, the “stores” that contained the affected product, at least as indicated in this first hearing, were primarily gas stations. Id. at 72.
57. Id. at 31.
58. Id.
respect to the Motrin. Goggins of Johnson & Johnson maintained that she had no knowledge that the third-party contractors were given instructions to purchase any product but emphasized that the FDA was aware of McNeil’s actions in every respect; she also, ironically, stressed the fact that she did not have all the information and so could not provide a full account of this event. Chairman Towns was particularly troubled by this event, which he later dubbed a “phantom recall,” and determined that a subsequent hearing was necessary to better understand the circumstances surrounding this clandestine recall by McNeil.

D. The Headache Continues: A Second Congressional Hearing Determined To Fully Investigate the “Phantom Recall”

Chairman Towns conducted another hearing in late September 2010 to determine the extent of the “phantom recall” performed by McNeil in 2009 on its eight-count Motrin products that were not dissolving properly. Prior to the second hearing, the Committee conducted extensive fact-finding and discovery of the McNeil Company’s internal emails as well as emails between McNeil and the FDA. This Hearing also attempted to determine the extent of the FDA’s knowledge and participation in the secret withdrawal of McNeil’s products from the market.

In addition to the witnesses at the May 2010 hearing, Bill Weldon, Chair and CEO of Johnson & Johnson, was present for the second hearing to defend his company. Members of the Committee presented Weldon with extensive documentation that McNeil attempted to conceal its recall of the ineffective Motrin so as to minimize any adverse publicity. With respect to the Motrin that did not dissolve properly, the Committee produced emails and letters that demonstrated elusive maneuvers by McNeil, apparently with the FDA at least knowing about certain stages of the “phantom recall” process. These emails disclosed precisely the sequence of events that led up to the “phantom recall.” At least as early as November of 2008, McNeil became aware of the sub-potency of the Motrin caplets owing to their inability to dissolve properly upon ingestion. Four months later,

59. Id.
60. Id. at 72.
61. See generally McNeil Hearing II, supra note 49 (further questioning FDA and Johnson & Johnson executives on the events leading up to the 2009–2010 McNeil recalls).
62. Id. at 4.
63. Id. at 2.
64. Id.
65. Id. at 22.
66. Id. at 8–9.
67. Id. at 2, 13.
68. Id. at 59. According to the testimony of Goggins, McNeil had sent a field alert to the FDA in November 2008. Id.
McNeil sent an email notifying the FDA that it intended to perform an assessment of the quantity of the ineffective Motrin product still on the market.69 About a week after this email, on April 1, 2009, McNeil contacted the independent contractors with information on how to conduct themselves in the stores with the affected Motrin: “‘purchase all of the product’ and ‘do not communicate to store personnel any information about this product.’”70 Two weeks later, one contractor notified McNeil that around 250 stores had been investigated as per orders, with the contractors purchasing any product found in those locations.71 Throughout the investigation, Bill Weldon accepted responsibility, was apologetic,72 and promised that McNeil had learned much from its mistakes and was implementing that knowledge in new quality-control and administrative procedures.73

Dr. Sharfstein of the FDA stressed that McNeil had informed the FDA in an early 2009 correspondence that no defective Motrin remained on the market.74 He then explained that this was the first time the FDA became aware of sub-potent Motrin still being on the market and McNeil’s third-party contractors purchasing any product remaining in stores.75 Most importantly, the FDA urged that McNeil was not forthright with the manner in which the recall occurred—leaving out the secret nature of the market withdrawal.76 It was not until July 2009 that the FDA requested that McNeil issue a formal recall, a request that often carries almost no legal weight whatsoever.77 But Dr. Sharfstein admitted that the FDA did not ask the right

69. Id. This email contained the following language that alluded to the FDA possibly knowing about the problems with the inadequately-dissolving Motrin: “attached please find the third followup to the field alert report for Motrin caplets submitted November 26, 2008.” Id. (emphasis added) (internal quotation marks omitted). This language, as construed by the Committee, suggests that McNeil was simply reminding the FDA of the dissolution problem with Motrin and was nothing new. Id. at 59–60.
70. Id. at 34.
71. Id.
72. Id. at 25.
73. Id. at 74 (statement of Bill Weldon) (“[T]he comment that I would make is that I think we have learned a lot of lessons through this unfortunate situation . . . . What I can assure you is that we are committed to ensuring to resolve these problems . . . .”). But one cannot help but wonder how genuine these assurances were in light of a recent recall for the same TBA-contamination. See Pierson, supra note 46.
74. McNeil Hearing II, supra note 49, at 93–95. This is in contrast to the statement of Goggins who suggested the FDA was aware of problems with the dissolution of Motrin in late 2008. See supra notes 68–69 and accompanying text.
76. Id. at 78.
77. Id. at 77–78. The exception to this is that the FDA can, under appropriate circumstances, obtain a court-ordered injunction and actually seize the product that it believes should be subject to a recall. Id. at 78. However, as Dr. Sharfstein points out, this process is especially time-consuming and not guaranteed to succeed in removing the product from the market. Id.
questions when it first learned of problems with the Motrin and the in-store assessment to be carried out by McNeil.\textsuperscript{78}

Though McNeil was extremely apologetic\textsuperscript{79} and the FDA accepted some responsibility for the series of recall events, people affected by this recall (and future ones) are without much comfort as to pharmaceutical safety without more stringent regulations. What is clear is that something—anything—needs to be done to reassure consumers of OTC medications and hold firms like McNeil accountable for conducting business in such a clandestine manner. Though the Motrin “phantom recall” posed little immediate threat to consumer health and safety, the pattern of concealment is more than troubling. Johnson & Johnson shareholders understand this, and this is likely what prompted them to file a class-action lawsuit on September 21, 2010 against the company for fraud and misleading statements related to the contamination of manufacturing plants and the Motrin “phantom recall.”\textsuperscript{80} There is also a pending criminal investigation over the conditions at McNeil drug-manufacturing facilities and “phantom recall” procedures.\textsuperscript{81} Apologies and promises to be better on the part of McNeil and Johnson & Johnson are simply not enough; the FDA promises to implement more transparency in their dealings with manufacturers with quality-control issues and consumer complaints with on-the-market medications. But transparency means little without more enforcement authority.

\textsuperscript{78} Id. at 91.
\textsuperscript{79} As with any similar situation, where a product manufacturer runs into legal problems with lax safety and regulation procedures, one cannot help but ask if the violator is truly sorry—or just sorry that it was caught. This lingering question, no doubt present in the minds of all those present at both congressional hearings, is one that prompts a serious analysis of the FDA’s regulatory and enforcement powers. See discussion infra Part III.
\textsuperscript{81} \textit{McNeil Hearing II}, supra note 49, at 92–93. The FDA has its own Office of Criminal Investigations and therefore can prosecute manufacturers in violation of the FDCA internally. PARKER, supra note 11, at 160. When matters are referred to the criminal division and adjudicated, the FDA publicly announces the results. See Inspections, Compliance, Enforcement, and Criminal Investigations, FDA, http://www.fda.gov/ICECI/CriminalInvestigations/ucm127086.htm (last updated Mar. 19, 2012).
III. USING THE “PHANTOM RECALL” TO ARM THE FDA WITH MORE TANGIBLE ENFORCEMENT POWERS

In response to the rash of safety problems plaguing McNeil’s OTC medications and its less-than-transparent method of alleviating the problem, lawmakers focused on preventing similar situations in the future. However, as Dr. Sharfstein remarked numerous times in his testimony in the McNeil Hearing I, the FDA lacks authority to require a company to recall drugs that are currently on the market. It was these urgings, in light of the McNeil “phantom recall” and pediatric medicine contamination controversies that prompted Chairman Towns to draft H.R. 5740, a bill that would have given the FDA mandatory recall authority.

This Part first illustrates the shortcomings of the current recall authority vested in the FDA, and then describes Chairman Towns’ proposed legislation that would have provided mandatory recall authority to the FDA. It then presents and examines the revived version of this failed legislation. After analyzing the deficiencies of the current legislation, this Note argues that mandatory recall authority must be accompanied by mandatory reporting of unexpected events associated with drugs in order to be truly effective at protecting public health and safety.

A. WHY DOESN’T THE FDA HAVE THE AUTHORITY TO MANDATE A RECALL FOR DRUGS IN VIOLATION OF THE FDCA?

It is clear that the FDA does have mandatory recall authority with respect to certain items: infant formula and medical devices in special circumstances. Therefore, Congress certainly has contemplated granting the FDA the power to require—as opposed to simply request—a manufacturer or distributor to recall a drug or device. But why hasn’t Congress given the FDA the authority to order a recall in all drug-related markets? The explanation may come from the fact that most manufacturers

82. McNeil Hearing I, supra note 48, at 30, 43, 57; see also McNeil Hearing II, supra note 49, at 78 (statement of Dr. Sharfstein) (“FDA has no legal authority to require a manufacturer to recall a drug product that is unsafe or is not in compliance with current good manufacturing process. The recall system depends on full and open disclosure, trust, and the industry’s acceptance of its responsibilities.”).

83. H.R. 5740, 111th Cong. (2010).

84. See supra note 21 and accompanying text. Recently, Congress passed a food safety bill that gives the FDA mandatory recall authority with respect to food items that are potentially unsafe for consumers. Emily P. Walker, President Signs Food Safety Bill, MEDPAGE TODAY (Jan. 5, 2011), http://www.medpagetoday.com/PublicHealthPolicy/FDAGeneral/24191. For a discussion on this legislation, see Shannon G. May, Importing a Change in Diet: The Proposed Food Safety Law of 2010 and the Possible Impact on Importers and International Trade, 65 FOOD & DRUG L.J. 1 (2010). See also Michael T. Roberts, Mandatory Recall Authority: A Sensible and Minimalist Approach To Improving Food Safety, 59 FOOD & DRUG L.J. 583 (2004) (proposing mandatory recall authority with respect to food and certain procedural measures that should accompany such power).
comply with FDA requests, and, even when they do not, the FDA has other enforcement powers at its disposal (court-ordered injunction and seizure orders) to ensure that unsafe and hazardous products are removed from the market.85

Thus, the FDA’s current enforcement powers are mostly based on court-ordered action, only after a manufacturer refuses to comply with the FDA’s request and advice on how to handle a drug- or device-related violation of the FDCA.86 The process begins with a warning letter issued by the FDA, advising the manufacturer of a drug or device that the FDA considers its product to violate some provision of the FDCA.87 Only after noncompliance with this warning letter does the FDA begin court-ordered remedies.88 But because this protocol is often time-consuming, expensive, and sometimes ineffective, the prospect of giving the FDA mandatory recall authority cannot escape the minds of legislators. Prompted by the McNeil controversy, Chairman Towns proposed a bill, H.R. 5740, that would have given the FDA mandatory recall authority with respect to pharmaceutical and other drug-related products.89 Though H.R. 5740 never passed, it serves as the predecessor to the currently proposed legislation, S. 1584, which also aims to provide the FDA with the same mandatory recall authority over drugs.90

B. AN ATTEMPT TO GIVE THE FDA MANDATORY RECALL POWER: H.R. 5740 AND S. 1584

Chairman Town’s proposed bill, H.R. 5740, first would have amended the “Prohibited Acts”91 provision of the FDCA to provide the FDA with authority to order a recall when the manufacturer is in violation of the FDCA in some serious manner.92 The mandatory recall authority derives from the amending language, which makes failure to comply with recall requests a “prohibited act” under the FDCA.93 H.R. 5740 would have also

85. See supra note 18 and accompanying text.
86. For an overview of the possible actions the FDA can take when a manufacturer’s noncompliance threatens public health and safety, see Nancy W. Mathewson, Prohibited Acts and Enforcement Tools, 65 FOOD & DRUG L.J. 545 (2010). See also Sharon B. Jacobs, Crises, Congress, and Cognitive Biases: A Critical Examination of Food and Drug Legislation in the United States, 64 FOOD & DRUG L.J. 599 (2009) (evaluating the history of the FDA and the development of its enforcement powers).
87. Mathewson, supra note 86, at 546.
88. See supra note 20 and accompanying text.
89. H.R. 5740, 111th Cong. (2010).
92. H.R. 5740 § 1(a). Again, recall is defined as an attempt to correct a situation with a product that, if not remedied, would merit enforcement action by the FDA. See supra notes 19–21 and accompanying text.
93. H.R. 5740 § 1(a).
inserted a provision at the end of Part E allowing the Secretary of Health and Human Services to issue an order requiring a manufacturer to cease distribution, with appropriate notification to the public, of a certain drug, provided the Secretary has reason to believe that consumption of the drug would cause "serious adverse health consequences or death to humans or animals." Also of significance in H.R. 5740 is the proposed amendment that would have required manufacturers to notify the FDA when it had reason to believe a drug is adulterated or misbranded and likely to cause serious adverse health consequences or death. These proposed regulations therefore aimed to give the FDA more enforcement authority, even rising to the level of required recalls when products do not conform to the FDCA and seriously threaten the welfare of consumers. The regulations also provided for heightened interaction between manufacturers and the FDA when violations arise. Though H.R. 5740 never passed, its successor, S. 1584, is currently before Congress.

The currently proposed legislation, S. 1584, is also an attempt to provide the FDA with mandatory recall authority over drugs. Similar to its predecessor, S. 1584 provides the Secretary with the power to order a manufacturer "to immediately cease distribution of [a] drug" when "the Secretary finds that there is a reasonable probability that a drug intended for human use would cause serious, adverse health consequences or death." It also provides that the Secretary may further order a recall with respect to such drug if the Secretary determines that a recall is necessary. S. 1584 also amends the “Prohibited Acts” of the FDCA to specifically make failure

---

94. Part E is entitled “General Provisions Relating to Drugs and Devices” under Subchapter V, “Drugs and Devices,” within the FDCA. To understand where the amendment would have been placed, see chapter beginning with 21 U.S.C. § 360bbb (2006). The provision would have been inserted after § 360bbb-6.

95. H.R. 5740 § 508(c)(1). This amendment would have also given the Secretary of Health and Human Services the authority to order an emergency recall when a manufacturer appeals the mandatory recall, pursuant to § 508(c)(2)(B)–(C), but the Secretary believes the product is an imminent threat to the public health and safety. § 508(d)(1).

96. Id. § 508(a)(1)(A)–(B).

97. See generally 21 U.S.C. § 351(a) (2006) (defining “adulterated” as unsanitary or not packaged or processed in conformity with good manufacturing practices, as determined by the FDA); 21 U.S.C. § 352(a) (defining “misbranded” as labeling that is false or misleading in any manner).

98. One cannot help but ask whether McNeil’s “phantom recall” violates the FDCA by being either adulterated or misbranded according to the FDA’s definitions. See discussion infra Part III.C.


100. Id. § 507(a)(1)(A).

101. Id. § 507(a)(1). The Secretary must first provide the manufacturer with an opportunity for an informal hearing. Id. § 507(a)(2).

102. Id. § 507(b)(1).
to comply with a recall order issued by the Secretary a prohibited act\textsuperscript{103} but it differs significantly from Towns’s bill in that it no longer requires manufacturers to notify the FDA when there is reason to believe that a drug is adulterated or misbranded and is likely to cause serious adverse health effects.\textsuperscript{104} However, this legislation does incorporate some of the lessons learned from the investigation surrounding the McNeil Company and its numerous recalls.\textsuperscript{105} For example, S. 1584 provides for more stringent quality-control procedures, which are reviewable by the Secretary.\textsuperscript{106} The bill also provides whistleblower protection to employees who directly report violations of the FDCA by their employers, and to employees who otherwise provide information related to violations in the course of an investigation by the FDA.\textsuperscript{107}

Some believe that mandatory recall authority is unnecessary in the medical-devices sector because manufacturers are almost always willing to proceed with a voluntary recall.\textsuperscript{108} This may be true in cases where there is a serious risk to public health and safety,\textsuperscript{109} but there are situations where the manufacturer will choose to use its discretion in not ordering a recall—a choice that may have grave future effects. Others even suggest that the FDA does not really want mandatory recall authority\textsuperscript{110} because it will be overly burdensome and its enforcement powers are currently sufficient.\textsuperscript{111} Again,

\textsuperscript{103} Id. § 507(b)(3). This is exactly what H.R. 5740 attempted. See supra notes 92–93 and accompanying text.

\textsuperscript{104} See supra notes 98–99 and accompanying text.

\textsuperscript{105} The bill itself actually contains a “Findings” section that specifically references the recalls of McNeil’s OTC products. S. 1584 § 2(3) (“More than 1,300,000 over-the-counter children’s medicines were recalled in 2010 for quality issues that presented possible risk to patient health, and the quality standards at many other over-the-counter manufacturers are unknown.”).

\textsuperscript{106} Id. § 3(b).

\textsuperscript{107} Id. § 1013(a)(1).

\textsuperscript{108} Edward M. Basile & Beverly H. Lorell, The Food and Drug Administration’s Regulation of Risk Disclosure for Implantable Cardioverter Defibrillators: Has Technology Outpaced the Agency’s Regulatory Framework?, 61 FOOD & DRUG L.J. 251, 255 (2006) (“In practice, the agency’s authority to require a recall likely is unnecessary because medical device manufacturers institute voluntary product recalls in order to ensure that they provide safe and effective products to their customers and to maintain their professional credibility.”).

\textsuperscript{109} It is unlikely that a manufacturer, after receiving reports of serious adverse health consequences such as death or disabling illness, would choose not to initiate a recall or notify the FDA. The worry in making such a sweeping statement is that there will be some threshold requirement that constitutes an event that should be worthy of FDA notification and perhaps recall-like behavior—a requirement that is likely left to the discretion of individual manufacturers and distributors.


\textsuperscript{111} That their enforcement powers are sufficient stems from the fact that, if a manufacturer does not comply with a request to recall, it is likely that the FDA would take further action such as court-ordered seizure, injunction, or other measures to force the noncompliant entity to rectify the problem.
these arguments must be taken in context: it is so unlikely that a manufacturer would refuse to comply with FDA requests if its product seriously threatened the health and safety of consumers. Such noncompliance would certainly roughen the road ahead of the violative manufacturer because the FDA would be less willing to cooperate with the manufacturer to lessen the damage to the company’s reputation.112

C. Does the Proposed Legislation Give the FDA Phantom Authority?

Despite not passing,113 H.R. 5740 was certainly a step towards making drugs, whether OTC or prescription, even safer for public use. And now Congress is currently considering S. 1584, a similar bill attempting to give the FDA mandatory recall authority. However, this analysis proposes that the possible amendments do not reach far enough to ensure that similar “phantom recalls” and other lax quality-control situations do not occur in the future.

H.R. 5740 did little to ensure that manufacturers will notify the FDA of product-related issues when manufacturers deem they are not likely to harm the public health or safety. The bill would have required drug manufacturers of adulterated or misbranded drugs,114 like McNeil, to notify the FDA when two conditions are satisfied: (1) the manufacturer has reason to believe that it introduced an adulterated or misbranded drug into interstate commerce and (2) there is a reasonable probability that death or some other serious adverse health event will occur.115 Neither the FDCA, FDA regulations and guidelines, nor this proposed amendment provide any definition for “reasonable probability.”116 This leaves manufacturers to determine whether there is a reasonable probability that their adulterated or misbranded product truly threatens the public health and safety, which would likely be gauged by internal personnel.117 The proposed amendments

112. See Bass, supra note 17, at 659.
114. See supra note 97 for definitions of “adulterated” and “misbranded.”
115. H.R. 5740, 111th Cong. § 1(b) (2010).
116. It is understandable that no hard-and-fast rule could be devised as to what constitutes “reasonable probability.” However, the FDA could propose guidelines as to what would constitute “reasonable probability” in a variety of circumstances to give manufacturers at least an idea of situations that the FDA considers report-worthy.
117. Many have struggled with the vague terms, such as “serious” and “life-threatening,” used by the FDA regulations and guidelines, which has led to considerable disagreement between manufacturers. See Barbara A. Noah, Adverse Drug Reactions: Harnessing Experiential Data To Promote Patient Welfare, 49 CATH. U. L. REV. 449, 471–72 (2000). Consider, for example, the term “life-threatening.” A manufacturer must determine what threshold to use for deciding when a condition is life-threatening, and such a threshold is subject to individual consumers’ overall health and particular susceptibilities. In the case of the B. cepacia contamination in McNeil’s pediatric pain-relievers, the bacteria may not pose a health risk to healthy individuals
of H.R. 5740 would likely not have prevented all future problems similar to the McNeil TBA-contamination, as the firm would have been left to determine whether there was a “reasonable probability” that gastrointestinal sickness was a serious threat to consumer health. More troubling is that the current legislation, S. 1584, does not include this same language requiring manufacturers to notify the FDA in similar situations, and so the default mandatory reporting provisions would apply.118

Even if this language would have covered the above situation and been included in S. 1584, the amendment does not account for the possibility of manufacturers concealing reports of adverse health events.119 That is, because the FDA simply cannot constantly monitor every drug manufacturer and product for adverse consequences, the reporting is left to the discretion of the manufacturer.120 Companies will try to minimize any publicity of unexpected side effects related to their products to avoid any FDA-mandated recall. Furthermore, with respect to McNeil’s “phantom recall,” neither this amendment, nor any that is currently in force in the FDCA or FDA regulations, requires a report of minor problems with drugs. Thus, the dissolution problem with Motrin encountered by McNeil in late 2008 would not compel any communication with the FDA, even with the proposed amendments.121 Thus, while it is true that if the FDA had the authority to order a recall it could have done so, there is little in the administrative and regulatory procedures that ensures the FDA will be apprised of the knowledge necessary to order a recall.122
The above analysis suggests there is no guarantee that companies would act differently in the future because these proposed amendments, in both H.R. 5740 and S. 1584, turn on the Secretary knowing or having reason to believe that certain products are not in conformance with the FDCA. Even if the FDA had mandatory recall authority, it is unlikely that such power would have much bite in situations like the McNeil “phantom recall” and pediatric pain-reliever situations. Rather, this analysis suggests that the problem lies in the fact that manufacturers and distributors are still left with discretion as to when to communicate reported problems to the FDA. Perhaps the solution is not mandatory recall authority alone, but requiring a different and more comprehensive system of reporting unexpected events with drugs and medical devices that truly approaches total transparency. Thus, this Note proposes that any amendment to the FDA regulatory regime for drugs should include a “notice” requirement.

D. Ensuring Proper Notice Begins with Mandatory FDA Notification

As discussed above, providing the FDA with mandatory recall authority does not go far enough to remedy the recent blatant safety violations of the McNeil Company; it does not reassure the public that similar violations will not occur in the future. Congress has revived H.R. 5740 by introducing S. 1584, but this bill should include an amendment that drastically changes the situations in which reporting is necessary as well as the method in which problems are communicated to the FDA.

The problem with providing mandatory recall authority to the FDA without also requiring that the FDA be apprised of all drug-related events is relatively straightforward. A manufacturer is simply left with too much label on or within the retail package of such drug.” (emphasis added)); see also 21 C.F.R. § 310.305 (2011) (requiring drug manufacturers, who were not required to get approval for marketing the drug under the old FDA regime, to still report serious and unexpected adverse events related to the product). The statute further elaborates that a “serious adverse event” is an adverse event that results in: death; life-threatening consequences; hospitalization; incapacitation or prolonged or serious disability; birth defect; or requires serious “medical or surgical intervention.” 21 U.S.C. § 379aa(a)(3). Certainly death is not subject to much interpretation, but many of the other words such as “life-threatening” can be interpreted differently by various manufacturers. See supra note 117.

123. This is because it hinges on the manufacturer informing the FDA of reported problems. Recall that McNeil did not report issues with TBA contamination of its pediatric pain-relievers and other products for at least several months after it received complaints. McNeil was chastised for violating the rule that a manufacturer must notify the FDA within three days of an adverse event. See McNeil Hearing I, supra note 48, at 64–70, 82–84 (testimony of Goggins and questions by Rep. Norton).

124. Arguably too much discretion in lieu of the recent discoveries about McNeil’s “phantom recall” of ineffective Motrin.

125. See discussion infra Part III.D. See generally Daniel R. Cahoy, Medical Product Information Incentives and the Transparency Paradox, 82 IND. L.J. 623 (2007) (discussing reasons why manufacturers opt not to disclose reported events to the FDA and how complete transparency may not be in the interest of drug-market—and legal—efficiency).
discretion as to when it should report an unexpected event to the FDA. The manufacturer is able to decide whether the threat to public health is “serious,” a term without much FDA guidance. In balancing its own interests with those of the public safety, the manufacturer may not choose to err on the side of safety. This danger illustrates the importance of adverse-health-event reporting in the FDA-enforcement regime.

1. Reporting Unexpected Drug Events to the FDA: The Who, Where, How, and Why

“Drug safety monitoring is, by necessity, a cooperative venture among the FDA, pharmaceutical manufacturers, physicians, and patients.”

Yet early on, even with strong support from the FDA, many affected consumers simply did not report adverse events to the manufacturer or the FDA. The development of direct-to-FDA reporting by physicians was a significant improvement that gave the FDA more access to information regarding events related to drugs. However, the system of reporting events to the FDA has evolved considerably since the agency’s inception, especially with the aid of the Internet. A notable advancement in adverse-event reporting was the implementation of MedWatch, an online system through which physicians and consumers can directly report to the FDA incidents that they consider related to a drug currently on the market. Yet many believe that there remains rampant underreporting of adverse medical events. It is not hard to imagine that underreporting would invariably lead to the FDA not knowing about recall-worthy drugs, unless the manufacturer somehow received a direct complaint and then reported it to the FDA—as it is required to do.

So we are faced with the following problem in the event that the proposed legislation passes: the FDA has the authority to recall drugs that violate the FDCA and pose a serious risk to the health and safety of the

126. Noah, supra note 117, at 452.

127. See Gerald A. Faich, Special Report: Adverse-Drug-Reaction Monitoring, 314 NEW. ENG. J. MED. 1589, 1592 (1986) (“The FDA and the medical community share the responsibility for providing continual evaluation of drug performance after marketing. . . . [However,] [a] number of factors may inhibit physicians from reporting adverse reactions they have observed.”). Some factors, as speculated in this study, were lack of knowledge of a reporting system as well as fear of becoming involved in litigation. Id.


129. For example, Noah, supra note 117, at 478–79, proposes that physicians are less likely to trace the interaction of a particular drug and a patient with less emphasis on long-term primary care providers these days.

130. This situation is worsened when one thinks about events that are not deemed “serious adverse events,” since minor problems are not required to be reported to the FDA. See supra note 115 and accompanying text.
public, but the FDA must first know about the violation and serious risk. The FDA has tried to reduce the possibility of being kept in the dark about serious adverse events by updating and modifying the MedWatch system.\footnote{See U.S. Gov’t Accountability Office, supra note 128, at 24–26.} Under the new system, manufacturers will be required to submit reports of adverse events electronically to the FDA.\footnote{See id.} This information will then be automatically categorized and transferred to the appropriate department in the FDA.\footnote{See id.} The new system, called MedWatchPlus, will be more user-friendly\footnote{A significant problem with the old system is that direct-to-FDA reporting by consumers often contained inaccurate drug names. Id. at 26.} and provide more important information to the FDA.\footnote{See id.} This proposal is perhaps the most important tool the FDA has in its enforcement arsenal; without the necessary information, being able to mandate a recall does not offer much authority to the FDA or security to drug consumers. However, the implementation of this improved electronic-reporting system needs to go one step further.

2. The FDA Should Be Notified of All Unexpected Events Related to Drugs and Medical Devices

As radical as it may seem, what the FDA really needs is to know about any and all unexpected effects of a particular drug or medical device. This analysis proposes that the “phantom recall” does not really violate FDA protocol,\footnote{See supra note 126.} though it is certainly disconcerting to consumers to know that McNeil withdrew its own product because of a dissolution problem without notifying the public. It is unlikely that anyone in the pharmaceutical industry or FDA would consider anything related to the Motrin “phantom recall” a serious adverse event related to the drug because the product

\footnote{This is because companies who undertake a recall (or engage in recall-like behavior) are requested—not required—to notify the FDA. 21 C.F.R. § 7.46 (2011); see also supra note 26. Some may argue, and perhaps this is the subject of the FDA’s criminal investigation, that McNeil committed a violative act by allowing the Motrin with dissolving problems to remain on the market, as an adulterated drug. See 21 U.S.C. §§ 331(b), 351(b) (2006). Adulterated can also mean where the “[s]trength, quality, or purity [of the drug] differ[s] from official compendium.” Id. § 351(b). However, the drug that McNeil sold was an appropriate strength as marketed; the problem was that, when consumed, the strength of the drug was different from what the consumer expected. This is because the strength and purity of the drug is measured by dry weight and not after it has entered the human body. It is also possible that McNeil’s Motrin constituted a “misbranded” drug by way of a “[f]alse or misleading label.” Id. § 352(a). The Motrin that did not dissolve properly could be termed misbranded because the label led the consumer to believe that it would alleviate her headache but did not effectively do so.}
simply did not pose any sort of health risk to consumers.\textsuperscript{137} Accordingly, there would be no impetus for McNeil informing the FDA of the dissolution problem with Motrin or even their recall-like behavior. Moreover, even the TBA-contamination arguably may not rise to the level of mandatory reporting either since the potential gastrointestinal side effects of \textit{B. cepacia} in OTC pain-relievers may not fit within the definition of “serious adverse event.” Therefore, while the proposed amendments certainly remedy similar problems when the FDA has knowledge of certain drug-related problems, the critical point is that the FDA needs to have better access to information in the first place. The proposed legislation should therefore include language that amends the mandatory-reporting provision\textsuperscript{138} to require manufacturers to report any unexpected events that are reported by consumers or healthcare providers that could reasonably be related to the drug.\textsuperscript{139}

How can the FDA assure that it receives the necessary information if it is entitled to all unexpected side effects or problems with drugs currently on the market? And how can this information ensure the public is adequately notified of possible concerns with the medication in their medicine cabinet? The MedWatchPlus system suggests a possible pathway to arming the FDA with critical knowledge. What needs to be developed is a co-reporting system where a report to a manufacturer automatically goes to the FDA as well.\textsuperscript{140} The best way to implement this, after statutorily requiring such mandatory and automatic reporting, is to automatically record consumer- and physician-generated reports at the manufacturer’s facility. This recorded message will then be given a certain identifying number and automatically (and electronically) sent to the FDA. The manufacturer will then have to submit to the FDA an electronic follow-up report of the unexpected event that was just reported, which would be labeled with the same identifying number as the voice recording.\textsuperscript{141}

The FDA could then analyze the report and manufacturer-generated follow-up and determine if the unexpected event raises any serious concern for the manufacturer and its current lot of the particular drug on the market. The FDA would also be able to determine if drug manufacturers are

\textsuperscript{137} McNeil Hearing II, supra note 49, at 23 (statement of Bill Weldon).

\textsuperscript{138} See supra notes 122, 124.

\textsuperscript{139} Mandatory reporting of “serious adverse events” should still be required, even when it is possible that the drug (or medical device) is not responsible for the side effect.

\textsuperscript{140} This proposal is obviously unnecessary to give the FDA necessary information when the consumer or healthcare provider reports directly to the FDA. However, it certainly would be in the interest of transparency and open communication if it went both ways. That is, if the FDA receives a direct report, it should be required to communicate such report to the manufacturer as well.

\textsuperscript{141} A voice recording is only a suggestion. The co-reporting system would also be amenable to electronic reports from consumers directly to the manufacturer. In that situation, the report would be submitted to the manufacturer and simultaneously submitted to the FDA.
not properly reporting all unexpected events because it would not have the corresponding electronic submission to accompany the voice recording. With these two pieces of information, the FDA could contact the company directly to express concern and request more information—or it could simply store the information in a database, which would be particularly useful in tracking problems with currently marketed drugs.

This proposed method of co-reporting unexpected problems to drug manufacturers and the FDA would greatly reduce the likelihood that drug manufacturers could engage in a pattern of concealment similar to that undertaken by the McNeil Company over the past several years. In the McNeil case, once a consumer had reported the musty odor or gastrointestinal discomfort to McNeil, the report of the unexpected events would have automatically been available to the FDA. If McNeil did not follow up within the required amount of time, the FDA could have initiated investigative procedures. Further noncompliance would have merited FDA agents entering the McNeil facility and discovering the rampant TBA-contamination much sooner. Moreover, the “phantom recall” probably would never have occurred: the FDA would have discovered the Motrin dissolution problem at the same time as McNeil. Once McNeil decided to remove the product, it would have reported such to the FDA in an electronic follow-up. And in each of these scenarios, after acquiring the above information, the amendments of S. 1584 would allow the FDA to mandate a recall of the affected product if appropriate. Therefore, co-reporting probably would have dramatically reduced the number of affected consumers and increased the efficiency of the myriad of recalls undertaken by McNeil. But such co-reporting is only beneficial if manufacturers are required to report all unexpected events associated with OTC and prescription drugs and medical devices.

IV. CONCLUSION

Regulation of the manufacture and distribution of drugs is paramount to the safe and efficient management of pain and other health problems of consumers. However, the power vested in the FDA does not go far enough to ensure consumer safety; drug manufacturers are left with too much discretion in determining when they report unexpected (and adverse) health events associated with their product to the FDA. One need look no further than the aforementioned McNeil controversies to see that companies will take chances and gamble with their marketed products—a gamble that certainly does not pay off when consumers are adversely affected and the government discovers concealment. Chairman Towns’s proposed bill and its successor S. 1584 are a significant step towards preventing similar harm to the consumers by giving the FDA mandatory recall authority when it learns of noncompliant drugs. However, this analysis proposes that the best method of preventing future “phantom recalls” is to
equip the FDA with necessary knowledge of drugs that potentially violate the FDCA. Mandatory recall authority must be accompanied by significant amendments to the mandatory reporting provisions of the FDCA.

The proposed legislation is a good start to ensuring consumers are adequately protected by the FDA, but without requiring more communication between manufacturers and the FDA (and consumers), the bill may only equip the FDA with phantom authority.