

FOOD AND DRUG LAW JOURNAL

*Analyzing the Laws, Regulations, and Policies
Affecting FDA-Regulated Products*

Challenging an Immediate Suspension of a DEA Registration: Is It Time for a New Tact?

Douglas J. Behr

Challenging an Immediate Suspension of a DEA Registration: Is It Time for a New Tact?

DOUGLAS J. BEHR*

I. INTRODUCTION

On February 3, 2013, DEA shut down Cardinal Health's Lakeland distribution facility, without prior notice, by immediately suspending its DEA registration to handle any controlled substance. DEA asserted that the Lakeland facility represented an imminent threat to the public health. At the time, the Lakeland facility supplied approximately 5,200 customer accounts including "thousands of hospitals, pharmacies, and other health care providers" in Florida, Georgia and South Carolina.¹ The facility shipped approximately 500,000 dosage units of controlled substances to its customers per month.² DEA's action was based on its allegation that Cardinal Health had supplied four retail pharmacies, including two operated by CVS, that were illegally filling prescriptions for a single, Schedule II narcotic drug, oxycodone. Yet, DEA suspended the Lakeland facility's DEA registration for all controlled substances in all schedules, that is, Schedules II through V.³ When Cardinal Health was unable to get a court to grant it temporary relief while DEA considered whether a revocation of the registration was justified, Cardinal Health was forced to settle DEA's complaint. Cardinal ended up agreeing to close the facility for two years in a settlement with DEA.⁴

A Drug Enforcement Administration ("DEA") registration is a valuable commodity in which the holder has a constitutionally protected property interest.⁵ A registration is required before a hospital or pharmacy can stock or distribute controlled substances or before a physician can purchase, prescribe or dispense them. Many physicians and small pharmacies cannot operate without a registration.⁶ A typical pharmacy's sales are between 5 and 20% controlled substances.⁷ And some wholesale drug distributors

* Mr. Behr is a partner in the litigation practice of the Washington, D.C. office of Keller and Heckman LLP. His practice includes representing doctors and pharmacists before the Drug Enforcement Administration. Mr. Behr appreciates the assistance of Alyssia Bryant, an associate at Keller and Heckman in preparing this article.

¹ Memorandum of Points and Authorities in Support of Cardinal Health's Motion for Preliminary Injunction at 6, *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203 (D.D.C. 2012) (No. 12-185(RBW)).

² *Id.*

³ There are five schedules of controlled substances. Controlled substances include narcotic drugs, depressants, stimulants, anabolic steroids and hallucinogens. DEA's list of controlled substances is twelve pages long. See UNITED STATES DEPARTMENT OF JUSTICE, DEA DIVISION, CONTROLLED SUBSTANCES (2013), available at http://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf.

⁴ *Cardinal Health Ends DEA Inquiry with Settlement*, ASSOCIATED PRESS (May 15, 2012, 10:27AM), <http://bigstory.ap.org/content/cardinal-health-ends-dea-inquiry-settlement>.

⁵ See Barry M. Schultz, M.D.; Decision and Order, 76 Fed. Reg. 78,695 (Dec. 19, 2011).

⁶ See, e.g., Kwan Bo Jin, M.D.; Decision and Order, 77 Fed. Reg. 35,021 (June 12, 2012) (regarding a physician awaiting a decision on DEA registration before deciding to return to practice).

⁷ See *Southwood Pharmaceuticals, Inc.; Revocation of Registration*, 72 Fed. Reg. 36,487, 36,492

will not sell anything to a pharmacy that does not purchase controlled substances as part of its ordering.⁸

DEA has the authority to summarily suspend a DEA registration by issuing an immediate suspension order (“ISO”) upon an *ex parte* finding that “there is an imminent danger to the public health or safety” without any prior notice or pre-suspension hearing at the initiation of the process to determine whether to revoke the registration.⁹ Concurrent with the service of an ISO, DEA serves an Order to Show Cause why the registration should not be revoked and seizes all controlled substances in the possession of the registrant.¹⁰ However, the Controlled Substances Act¹¹ (“CSA”) has no regulatory or statutory provision under which a registration is entitled to a post-suspension hearing on the ISO. Rather, the registrant has either to endure a prolonged administrative process adjudicating the merits of the individual’s continued registration while being suspended or to seek to have the ISO “dissolved by a court of competent jurisdiction.”¹² Registrants who have gone to court to challenge an ISO have generally sued DEA under the Administrative Procedure Act (“APA”),¹³ and then applied for a temporary restraining order and/or a preliminary injunction to set aside the ISO. This approach invokes procedures and standards that advantage DEA. Rather, I suggest that the approach should be to file a motion to dissolve the ISO pursuant to 21 U.S.C. § 824(d) and seek to have the court review the ISO to determine whether there is an imminent harm that justifies continuation of the ISO pending the final determination on the agency’s action against the registration and that the scope of the ISO is not overly broad given the allegations made in the Order to Show Cause.

Part I briefly discusses the DEA registration process including the grounds for registration suspension or revocation. Part II explains how a registrant may challenge an ISO. This Part examines whether an administrative challenge is available and the process of challenging an ISO in court. Finally, Part III questions whether there is a better way to challenge ISOs and explores alternate methods.

II. DEA’S STATUTORY AND REGULATORY SCHEME

Registration with DEA is required before anyone can distribute, prescribe, or dispense a controlled substance.¹⁴ Every drug wholesaler, every pharmacy, and every doctor prescribing controlled substances must first register with DEA.

Once issued, a registration may be suspended or revoked by the Attorney General if the registrant “has committed such acts as would render his registration . . . inconsistent with the public interest as determined under 21 U.S.C. § 823.”¹⁵ A revocation or suspension can be limited to a particular controlled substance.¹⁶ Although the statute

(July 3, 2007).

⁸ See Physician’s Pharmacy, LLC; Decision and Order, 77 Fed. Reg. 47,096 (Aug. 7, 2012).

⁹ See 21 U.S.C. § 824(d) (2012).

¹⁰ *Id.* § 824(f).

¹¹ 21 U.S.C. §§ 801 *et seq.* (2012).

¹² See *Id.* at § 824(d).

¹³ 5 U.S.C. §§ 500 *et seq.* (2012).

¹⁴ See 21 U.S.C. § 822 (2012).

¹⁵ 21 U.S.C. § 824(a)(4) (2012).

¹⁶ See *Id.* § 824(b); see also *In the Matter of Mary Thomson, M.D.; Continuation of Registration with Restrictions*, 65 Fed. Reg. 75,969, 75, 972 (Dec. 5, 2000) (ordering that respondent’s registration may continue however no registration for narcotic controlled substances).

does not address it,¹⁷ the revocation or suspension can be limited to a particular Schedule of controlled substances as well.¹⁸

Before taking action to suspend or revoke a registration, the Attorney General must serve the registrant with an Order to Show Cause why the registration should not be revoked or suspended.¹⁹ The Order to Show Cause “shall contain a statement of the basis thereof” and direct the registrant “to appear before the Attorney General [or his designee] at a time and place stated in the order, but in no event less than thirty days after the date of receipt of the order.”²⁰ In conjunction with an Order to Show Cause, the Attorney General or his designee may immediately suspend a registration “in cases where he finds that there is an imminent danger to the public health or safety.”²¹ An immediate suspension “shall contain a statement of [the Administrator’s] findings regarding the danger to public health or safety.”²² According to DEA, all that is required is a “non-exhaustive summary of the factual and legal basis for the immediate suspension,” an “interpretation” to which deference has been given.²³ Pursuant to the CSA, “a suspension . . . shall continue in effect until the conclusion of such [revocation] proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction.”²⁴

Neither the Controlled Substances Act nor DEA’s regulations provides for a post-suspension review proceeding for an immediate suspension. Rather, DEA provides by regulation that if a registration is suspended immediately upon service of an Order to Show Cause, the registrant may request an “expedited” hearing on the merits of the Order to Show Cause at a time earlier than specified in the Order to Show Cause.²⁵ The Administrator “shall” grant the request for an earlier hearing and fix a date “as early as reasonably possible,” although there is no statutory or regulatory deadline on the ultimate decision, which often takes more than a year.²⁶ No further guidance is offered in the regulations on whether the immediate suspension can be addressed separately or how or when the ultimate decision on the Order to Show Cause must be made.

III. CHALLENGING AN IMMEDIATE SUSPENSION

By statute, an ISO remains in effect until the conclusion of the revocation proceeding “unless sooner withdrawn” by the DEA Administrator “or dissolved by a court of

¹⁷ See generally, 21 U.S.C. §§ 801 *et seq.* (2012).

¹⁸ See, e.g., Michael Alan Patterson, M.D.; Grant of Restricted Registration, 65 Fed. Reg. 5,682, 5,686 (Feb. 4, 2000) (ordering that Dr. Patterson’s registration not permit Schedule II drugs).

¹⁹ 21 U.S.C. § 824(c) (2012); 21 C.F.R. §§ 1301.36(d), 1301.37 (2013).

²⁰ 21 U.S.C. § 824(c); see also 21 C.F.R. § 1301.37(c) (“[The statement shall contain] the legal basis for such hearing and for the denial, revocation, or suspension of registration and a summary of the matters of fact and law asserted.”).

²¹ 21 U.S.C. § 824(d) (2012); 21 C.F.R. § 1301.36(e) (2013).

²² 21 C.F.R. § 1301.36(e) (2013).

²³ *Holiday CVS, L.L.C. v. Holder*, 839 F. Supp. 2d 145, 154 (D.D.C. 2012).

²⁴ 21 U.S.C. § 824(d) (2012); 21 C.F.R. § 1301.36(h) (2013).

²⁵ 21 C.F.R. § 1301.36(h).

²⁶ *Id.* DEA holds an evidentiary hearing on the Order to Show Cause before an Administrative Law Judge (“ALJ”). The ALJ takes evidence and at the close of that evidence issues a recommended decision that reviews and summarizes the evidence presented, makes factual and credibility findings and recommends a resolution to the DEA Administrator. Neither the recommendation nor the ALJ’s findings are binding on the Administrator. The parties to the hearing have the opportunity to submit exceptions to the recommended decision to the DEA Administrator prior to her consideration of the matter. *Id.*

competent jurisdiction.”²⁷ The legislative history of the CSA offers no information about the process through which a suspended registrant should seek to have his suspension withdrawn or dissolved nor does it explain the standard to be used in such a review.

A. *Challenging the ISO before the DEA Administrative Law Judge*

In practice, registrants do not try to challenge an ISO before the DEA. Whether such a challenge is available is unclear, although it appears that such a challenge is not. Neither the CSA nor the DEA regulations provide for a post-suspension hearing on an ISO before the agency. Rather, the regulations only provide that the Administrative Law Judge (“ALJ”) shall grant any request for a hearing “at a time earlier than specified in the Order to Show Cause” and shall schedule a hearing “as early as reasonably possible.”²⁸ The hearing is on the merits of the Order to Show Cause, however.

We have found only one reported instance where a registrant challenged an ISO before DEA and that challenge did not result in agency action. In *Novelty Distributors, Inc. v. Leonhart*,²⁹ the District court noted that Novelty had challenged its ISO during a hearing before the DEA ALJ and that the ALJ had recommended to the DEA Administrator that the registration be reinstated.³⁰ No decision had been made on the recommendation by the time Novelty’s court challenge was decided and the court did not identify what procedure provided for such a review.³¹

More recently, the same DEA ALJ who had heard Novelty’s challenge noted, in a Report and Recommendation that was adopted by the Administrator, that the issuance of an immediate suspension is not reviewable during DEA’s hearing process.³² According to the ALJ, “to the extent that the Respondent believes that the agency’s immediate suspension of the Respondent’s registration was inappropriate, either substantively or procedurally, that matter is not reviewable by this tribunal and must be pursued in federal district court or directly to the Administrator.”³³

If a challenge is available before the Administrator, there is no stated procedure for it. As evidenced by the *Novelty* case, such a challenge is not likely to be effective or timely. In *Novelty*, there was a little over a two-month delay between the issuance of the ISO and the beginning of the hearing on the Order to Show Cause.³⁴ Two months later, or four months after the ISO was issued, the ALJ recommended the reinstatement of Novelty’s registration.³⁵ The DEA Administrator had not acted on the recommendation a month later when the District Court issued its opinion.³⁶

There is no process for petitioning the DEA Administrator to withdraw an immediate suspension under DEA’s regulations or published procedures. At best, the registrant is forced into a negotiation with the Agency. There are no reported cases either before the Agency or before a court that refer to the lifting of an immediate suspension by

²⁷ 21 U.S.C. § 824(d) (2012).

²⁸ 21 C.F.R. § 1301.36(h) (2013).

²⁹ *Novelty Distributors Inc. v. Leonhart*, 562 F. Supp. 2d 20 (D.D.C. 2008).

³⁰ *Id.*

³¹ *Id.*

³² See Barry M. Schultz, M.D.; Decision and Order, 76 Fed. Reg. 78,695 (Dec. 19, 2011).

³³ *Id.* at 78,697.

³⁴ *Novelty*, 562 F. Supp. 2d at 23.

³⁵ *Id.*

³⁶ *Id.*

the Administrator. More likely, any such action would be linked to a settlement of the entire matter.

B. *Challenging an ISO in Court*

Under the Controlled Substances Act, the authority to “dissolve” an immediate suspension rests with a “court of competent jurisdiction.”³⁷ In practice, the court of competent jurisdiction has been the United States District Court. Whether a district court has proper jurisdiction has been analyzed, once.

1. *Court of Competent Jurisdiction*

Only one case has addressed the question of whether jurisdiction rests with a court of appeals rather than a district court. DEA challenged the jurisdiction of the district court in *Novelty, Inc. v. Leonhart*.³⁸ DEA based its argument on the provision of the CSA that provides that only a court of appeals may review “final determinations, findings, and conclusions of the Attorney General.”³⁹ DEA’s argument was rejected. The *Novelty* court noted that “[t]he parties concede that the suspension of Novelty’s registration in the present case is neither a ‘final agency action’ under the APA, 5 U.S.C. § 704, nor a ‘final determination[], finding[] or conclusion[]’ under the CSA, 21 U.S.C. § 877.”⁴⁰ The *Novelty* court further noted that Novelty was not seeking a final judgment on the merits but merely “temporary relief pending a final agency determination regarding its suspension.”⁴¹

Other district courts have considered challenges to a DEA ISO on the merits without any discussion of the court’s jurisdiction, presumably because government did not raise a challenge under § 877 of the CSA.⁴² Additionally, the statutory language appears to grant jurisdiction to the district court. First, §824 grants the authority to review an ISO to a “court of competent jurisdiction” and is not limited to a court of appeals as is a review of a final action.⁴³ Had Congress wanted to limit the review under § 824, it could have done so. Congress’ failure implies that jurisdiction is not limited. Second, the “court of competent jurisdiction” phrase also appears in the judicial review section of the APA § 703. Under the APA, jurisdiction to review an agency action lies with a

³⁷ See 21 U.S.C. § 824(d) (2012).

³⁸ *Novelty, Inc. v. Leonhart*, 562 F. Supp. 2d 20 (D.D.C. 2008).

³⁹ 21 U.S.C. § 877 (2012); see *Novelty, Inc.*, 562 F. Supp. 2d at 25.

⁴⁰ *Novelty, Inc.*, 562 F. Supp. 2d at 26.

⁴¹ *Id.*

⁴² See, e.g., *Norman Bridge Drug Co. v. Banner*, 529 F.2d 822 (5th Cir. 1976) (discussing a DEA suspension without prior notice); *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203 (D.D.C. 2012) (denying Cardinal Health’s motion for preliminary injunction and complaint challenging the DEA ISO on the grounds that it was issued without authority under the APA); *Keysource Med., Inc. v. Holder*, No. 1:11-cv-393, 2011 WL 3608097, at *8 n.4 (S.D. Ohio Aug. 16, 2011) (“The Court does find, however, that Plaintiff was entitled to challenge the propriety of the immediate suspension in this Court pursuant to 21 U.S.C. § 824(d).”); *Neil Labs., Inc. v. Ashcroft*, 217 F. Supp. 2d 80 (D.D.C. 2002) (reviewing a suit alleging that the DEA wrongfully suspended the laboratories’ registration to sell Schedule I chemicals).

⁴³ Compare 21 U.S.C. § 824(d) (2012) (“The Attorney General may, in his discretion suspend any registration simultaneously with the institution of proceedings . . . [and such a suspension] shall continue in effect until the conclusion of such proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction.”) with § 877 (“All final determinations, findings, and conclusions of the Attorney General under this subchapter shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the District of Columbia or the circuit in which his principal place of business is located”) (emphasis added)

“court of competent jurisdiction” unless Congress has set up a special statutory scheme.⁴⁴ The United States Court of Appeals for the District of Columbia Circuit has noted that § 703, which vests review in a “court of competent jurisdiction,” “makes no reference to the court of appeals.”⁴⁵ Under § 703, “the normal default rule [under the APA] is that persons seeking review of agency action go first to district court rather than to a court of appeals.”⁴⁶ Therefore, by analogy, the CSA vests the authority to dissolve an ISO in the district courts. Although the CSA vests a “court of competent jurisdiction” with the power to “suspend” an ISO, the statute does not establish a process by which that is to be done.

2. *Scope and Nature of Court Review*

In one of the earliest cases under the “court of competent jurisdiction” provision, the registrant filed a motion with the district court seeking suspension of an ISO. Since that time, registrants have generally filed for a preliminary injunction based on a complaint alleging a violation of the APA. An APA challenge sets up an almost insurmountable barrier for the registrant because courts generally assume the correctness of an agency’s finding and will only reverse such a finding under limited circumstances.⁴⁷ Similarly, the standard relating to a preliminary injunction also set up significant hurdles to the registrant.

The first reported case involving a challenge to an ISO arose from an ISO issued in 1974, four years after the statute went into effect.⁴⁸ In *Norman Bridge*, DEA issued an ISO on November 11, 1974, citing nine supporting bases for the ISO including the pharmacy’s alleged record keeping violations in May 1971 and May 1973 and the May 1974 conviction of its owner and chief pharmacist for illegally distributing controlled substances. Norman Bridge first sought and obtained a temporary restraining order (“TRO”) followed by a preliminary injunction.⁴⁹ The district court issued a TRO based on the findings that “the plaintiff would suffer immediate and irreparable injury, and that there had been no showing by the Drug Enforcement Administration or its agents of imminent danger to the health or safety of the public within the meaning of 21 U.S.C. § 824.”⁵⁰

The subsequent preliminary injunction was based, in part, on the testimony of Roy Vann, the president of Norman Bridge whose conviction was cited as a basis for the ISO. Vann testified that he had been convicted on May 3, 1974, and he had stopped filling prescriptions in June. DEA issued the ISO on November 11, 1974, some six months after the conviction. The trial court issued a preliminary injunction based, in part, on its finding that Norman Bridge was likely to prevail at the show cause hearing because “the record keeping inconsistencies cited in the DEA’s suspension order were not grounds for revocation.”⁵¹ The court further found that there was no showing of imminent danger to the public “in light of the seven month delay by DEA in acting on

⁴⁴ 5 U.S.C. § 703 (2012).

⁴⁵ *Micei Int’l v. Dep’t of Commerce*, 613 F.3d 1147, 1152 (D.C. Cir. 2010).

⁴⁶ *Watts v. SEC*, 482 F.3d 501, 502 (D.C. Cir. 2007) (quoting *Int’l Bhd. of Teamsters v. Pena*, 17 F.3d 1478, 1481 (D.C. Cir. 1994)).

⁴⁷ See 5 U.S.C. § 706.

⁴⁸ See *Norman Bridge Drug Co. v. Banner*, 529 F.2d 822, 823-24 (5th Cir. 1976).

⁴⁹ *Id.*

⁵⁰ *Id.* at 828.

⁵¹ *Id.*

the record keeping violations and the criminal conviction of Roy Vann.”⁵² Finally, the court found that “DEA had abused its discretion.”⁵³

The *Norman Bridge* court relied on the authority of 21 U.S.C. § 824(d) to grant relief. 21 USC § 824(d) states that an ISO remains in effect until the show cause is resolved, it is withdrawn by the Attorney General, or it is “dissolved by a court of competent jurisdiction.” As the Fifth Circuit noted in *Norman Bridge*:

The appellants fail to notice that what we have in this case is a statutory scheme specifically mandated by Congress. Apparently in an effort to preserve constitutional safeguards with reference to the seizure of property or the deprivation of professional status without notice, Congress was careful to prescribe two requirements for the suspension of registration and the seizure of property without notice, 21 U.S.C. § 824. Such a suspension, or such a seizure, may be invoked only to avoid imminent danger to the public health and safety. In the absence of that factor there can be no suspension and no seizure without notice and an opportunity to be heard. Moreover, when such action is taken, it survives only so long as it goes undissolved by a court of competent jurisdiction.⁵⁴

The *Norman Bridge* court reviewed the ISO on the merits; that is, it determined whether there was “imminent danger.”⁵⁵ The trial court in *Norman Bridge* held an evidentiary hearing and found, based on the evidence presented, that there was not “imminent danger” and therefore no justification for an ISO. The trial court did not give deference to DEA’s decision nor did it limit its review to determining whether issuing the ISO was an abuse of discretion.⁵⁶

Another ISO challenge-case is *In the Matter of Edward R. Burka, M.D.*⁵⁷ In that case, Petitioner, Dr. Burka, also petitioned the district court to dissolve his immediate suspension pursuant to 21 U.S.C. § 824(d). In his petition, Dr. Burka asserted that there was no admissible evidence to support the findings upon which the ISO was based, because, according to Burka, the evidence seized from his office should be suppressed.⁵⁸ The court rejected the motion to suppress and therefore found that there was evidence to support the ISO. However, the district court further found that its review of the ISO was limited to an APA review. According to the *Burka* court, the court was tasked only with determining whether “the agency action was rational, based on relevant factors, and within the agency’s statutory authority.”⁵⁹

Other reported cases generally involve the filing of a complaint alleging a violation of the APA and a request for a TRO and preliminary injunction.⁶⁰ The first problem

⁵² *Id.* at 826.

⁵³ *Id.*

⁵⁴ *Id.* at 828.

⁵⁵ *Id.* at 828-29.

⁵⁶ *Id.* The administrative process was completed before the Court of Appeals ruled, so the preliminary injunction phase of the case was mooted before review. *Id.* at 827.

⁵⁷ *In the Matter of Edward R. Burka, M.D.*, 684 F. Supp. 1300 (E.D. Pa. 1988).

⁵⁸ *Id.* at 13000.

⁵⁹ *Id.* at 1305 (quoting *Shane Meat Co. v. U.S. Dep’t of Defense*, 800 F.2d 334, 336 (3d Cir. 1986)). However, the *Shane Meat* case was an APA review of a final agency action and therefore not directly applicable to Dr. Burka’s situation. See generally *Shane Meat Co. v. U.S. Dep’t of Defense*, 800 F.2d 334 (3d Cir. 1986).

⁶⁰ See, e.g., *Cardinal Health v. Holder*, 839 F. Supp. 2d 203, 203 (D.D.C. 2012); *Keysource Med. Inc. v. Holder*, No. 11-cv-393, 2011 WL 3608097, at *6 (S.D. Ohio Aug. 16, 2011) (applying the arbitrary and capricious standard to review a DEA ISO under the APA); *Novelty Distributors, Inc. v. Leonhart*, 562

with this approach is satisfying the requirements for an injunction⁶¹ – particularly demonstrating irreparable harm. Second, by conceding the application of the standards set out in the APA, registrants have conceded that the court’s review is deferential and that there need only be substantial evidence to support the ISO.

While doctors have generally been able to demonstrate irreparable harm from the temporary loss of their registration,⁶² several cases involving businesses have floundered on the question of irreparable harm.⁶³ In those cases, the registrant generally attempted to demonstrate significant economic loss that is not recoverable because DEA is immune. However, such a demonstration must be based on quantifiable evidence and the showing of loss must be “great, certain and imminent.”⁶⁴ These showings can be difficult for a successful business particularly those above the retail level.

For instance, in *Easy Returns Worldwide, Inc. v. United States*,⁶⁵ the plaintiff challenged an ISO by citing *Norman Bridge* and seeking a preliminary injunction based primarily on a claim that the information relied upon by the government was stale. Easy Returns noted that many of the allegations cited by the government were over two years old. In ruling on Easy Returns’ motion for a preliminary injunction, the court found that Easy Returns had not demonstrated that it would be irreparably harmed if no injunction were issued.⁶⁶ Even though the Easy Returns’ CEO testified that his customers told him that they could not do business with Easy Returns if it was not registered, the court found that the testimony of the CEO did not carry Easy Returns’ burden of proof because he had not provided sufficient concrete evidence of likely harm.⁶⁷ The court further found that Easy Returns was not likely to succeed on the merits.

Similarly, the court in *Cardinal Health v. Holder* found that Cardinal Health, one of the nation’s largest wholesale pharmaceutical drug distributors, had not demonstrated that it would be irreparably harmed from the temporary closing of one of its regional distribution centers.⁶⁸ According to the court, Cardinal’s claims “of lost customers, reduced profits, costs associated with rerouting drug shipments from other facilities, and reputational harm, all of which it claims will be unrecoverable due to the government’s sovereign immunity” were not enough.⁶⁹ The court found both that Cardinal had not “shown economic harm in certain, non-speculative terms” and that even those losses

F. Supp. 2d 20, 29 (D.D.C. 2009); *Neil Labs., Inc. v. Ashcroft*, 217 F. Supp. 2d 80, 87 n.6 (D.D.C. 2002); *United Prescription Servs., Inc. v. Gonzalez*, No. 07-cv-316, 2007 WL 1526654, at *2 (M.D. Fla. May 23, 2007) (applying the arbitrary and capricious standard to review a DEA ISO under the APA); *Easy Returns Worldwide, Inc. v. United States*, 266 F. Supp. 2d 1014 (E.D. Mo. 2003) (same).

⁶¹ “A plaintiff seeking a preliminary injunction must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tip in his favor, and [4] that an injunction is in the public interest” *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008).

⁶² Memorandum Decision and Order, *Mackay v. Bolman*, Case No. 2:09-cv-00285 (D. Utah Apr. 7, 2009), ECF No. 13 [hereinafter *Mackay*, Decision and Order].

⁶³ See cases cited *supra* note 60.

⁶⁴ *Cardinal Health*, 839 F. Supp. 2d at 203.

⁶⁵ *Easy Returns Worldwide, Inc.*, 266 F. Supp. at 1014. Easy Returns was a reverse distributor, a company that retrieves pharmaceutical products, including controlled substances, from retailers and others in order to destroy them. *Id.*

⁶⁶ *Id.* at 1017-18.

⁶⁷ *Id.* at 1017-19.

⁶⁸ *Cardinal Health*, 839 F. Supp. 2d at 210-211.

⁶⁹ *Id.* at 211.

that it had estimated were not sufficient to demonstrate irreparable harm, because they were less than 1% of Cardinal's annual sales of \$102 billion.⁷⁰

In *Holiday CVS, L.L.C. v. Holder*,⁷¹ a case related to *Cardinal Health* before the same judge, the court found that two pharmacies owned by a subsidiary of a national chain of pharmacies had not shown irreparable harm from an ISO. The court found that the Registrant had not quantified the extent of economic harm it was likely to suffer and certainly had not shown "that the ISO would *likely* cause the two pharmacies to shut down."⁷²

Registrants have also generally been unsuccessful in demonstrating a likelihood of success on the merits. The primary difficulty is that the arbitrary and capricious standard of review under the APA is "highly deferential" and the court presumes that the agency action was valid.⁷³ Additionally, APA review generally is limited to the administrative record.⁷⁴ Thus, the question is not whether there was at the time of the issuance of the ISO an imminent threat to the public safety and health, nor whether such a threat remains, but rather whether the Administrator acted arbitrarily and capriciously in determining that there was.

One result of bringing a challenge under the APA is to limit the evidence upon which the review of the ISO is conducted. Generally, the court only considers the evidence in the administrative record when conducting an APA review. As the court observed in *Mackay v. Bolman*, under well-established standards:

Judicial review of the agency action must be based on the whole administrative record, which includes everything that was before the agency pertaining to the merits of its decision. The whole administrative record, therefore, consists of all documents and materials directly or indirectly considered by agency decision-makers and includes evidence contrary to the agency's position. An incomplete record must be viewed as a fictional account of the actual decision-making process. The whole record is not necessarily those documents that the agency has compiled and submitted as the administrative record; the court must look at all the evidence that was before the decision-making body.⁷⁵

Under DEA's regulations, the ISO must contain "a statement of [the Administrator's] findings regarding the danger to public health or safety."⁷⁶ DEA has argued that "the administrative record should be limited to the four corners" of that statement.⁷⁷ In

⁷⁰ *Id.* at 213.

⁷¹ *Holiday CVS, L.L.C. v. Holder*, 839 F. Supp. 2d 145 (D.D.C. 2012).

⁷² *Id.* at 169.

⁷³ See *Chevron U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 844-45, 865-66 (1984); *Am. Horse Protection Ass'n v. Yeutter*, 917 F.2d 594, 596 (D.C. Cir. 1990).

⁷⁴ See Susannah T. French, *Judicial Review of the Administrative Record in NEPA Litigation*, 81 Calif. L. Rev. 929, 931 (1993), available at <http://scholarship.law.berkeley.edu/cgi/viewcontent.cgi?article=1745&context=californialawreview> ("[C]ourts have tended to apply . . . the 'record rule.' Under the record rule courts refuse to consider evidence that was not first presented to the agency."); see also 5 U.S. C. § 551 (2012).

⁷⁵ *Am. Horse Protection Ass'n*, 917 F.2d at 596 (quoting *Ctr. for Biological Diversity v. United States BLM*, No. C-06-4884, 2007 U.S. Dist. Lexis 81114, at *10 (N.D. Cal. Oct. 18, 2007). Thus, returning to *Easy Returns*, the court granted the government's motion to limit its review to "the administrative record" which consisted of the Order to Show Cause, ISO, and a DEA Report of Investigation. *Easy Returns Worldwide, Inc.*, 266 F. Supp. 2d at 1018-19.

⁷⁶ 21 C.F.R. § 1301.36(e) (2013).

⁷⁷ See *Mackay*, Decision and Order at 3.

Mackay v. Bolman, the court rejected DEA's request that the administrative record be limited to the Administrator's statement of findings on the danger to public health or safety.⁷⁸ According to the court, the administrative records included "a transcript from a taped conversation, investigative reports from former patients, autopsy reports, and an expert report," all of which were referenced in the ISO.⁷⁹ Additionally, the *Mackay* court did consider, without explanation, evidence from medical experts submitted by Dr. Mackay to contest conclusions in the ISO attributed to the government's experts whose reports were not submitted by DEA.⁸⁰

In contrast, in *Holiday CVS*, it was the registrant who unsuccessfully sought to limit the court's review to the four corners of the ISO.⁸¹ The *Holiday CVS* court found that DEA's interpretation of its regulation as requiring only that a "non-exhaustive summary of the factual and legal basis for the ISO" was entitled to deference.⁸² There, the *Holiday CVS* court remanded the matter to DEA for the compilation of an administrative record of the information before the Administrator at the time the ISO was issued.⁸³ Furthermore, the *Holiday CVS* court allowed DEA to seemingly supplement the record by submitting the declarations of the Deputy Assistant Administrator and the Administrator that were offered by DEA to "distill the voluminous evidence compiled in the course of DEA's investigation . . . , and summarize . . . what informed the Administrator's ultimate decisions to issue the ISOs."⁸⁴

One problem with a review limited to the administrative record is that the registrant does not have an opportunity to confront the government's evidence nor does she have a chance to offer contrary evidence. This limitation is particularly detrimental since the registrant has not had a chance to participate in the administrative decision to this point and therefore the evidence is entirely one-sided.

In reviewing agency action under the APA, the courts have consistently found that the Administrator did not act arbitrarily and capriciously. For instance, in *Neil Laboratories, Inc. v. Ashcroft*,⁸⁵ the court considered a challenge to an immediate suspension based on both the APA and the CSA.⁸⁶ Neil Laboratories was registered by DEA to handle List 1 chemicals, particularly pseudoephedrine, a chemical used in the illicit manufacturing of methamphetamine. Based on evidence that Neil's customers were using the pseudoephedrine for illegal purposes and upon an undercover operation which purchased pseudoephedrine from Neil under suspicious circumstances, DEA immediately suspended Neil's registration.⁸⁷ Neil challenged DEA's actions as violating due process because DEA waited six months from the last alleged illegal act to issue the ISO. The court rejected Neil's challenge and granted summary judgment to DEA.⁸⁸ The court did not make an independent finding of imminent harm. Rather, the court reviewed DEA's articulated basis for its decision. The court found that DEA suspected

⁷⁸ *Id.*

⁷⁹ *Id.* at 4.

⁸⁰ *Id.*

⁸¹ *Holiday CVS, L.L.C. v. Holder*, 839 F. Supp. 2d at 154-56.

⁸² *Id.* at 154.

⁸³ *Id.* at 155.

⁸⁴ *Id.* at 153.

⁸⁵ *Neil Labs, Inc. v. Ashcroft*, 217 F. Supp. 2d 80 (D.D.C. 2002).

⁸⁶ *Id.*

⁸⁷ *Id.* at 83.

⁸⁸ *Id.* at 88.

Neil “of being an active participant in the chain of production for methamphetamine.”⁸⁹ Furthermore, DEA explained its delay as the result of its ongoing criminal investigation.⁹⁰ Relying on the statutory grant of discretion to the Attorney General and its conclusion that “DEA provided a rational connection between the facts and the conclusion that Neil Labs’ continued registration would constitute an imminent danger to the public, and showing deference to the agency as required,” the court concluded “that the DEA did not abuse its discretion” in issuing the ISO.⁹¹

Further, there are two recent cases where the court found that a registrant had demonstrated a likelihood to succeed on an APA challenge at the TRO stage, *Mackay v. Bolman* and *Bates Drug Stores, Inc. v. Holder*.⁹²

In the *Mackay* case, the court found that the bases for the administrator’s conclusions were in some instances stale and in other instances equivocal.⁹³ The court also found that DEA has significant evidence such as transcripts of taped conversations, reports of investigation, autopsy reports and expert reports that were not submitted to the court to review and the court drew a negative inference from the absence of the supporting evidence.⁹⁴ Additionally, the *Mackay* court allowed Dr. Mackay to submit evidence to support expert reports supporting his positions, which would not ordinarily be allowed in a “record review.”⁹⁵

In *Bates Drug*, the ISO was based primarily on violations of various regulations, such as accepting returns of controlled substances, dispensing to doctors for their office use, and dispensing based on prescriptions without all the “required” information. The court found that there were no allegations or evidence that any diversion had occurred. The court “doubted” that the alleged violations “pose[d] an imminent danger to public health and safety.”⁹⁶ Thus, current litigation has not been particularly successful in securing relief from an ISO. A new approach needs to be tried.

IV. IS THERE A BETTER WAY?

As noted at the outset, DEA acknowledges that a registrant has a constitutionally protected property right in the registration.⁹⁷ Because of that protected property right, due process requires a post-suspension hearing after having been subjected to an *ex parte* ISO.⁹⁸ Once the government has granted a business license to an individual, the government cannot “depriv[e] [the individual of] such an interest... without appropriate

⁸⁹ *Id.* at 87.

⁹⁰ *Neil Labs, Inc. v. Ashcroft*, 217 F. Supp. 2d 87 (D.D.C. 2002).

⁹¹ *Id.*

⁹² *Bates Drug Stores, Inc. v. Holder*, No. CV-11-0167-EFS, 2011WL 1750066 (E.D. Wash. May 6, 2011). The Bates case did not progress any further and ultimately was dismissed. It appears that Bates entered into an agreement with DEA to accept a five-month suspension of its registration for Schedule II controlled substances and DEA agreed to allow Bates to keep an active registration for all other schedules during that period and not to seek to revoke Bates’ registration. See John Stucke, *Bates Drug Stores Inc. Agrees to Pay Settlement*, SPOKESMAN-REV. (Mar. 28, 2012), <http://www.spokesman.com/stories/2012/mar/28/bates-drug-stores-inc-agrees-to-pay-settlement/>.

⁹³ *Mackay*, Decision and Order at 4-5.

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ *Bates Drug Stores*, 2011WL 1750066, at *1.

⁹⁷ See Barry M. Schultz, M.D.; Decisions and Order, 76 Fed. Reg. 78,695 (Dec. 19, 2011).

⁹⁸ See *Spinelli v. City of New York*, 579 F.3d 160 (2nd Cir. 2009); *Questcare, LLC v. Poynter*, Nos. 12-cv-92-ART, 12-93-ART, 2013WL 794376 (E.D. Ky. Mar. 4, 2013); *Feinberg v Fed. Deposit Ins. Corp.*, 420 F. Supp. 109, 118 (D.D.C. 1976).

procedural safeguards.”⁹⁹ The CSA’s statutory grant of jurisdiction to the courts to dissolve an ISO is a recognition of that due process right.

While the nature and scope of a due process hearing can vary, it generally requires a review of the suspension and a determination that continued suspension is justified; that is, whether the registrant represents a threat to the public safety.¹⁰⁰ The court review of an ISO provided for by the CSA should be treated as such a hearing. When viewed as a post-ISO due process hearing, the court review begins with a Petition to Dissolve the ISO. There is no need to sue DEA nor is there a need to apply for an injunction. The plain language gives the court the authority to dissolve the ISO which is the relief that the registrant is seeking. Therefore, the CSA must authorize a proceeding directed to that question.

Furthermore, the plain language of the CSA provides for a substantive review of the ISO and a determination that an immediate suspension is justified to protect the public health and safety.¹⁰¹ An ISO is the equivalent of an affirmative TRO requiring a registrant to surrender its registration pending a final determination on the agency’s attempt to revoke the registration based solely on a finding of imminent harm. The court’s review is similar to that of a follow-on request for a preliminary injunction—that is, a *de novo* determination of the propriety of an injunction. In this case, the review should be a *de novo* determination of two questions: (1) whether there is an imminent danger to the public health or safety; and if so, (2) is the suspension order overbroad or not? The court should either “dissolve” or modify the ISO or not. No further action is appropriate or required.

Additionally, because the court is authorized to “dissolve” the ISO, the case should not be litigated as an injunction action. Simply put, the court is not enjoining the DEA from suspending a registration but rather is “dissolving” the immediate suspension thereby reinstating the registration. The elements relating to an injunction are irrelevant to whether the ISO should be dissolved or not. Rather, the questions are whether there is an imminent danger to the public health or safety and what is the scope of the ISO.

The APA does not require a different approach. APA review is available for “[a]gency action made reviewable by statute and final agency actions for which there is no other adequate remedy in a court.”¹⁰² Because an ISO is not a “final order,” it is only subject to review under the APA if it is “made reviewable by statute.”¹⁰³ The CSA states that the ISO is subject to being “dissolved” by the court, not that it is subject to review.¹⁰⁴ In contrast, final orders are subject to “review” by the court of appeals.¹⁰⁵ Based on the

⁹⁹ *Arnett v. Kennedy*, 416 U.S. 134, 167 (1974) (Powell, J., concurring in part); see also *Bell v. Burson*, 402 U.S. 535, 539 (1971) (“Once licenses are issued, . . . their continued possession may become essential in the pursuit of a livelihood.”); *Spinelli*, 579 F.3d at 169 (discussing the protected interest in a gun dealership license).

¹⁰⁰ See *Barry v. Barchi*, 443 U.S. 55, 66 (1979) (due process contains the concept that “the opportunity to be heard must be at a meaningful time and in a meaningful manner.”); *Mathews v. Eldridge*, 424 U.S. 319 (1976); *Nnebe v. Daus*, 644 F.3d 477 (2d Cir. 2011) (remanding to the district court to determine whether a taxi driver has the opportunity at a post-suspension hearing based on a pending criminal charge to demonstrate that even if the criminal charges are true, continued licensure does not pose any safety concerns); *Simms v. D.C.*, 872 F.Supp.2d 90 (D.D.C. 2012) (due process requires post-seizure hearing to contest validity of initial seizure as well as continued retention of property seized for forfeiture); *Rutigilano Paper Stock, Inc. v. U.S. G.S.A.*, 967 F.Supp. 757, 767 (E.D.N.Y. 1997) (“Due process is satisfied when a meaningful opportunity to be heard on the issue of the appropriateness of a suspension is granted within a reasonable time.”).

¹⁰¹ See *Rutigilano Paper*, 967 F.Supp. at 767.

¹⁰² Administrative Procedure Act, 5 U.S.C. § 704 (2012).

¹⁰³ *Id.*

¹⁰⁴ 21 U.S.C. § 824(d) (2012).

¹⁰⁵ *Id.*

language of the CSA, the court has the authority to examine the ISO and determine whether it should continue or not. The court's examination is not limited to a "review" because the court has the authority to "dissolve" the suspension.

Furthermore, even a review under the APA should be "de novo." The Supreme Court observed that "de novo review is appropriate only where there are inadequate fact finding procedures in an adjudicatory proceeding, or where judicial proceedings are brought to enforce certain administrative actions."¹⁰⁶ The issuance of an ISO is an *ex parte* act based on the issuance of an Order to Show Cause which initiates an adjudicatory proceeding. The adjudicatory proceeding does not have any "fact-finding procedures" related to the ISO; rather, the ISO is issued *ex parte* and is not subject to review during the Order to Show Cause process. For that reason, the APA should not stand in the way of a *de novo* determination of the continuing basis for the ISO.

An analogy can be drawn to the situation in which the court issues a seizure order against property identified for forfeiture in an indictment. In the context of the forfeiture provisions of 21 U.S.C. § 853(e) that allow for the *ex parte* seizure of assets pending forfeiture based upon an indictment, the courts have held that an immediate post-restraint hearing at which the government was required "to prove the likelihood that the restrained assets are subject to forfeiture."¹⁰⁷ In contrast, in *United States v. Kaley*,¹⁰⁸ the United States Court of Appeals for the Eleventh Circuit held that the Kaleys, as movants challenging a restraint on property imposed post-indictment, had the burden of demonstrating that the property was not subject to seizure.¹⁰⁹ Both *Moya-Gomez* and *Kaley* held that the defendant could not challenge the probable cause basis for the indictment. In contrast, the court of appeals in *United States v. Michelle's Lounge*¹¹⁰ and *United States v. Monsanto*¹¹¹ held that the hearing must address the probable cause for both the commission of a narcotics offense as alleged in the indictment and the forfeit ability of the specified property. While the exact scope of the hearing is currently being reviewed by the Supreme Court, the importance here is that in all four cases, the courts held that an evidentiary hearing on the merits was required.¹¹²

The same should apply in the case of an ISO. An ISO seizes property in the same manner as a seizure warrant. Unlike a seizure warrant, an ISO is not based on a finding of probable cause by an independent body such as a grand jury. Rather, the "findings" supporting an ISO are *ex parte* conclusions of the administrative agency itself. In that context, the rationale supporting an adjudicatory hearing on the merits in the case of a pre-forfeiture seizure certainly applies in the ISO context.

Not only should the court make an independent determination of "imminent harm," it should also review the scope of the ISO. The Administrator has the authority to limit the scope of an ISO in any fashion she desires.¹¹³ In the revocation context, the Administrator

¹⁰⁶ *Camp v Pitts*, 411 US 138, 141 (1973).

¹⁰⁷ *United States v. Moya-Gomez*, 860 F.2d 706, 731 (7th Cir. 1988). The courts have held that the hearing is only required if the defendant needs funds to retain counsel of his choice. Otherwise, the deprivation of his assets is temporary pending the outcome of the criminal trial and therefore an immediate hearing is not required. *Id.*

¹⁰⁸ *United States v. Kaley*, 579 F.3d 1246 (11th Cir. 2009).

¹⁰⁹ *Id.* at 1246.

¹¹⁰ *United States v. Michelle's Lounge*, 39 F.3d 684 (7th Cir. 1994).

¹¹¹ *United States v. Monsanto*, 924 F.2d 1186, 1197 (2d Cir. 1991).

¹¹² See *United States v. Kaley*, 579 F.3d 1246 (11th Cir. 2009) *cert granted* Mar. 18, 2013; see, e.g., *United States v. Clarkson Auto Elec., Inc.*, No. 10-cr-6111CJS, 2012 WL 345911 (W.D.N.Y. Feb. 1, 2012) (an example of the determination under these holdings).

¹¹³ See 21 U.S.C. § 824(b) ("The Attorney General may limit revocation or suspension of a registration to the particular controlled substance or list I chemical with respect to which grounds for revocation or

has limited a license registration to certain drugs or to certain schedules.¹¹⁴ However, the Administrator does not appear to have ever issued such a limited ISO. “The initial *ex parte* order will ordinarily be very broad and subsequent fine tuning may be necessary to avoid unnecessary or collateral effects.”¹¹⁵

The courts should review the ISO to determine whether its scope is overbroad so that the public safety can be protected, temporarily, with a more limited suspension. As the courts have noted in the context of injunctions, “[t]he law requires that courts closely tailor injunctions to the harm that they address.”¹¹⁶ “[T]he scope of an injunction should be determined by balancing harm to the plaintiff, other means of avoiding such harm, and the relative inconvenience to the defendant.”¹¹⁷ As noted in the context of a revocation, but equally applicable here, the court may reject the punishment imposed by DEA if it is unwarranted by law or without justification in fact.¹¹⁸

Such a review would be warranted even if conducted under an abuse of discretion standard because the agency must justify the scope of the ISO based on the findings it has made. For instance, in most cases, the evidence relates to actual, or suspected, diversion of Schedule II controlled substances, usually narcotics. In such a case, the Administrator should be required to establish a basis for her conclusion that the registrant could not be trusted to handle controlled substances in other schedules, or non-narcotic drugs, particularly if there is not a proven abuse problem in the registrant’s locale. For instance, the two pharmacies involved in *Holiday CVS* were retail pharmacies that were part of a national pharmacy chain. According to the court’s review of the facts, DEA focused exclusively on the dispensing of oxycodone, a Schedule II narcotic drug controlled substance. According to the ISO, there was an “oxycodone epidemic in Florida” where the two pharmacies were located.¹¹⁹ DEA’s investigation related only to the dispensing of oxycodone by the pharmacies. However, the ISO suspended the pharmacies’ registrations, thereby making it illegal for them to stock or dispense any controlled substance—including non-narcotic drugs in Schedule II and all of the drugs in Schedules III, IV, and V. The court did not review whether the ISO was overly broad on the facts set out in the Order to Show Cause.

V. CONCLUSION

An ISO can spell the death of a registrant that does not have the financial resources to operate his business without controlled substances. Therefore, challenging an ISO becomes critically important. To date, the procedures employed have generally been unsuccessful. Whether the approach we have suggested will be successful awaits registrants with the financial resources to challenge DEA in court.

suspension exist.”).

¹¹⁴ See *Chein v. DEA*, 533 F.3d 828 n.13 (D.C. Cir. 2008).

¹¹⁵ *United States v. Gelb*, 826 F.2d 1175, 1177 (2d Cir. 1987).

¹¹⁶ *ALPO Petfoods, Inc. v. Ralston Purina Co.*, 913 F.2d 958, 972 (D.C. Cir. 1990).

¹¹⁷ *Foxtrap, Inc. v. Foxtrap, Inc.*, 671 F.2d 636, 640 (D.C. Cir. 1982); see also, *National Audubon Soc’y v. Dep’t of Navy*, 422 F.3d 174, 202 (4th Cir. 2005).

¹¹⁸ See *Affum v. United States*, 566 F.3d 1150, 1161 (D.C. Cir. 2009); *Morall v. DEA*, 412 F.3d 165, 181 (D.C. Cir. 2005).

¹¹⁹ *Holiday CVS, L.L.C. v. Holder*, 839 F. Supp. 2d 145, 159 (D.D.C. 2012).

Legal Considerations for Social Media Marketing by Pharmaceutical Industry

Y. TONY YANG*

BRIAN CHEN**

I. INTRODUCTION

To say that social media advertising is the next frontier in marketing and product placement may be the understatement of the digital age. Savvy marketing through – and at times even the mere presence on – social networks has launched the careers of teen crooners with sugary tunes, international stars with distinctly equine moves, and even an unlikely contender in the 2008 U.S. presidential campaigns. Still in its infancy, the market is projected to grow by \$6.3 billion over the next five years, driven by locally targeted advertisements and mobile advertising.¹ Not surprisingly, the lion's share of this growth will likely go to the two giants in social media networking, Facebook and Twitter.² Given the ability to individualize messages, target specific groups, interact in real time with potential consumers, and the potential benefits of instantaneous referrals among trusted individuals, the surge in interest in social media advertising is far from surprising. Drug makers are no exception, and some of the more venturesome have begun to stake out their social media presence in recent years.

Despite this upside potential, social media marketing remains a relatively uncharted territory, fraught with unexpected pitfalls and challenges. Indeed, drug marketers interested in capturing the upside potential from social marketing must also contend with the rapid dissemination of negative information through social media. The drug maker Sanofi, for example, experienced a public relations meltdown in 2010 when a patient, who claimed to have suffered permanent hair loss from Taxotere (a chemotherapy medication for breast cancer), posted photos and complaints on Sanofi's unmonitored Facebook page.³ This public relations scandal engendered questions regarding potential

* Y. Tony Yang is an Associate Professor in the Department of Health Policy and Management at George Mason University. He was the 2009-2010 CDC-NCHS/AcademyHealth Health Policy Fellow. He was the principal investigator of two public health law research grants funded by the Robert Wood Johnson Foundation. He holds graduate degrees in Public Health (Harvard), Health Policy (Harvard), and Law (University of Pennsylvania).

** Brian Chen is an Assistant Professor of Health Services Policy and Management at the University of South Carolina. Dr. Chen's work focuses on comparative health systems, health service delivery globally, and health law, a theme that encompasses the historical evolution of health policies, legal and organizational innovation, and chronic disease management and service coordination for aging populations. Dr. Brian Chen received his Ph.D. in Business Administration from the University of California at Berkeley, and his J.D. from Stanford Law School.

¹ Sarah Meehan, *Social media ad revenue expected to grow by \$6.3B over next five years*, Baltimore Business Journal available at <http://www.bizjournals.com/baltimore/blog/socialmadness/2013/04/social-media-ad-revenue-expected-to.html> (last visited May 30, 2013).

² *Id.*

³ Jim Edwards, *Sanofi's Latest Challenge: Women Who Say Its Chemotherapy Left Them Permanently Bald*, CBS MONEY WATCH, (Mar. 6, 2010), http://www.cbsnews.com/8301-505123_162-42844348/sanofis-latest-challenge-women-who-say-its-chemotherapy-left-them-permanently-bald/.

violations of 21 CFR 314.80 for Sanofi's failure to report known adverse events to the FDA based on the social-media complaints.⁴ The rapid dissemination of negative information via social media is illustrated yet again, when one study of Twitter messages showed that negative tweets "went viral" much more readily than positive placement messages after analyzing over 300,000 tweets about the H1N1 flu vaccine at the height of the 2009 swine flu epidemic.⁵ Compounding the complexity of social media advertising in the digital age, the same study showed that positive endorsements from social peers – reminders to get vaccinated – actually resulted in more negative views.⁶

The difficulties of venturing into a new medium of communications aside, part of the reason that drug companies have demonstrated reluctance to embrace social media advertising *fully* despite clear interests and upside potential is the lack of a transparent regulatory framework. The Sanofi example illustrates the unforeseen litigation and regulatory risks that arise when companies expand marketing into a new media. As of 2008, the U.S. pharmaceutical industry spent no more than a miniscule fraction of its direct-to-consumer-advertising (DTCA) budget – approximately 4% - on social media advertising.⁷ To date, only the most venturesome pharmaceutical firms (such as Sanofi) have staked their presence in this new medium, while most await clearer guidance from the Food and Drug Administration (FDA). This is because unlike other product advertisement, DTCA involving pharmaceuticals must adhere to strict FDA guidelines so as not to run afoul of FDA regulations.

Yet the underlying DTCA, which provides a framework for analyzing future regulation of social media marketing for pharmaceuticals, is itself not without controversy. Indeed, commentators frequently attribute medical waste and adverse events to excess consumer demand generated by such advertising of prescription drugs. Expanding DTCA to encompass social media advertising of pharmaceuticals is likely to meet further resistance, as a clear regulatory framework may further increase the reach of DTCA and magnify its negative role in induced demand for drugs and associated adverse events. In addition, the widespread use, ease of access, and diffuse nature characteristic of social media may create a challenging environment to assure the FDA's objective that pharmaceutical manufacturers "provide information that is truthful, balanced, and accurately described."⁸ Nonetheless, the Internet is the primary medium of information transmission today, with greater numbers of potential patients turning to the web for health care information. It would be a disservice to the public and public health not to provide clear legal guidance on social media-based DTCA that accounts for the unique characteristics of the flow of information on the internet. In this article, we address the current status of FDA regulations on social media advertising, their historical origins, challenges to implementation, and their likely future direction.

⁴ Jim Edwards, *Sanofi, European Regulators to Bald Breast-Cancer Patients: Drop Dead*, CBS Money Watch, (Mar. 8, 2010), http://www.cbsnews.com/8301-505123_162-42844356/sanofi-european-regulators-to-bald-breast-cancer-patients-drop-dead/.

⁵ Marcel Salathe et al., *The Dynamics of Health Behavior Sentiments on a Large Online Social Network*, 2 EPJ DATA SCIENCE, no. 4, 2013, at 6.

⁶ *Id.*

⁷ Jeremy A. Greene & Aaron S. Kesselheim, *Pharmaceutical Marketing and the New Social Media*, 363 New Eng. J. Med, 2087 (2010).

⁸ *Background on Drug Advertising*, F.D.A., available at <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm071964.htm>. (last visited Oct. 31, 2013)

II. SOCIAL MEDIA AND THE PHARMACEUTICAL INDUSTRY

The concept of marketing is defined as “a process by which one identifies the needs and wants of the people, creates a product/service to meet the needs and wants, develops a way of taking the product/service to the market place, determines the way of communicating the product to the market place, determines the value for the product, targets the people (segmentation) who have needs/wants and then creating a transaction for exchanging the product for a value and thus creating a satisfaction to the buyer’s needs/wants.”⁹ As related to the field of pharmaceuticals in particular, marketing has been defined as “a management process that serves to identify and meet patients’ needs in a profitable way.”¹⁰ Typical examples of pharmaceutical marketing include free samples of new drugs given to physicians, distribution of product literature, pharmaceutical detailing, and more recently, Internet-based initiatives.¹¹

The advertising of pharmaceuticals has typically been highly regulated, and is subject to the oversight by the FDA’s Office of Prescription Drug Promotion. Stringent regulations notwithstanding, drug companies have previously not shied away from engaging in marketing pharmaceuticals to increase sales. Among the traditional methods employed by the industry are direct-to-prescriber advertising, sponsorship of medically-centered events, and personal selling of drugs brands.¹² But perhaps no method has been embraced with greater gusto by the industry in recent years than direct-to-consumer advertising (“DTCA”).¹³ Currently, mass media marketing of prescription pharmaceuticals is legal in only two developed countries in the world: the United States and New Zealand. Although the industry was initially ambivalent about the use of DTCA in the United States through the early 90s, expenditures on DTCA quintupled between 1997 and 2005¹⁴ and have since remained relatively steady to the present day, even though there was a slowdown in such spending during the Financial Crisis of 2008.¹⁵

The effect of pharmaceutical companies’ embrace of DTCA on patient health decisions has been dramatic. Nadal concludes:

[T]he pharmaceutical industry has expanded its marketing to consumers. With patients now playing a larger role in their health care decisions, manufacturers have found that familiarizing consumers to prescription pharmaceuticals has led to profound increases in their profit margins. Consumers exposed to print, television, and radio advertisements and Internet web sites are more likely to ask their doctors for specific brands of prescription drugs. Doctors, out of fear of losing patients and/or due to less time spent per patient, are more inclined to grant patients’ requests.

⁹ Imran Masood et al., *Evolution Of Marketing Techniques, Adoption In Pharmaceutical Industry And Related Issues: A Review*, 3 J. of Clinical & Diagnostic Res. 1942 (2009).

¹⁰ *Id.* at 1943.

¹¹ C. Lee Ventola, *Direct-To-Consumer Pharmaceutical Advertising: Therapeutic or Toxic?*, 36 PHARMACY & THERAPEUTICS 669, 671 (2011) (“In recent years, drug marketers have also increased their expenditures for marketing efforts on the Internet.”).

¹² Masood et al., *supra* note 9, at 1943.

¹³ Ashely Porter, *Old Habits Die Hard: The Learned Intermediary Doctrine in the Era of Direct-to-Consumer Advertising*, 43 McGeorge L. Rev. 433, 446 (2012).

¹⁴ U.S. Gov’t Accountability Office, GAO-07-54, *Prescription Drugs: Improvements Needed in FDA’s Oversight of Direct-To-Consumer Advertising* 14 (2006), available at <http://www.gao.gov/products/GAO-07-54> (last visited May 30, 2013).

¹⁵ Ventola, *supra* note 11, at 670.

Hence, manufacturers have begun inundating consumers with more advertisements.¹⁶

The empirical evidence shows that drug manufacturers have been recompensed handsomely for their investments in DTCA. A study conducted in 2011 estimated that for every dollar spent on DTCA, sales of the drug advertised increased by anywhere from \$2.20 to \$4.20.¹⁷

Spurred by such financial returns, advertisers have turned their attention to another type of mass media to advertise their products: social media, defined as those “forms of electronic communication (such as websites for social networking and microblogging) through which users create online communities to share information, ideas, personal messages, and other content (such as videos).”¹⁸ Common examples of social media used for advertising are Facebook and Twitter. Social media has greatly expanded its Internet presence in the past few years, with social media-based sites such as LinkedIn, Blogspot, Twitter, YouTube, and Facebook figuring in the Top 20 websites with the most worldwide traffic.¹⁹ Given its wide, low-cost, and instantaneous reach, it comes as no surprise, then, that the use of social media by advertisers has shown to be an effective (and cost-effective) method to market products directly to consumers. Nielsen concluded that while 33% of consumers find social media ads “more annoying” than other types of Internet-based advertising, 26% are still more likely to pay attention to an ad posted by an acquaintance on a social media site and 17% feel more connected to brands that they have seen with a social media presence.²⁰ Moreover, at least 25% of consumers are comfortable with advertisers using information from their social media profiles to advertise directly to their interests.²¹

With such statistics, it is no wonder that the pharmaceutical industry has been interested in entering the world of marketing with social media. Factors unique to the pharmaceutical industry have intensified this interest. First, the industry itself has promoted the idea that social media marketing cannot be ignored in the modern webscape.²² Miley, an author who specializes in health, culture and the environment, states succinctly that “all signs point to a digital future for pharma.”²³ Additionally, modern consumers are turning to the Internet and social media in larger and larger numbers to seek information on healthcare.²⁴ Miley and Thomaselli illustrate this point using the example of the multiple sclerosis community in the United States. While only about 300,000 in number, this community “searches ferociously for information

¹⁶ Caroline L. Nadal, *The Societal Value of Prescription Drugs Advertisement in the New Millennium: Targeted Consumers Become the Learned*, 9 J.L. & Pol’y 451, 479 (2001).

¹⁷ Ventola, *supra* note 11, at 671.

¹⁸ <http://www.merriam-webster.com> (last visited May 30, 2013).

¹⁹ Alexa, *Top Sites*, available at <http://www.alexa.com/topsites> (last visited May 30, 2013).

²⁰ Nielsen, *State of the Media: The Social Media Report*, available at <http://www.nielsen.com/us/en/reports/2012/state-of-the-media-the-social-media-report-2012.html> (last visited May 30, 2013).

²¹ *Id.*

²² Dave Folkens, *Why Social Media is a Must in Pharma Marketing*, Top Rank: Online Marketing Blog, available at <http://www.toprankblog.com/2011/01/social-media-marketing-pharma/> (last visited May 30, 2013).

²³ Marissa Miley & Rich Thomaselli, *Big Pharma Finally Taking Big Steps to Reach Patients With Digital Media*, available at <http://adage.com/article/news/big-pharma-taking-steps-reach-patients-digital-media/136538/> (last visited May 30, 2013).

²⁴ See Ventola, *supra* note 11, at 671 (noting that “searching for health-related information has become the third most common activity for online users”).

online.”²⁵ Social media may be the most effective way to keep such patient communities digitally connected to each other and to pharmaceutical manufacturers, as well as keep them informed about new drugs, clinical trials, and the results of such trials. The confluence of these trends has caused some pharmaceutical companies to begin establishing at least a minimal social media presence.²⁶

And yet the pharmaceutical industry remains extremely cautious in its approach to social media. This is demonstrated by the fact that “[t]he drug industry allocated less than 4% of the more than \$4 billion it spent on direct-to-consumer advertising to Internet outlets in 2008, and only a tiny fraction of that was for social networking sites.”²⁷ This cautious approach is likely due to uncertainty regarding current regulations on pharmaceutical advertising and risk of liability in state tort actions, both of which are discussed in greater detail in the next section. For now, it is sufficient to say that the industry has been “late to the game because no one wants to get a warning letter [from the FDA].”²⁸ Pharmaceutical companies are wary of entering social media because of the potential liability resulting from the lack of control over their messaging that they have in other types of mass media due to attributes like comment and discussion sections—the Sanofi Facebook controversy provides a perfect example of this lack of control when social media sites are unmonitored.²⁹ The uncertain regulatory framework, in combination with a lack of control over their messaging in a diffuse Internet environment, gives pharmaceutical companies pause before launching a social media marketing campaign.³⁰ For now, it suffices to conclude that the industry is largely standing on the sidelines despite recognizing the tremendous advertising potential from social media, as it awaits further guidance from the FDA before treading into the world of social media advertising.

III. CURRENT DIRECT-TO-CONSUMER ADVERTISING REGULATIONS

Regulation of DTCA for pharmaceuticals is enforced both *ex ante* by federal regulation and *ex post* by private causes of action in tort. State regulation has been all but completely preempted by federal law.³¹ Federal regulation and enforcement of DTCA laws concerning pharmaceuticals is divided between two agencies: the Federal Trade Commission (FTC) for over-the-counter drugs³² and the Food and Drug Administration for prescription pharmaceuticals.³³ The FTC’s authority over OTC drugs is a subset of its general authority to monitor dissemination of false advertisements generally. Because this Article focuses on the unique nature of social media advertising in the realm of prescription drugs, the FTC’s enforcement authority will not be discussed in detail, though its recent regulations concerning social media guidance in false advertising are helpful when discussing the future of DTCA for pharmaceuticals regulated by the FDA.

²⁵ Miley & Thomaselli, *supra* note 23.

²⁶ Bryan A. Liang & Timothy K. Mackey, *Prevalence and Global Health Implications of Social Media in Direct-to-Consumer Drug Advertising*, 13 *J Med Internet Res*. 64 (2011).

²⁷ Greene & Kesselheim, *supra* note 2, at 2087-2089.

²⁸ Miley & Thomaselli, *supra* note 15.

²⁹ Greene & Kesselheim, *supra* note 2, at 2087-2089.

³⁰ Folkens, *supra* note 14.

³¹ See *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

³² 15 U.S.C. § 52-54 (requiring advertisements to be truthful, non-deceptive, unfair, and with evidence to back up claims).

³³ 21 U.S.C. §§ 301 -392.

Currently, the FDA monitors and regulates DTCA as part of its overall program to regulate the advertising of drugs in general.³⁴ To that end, it has assigned a “Review Group” from its general Office of Prescription Drug Promotion (formerly the Division of Marketing, Advertising, and Communications) to provide a thorough and comprehensive review of DTCA.³⁵ According to current law, drug manufacturers are legally permitted to begin DTCA campaigns immediately after obtaining FDA approval for a given new molecular entity.

The FDA’s primary standard for evaluating DTCAs is the “major statement rule,” which requires the manufacturer to present a major statement that represents a “fair balance of risks and benefits” as well as lists any side effects or contraindications of the drug.³⁶ The major statement requirement exists to ensure that consumers are not misled about the characteristics of a product—that they “receive a fair and accurate impression of the drug being promoted.”³⁷ Under this standard, the manufacturer must also provide adequate information on the drug’s pre-approved product labeling, either through a toll-free phone number or a website.³⁸

Whether the major statement rule applies depends on the nature of the drug maker’s advertising activity. The Office divides advertisements into three distinct groups: reminder advertisements, help-seeking advertisements, and product-claim advertisements.³⁹ Reminder advertisements simply alert the consumer of the product’s name but do not give further information about the product. Health-seeking advertisements alert a consumer about a certain medical condition but do not make recommendations about treatment or recommend a specific drug. Product-claim advertisements market the name, efficacy, and risks of the drug.⁴⁰ The classification of an advertisement becomes crucial because, while product-claim advertisements require a major statement, reminder and health-seeking advertisements do not.⁴¹

While the FDA has authority to initiate both criminal and civil sanctions against a manufacturer that violates DTCA regulations,⁴² most FDA action within the realm of DTCA comes in the form of regulatory letters.⁴³ In 2011, for example, total of 1700 warning letters were delivered.⁴⁴ A Notice-of-Violation Letter notifies a manufacturer of a minor violation in an advertisement, while a Letter of Warning threatens further action by the FDA if the manufacturer does not correct a violation in an advertisement or cease the advertising campaign altogether.⁴⁵ Manufacturers are generally quick to respond to these letters to avoid an escalation of liability that may include criminal and

³⁴ Porter, *supra* note 6, at 444.

³⁵ *Id.*

³⁶ Cetel, *supra* note 27, at 656-67.

³⁷ Direct-to-Consumer Prescription Drug Advertisements; Presentation of the Major Statement in Television and Radio Advertisements in a Clear, Conspicuous, and Neutral Manner, 75 Fed. Reg. 15,376, 15,377 (Mar. 29, 2010).

³⁸ Victor E. Schwartz, et al., *Marketing Pharmaceutical Products in the Twenty-First Century: An Analysis of the Continued Viability of Principles of Law in the Age of Direct-to-Consumer Advertising*, 32 Harv. J.L. & Pub. Pol’y 333, 344 (2009).

³⁹ Porter, *supra* note 6, at 444.

⁴⁰ 60 Fed. Reg. 42,581.

⁴¹ 21 C.F.R. § 202.1(e)(2)(i).

⁴² 21 U.S.C. § 333.

⁴³ Francis Palumbo & C. Daniel Mullins, *The Development of Direct-to-Consumer Prescription Drug Advertising Regulation*, 57 Food & Drug L.J. 423, 429 (2002).

⁴⁴ FDA Enforcement Statistics Summary Fiscal Year 2011. <http://www.fda.gov/downloads/ICECI/EnforcementActions/UCM285781.pdf>. (last visited October 31, 2013).

⁴⁵ *Id.*

civil penalties. Drug manufacturers take FDA oversight of DTCA quite seriously, as illustrated by the fact that many manufacturers have begun submitting advertisements to the FDA for pre-approval to prevent the negative effects that receiving either type of FDA Letter can have on the company's stock. Nevertheless, pre-approval is not legally required, and the FDA's capacity for pre-approval is highly limited.⁴⁶

DTCA for pharmaceuticals is also regulated ex post by private tort actions. In practice, such actions mainly involve failure to warn claims under state tort laws that have not been preempted by federal law,⁴⁷ although legal commentators have theorized other possible causes of action.⁴⁸ The typical failure to warn claim involves proving that the manufacturer of a product knew or should have known that a specific type of harm was possible from the use of its product but did not reasonably provide the consumer warning of that risk.⁴⁹ Generally, a failure to warn case is a claim in strict liability, i.e., the harm caused by the product is itself proof enough that the product was defective,⁵⁰ and that plaintiffs need not establish negligence or willful misconduct by the defendant in order to prevail in court. However, medical devices and pharmaceuticals are considered to be in a class of "unavoidably unsafe products" because even the most careful preparation will not prevent all harm in all cases.⁵¹ For such products, the standard of liability is relaxed to that of negligence, meaning that a drug manufacturer need only warn about risks that it reasonably should have known.⁵²

The doctrine of failure to warn has been used successfully in state courts (and affirmed by the U.S. Supreme Court), resulting in large tort awards. In *Wyeth v. Levine* (555 U.S. 555), for example, the Supreme Court rejected defendant Wyeth Pharmaceuticals' claim of Federal Preemption of state law, and ruled that the pharmaceutical company's inadequate product labeling failed to warn Levine of the risk of gangrene from its anti-nausea drug Phenergan. The verdict resulted in a claim for \$7.4 million. The failure to warn doctrine, however, is mitigated by the "learned intermediary doctrine," which holds that if the manufacturer adequately informs the *physician* to whom it sells its drugs, it cannot be held liable for subsequent harm to a patient to whom that physician prescribed the drug.⁵³ Courts adopting the "learned intermediary doctrine" recognize that most medical care decisions are made between patients and physicians without direct participation from the drug companies, and assume that patients would be apprised of the manufacturer warning given to the doctor during the physician-patient consultation.⁵⁴

DTCA has had a major effect on the learned intermediary doctrine by upending the assumption that drug manufacturers do not participate in the patient-physician decision. With the rising prevalence of DTCA, courts have begun to carve out exceptions to the doctrine, particularly in three cases: 1) where DTCA has so eroded the physician-patient relationship that a court cannot rely on physicians to prove adequate warning;⁵⁵ 2) in mass immunization programs, where healthcare providers administering the drug are

⁴⁶ Porter, *supra* note 6, at 457.

⁴⁷ See *Wyeth v. Levine*, 555 U.S. 555 (2009).

⁴⁸ Cetel, *supra* note 27 (arguing that DTCA could lead to IIED, NIED, or other tort actions).

⁴⁹ Restatement (Second) of Torts, § 402A.

⁵⁰ *Id.*

⁵¹ *Id.* at cmt. k.

⁵² See, e.g., *Carlin v. Superior Court*, 13 Cal.4th 1104, 1112-13 (1996).

⁵³ Heather Harrell, *Direct-to-Consumer Advertising of Prescription Pharmaceuticals, the Learned Intermediary Doctrine, and Fiduciary Duties*, 8 Ind. Health L. Rev. 69, 75-78 (2011).

⁵⁴ *Id.*

⁵⁵ *Perez v. Wyeth*, 161 N.J. 1 (1999)

usually not physicians;⁵⁶ and 3) for oral contraceptives because the physician often plays a “passive role” in this decision.⁵⁷ By communicating directly with consumers through DTCA, drug makers may have sown the seeds for the erosion of the protective shield of the learned intermediary doctrine. Indeed, most commentators have attributed recent judicial carve-outs in the learned intermediary doctrine either directly to DTCA⁵⁸ or have blamed the rise of DTCA for the degradation of the physician-patient relationship.

IV. LEGAL FRAMEWORK FOR PHARMACEUTICAL MARKETING VIA SOCIAL MEDIA

Calls for guidelines in pharmaceutical advertising through social media have not gone unnoticed by the FDA, which held a “Public Hearing on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools” in November of 2009.⁵⁹ After two days of comments, however, only one guideline has been issued (which will be discussed below). In the meantime, the pharmaceutical industry has found various strategies for entry that attempt to accommodate the current regulatory framework. One example is the use of “one-clicks.” One-clicks ensure that risk information for a given pharmaceutical is no further than ‘one click’ away from any mention of that product. Its use may be particularly relevant to ads placed in certain social media websites with space constraints, especially Twitter. However, as Greene and Kesselheim point out, the use of one-clicks remains controversial outside the social media setting as the effectiveness of the technique has been called into question.⁶⁰ In April 2009, for example, the FDA issued 14 warning letters to manufacturers utilizing one-clicks based on their relative unavailability when using a search engine.⁶¹ In the letters, the FDA emphasized that the sponsored links advertised the drugs in question but gave no indication of their risks. Instead, the advertisement simply linked back to the manufacturer’s homepage.⁶² Unless risk information can be guaranteed to be no more than one click away under all circumstances, the future of one-clicks is uncertain.

Another strategy that pharmaceutical companies have adopted has been the use of human-interest stories that do not refer to a specific drug.⁶³ While the advertising of specific pharmaceuticals subjects a manufacturer to the FDA’s DTCA regulations, general stories on health policy or human welfare do not. Based on this regulatory distinction between advertisement and general human interest stories, drug companies have begun to capitalize on the surge in communities looking for Internet-based health information. An example of this comes from Pfizer’s Twitter account, @pfizer_news, which included a tweet that read “PFE’s John Young: Patient voice contributes critical insights into health policy debate.” Closely related are strategies that boost the company’s image generally. For example, AstraZeneca’s Twitter account, @AstraZeneca, tweeted on March 21 “Soriot: ‘This is a company with tremendous strengths; how we deliver will

⁵⁶ *Davis v. Wyeth*, 399 F.2d 121 (9th Cir. 1968).

⁵⁷ *Odgers v. Ortho Pharmaceutical*, 609 F. Supp. 867, 875 (E.D. Mich. 1985).

⁵⁸ Timothy S. Hall, *Regulating Direct-to-Consumer Advertising with Tort Law: Is the Law Finally Catching Up with the Market?*, 31 W. New Eng. L. Rev. 333 (2009).

⁵⁹ Food and Drug Administration, *Public Hearing on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools*, available at <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm184250.htm> (last visited May 31, 2013).

⁶⁰ Greene & Kesselheim, *supra* note 2, at 2087-2089.

⁶¹ *Id.*

⁶² *See, e.g.*, Letter from Michael Sauer, Reg. Rev. Officer, Div. of Drug Marketing, Advertising and Communications, to Margaret J. Jack, Hoffman-La Roche Inc. (Apr. 2, 2009); Letter from Shefali Doshi, Reg. Rev. Officer, Div. of Drug Marketing, Advertising and Communications, to Sandra A. Kerr, Merck & Co., Inc. (Apr. 2, 2009).

⁶³ Folkens, *supra* note 14.

define our future success.” Johnson & Johnson has a well-regarded and well-known blog that combines the use of these strategies.⁶⁴ Such use of social media, again, does not require compliance with the FDA’s regulations for product claim advertisements.

Under the current regulatory framework, certain social media activities that manufactures have engaged in have generally been considered less risky than others. For example, developing “branded” advertisements (i.e., product claim ads under the current DTCA regulatory framework) for social media platforms such as YouTube (audio/video) or Podcasts (audio) is not all that different from developing advertisements for TV (audio/video) or radio (audio). Consequently, it is far simpler to comply with the current DTCA regulations in these contexts. Such limited use of social media, however, only scratches the surface of its potential for individually targeted DTC advertising, which pharmaceutical companies have hitherto avoided given the legal uncertainty of advertising using these forms of social media (e.g., blogs, bulletin boards, Wikis, forums). Thus, it comes as no surprise that pharmaceutical manufacturers are looking for further guidance so that they can tap into this potential without accidentally contravening the law in unexpected ways. Yet guidance has not been forthcoming, with two notable exceptions in the form of “soft” guidelines: FTC regulations for non-prescription drugs⁶⁵ and a single FDA draft guideline on responding to unsolicited requests for off-label information.⁶⁶

With respect to the FTC guidelines, the FTC recognizes that “[m]ost of the general principles of advertising law apply to online ads, but new issues arise almost as fast as technology develops.”⁶⁷ In its guidance, however, the FTC offers several principles that could be helpful in the context of online advertising for prescription drugs: 1) to the extent practical, advertisers should incorporate important information on the product itself, rather than separate from the advertisement; 2) disclosures should be “clear and conspicuous” based on the relevant platform in which the advertisement is being placed; and 3) where a necessary disclosure cannot be placed clearly and conspicuously, then the advertisement should not be disseminated at all. Of particular applicability to the use of ‘one-clicks’ is the FTC endorsement of the use of hyperlinks for necessary disclosures. As long as the link is obvious, and the advertisement conveys that the disclosure it contains is important to evaluate the claim being made by the product, and the disclosure is not an “integral part of a claim or inseparable from it,” the use of a hyperlink that contains additional disclosures about the product is permissible. Additionally, it advises that advertisers using “space-constrained” social media platforms like Twitter designate that it is an advertisement (e.g., using “Ad.” before the tweet) and make necessary disclosures obvious.

These principles provide some, albeit limited, guidance in the context of online pharmaceutical advertising. Perhaps the best advice for manufacturers is that advertising in social media should be handled under substantially the same principle as advertising through any other medium, even while respecting the unique limitations of online social media. If these limitations cannot be accommodated, the advertiser should reconsider using the medium altogether. Moreover, given the fast-paced environment of social media, advertisers must be certain to make it obvious that a given communication in

⁶⁴ <http://www.blognj.com/> (last visited May 31, 2013).

⁶⁵ Federal Trade Commission, *.com Disclosures: How to Make Effective Disclosures in Digital Advertising*, March 2013, available at <http://www.ftc.gov/os/2013/03/130312dotcomdisclosures.pdf> (last visited May 31, 2013).

⁶⁶ Draft Guidance for Industry on Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices; Availability, 76 Fed. Reg. 82,303 (Dec. 30, 2011).

⁶⁷ Federal Trade Commission, *supra* note 65.

social media is an advertisement (tweets/sponsored google links/facebook posts need to explicitly say “this is an advertisement.”), and that additional information—including every applicable FDA disclosure, like the major statement—is immediately available about the product. Indeed, the FTC guidelines might foreshadow an FDA endorsement of the previously controversial use of one-clicks, given that the FTC endorsed both the use of hyperlinks for additional information and the use of space-constrained advertising where incorporation of necessary disclosures would otherwise be next to impossible. Similar guidelines could also be issued to comply with the FDA’s ‘major statement’ requirement. However, many commentators are doubtful that this will be the case, especially since the FTC itself deemed these guidelines inapplicable in cases where the disclosure was “integral” or “inseparable.”⁶⁸ In the end, the applicability of the FTC guidelines could come down to whether the FDA considers a drug’s major statement ‘inseparable’ (and therefore cannot be placed in a hyperlink) or whether the FDA reworks the major statement rule altogether to better fit the social media context.

There are certainly limitations in comparing the FTC’s regulations and the FDA’s. This is so because advertisers of prescription pharmaceuticals expose themselves to significantly greater liability than a typical advertiser through DTCA, and so are less likely to rely on ‘soft’ guidance. The single guideline to be issued by the FDA concerning social media advertising to date is illustrative. Titled “Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices,”⁶⁹ the draft guidance offers limited situations in which a manufacturer may respond to public questions about its product in an online forum. Such a response is allowed only when: 1) it is about a specific product; 2) the response is limited to providing the firm’s medical or science department’s contact information; 3) the responding representative discloses his affiliation with the firm; 4) the response is not promotional in nature or tone; and 5) the response makes FDA-approved labeling readily available. If this guideline is any indication of where the FDA is headed, it seems unlikely that it will be willing to endorse a policy favorable to social media advertising. This hardline position also makes the dismissal of a one-click policy more likely.

Perhaps the FDA’s previous enforcement activity with respect to the major statement and fair balance requirements in DTCA can shed some light on its eventual social media policy. In the past, regulatory letters from the FDA regarding violations of these requirements have been a case study in strictness. One such letter that is directly applicable to social media bears examination.⁷⁰ In 2010, the pharmaceutical company Novartis created a social media Facebook “widget” for its product “Tasinga,” a risky medication used to treat a certain variant of leukemia. Users could share news about the drug via the widget, which would be transmitted to Facebook friends without any disclosure of risks accompanying the advertising. Predictably, the warning letter requested that Novartis immediately cease these practices.⁷¹ Along with its single

⁶⁸ Tish Eggleston Pahl & Mason Weeds, *FTC Offers Updates Guidance on Social Media; Still Waiting on FDA*, available at <http://agfdablog.com/2013/03/22/ftc-offers-updates-guidance-on-social-media-still-waiting-on-fda/> (last visited May 31, 2013).

⁶⁹ Food and Drug Administration, *Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices*, available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf> (last visited May 31, 2013).

⁷⁰ Warning Letter to Novartis Pharmaceuticals Corp. Re: NDA # 022068 Tasinga (nilotinib) Capsules MACMIS # 18870, FDA.gov (Jul. 29, 2010), <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/%20WarningLettersandNoticeofViolationLetter/UCM221325.pdf>.

⁷¹ *Id.*

guideline on unsolicited inquiries, the FDA stance taken in this letter would seem to dispose of not only the one-click policy, but also any potential social media advertising that falls short of preexisting FDA requirements, regardless of spatial or other limitations inherent in such media.

The future, however, remains to be seen because the only proposed guideline remains, as of the date of this writing, a draft without any legal effect. The only counterforce to the FDA's apparent anti-social media policy currently observable on the horizon is Congress. Recently, Congress has shown itself impatient on the FDA's glacial pace to act in this area, requiring that the Secretary of Health and Human Services to issue guidelines within two years.⁷² Congressional impatience might suggest that it would not embrace an FDA policy that effectively precludes all use of social media for pharmaceutical advertising, which would be the likely result of FDA's wholesale rejection of a hyperlink-based policy. Additionally, some industry stakeholders have voiced concern about the FDA's approach to this issue. Pfizer, for instance, wrote in 2010 rulemaking comments that "[c]lear, enforceable, evidence-based regulatory requirements that reflect real-world user expectations are necessary to encourage manufacturers to provide truthful and non-misleading product information."⁷³

If one is to augur future FDA positions on social media advertising based on its previous pronouncements on the major statement rule and risk disclosure requirements in DTCA, combined with the hardline approach taken in the unsolicited advice guideline, it seems likely that the agency will view social media advertising with a circumspect eye. Pharmaceutical companies interested in expanding marketing activities online should operate with the expectation that the FDA will enforce all previously existing regulatory requirements, regardless of the aforementioned unique limitations of social media. As such, until concrete policy guidance is released, social media marketing should be conducted only to the extent that regulatory requirements can be met in spite of the limitations in the social media venue of choice. For instance, a sponsored link or Tweet with insufficient space to provide the FDA-mandated major statement and disclosure of risks should not include any advertisement that, if lacking such statement, would run afoul of FDA regulations. It is also imperative that pharmaceutical companies interested in social media advertising thoroughly understand the unique nature, context and limitations of any particular media they elect to use.

V. CONCLUSION

Even though still very much in its infancy, there has been no lack of superlative qualifiers for the social media phenomenon. Social media sites such as Google, LinkedIn, Youtube, Facebook and Twitter are all among the top ten frequented websites in the world.⁷⁴ Facebook's initial public offer on May 18, 2012 was the largest in Internet history, and among the largest among all technology IPOs.⁷⁵ At its peak valuation, the fledgling company was worth \$104 billion,⁷⁶ with a price earnings ratio of 85 by the

⁷² 21 USC § 379d-5.

⁷³ Comments on the Use of Internet and Social Media in Promoting FDA-Regulated Medical Products, by Geoffrey Levitt, Sr. Vice Pres. & Ass. Gen. Counsel, Pfizer, (Feb. 26, 2010), <http://forums.pharma-mkting.com/attachment.php?attachmentid=100&d=1267619924>.

⁷⁴ Alexa, *Top Sites*, available at <http://www.alexa.com/topsites> (last visited May 30, 2013).

⁷⁵ Tomio Geron, *Facebook Prices Third-Largest IPO Ever, Valued At \$104 Billion*, available at <http://www.forbes.com/sites/tomiogeron/2012/05/17/facebook-prices-ipo-at-38-per-share/> (last visited May 31, 2013).

⁷⁶ *Id.*

end of the first week after the IPO.⁷⁷ While these numbers have subsequently retreated amidst controversy and recrimination, Facebook remains one of the most valuable internet companies today, with over 1 billion active users worldwide.⁷⁸ These impressive figures underlie the enthusiasm with which marketers have been contemplating the potential of social media for product placement, given its interactive, instantaneous and personalized networks.

Pharmaceutical companies are no exception. While recognizing the potential for DTCA through social media, all but the most venturesome drug makers have held back from implementing an aggressive social media advertising campaign. Marketers using DTCA in other consumer product markets generally need only refrain from making false claims to avoid liability. Pharmaceutical firms, however, must be certain not to violate strict DTCA regulations promulgated by the FDA or face potentially severe sanctions and/or lose immunity afforded under state tort laws according to the “learned intermediary doctrine.” Unfortunately, current FDA regulations and guidelines with respect to DTCA were issued well before the advent of the social media phenomenon, leaving a large degree of uncertainty for drug makers desiring to enter social media advertising.

Pre-social media DTCA regulations made clear distinctions among advice for health-seeking behavior, general reminders, and product-claim advertisements. Of these three, only product claims require a major statement presenting a fair depiction of the risk-benefit tradeoffs of the drug. A major statement, however, may not necessarily be adequately expressed in space-constrained media such as Twitter, and may not adhere to strict DTCA guidelines as the advertisement propagates through cyberspace, often without control by the drug maker. Many drug makers steer clear of potential liability by restricting their social media activities to informational communities that conform to the definition of health-seeking behaviors and general reminders. To date, only two guidelines, one from the FTC and another from the FDA in the form of draft guidance, have direct bearing on online social media advertising. The FTC guideline allows information to be placed in a hyperlink as long as it is clear that the link contains information important for the evaluation of the product, and that such hyperlinked information is not “inseparable” from the other claims. The FDA gave a much more limited soft guideline, allowing drug companies to respond to public questions in an online forum as long as a number of strict requirements are met.

As such, until the FDA develops definitive social media policy guidelines, pharmaceutical companies must approach the issue with great care. Drug companies must be mindful of the limitations of social media that render it impossible to comply with current regulations, and until regulatory and litigation risks are clarified with FDA action, should not place online advertisements that do not account for these limitations. In other words, no drug maker should assume that social media would be held to different enforcement standards from those applying to traditional media under existing FDA regulations and guidance. To operate within the confines of current laws and regulations and to avoid legal liability, pharmaceutical companies should respond to the uncertainty in social media advertising by complying with all existing FDA requirements.

The explosive growth in social media signifies that the scant existing guidelines are unlikely to suffice for much longer. An impatient Congress has intervened, requiring the

⁷⁷ Robert Leclerc, *Overvaluing Facebook*, available at <http://opinion.financialpost.com/2012/06/06/overvaluing-facebook/> (last visited May 31, 2013).

⁷⁸ Donna Tam, *Facebook by the numbers: 1.06 billion monthly active users*, available at http://news.cnet.com/8301-1023_3-57566550-93/facebook-by-the-numbers-1.06-billion-monthly-active-users/ (last visited May 31, 2013).

FDA to provide further guidance within two years. In the meantime, consumers have been increasingly flocking to the Internet as one of the primary sources of health care information. With the United States and New Zealand as the only two industrialized nations in the world that permit DTCA for pharmaceuticals, any expansion thereof to the online setting will likely not be without controversy because of its role in inducing demand and potentially exposing patients to unnecessary adverse events. Given the checkered history of DTCA in traditional media, some may argue that a hardline stance by the FDA toward social media advertising is not unwarranted. Nevertheless, the rapid evolution of online interactive DTCA capabilities will not tolerate a regulatory vacuum for much longer, and the FDA must move forward with a clear, transparent standard for the regulation of online advertising of prescription drugs.