First Amendment Limits on Compulsory Labeling

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Abstract

Government-mandated labeling requirements have a long history, and are used extensively by the FDA in regulating the industries under its jurisdiction. All such requirements can be characterized as a form of "compelled speech," opening the door to First Amendment challenges. And some of these challenges, depending on the nature of the labeling requirement, have even been successful.

Under *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, regulations that compel disclosure of information will, in many cases, merit only very limited First Amendment scrutiny — less, even, than most other regulations of commercial speech, which receive a type of "intermediate scrutiny." The labeling requirement that can best avoid or overcome a First Amendment challenge, therefore, will follow the example of the regulation described in *Zauderer*. For example, *Zauderer* applied its lower scrutiny by noting that the compelled speech at issue was a disclosure of "purely factual and uncontroversial information." Conversely, a successful First Amendment challenge to a labeling requirement will often involve an argument that the labeling requirement is outside the scope of what the *Zauderer* Court contemplated: so, for example, one may argue that a compelled disclosure is either "not factual" or else "controversial," putting it beyond *Zauderer*'s reach.

After briefly reviewing the major Supreme Court cases that establish the levels of scrutiny for commercial speech and compelled disclosures, the paper will discuss how the various elements of *Zauderer* have been analyzed by several lower courts, and how some courts have distinguished *Zauderer* in the context of labeling and other mandatory disclosure laws. In particular, the paper will focus on cases involving First Amendment challenges to food, tobacco, and drug labeling requirements — some successful, some not, and some ongoing — including cases challenging FDA, USDA, and state-level labeling requirements.

The decided cases do not all agree on how to understand the elements of *Zauderer* — for example, must a disclosure be *factually* controversial to fall outside of *Zauderer*'s limited review, or may it be factually unquestionable but relating to a controversial topic? What role, if any, should public acceptance, knowledge, and history play? What sorts of interests may the government invoke

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to justify a labeling requirement? Although some courts have taken (or at least hinted at) strict limits on the meaning of *Zauderer*, most courts have read *Zauderer* as applying somewhat more expansively to circumstances beyond its facts. The paper concludes that generally, courts have read *Zauderer* more expansively in part because such a reading is consistent with existing, familiar labeling requirements, and a narrow reading of *Zauderer* limited to its facts would rest on a slippery slope to abolishing many accepted and historically unquestioned labeling requirements. Any future attempts to expand judicial review of labeling requirements would do well to highlight limiting principles that address such concerns.

I. Introduction

Turn over the nearest food package, and you will likely find information about the food's calorie content,[1] its macronutrient and micronutrient composition,[2] and its ingredients.[3] Pick up a piece of fruit or a vegetable in the grocery store, and you will (usually) find a tiny sticker that notes the country where the produce was grown.[4] Inpsect any dietary supplement label bearing a structure/function claim, and you will also find a boldface disclaimer that such claim "has not been evaluated by the Food and Drug Administration."[5] Glance at a bottle of ibuprofen or a stick of antiperspirant in the drug store, and you will find a prominent, standardized "Drug Facts" panel stating the active and inactive ingredients, approved uses, contraindications, and warnings, among other information.[6]

All of these common labels (and many, many more like them), which are familiar to food and drug lawyers and the general public alike, are required by federal laws and regulations. They are also, in the modern parlance of constitutional law, examples of "compelled speech," or more specifically, compelled commercial speech. Yet most people do not think of these mundane examples as unconstitutional impositions by the government (if, indeed, they think about any constitutional dimension to these examples at all). But what are the limits (if any) on the government's ability to mandate disclosures on product labels? What kinds of information may be subject to government-mandated labeling, and why? What, exactly, can distinguish the labeling requirements listed above (which most people would not doubt the constitutionality of) from *any* new

[1] 21 U.S.C. § 343(q)(1) (2014); 21 C.F.R. § 101.9(c)(1) (2015).
[2] 21 U.S.C. § 343(q)(1) (2014); 21 C.F.R. § 101.9(c)(2)–(8) (2015).
[3] 21 U.S.C. § 343(i)(2) (2014); 21 C.F.R. § 101.4 (2015).
[4] 7 C.F.R. § 65.400 (2015).
[5] 21 U.S.C. § 343(r)(6) (2014); 21 C.F.R. § 101.93 (2015).
[6] 21 C.F.R. § 201.66(c)(1)–(9) (2015).

labeling requirement a legislator or FDA official can dream up? This paper seeks to give some possible answers these questions, based on the case law in this area to date.

After a brief review of the history of the First Amendment doctrines of commercial speech and compelled speech, this paper focuses on the so-called "*Zauderer* test" that has been derived from *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*.[7] Specifically, this paper describes how this 1985 decision has been interpreted by the federal courts with regard to labeling requirements, with particular attention to those cases involving labeling requirements for food, drugs, dietary supplements, and tobacco. Notably, the cases involving these (dominant) categories of consumer goods account for most (though not all) of the cases throughout the federal courts dealing with labeling-related compelled commercial speech.[8]

Through these cases, one can begin to see how new labeling requirements can be distinguished in various ways, and in some cases, may fail to stand up to constitutional scrutiny. Some of the more significant distinctions discussed will be whether certain labels are truly "factual and uncontroversial," and whether the government's interest in requiring the label is "substantial" enough. The paper concludes with some thoughts on the future of the "*Zauderer* standard," particularly analyzing which types of labeling requirements are most likely to be upheld, and which types are most open to constitutional challenge.

II. Background: A Brief History of Commercial Speech and Compelled Speech Doctrines

A. Commercial Speech

Commercial free speech, as a doctrine, dates only back to 1976; before that, restrictions on commercial speech received absolutely no protection under the First Amendment. Of note to practitioners to food and drug law, the seminal case extending constitutional protection to commercial speech, *Virginia State Board of*

[7] 471 U.S. 626 (1985).

[8] It goes without saying that the First Amendment does not limit itself to food and drug law, and as a result, some cases necessarily discussed herein will deal with subject matter outside of the regulated fields most familiar to food and drug practitioners. Such cases, when they must be discussed, will nonetheless often present very familiar themes, and otherwise will not be analyzed any more than necessary to understand the doctrinal points made in each case.

Pharmacy v. Virginia Citizens Consumer Council,[9] involved a state pharmacist licensing board's total prohibition on the advertising and marketing of prescription drugs. Over the sole dissent of then-Associate Justice William Rehnquist,[10] the Supreme Court repudiated earlier precedents that held "purely commercial advertising" to be wholly unprotected by the First Amendment, and went on to hold that the state may not impose a blanket ban on advertising by pharmacists.[11] In establishing First Amendment protection for commercial speech, the Court noted that the interests served by the First Amendment — including the free flow of information — protect the right to "receive information and ideas" (which extended to the would-be purchasers of prescription drugs, i.e. consumers) as well as the right of the pharmacists to speak (which included their right to advertise prescription drugs and their prices).[12] The Court also noted that, to the extent commercial advertising presents potential risks to professionalism among pharmacists (as among lawyers), the government has other means of regulating the profession to ensure professional conduct, without imposing blanket advertising bans.[13] And the Court was careful to note various distinctions that could justify restrictions on speech (and thus advertising) — for example, the Court noted that untruthful or misleading speech, or speech proposing illegal business transactions, still remained unprotected.[14]

Four years later, the Court announced its opinion in *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*,[15] and with it, the now-familiar four-factor "*Central Hudson* test" for evaluating whether commercial

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[9] 425 U.S. 748 (1976).

[10] In one memorable passage, Justice Rehnquist wrote that, although the Court's outcome in the case may reflect "desirable public policy," "there is certainly nothing in the United States Constitution which requires the Virginia Legislature to hew to the teachings of Adam Smith in its legislative decisions regulating the pharmacy profession." 425 U.S. at 784. Although few today continue to argue that commercial speech merits no First Amendment protection at all, echoes of this sentiment can still be heard from courts and commentators who caution against taking this judge-created doctrine too far. A common refrain in this spirit is that notions of "commercial free speech," if taken too far, are effectively a new line of "economic liberty" arguments for invalidating democratically enacted laws regulating economic activity — akin to the oft-decried (and largely repudiated) *Lochner* line of cases. *See, e.g.* JOHN C. COATES, IV, *Corporate Speech and the First Amendment: History, Data, and Implications* 30 CONST. COMMENT. 223, 269 & n.157 (2015); ROBERT POST, *Compelled Commercial Speech* 117 W. VA. L. REV. 867, 919 (2015); Sorrell v. IMS Health, Inc., 131 S. Ct. 2653, 2679 (2011) (Breyer, J., dissenting).

[11] 425 U.S. at 755, *overruling* Valentine v. Chrestensen, 316 U.S. 52 (1942).

[12] 425 U.S. at 756–57, 765.

[13] *Id.* at 770.

[14] *Id.* at 771–73.

[15] 447 U.S. 557 (1980).

speech may be restricted consistent with the First Amendment.[16] Commercial speech which (1) concerns lawful activity and is not false or misleading, may be restricted to serve (2) a substantial government interest, if (3) the regulation directly advances the government interest, and (4) the regulation is not more extensive than necessary to serve that interest.[17] In striking down another advertising ban (forbidding electric utilities that wished to promote energy consumption), the Court acknowledged "substantial government interests" in energy conservation and averting potential market effects that could lead to rate increases.[18] But the Court noted that the efficacy of advancing the latter, rate-reducing interest through an advertising ban was "tenuous" or "speculative" at best,[19] and that the complete advertising ban was also "more extensive than necessary to further the State's interest in energy conservation."[20] The four-part test announced and applied in *Central Hudson* has been termed a type of "intermediate" scrutiny,[21] in that it is less stringent than the "strict scrutiny" applied to most speech restrictions (including those that are content- or speaker-based), but stricter than the "rational basis" scrutiny applied to most laws, usually including those laws that regulate economic activity. And, as noted above, the four-part *Central Hudson* test is now very familiar, as courts routinely invoke it when analyzing almost any commercial speech restriction, with very few exceptions.

B. Compelled Speech

First Amendment protection against government-compelled speech has a (somewhat) longer history than the commercial-free-speech doctrine just discussed; its roots are found in cases involving core political speech and religious objectors. For example, in *West Virginia Board of Education v. Barnette*,[22] the Supreme Court held that a school board may not compel students to salute the American flag and pledge allegiance, with Justice Jackson writing famously: "If there is any fixed star in our constitutional constellation, it is that no official, high or petty, can prescribe what shall be orthodox in politics, nationalism, religion, or

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[16] Justice Rehnquist again dissented from the Court's decision to invalidate the advertising ban at issue in the case, this time outright accusing the Court of "return[ing] to the bygone era of *Lochner* . . . in which it was common practice for this Court to strike down economic regulations adopted by a State based on the Court's own notions of the most appropriate means for the State to implement its considered policies." 447 U.S. at 589.

[17] 447 U.S. at 566.

[18] *Id.* at 568–69.

[19] *Id.* at 569.

[20] *Id.* at 569–71.

[21] *See, e.g.* Florida Bar v. Went For It, Inc., 515 U.S. 618, 623 (1995).

[22] 319 U.S. 624 (1943).

other matters of opinion or force citizens to confess by word or act their faith therein."[23] In *Wooley v. Maynard*,[24] a resident of New Hampshire was arrested after he covered up the "Live Free or Die" state motto on his license plate, which he did because he found this slogan "morally, ethically, religiously, and politically abhorrent."[25] The Court addressed the question of "whether the State may constitutionally require an individual to participate in the dissemination of an ideological message by displaying it on his private property," and answered that the state "may not do so."[26] And early in the development of this doctrine, too, the Court included (arguably commercial) businesses in its scope, striking down, for example, a Florida law compelling newspapers to publish responses of political candidates whom they had criticized.[27]

With these strong early precedents against state-compelled speech, and the development of commercial free speech jurisprudence, it was only a matter of time before First Amendment challenges were brought against compelled speech in the commercial sphere. (Though indeed, as noted in the next section, the line delineating "commercial" from "non-commercial" speech can often be unclear.) One noteworthy case in which an arguably "commercial" (but also arguably non-commercial) compelled speech requirement was struck down was *Riley v. National Federation of the Blind of North Carolina*.[28] There, professional fundraisers (who collect fees for soliciting charitable contributions from donors) were required to disclose to potential donors what percentage of donated revenues they ordinarily received as a fee for their services (and therefore, how much of the donation would actually go to the charity). Assuming (without deciding) that the speech in that case was "commercial" due to the professional fundraiser's profit motive, the Court held that the speech does not "retain[] its commercial character when it is inextricably intertwined with otherwise fully protected speech" — solicitation of charitable donations.[29] Thus, the Court applied strict scrutiny in striking down the part of the North Carolina law compelling disclosure of the ordinary fee the fundraiser would retain.[30]

Somewhat paradoxically, however, the Supreme Court has sometimes spoken *favorably* of compelled disclosure requirements as a "least restrictive

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[23] *Id.* at 642; *see also id.* at 645 (Murphy, J., concurring) ("The right of freedom of thought and of religion . . . includes both the right to speak freely and the right to refrain from speaking at all . . . .")
[24] 430 U.S. 705 (1977).
[25] *Id.* at 713.
[26] *Id.*
[27] Miami Herald Publishing Co. v. Tornillo, 418 U.S. 241 (1974).
[28] 487 U.S. 781 (1988).
[29] *Id.* at 795–96.
[30] *Id.* at 798.

means" of serving substantial government interests, even when addressing compelled disclosures in the realm of *political* speech. For example, in the landmark campaign finance case *Buckley v. Valeo*,[31] the Court noted that mandatory disclosure of campaign contributions was a relatively unrestrictive means of curbing "campaign ignorance and corruption" – at least, compared to other restrictions Congress imposed (or attempted to impose).[32]

In any event, when the Court squarely reached the issue of compelled disclosures that are indisputably in the commercial sphere (as in advertising), the result was *Zauderer*, which will be analyzed in detail next, after a brief aside on the nature of "commercial" speech itself.

C. Side note: When is speech "commercial"?

Before analyzing speech regulations under *Central Hudson* or *Zauderer*, there is one preliminary question raised by some cases, such as *National Federation of the Blind* (paid fundraisers for charities) or *Miami Herald* (newspapers). How do we decide whether speech is commercial in nature?

In *Virginia State Board of Pharmacy*, the Court framed the question presented as "whether speech which *does 'no more than propose a commercial transaction*' . . . is so removed from 'any exposition of ideas' . . . that it lacks all protection."[33] (Again, that case involved the advertising of the price of drugs; in the Court's view, pricing information is an example of speech that does no more than propose a commercial transaction.) This could be read as a limitation on the scope of what counts as "commercial speech" — and sometimes, has been so read.[34]

Yet other cases have suggested that the category of "commercial speech" includes more than this simple definition. In *Bolger v. Youngs Drug Products Corp.*,[35] the Supreme Court dealt with a prohibition on using U.S. mail to send advertisements for contraceptives. The defendant company in that case did indeed seek to use the mail to send advertisements for contraceptives, which it produced,

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[31] 424 U.S. 1 (1976).
[32] *Id.* at 68; *see also* McCutcheon v. Fed. Election Comm'n, 134 S. Ct. 1434, 1459–60 (2014) (noting a First Amendment *benefit* of disclosure: that "[w]ith modern technology, disclosure now offers a particularly effective means of arming the voting public with information."); Citizens United v. Fed. Election Comm'n, 130 S. Ct. 876, 916 (2010).
[33] 425 U.S. at 762 (emphasis added) (internal citations omitted); *see also id.* at 776 (Stewart, J., concurring).
[34] *See e.g.* Nat'l Ass'n of Mfrs. v. Nat'l Labor Rel. Bd., 846 F. Supp. 2d 34, 60 n. 22 (D.D.C. 2012).
[35] 463 U.S. 60 (1983).

sold, and distributed.[36] But some of its mailings consisted solely of "informational pamphlets," with titles like "Plain Talk about Venereal Disease."[37] The Court noted that these pamphlets "cannot be characterized merely as proposals to engage in commercial transactions."[38] The Court still concluded that they were commercial speech, however, considering the totality of circumstances, including that they were "conceded to be advertisements," "reference[d] a specific product," and that the speaker "ha[d] an economic motivation for mailing the pamphlets . . . ."[39] And such mailings were still commercial speech "notwithstanding the fact that they contain discussions of important public issues such as venereal disease and family planning."[40]

In the recent (and noteworthy) *U.S. v. Caronia* case, the Second Circuit has characterized commercial speech as "expression solely related to the economic interests of the speaker and its audience," applying a *Central Hudson* inquiry to a criminal prosecution against a sales representative who promoted off-label uses of FDA-approved drugs.[41] Unlike in *Youngs Drug Products*, the court in *Caronia* did not question whether communications about off-label uses (when the speaker represents the manufacturer of a drug) were inherently commercial. (Nor did the recent *Amarin v. FDA* decision, the latest case applying *Caronia* to off-label promotion.)[42] Yet it is hard to characterize even this speech as "*solely* related to the economic interests of the speaker and its audience," although the speaker does indeed have an economic motivation for, e.g., informing doctors of the results of studies showing their drugs to be effective for certain off-label uses.

Another case that could have addressed this question (but did not) was *Sorrell v. IMS Health*, involving restrictions on disclosing data to pharmaceutical marketers.[43] The Court suggested that because the law in question was content-based and viewpoint-discriminatory, greater scrutiny may apply. But ultimately the Court found it unnecessary to decide whether the speech regulated was commercial or not, because, in the Court's opinion, the regulation would fall under

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[36] *Id.* at 62.
[37] *Id.* at 81–82 (Stevens, J., concurring).
[38] *Id.* at 66.
[39] *Id.* at 66–67. The Court went on to invalidate the ban as applied to the company's mailings under a *Central Hudson* analysis. *Id.* at 68–75.
[40] *Id.* at 67–68.
[41] 703 F.3d 149, 163 (2d Cir. 2012).
[42] Opinion and Order, 15-cv-3588 (S.D.N.Y. August 7, 2015).
[43] 131 S. Ct. 2653 (2011).

either a commercial speech *Central Hudson* analysis or more exacting scrutiny.[44] Other courts have taken similar approaches in avoiding this question.[45]

Ultimately, the limits of what counts as "commercial speech" are not very well-explored. In the off-label promotion context, the Second Circuit has readily found that statements from pharmaceutical sales representatives to doctors are commercial speech. But a company publishing a press release about a new study on an off-label use, or even simply posting a favorable journal article on the company's website, might be closer to the line between purely commercial and non-commercial speech. Courts might still conclude that such speech is economically motivated and in reference to a specific product (although even the latter may be a tough question in the case of a generic drug with multiple manufacturers), but such a company would have a better argument that its speech might be entitled to the heightened scrutiny suggested by *IMS Health*.

But more relevantly for this article, courts have readily concluded that an item's packaging (its label) *is* commercial speech; indeed, in none of the labeling cases analyzed in the next section is the issue even seriously questioned. A product label sitting on a store shelf, in a very real sense, proposes a commercial transaction by saying, "Here is what is in this box. Please buy it."

However, labels for products *not* sold directly to consumers on store shelves (e.g. prescription drugs or vaccines) may be arguably non-commercial. They do not directly propose a commercial transaction, because they are not seen by the purchaser until after purchase (if at all). In such contexts, labeling requirements might be justified as commercial either based on the sale to intermediaries (doctors or pharmacists) or the role of such intermediaries in informing the consumer, or owing to the possibility of repeat purchases of the product by the consumer, or perhaps even owing to the fact that the consumer could return the item based on information learned from the label. Otherwise, such labeling requirements would need to be justified on health, safety, or other grounds outside of a commercial speech inquiry, but in such a case, the legal test of what the government may require on these labels would be more exacting.

Whether package inserts[46] also qualify as commercial speech presents a similar question, as these are also not seen by the consumer until after the product has already been purchased. Calling such inserts "commercial speech" might be justified for reasons similar to those just discussed. In at least one case discussed in the next section (*CTIA*), a commercial speech inquiry was applied to a package

[44] *Id.* at 2667–72.
[45] *See, e.g.* cases cited infra at notes 75, 112.
[46] *See, e.g.* 21 C.F.R. § 310.501 (requiring package inserts for oral contraceptives).

insert, and this issue did not generate discussion in the (very brief) opinion in that case.

In sum, there seems to be little question that labeling of a product counts as commercial speech. This particular step of the analysis will therefore be easily satisfied when analyzing regulations compelling on product labels, although compelling speech elsewhere may call for further analysis.

III. Compelled Commercial Speech and *Zauderer*.

In *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*,[47] the Supreme Court confronted Ohio's various restraints on attorney advertising. But the case is truly known for its treatment of one restraint in particular: a compelled disclosure about the services offered in the advertisement. In this way, it may be viewed as the first case to answer the question of how one analyzes the compulsion of pure commercial-related speech in the indisputably pure commercial speech setting of advertising goods or services – a synthesis of the two lines of doctrine described in the previous section.

In *Zauderer*, Ohio required that attorneys who advertised "availability on a contingent-fee basis" also must "disclose that clients will have to pay costs even if their lawsuits are unsuccessful (assuming that to be the case)."[48] Distinguishing past compelled speech cases, in which the Court forbade the State from "prescrib[ing] what shall be orthodox in politics, nationalism, religion, or other matters of opinion," the *Zauderer* Court noted that Ohio had "attempted only to prescribe what shall be orthodox in commercial advertising," which (in the Court's view) was an important distinction.[49] The regulation only required attorneys to include "purely factual and uncontroversial information about the terms under which [their] services will be available," and the Court characterized the attorneys' "constitutionally protected interest in *not* providing any particular factual information" as "minimal."[50] (In reaching this conclusion, the Court invoked the language described above in *Virginia Pharmacy Board*: that "the extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides.")[51] And the Court noted that its past commercial speech decisions (including *Central Hudson*) had stated that disclosure requirements "trench much more narrowly . . . than do flat prohibitions on speech," and that these cases correctly noted that "warning[s] or

[47] 471 U.S. 626 (1985).
[48] *Id.* at 652.
[49] *Id.* at 651, *quoting* Barnette, 319 U.S. at 642.
[50] *Id.*
[51] *Id.*

disclaimer[s] might be appropriately required . . . in order to dissipate the possibility of consumer confusion or deception."[52] The Court left open the possibility that "unjustified or unduly burdensome disclosure requirements might offend the First Amendment," but held that First Amendment rights were "adequately protected as long as disclosure requirements are reasonably related to the State's interest in preventing deception of consumers."[53]

For the most part, the language quoted above is descriptive: the Court in *Zauderer* described why it believed the compelled commercial speech in that case passed constitutional muster. In these passages, the *Zauderer* Court did not, like the *Central Hudson* Court, announce a clear prospective four-part test for analyzing all compelled commercial speech. As a result, various readers have taken greatly different interpretations of the meaning of *Zauderer*, as we will see in the following sections. On the one hand, one can read *Zauderer* for its broad principles: compelled disclosures further consumers' First Amendment interests by spreading information (*Virginia Pharmacy Board*); a commercial speaker's interest in not providing factual information is "minimal"; and the State may prescribe "what shall be orthodox" in commercial advertising, particularly when requiring disclosure of "purely factual and uncontroversial" information about the product or service being advertised.

On the other hand, *Zauderer* can also be read much more narrowly. *Zauderer* described a disclosure requirement that was specifically directed to preventing consumer deception, and "preventing deception" could therefore be read as the only state interest triggering the lenient *Zauderer* level of scrutiny — this would limit *Zauderer*'s reach considerably. One could read the "factual and uncontroversial" language as a strict legal test as well, giving an expansive meaning to "uncontroversial" in particular. One could also read *Zauderer* as implying that disclosures veering too close to "matters of opinion" merit strict scrutiny under the compelled speech cases cited above, even in the commercial speech context where *Central Hudson* "intermediate scrutiny" ordinarily applies.

These various, disparate angles (among others) of interpreting *Zauderer* abound in the various cases involving compelled commercial speech in labeling requirements. In the following sections, we will see how courts have determined when and whether *Zauderer* applies to specific compelled disclosures, with reference to the passages from *Zauderer* quoted above. We will also see how the courts apply *Zauderer* (when it is found to apply), and how the courts analyze statutes when *Zauderer* is found *not* to apply. Throughout this analysis, we must keep in mind that some (and perhaps all) courts do not accept each possible limitation of *Zauderer* as a true "factor" in applying the *Zauderer* "test." Indeed,

[52] *Id., quoting* In re R.M.J., 455 U.S. 191, 201 (1982).
[53] *Id.*

the whole reason this kind of analysis is necessary is precisely because *there is no* universally agreed "*Zauderer* test." Instead, for each possible element in turn, this article analyzes those cases that substantially discuss that element, and what conclusions those cases reached.

A. How have courts determined when *Zauderer* applies?

(1) Does the required disclosure convey "purely factual" information?

In *Zauderer*, the Court twice referred to the "factual" nature of the mandatory disclosure at issue in that case in explaining its constitutionality: by referring to the fact that it conveyed "purely factual and uncontroversial information," and by characterizing an advertiser's "constitutionally protected interest in *not* providing any particular factual information" as "minimal."[54] The Court also contrasted the factual disclosure in that case with speech compelled in other cases involving "politics, nationalism, religion, or other matters of opinion."[55] On this basis, as we will see below, courts have generally limited *Zauderer*'s reach to disclosures involving "factual" matter. However, as we will also see, courts have disagreed on the meaning of "factual." As some courts and commentators have noted, what delineates "fact" from "opinion" is not always clear, particularly in complex scientific and policy matters (such as public health) faced by modern administrative agencies like the FDA.[56]

One noteworthy set of recent cases illustrating the difficulty in defining "factual" involves FDA's efforts to update warning labels on cigarettes to include illustrative graphics as well as text. The Family Smoking Prevention and Tobaco Control Act of 2009[57] required these graphic warnings, and after the FDA proposed the color graphic images to accompany the new warning text,[58] tobacco companies challenged them in court. And in *R.J. Reynolds Tobacco Co. v. FDA*,[59] the D.C. Circuit (in affirming the district court's decision[60] along similar lines)

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[54] *Zauderer*, 471 U.S. at 651.
[55] *Id.*
[56] *See, e.g.* Post, supra note 10, at 901–10; American Meat Institute v. U.S. Dep't of Agriculture, 760 F.3d 18, 54 (D.C. Cir. 2014) (en banc) (Brown, J., dissenting) ("In a word in which the existence of truth and objective reality are daily denied, and unverifiable hypotheses are deemed indisputable, what is claimed as fact may owe more to faith than science, and what is or is not controversial will lie in the eye of the beholder.")
[57] Pub. L. No. 111-31, 123 Stat. 1776 (2009).
[58] FDA, Final rule: Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36628 (2011).
[59] 696 F.3d 1205 (D.C. Cir. 2012).
[60] R.J. Reynolds Tobacco Co. v. FDA, 845 F. Supp. 2d 266 (D.D.C. 2012).

held that *Zauderer* did not apply to the graphic warnings that FDA had chosen in its rulemaking. In striking down the regulation compelling the FDA's chosen graphics to appear on cigarette labels and advertising, the panel opinion reasoned (in part) that the graphic warnings selected were not "'purely' factual" because "they are primarily intended to evoke an emotional response, or, at most, shock the viewer into retaining the information in the textual warning."[61] The court also noted that the images chosen could not be "interpreted literally," but rather "symbolize[d] the textual warning statements."[62] The court noted that the images, standing alone, could be misinterpreted by consumers, and that some of the images (again, taken on their own) did not convey "*any* warning information at all."[63]

Judge Rogers, dissenting in *R.J. Reynolds*, took a different view of whether the warning images were "nonfactual." She noted that each challenged image accompanied a *textual* statement, and that none of these textual statements were challenged in the lawsuit for their factual accuracy.[64] The images, in her view, needed to be viewed in context "with the textual warnings they accompany" in order to determine whether the disclosures as a whole were factual.[65] She quoted from *Zauderer* itself, which noted that "illustrations or pictures in advertisements serve[] important communicative functions" and may "serve to impart information directly."[66] And she took particular issue with the majority's reasoning that the images were nonfactual because they were "primarily intended to evoke an emotional response," noting that "factually accurate, emotive, and persuasive are not mutually exclusive descriptions; [and] emotive quality . . . does not necessarily undermine . . . factual accuracy."[67]

Discount Tobacco City & Lottery, Inc. v. United States,[68] in the Sixth Circuit, dealt with the same issue[69] of graphic warning images on tobacco labeling, but the majority opinion on this point answered that certain images could indeed be factual in nature, even if they provoke an emotional response.[70] The majority opinion, like Judge Rogers in the D.C. Circuit, took issue with drawing a

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[61] *R.J. Reynolds*, 696 F.3d at 1216.
[62] *Id.*
[63] *Id.* (emphasis in original).
[64] *Id.* at 1229–30.
[65] *Id.* at 1230.
[66] *Id.* (quoting *Zauderer*, 471 U.S. at 647).
[67] *Id.*
[68] 674 F.3d 509 (6th Cir. 2012), *cert denied sub nom.* Am. Snuff Co. v. United States (Apr. 22, 2013).
[69] However, the cases are distinguishable in that *Discount Tobacco* was a challenge to the Tobacco Control Act's requirement for graphic labeling images, whereas *R.J. Reynolds* challenged the particular images chosen by FDA in its Final Rule implementing the Act.
[70] 674 F.3d at 559 (opinion of Stranch, J.)

distinction between "emotional" and "factual," noting: "Facts can disconcert, displease, provoke an emotional response, spark controversy, and even overwhelm reason, but that does not magically turn such facts into opinions."[71] Labeling requirements mandating graphics and images are rather uncommon, and other courts have not had much opportunity to address when these are permissible. The extent to which images' "emotional" content may overpower their factual nature remains an open question — and perhaps one that will be addressed again if the FDA eventually attempts to implement the graphic-warning provisions of the Tobacco Control Act again.[72]

Another possible limitation on what is "factual" that can be found in case law involves facts relating to statutory or regulatory definitions. Some cases have suggested that the mere fact that a term is statutorily defined is not sufficient to render a labeling requirement including that term "factual." For example, in *Entertainment Software Association v. Blagojevich*,[73] the Seventh Circuit confronted an Illinois law requiring an "18" label to be affixed to any video games that are "sexually explicit." The court noted that even if the State's "definition of 'sexually explicit' is precise, it is the State's definition–the video game manufacturer or retailer may have an entirely different definition . . . ."[74] The court therefore found that the labeling requirement was opinion-based.

In a similar vein, the D.C. Circuit's recent decision in *National Association of Manufacturers v. SEC*[75] ("*NAM*") indicates that the fact that a term may be defined by statute does not make labels involving that term inherently "factual." In *NAM*, manufacturers of products containing certain "conflict minerals"[76] were compelled to indicate (on their website, not on product labels) whether or not they could certify their products as "DRC-conflict free," in reference to the conflict in the Congo. In striking down this disclosure requirement, it was of no moment that the phrase "not been found to be DRC-conflict free" referred to a statutory term of art; the court reasoned that the label was "a metaphor that conveys moral responsibility for the Congo war [and] requires an issuer to tell consumers that its products are ethically tainted, even if they only indirectly finance armed groups."[77]

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[71] *Id.* at 569.
[72] The FDA decided not to appeal *R. J. Reynolds*, and has yet to release a new proposed rule.
[73] 469 F.3d 641 (7th Cir. 2006).
[74] *Id.* at 652.
[75] Opinion on Petition for Panel Rehearing, No. 13-5252 (D.C. Cir., Aug. 18, 2015). On October 2, 2015, the SEC filed a petition for rehearing *en banc*.
[76] Minerals sourced from regions of the Democratic Republic of the Congo, where there is a likelihood that the trade in those minerals finances longstanding armed conflict.
[77] *Id.*, *slip op.* at 24, *quoting* Nat'l Ass'n of Manufacturers v. SEC, 748 F.3d 359, 371 (D.C. Cir. 2014).

However, one judge dissented from this decision, in part because this disclosure was defined by statute and therefore factual; the manufacturer was permitted to explain this, for example, by saying in its SEC report (where the disclosure was mandated), that these "products have not been found to be 'DRC conflict free' (where 'DRC conflict free' is defined under the federal securities laws to mean . . .)."[78] But the majority explicitly and sharply rejected the argument that a statutory definition could provide a "factual" basis for saving the law.[79]

From the above cases we see that, although cases involving disclosed facts based on terms defined by statute or regulation continue to be subject to reasonable debate, the terms most susceptible to constitutional challenge are those that could be characterized as opinions or as having other implicit meaning, independent of their statutory definitions. Conversely, labels that are least prone to constitutional challenge are those in which a statutorily-defined term is, considered in isolation, not factually objectionable and does not bear other meanings, controversial innuendo, or potential to mislead the consumer by itself. In other words, it is of absolutely no moment (to at least some judges) whether a term is statutorily defined; rather, the language itself, independent of any government-imposed definition, must be evaluated on its own for whether it satisfies the *Zauderer* criterion of "purely factual" information.

A third line of cases also helps to delineate the fact/opinion boundary; broadly speaking, courts have been wary of upholding compelled commercial speech where the government is allowed to express a position on the matter in that very same compelled speech. One such case is *R.J. Reynolds*, discussed above, in which the D.C. Circuit found unconstitutional the mandatory inclusion of the smoking cessation hotline number, 1-800-QUIT-NOW.[80] The court noted that this number "hardly sounds like an unbiased source of information" and ruled that the "provocatively-named hotline cannot rationally be viewed as [a] pure attempt[] to convey information to consumers."[81] (Even the dissenting judge, Judge Rogers, who disagreed with the panel in practically every other respect, found this government-mandated "imperative" "directing consumers to 'QUIT NOW'" did not qualify for *Zauderer* review, and subsequently invalidated this requirement under *Central Hudson*'s tailoring prong.[82]) Similarly, in an unpublished opinion

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[78] *Id.*, dissenting op. of Judge Srinivasan at 16–18 (quoting SEC, *Conflict Minerals*, 77 Fed. Reg. 56,274, 56,322 (Sept. 12, 2012)).
[79] On this point, the majority cited George Orwell's Nineteen Eighty-Four in evoking the dangers of "governmental redefinition": "WAR IS PEACE / FREEDOM IS SLAVERY / IGNORANCE IS STRENGTH." *Id.*, slip op. at 23–24 n.29.
[80] *R.J. Reynolds*, 696 F.3d at 1216–17.
[81] *Id.*
[82] *Id.* at 1236–37.

in *CTIA–The Wireless Association v. City & County of San Francisco*,[83] the Ninth Circuit held that *Zauderer* did not apply to a regulation requiring disclosure of radiofrequency emissions from cell phones. Although the facts about radiofrequency emission in the compelled fact sheets were "accurate and not misleading," the regulation went further: it contained "San Francisco's recommendations as to what consumers should do if they want to reduce exposure to radiofrequency energy emissions."[84] The language could therefore be interpreted as "expressing San Francisco's opinion that using cell phones is dangerous."[85] In these cases we see a principle that, where the government regulations "take sides" in a debate or tell consumers *how* to act based on the information disclosed, such required disclosures of the government's own view (opinion) may cease to qualify as "factual."

In light of all of the above cases, we now turn to the fact that *Zauderer* did not say merely "factual information," but rather "purely factual and uncontroversial information." This raises certain questions – can something be clearly, purely, and truly factual, and still be controversial? If so, what does "factual" mean? If not, why say "purely factual and uncontroversial"? Was the *Zauderer* Court setting forth a two-part legal test when it used this phrase, or merely describing the information of which found compulsion appropriate in *that* case? With these questions in mind to frame the discussion, we now address how cases have (or perhaps have not) given independent meaning to "uncontroversial."

(2) Does the required disclosure convey "controversial" information?

We begin this section by noting that in *all* of the cases discussed in the previous section, in which the compelled disclosures were found to be "not factual" (or "opinion-based"), they were *also* characterized by challengers (and usually by the courts) as "controversial." To review, these cases included the graphic cigarette warning labels in *R.J. Reynolds*;[86] the "sexually-explicit" video game labels in *Blagojevich*;[87] the conflict-minerals disclosures in *NAM*;[88] and the

[83] 494 Fed. Appx. 752 (9th Cir. 2012).
[84] *Id.* at 753.
[85] *Id.*
[86] 696 F.3d at 1217 ("these images . . . certainly do not impart purely factual, accurate, or *uncontroversial* information to consumers.") (emphasis added).
[87] 469 F.3d at 652 ("The sticker ultimately communicates a subjective and highly *controversial* message–that the game's content is sexually explicit.") (emphasis added).
[88] As discussed further below, the court there found the "uncontroversial" label problematic in several ways, and preferred the terminology used in the original panel opinion: that the requirement was "hardly 'factual and non-ideological.'" *See NAM*, slip op. at 18–22, 24 (quoting *NAM*, 748 F.3d at 371.)

recommendations on how to reduce RF energy exposure in *CTIA*.[89] If the "uncontroversial" prong of *Zauderer* has any meaning independent of "factual," one would expect it to be revealed (eventually) in cases explicitly relying on this element in rejecting an otherwise "factual" disclosure.

But no such cases are apparent to date, which provides some support for the notion that the phrase "purely factual and uncontroversial information" must be read as a whole, rather than separated into two independent elements. However, some noteworthy cases have indicated in *dicta* that "uncontroversial" may have some independent meaning, the contours of which have yet to be defined.

For example, in *American Meat Institute v. USDA*,[90] the en banc D.C. Circuit addressed a country-of-origin labeling rule for beef. There, the challengers conceded that the country (or countries) in which an animal was born, raised, or slaughtered is indisputably a piece of "factual" information, and obviously so.[91] And although the challengers objected (in their reply brief) to the use of the word "slaughtered" on the labels, the court declined to address the possibility that this might be controversial because the regulation allowed the use of the word "harvested" instead.

The court went on to say that it did not understand the compelled labeling to be "controversial in the sense that [the label] communicates a message that is controversial for some reason other than dispute about simple factual accuracy."[92] The court then explained that it was possible that "some required factual disclosures could be so one-sided or incomplete that they would not qualify as 'factual and uncontroversial,'"[93] again referring back to *Zauderer*'s phrase as a whole. But the challenger in the case did "not suggest anything controversial about the message that its members are required to express."[94] The court therefore had no opportunity to give further meaning to "controversial." Its language on this point was therefore arguably *dicta*, and aside from these vague suggestions that the meaning of "controversial" could be elucidated in future cases, the question of what might qualify as "controversial" (independent of "factual") was left for another day.[95]

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[89] 494 Fed. Appx. at 753 ("We cannot say . . . that the fact sheet . . . is both 'purely factual and *uncontroversial*.'") (emphasis added).
[90] 760 F.3d 18 (D.C. Cir. 2014) (en banc).
[91] *Id.* at 27.
[92] *Id.*
[93] *Id.*
[94] *Id.*
[95] *See also id.* at 34–35 (opinion of Kavanaugh, J., concurring)

The majority in *NAM* further noted this *dicta* from AMI and expanded on it with some considerable *dicta* of its own.[96] In the *NAM* court's view, "'uncontroversial,' as a legal test, must mean something different than 'purely factual.'"[97] The majority opinion therefore criticized the dissent, which argued that "purely factual and uncontroversial" means "purely factual" and "accurate."[98] In the majority's view, this is a "redundancy" as, in its view, there is no such thing as a "purely factual" proposition that is not "accurate."[99] Instead, the majority suggested that "perhaps the distinction is between fact and opinion."[100]

As an aside, this view of "controversy" is wrought with its own problems. If "uncontroversial" means "not opinion-based," then the *Zauderer* test is reduced to "factual and not opinion-based." If, as the *NAM* majority writes, "factual and accurate" is a redundancy, it is hard to see how "factual and not opinion" is any less so![101] Indeed, the cases and analysis in the previous section clearly indicate that, when compelled commercial speech veers into matters of opinion, such restrictions are outside of the scope of *Zauderer* because they are not "factual." The *NAM* majority therefore leaves us back at square one: does "uncontroversial" really mean anything different from "factual"?

By contrast, the dissent in *NAM* took the position that "the disclosed information must in fact be 'factual,' and it must also be 'uncontroversially' so, in the sense that there could be no 'disagree[ment] with the truth of the facts required to be disclosed.'"[102] But it is still not entirely clear that this test indeed encompasses two separate factors: if there can be reasonable disagreement as to the truth of certain facts (e.g. how to interpret scientific data), is that not one definition of "opinion"? Such puzzles will be discussed further in Section IV, *infra*.

While it is still unclear whether "controversial" has any meaning independent of "factual" under *Zauderer*, some cases have made clear, however,

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[96] *NAM*, slip op. at 19–20. The *NAM* court also noted (as possibly persuasive) the view that "purely factual and controversial" might properly be viewed as descriptive rather than as a rigid legal test (*id.* at 19), but argued that the en banc court in *AMI* had repudiated that view by stating it as something *Zauderer* required.
[97] *Id.* at 20.
[98] *Id.* at 21 n.28 (citing dissenting opinion of Srinivasan, J., at 12–15).
[99] *Id.*
[100] *Id.* at 20.
[101] Of course, this all assumes there is some intrinsic problem with redundancy. Descriptive redundancies are common in spoken and written language, non-legal as well as legal, as embodied for example in the *noscitur a sociis* canon of statutory interpretation.
[102] *Id.*, dissenting opinion of Srinivasan, J., at 14 (quoting *AMI*, 760 F.3d at 27).

what usually does *not* count as "controversial." As noted by the dissent (and the majority) in *NAM*, it would be impracticable if "controversial" meant "touch[ing] on a 'controversial' topic."[103] Indeed, *any* requirement that motivates an entity to file a lawsuit challenging it is, in some sense, controversial – putting the motivation for challenging it aside, the lawsuit *itself* satisfies an ordinary (and dictionary) definition of "controversy!"[104] To quote a court opinion discussing compelled speech remedies applied to a tobacco company, "controversy [in the context of *Zauderer*] must mean more than 'the fact that some people may be highly agitated and be willing to go to court over the matter.'"[105]

Finally, one notable recent (and ongoing) case squarely addresses the question of "controversial" as distinct from factual. Vermont recently passed a labeling law requiring foods containing genetically-engineered ingredients to disclose that fact. Food product manufacturers sued, challenging the law under the First Amendment (among other grounds).[106] In upholding this labeling requirement at the preliminary injunction stage by applying *Zauderer*, the district court noted, consistent with the above analysis, that "the fact that Plaintiffs would prefer not to make the required disclosure is insufficient to render it 'controversial.'"[107] Instead, in the district court's view, "controversial" means "the compelled information must, itself, be 'controversial,'" and the court also noted that "opinion-based" is another standard for judging what is "controversial."[108] This decision is currently on appeal to the Second Circuit, and front-and-center in appellant's brief in that case is an argument that the compelled "contains GE ingredients" labeled is "controversial."[109] The challengers argue specifically that it "is difficult to point to a current topic *more* hotly debated . . . than genetic engineering of crops. . . . The social debate continues, at a fast clip, and at high decibel levels."[110] Contrary to (all of) the cases discussed above, this argument takes "controversial" to mean "dealing with controversial subject matter." If this argument were adopted, it would be a first.[111] (Then again, as

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[103] *Id.* at 15 (citing the majority opinion at 21–22).
[104] *NAM*, majority op. at 21–22.
[105] US v. Philip Morris USA, Inc., 907 F. Supp. 2d 1, 17 (D.D.C. 2012).
[106] Grocery Manufacturers Association v. Sorrell, 14-cv-117 (D.Vt. April 27, 2015).
[107] *Id.*, op. at 55.
[108] *Id*., op. at 55–56 (citing *Blagojevich* and *CTIA*).
[109] Brief for Plaintiffs-Appellants, *Grocery Manufacturers Association v. Sorrell*, 15-1504-cv (2d Cir., Jun. 24, 2015) at 26–34.
[110] *Id*. at 26.
[111] The challengers also briefly argue that the factual accuracy of "produced with genetic engineering," and the statutory definition of that term, were subject to dispute. Reply Brief for Plaintiffs-Appellants, *GMA v. Sorrell*, 15-1504-cv (2d Cir., Sept. 9, 2015) at 4–5. However, because they only make this argument in a cursory fashion – and only in their reply brief – it seems unlikely that this argument will be the one that wins the day.

discussed, it might be the first time any meaning is actually given to "uncontroversial" standing on its own!)

Although the Second Circuit's adoption of the challengers' definition of "controversial" in the pending *GMA* case seems unlikely in light of everything that has come before, the challengers are not utterly without any legal support. Another recent Second Circuit opinion, *Evergreen Association v. City of New York*,[112] gives them some support in one footnote. In that case, New York City imposed mandatory disclosures on centers offering "pregnancy services," some of which are operated by groups that are strongly opposed to abortions. The City required each pregnancy service center to disclose "whether or not they 'provide or provide referrals for abortion,' 'emergency contraception,' or 'prenatal care.'"[113] Although the court analyzed this provision under strict scrutiny and intermediate scrutiny, and found it lacking, it also noted in a footnote: "Assuming *arguendo* that . . . [the disclosures] regulate[s] commercial speech, we do not believe that the law regulates 'purely factual and uncontroversial information,'" because it "requires centers to mention controversial services that some pregnancy services centers, such as Plaintiffs in this case, oppose."[114] This, too, seems to be a "controversial-subject-matter" test: whether a particular pregnancy center offers or refers for abortion or emergency contraception is clearly a matter of fact, and the accuracy of that fact cannot be subject to reasonable dispute or characterized as "opinion-based." The only basis for this reasoning must be that abortion is a controversial topic, about which the pregnancy center challengers feel strongly.

Thus, whether the Second Circuit relies on this footnote in *Evergreen*, or instead relegates it to *dicta* based on the *Evergreen* court's analysis of the law under strict and intermediate scrutiny, may have substantial bearing on whether the challengers in the Second Circuit are successful in expanding the definition of "controversial" to include "controversial subject matter."

(3) Does the required disclosure combat possible consumer deception?

As described at the beginning in this section, the Supreme Court in *Zauderer* made references to the State's interest in "dissipat[ing] the possibility of consumer confusion or deception"[115] and "preventing deception of consumers."[116] Labeling requirements that do so, and do so through disclosures of "purely factual and uncontroversial information," qualify for *Zauderer*-level scrutiny. Yet one question still debated is whether this "deception" language should be interpreted

[112] 740 F.3d 233 (2d Cir. 2014).
[113] *Id.* at 238.
[114] *Id.* at 245 n.6.
[115] *Zauderer*, 471 U.S. at 651, *quoting* In re R.M.J., 455 U.S. 191, 201 (1982).
[116] *Id.*

as a limiting principle of *Zauderer*: does *Zauderer* only apply when the asserted state interest is the prevention of consumer deception?

Certain cases in the D.C. Circuit (such as *R.J. Reynolds*, discussed above) once suggested that the answer to this question was "yes." Howver, the *en banc* D.C. Circuit overruled these decisions as to such holdings in *American Meat Institute*.[117] However, some other courts have implied that the answer is yes (although none appear to have held that *Zauderer* does not apply simply because the asserted state interest is one other than preventing deception.) For example, in the Sixth Circuit, the *Discount Tobacco* court analyzed the graphic cigarette warning labels extensively through a consumer-deception lens, repeatedly quoting *Zauderer*'s language on the "State's interest in preventing deception of consumers."[118] (The court found the existence of this interest based on the massive misinformation scheme that tobacco companies had been found to have engaged in, and lingering confusion in the public's mind about the safety concerns related to tobacco products.)[119] If another state interest would suffice, such as the obvious one in public health, the reason for this complicated detour through "consumer deception" would be unclear.

Similarly, in *International Dairy Foods Association v. Boggs*,[120] the Sixth Circuit upheld a mandatory disclosure requirement for milk that claimed to be "from cows not supplemented with rbST [an artificial hormone that increases milk production]." The State of Ohio required labels bearing such language to include the disclaimer that "[t]he FDA has determined that no significant difference has been shown between milk derived from rbST-supplemented and non-rbST-supplemented cows."[121] Even though the court in that case doubted the accuracy of FDA's judgment on the matter, it upheld the compelled disclosure requirement as preventing a "risk of deception" that was more than "speculative."[122]

Finally, we return briefly to the ongoing *GMA* case in the Second Circuit. There, the challengers are attempting to limit *Zauderer* to cases involving deception, notwithstanding the fact that the Second Circuit, as will be discussed next, has repeatedly sustained the application of *Zauderer* to various interests other than preventing deception. The challengers there argue that the Second Circuit's precedents in this regard have been undermined by the recent case of

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[117] *AMI*, 760 F.3d at 22–23, *overruling in part NAM*, 748 F.3d 359 (D.C. Cir. 2014), Nat'l Ass'n of Mfrs. v. NLRB, 717 F.3d 947 (D.C. Cir. 2013), and *R.J. Reynolds*.
[118] *See e.g. Disc. Tobacco*, 674 F.3d at 567, 568, 569.
[119] *Id.* at 562, 564.
[120] 622 F.3d 628, 642 (6th Cir. 2010).
[121] *Id.* at 640.
[122] *Id.* at 628.

Milavetz, Gallop & Milavetz v. United States.[123] However, because the Supreme Court was simply repeating the same kind of descriptive language that the Second Circuit had previously considered from *Zauderer*, it seems unlikely that this argument will carry the day (at least, in the Second Circuit).

(4) Does the required disclosure serve a substantial state interest other than combating deception?

As just noted, some courts have extended *Zauderer*'s scope to extend to state interests beyond preventing consumer deception. But even some of the courts that have done so have imposed some limits on what sorts of interests qualify as "substantial" enough to mandate disclosure of information under *Zauderer*.

Among the federal courts of appeals, the Second Circuit is noteworthy for the development of the law in this area. That court has explicitly upheld labeling requirements that serve state interests other than preventing deception. For example, in *National Electric Manufacturers Association v. Sorrell*, the court upheld a Vermont law mandating mercury disclosures on lamps, citing "Vermont's interest in protecting human health and the environment from mercury poisoning."[124] In *New York State Restaurant Association v. New York City Board of Health*, the court upheld calorie labeling on fast food menus, citing "New York's interest in preventing obesity."[125]

But the Second Circuit also presents a noteworthy case that rejected a labeling requirement that was *not* found to be supported by a substantial interest. In *International Dairy Foods Association v. Amestoy* (another case involving the use of the rBST growth hormone in dairy cows), the court found that the interest claimed by Vermont of merely satisfying "consumer curiosity" was not substantial enough to compel disclosure under *Central Hudson*.[126] (Unlike the disclosure at issue in *Boggs*, the Vermont statute at issue in *Amestoy* required all milk to disclose whether it was from cows treated — or which might have been treated — with rBST.) And although the court cited *Zauderer*, it apparently believed it was limited to interests in preventing deception, as it did not analyze the challenged statute under this framework. Because the state of Vermont disavowed any state interests other than giving information to citizens, the court struck the requirement down, finding that this interest was "insubstantial."

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[123] 559 U.S. 229 (2010).
[124] 272 F.3d 104, 115 (2d Cir. 2001).
[125] 556 F.3d 114, 134 (2d Cir. 2009).
[126] 92 F.3d 67, 74 (2d Cir. 1996).

Because *Amestoy* did not explicitly apply *Zauderer*, how substantial a state interest must be to satisfy *Zauderer* review is an open question in the Second Circuit. (Indeed, *Zauderer* did not use the word "substantial" in characterizing the State interest justifying the disclosure requirement in that case.[127])

This is also an open question in the D.C. Circuit, where in *American Meat Institute*, the *en banc* court reserved the question of "whether a lesser interest [than the one found in that case] could suffice under *Zauderer*."[128] In that case, the court noted several possible interests justifying country-of-origin-labeling: consumer interest; the established history of such labels; and the possibility that some additional information about product origins could be useful (to consumers, and in alleviating market impacts) during food-borne illness outbreaks.[129] (Judge Kavanaugh, in concurrence, also noted an interest in protectionism, which he deemed a valid state interest, although the government disavowed that interest in litigation.)[130]

Of note, the fact that the *AMI* court found "consumer interest in the information" to be a suitable interest puts it in tension with *Amestoy* from the Second Circuit, which held that interest *insubstantial*, albeit in a *Central Hudson* analysis. Thus, the still-to-be-defined "substantiality" piece of *Zauderer* could really grow in either direction in the future, either limiting the scope of when *Zauderer* applies (as in *Amestoy*) or expanding it (as the *AMI* court implicitly did). But overall, the trend seems to be that *Zauderer* includes a broad range of interests, including at least those that may be asserted as "substantial" in a *Central Hudson* analysis – and possibly more.

(5) Is it labeling or advertising?

Closely related to the "is it commercial" inquiry discussed in section II.C., above, is the question of whether *Zauderer* applies outside of the narrow areas of labeling and advertising. (Again, because this paper deals primarily with labeling, this issue will only be briefly discussed.) The D.C. Circuit in the recent *NAM v. SEC* decision suggested that this could be a substantial limit on the scope of *Zauderer*, noting that the Supreme Court's opinion in *Zauderer* "is confined to advertising," and reading that limitation in the facts of the case as a general principle limiting the scope of the case.[131] In *NAM*, the compelled disclosure was a document on the company's website, and the Court held that *Central Hudson* (rather than *Zauderer*) applied, because *Zauderer* does not reach "compelled

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[127] 471 U.S. at 651.
[128] 760 F.3d at 23.
[129] *Id.*
[130] *Id.* at 32-33 (Kavanaugh, J., concurring in the judgment).
[131] *NAM*, *supra* note 75, at 8.

disclosures that are unconnected to advertising or product labeling at the point of sale."[132]

This suggested limitation is of recent vintage.[133] Even on its own terms, it would not affect the analysis as applied to labeling requirements. But it might have an impact on compelled disclosures in other contexts suggested in section II.C, supra, such as package inserts or labels that are not sold direct-to-consumer. As noted already, the analysis of disclosure requirements in these contexts is an open (and at least debatable) question on this point.

B. How have courts applied *Zauderer*?

If all of the above factors are satisfied (compelled disclosure in a commercial context of purely factual, uncontroversial information in service of some valid state interest), then *Zauderer* applies. But what does that mean, exactly? Many have compared *Zauderer* scrutiny to "rational basis" scrutiny, a notoriously permissive standard of judicial review.[134] However, this analogy is not without its critics, for instance Judge Kavanaugh, concurring in *AMI*.[135] In his view, under *Zauderer*, if "the Government articulates a substantial government interest, the Government must show that the disclosure is purely factual, uncontroversial, not unduly burdensome, and reasonably related to the Government's interest."[136] However, most of these requirements (as framed in this article) may be described as factors determining *whether Zauderer*-type scrutiny, or another type of scrutiny, applies. Perhaps it is an issue of semantics more than anything else, but once *Zauderer* has been found to apply, the only remaining requirements (that the regulation be "reasonably related" to the state interest and not "unduly burdensome") seems much like rational basis scrutiny. Indeed, consistent with such a permissive standard, the author is aware of no cases where a regulation was invalidated under *Zauderer* for failing the "reasonable relation" test.

In sum, just as with rational-basis scrutiny, if *Zauderer* is found to apply, it is extremely likely the regulation will be upheld. As of now, no constraints seem apparent from the case law with respect to *Zauderer*'s application.

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[132] *Id.* at 7. The dissent argued that it was anomalous to apply *greater* scrutiny to a requirement that is clearly much less burdensome than disclosures on product labels. *Id*., dissenting op. at 9–10.

[133] And as noted above, the SEC has filed a petition for rehearing *en banc*, arguing that the opinion contradicts *AMI*.

[134] *AMI*, 760 F.3d 18, 34 n.2 (concurring opinion of Kavanaugh, J.) (citing cases).

[135] *Id.* at 33–34.

[136] *Id.* at 34.

C. Note: What happens when *Zauderer* does not apply?

On the other hand, what happens to those compelled commercial disclosures that fail one of the requirements in reaching *Zauderer* scrutiny: those that are "not purely factual" and (or?) are "controversial," or that do not serve to prevent deception, or that do not serve other (substantial?) interests. What type of scrutiny do the courts apply to those disclosures that fail to satisfy one or more of the criteria in *Zauderer*? Does one apply *Central Hudson* intermediate scrutiny (as for commercial speech), or *Wooley*-type strict scrutiny (as for compelled political speech).

Some courts decidedly avoid answering this question; when they can decide that the regulation fails intermediate scrutiny, there is no need to answer this question because it would also clearly fail strict scrutiny. *NAM* took this approach,[137] as *Evergreen Association* arguably also did.[138] But at least one case, *Blagojevich*, did not even question whether intermediate scrutiny might apply: it applied strict scrutiny when it found the "sexually explicit" labeling requirement to be "opinion-based."[139] *Discount Tobacco* cited *Blagojevich* for this approach (though this seems to be dicta, as the majority there ruled that *Zauderer* applied.)[140]

However, in the D.C. Circuit, when *Zauderer* is found not to apply to compelled commercial speech, *Central Hudson* governs.[141] This seems to be the case in the Second Circuit as well.[142] And this makes good sense – it would be anomalous for commercial speech *restrictions* to be analyzed with lesser scrutiny than commercial speech *disclosures*, which are inherently less restrictive. It seems likely that future courts that consider the issue directly will usually conclude that *Central Hudson* governs, as long as the compelled speech can be fairly characterized as commercial; *Blagojevich* seems to be an anomaly.

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[137] Op. at 12 (citing the original opinion in *NAM*, 748 F.3d at 372). But note that *NAM*, after finding the disclosure to be unrelated to labeling or advertising, suggested that *Central Hudson* applied, at least when an otherwise commercial regulation failed on that count. Op. at 8–9.

[138] 740 F.3d at 245.

[139] 469 F.3d at 652.

[140] 674 F.3d at 554.

[141] *R.J. Reynolds*, 696 F.3d at 1217 (citing *United States v. Philip Morris*, 566 F.3d 1095, 1142–43 (D.C. 2009)) (noting the contrary authority of *Blagojevich* and *Discount Tobacco*).

[142] *See GMA*, 14-cv-117, op. at 52–54; Brief for Plaintiffs-Appellants, *GMA*, 15-1504-cv, at 26 (arguing only for intermediate scrutiny, not strict scrutiny).

IV. Analysis: How might the scope of *Zauderer* change in the future?

Based on the cases analyzed above, we have seen the current limits of *Zauderer*, including open questions as to these limits. With a full view of the past cases and the questions they left open, we can begin to make educated guesses on the future of the doctrine. But such an endeavor, however careful, is all speculation; if, for example, the Supreme Court decides to take a radically different course from that charted by the appeals courts on certain issues, such speculation is not worth much. With that in mind, I present the following thoughts on the future of the so-called "*Zauderer* standard".

The language from *Zauderer*, describing its lower form of scrutiny as applying in the case of disclosure of "purely factual and uncontroversial information," will probably continue to be debated, particularly in light of the slipperiness of "controversial" as a legal standard. Perhaps some future courts will continue to note that this may not be a rigid two-part legal test; in *Zauderer*, it seemed to be descriptive more than anything else, as the majority in the recent *NAM* opinion noted. On this view, it was uttered only in contrast with "matters of opinion" in *Zauderer* itself. *NAM* suggested that maybe the line for "controversy" was that "between fact and opinion," but as noted above, if one thinks separate meaning should be given both to "factual" *and* "controversial", "factual" itself is frequently contrasted with opinion, too. Thus, saying that "controversial" means "opinion-based" may not readily distinguish it from "factual" and may not really be creating a two-part legal test.

And as noted above, the dissent's approach in *NAM* fares not much better in creating a truly two-part legal test. There, Judge Srinivasan argued that the information must be not only (1) "factual" but also (2) "uncontroversially" factual, in the sense that "there could be no disagreement with the truth of the facts." One problem with this statement (taken literally) is obvious: anyone can (and many routinely *do*) disagree with the truth of factual matters, even ones that *should* be uncontroversial in light of all we know. Is the overwhelming scientific consensus that modern vaccines do not cause autism "controversial" simply because some people disagree, against the evidence to the contrary? How about the consensus that cigarette smoke causes certain types of cancer? Or the scientific consensus that genetically-engineered plants pose no greater risks to human health than conventionally produced varieties? All of these questions are "controversial" in the sense that (many) people may disagree with the scientific consensus (shared by the FDA, CDC, EPA, and so forth). Does that mean all of these (and other similar matters) are not proper subjects for government-compelled cautionary statements?

The answer, of course, is no, and this is apparent from case law. We *do* allow compelled labeling statements warning about the risks of cigarette smoke, despite the fact that these risks were publicly disputed for decades through well-organized campaigns by the tobacco industry. And *Boggs*, for example, approved a cautionary disclosure that the FDA has found no differences in the milk produced by rBST-treated and non-rBST treated cows; a similar disclosure regarding genetically engineered crops would surely pass *Zauderer* scrutiny, no matter how much some people may disagree with the FDA's assessment on this point. And if childhood vaccines had a robust direct-to-consumer market, one can imagine that claims of "no preservatives!" could reasonably be accompanied by a cautionary statement that "the FDA has not found vaccine preservatives to present any human health risk. Ultimately, it cannot be that *any* level of disagreement suffices to render a subject "controversial" and therefore defeat *Zauderer* scrutiny of commercial disclosures regarding said subject.

The question, then, may be not only whether disagreement with the facts is possible, but *reasonable* disagreement. But then, as noted, we are in the domain of reasonable disagreements about factual matters: is that not the definition of opinion? Once again, this causes "factual and uncontroversial" to be reduced to "not opinion-based."

Of course, there is nothing wrong with reducing this language to a mere contrast with "opinion-based" – many courts have done just that, whether making it a part of "factual," "uncontroversial," or both. Indeed, the past popularity of this approach — as well as the fact that many alternative approaches reach essentially the same result — means it is rather likely that a similar approach will be applied in the future.

As noted above, the plaintiffs in the ongoing GE-food labeling case in the Second Circuit have asked for a completely different definition of "controversial" – one relating to controversial *subject matters*. As courts, such as *NAM*, have correctly noted, this cannot be taken too far: *any* labeling requirement that provokes a lawsuit is, in a sense, controversial by definition. At best the challengers are asking the court to find that genetically-engineered foods are not only "controversial," but *extremely* so, and are matters of intense public discussion and strong emotions — somewhat akin to social issues like abortion (as they cite to *Evergreen Association*). This does limit the scope of such a rule somewhat, but even a "highly controversial subject matter" definition seems unlikely in light of all the cases that have come before.

What's more, if the courts *did* adopt this sort of a rule solely for the context of genetic engineering, the purveyors of genetically engineered crops and foods derived from them may be dismayed when they learn that this ruling would necessarily cut both ways. Boldly advertised claims that foods are *not* genetically

engineered could proliferate the marketplace, but because the whole subject matter would be "controversial," the government would not be able to restrict them, even by the relatively unintrusive means of *Zauderer*-type disclosures. A required FDA disclaimer about such claims would evade *Zauderer* review, because under this rule, the subject is too controversial for the government to compel *any* such speech.

Already, the government's ability to correct deception like this may be in jeopardy if rulings such as *R.J. Reynolds* and *CTIA* are read too broadly to stand for the principle that the government may not take sides or express its own views in a matter of public debate (or at least, may not do so when compelling speech). If this is the principle, then what of the Surgeon General's Warnings on cigarettes, or statements that the FDA does not consider X to be any different from Y? These disclosures state facts insofar as they identify *the fact that* someone (the government) has reached a certain conclusion based on its view of the evidence. On the other hand, they also compel products to carry the government's message, which is forbidden under these cases if construed broadly.

Alternatively, those cases can instead be analyzed as concluding that the government may not use compulsory labels to *tell* consumers what to do; they may only *inform* consumers and allow them to make up their own minds. The problem in *R.J. Reynolds* was telling consumers to QUIT NOW, and in *CTIA* it was telling consumers how to reduce their RF exposure. By contrast, telling consumers that quitting smoking helps avert various medical problems, or that cell phones emit X amount of RF energy, was permissible in those cases, because doing so merely gives consumers information.

Regarding whether substantial interests other than preventing consumer deception will continue to receive the benefits of *Zauderer*, the answer is almost assuredly yes. Very few familiar labeling requirements actually involve potential deception. If guarding against consumer deception were the only permissible labeling goal under *Zauderer*, then how can we understand the various mundane labels described in the introduction? Calorie counts, nutrient information, allergen information, drug facts, and even warnings about the dangers of cigarettes: all of these primarily motivated by interests other than avoiding possible "deception." Health, safety, and simply providing consumers with information they find relevant to their decision-making are all interests served by labeling requirements. And courts have reasonably looked to this historical backdrop in interpreting, and likely will continue to do so.

V. Conclusion

Regarding food, drugs, and other consumer products, compulsory labeling laws have been around for a while — before the evolution of commercial speech law. This long history (and public acceptance) likely explains why such well-established labels are very likely to survive any new developments in the law of commercial speech.

Yet as we have seen in this article, *new* labeling requirements may, in some instances, run afoul of the First Amendment as recently interpreted in the commercial context. But any challenge to such requirements should be ready to answer one basic question: why invalidate this labeling requirement, and not those that we have grown to accept? What is the limiting principle in the challenge?

Before the full D.C. Circuit, counsel for the challengers of country-of-origin labeling was peppered with such questions. Why, the judges asked, compel labeling of sodium, fat, cholesterol, sugar, when the public health implications of these continue to be debated? Clearly these are not addressed to deception. Clearly they may relate to controversial subject matter. And some may do nothing more than inform consumers. No limiting principle appeared to distinguish such well-accepted requirements from country-of-origin labeling: the result was that nine of eleven judges on a very influential court of appeals broadly upheld the government's ability to compel such labeling.

But future challengers are not without any line of attack against any compulsory labeling that the government can come up with. As we have seen, speech that is too opinion-based, or one-sided, may not be compelled. Nor may speech that serves no substantial interest be compelled, although the scope of allowable interests may be either expanded or narrowed in the future. And the extent to which speech may be compelled when it relates to "controversies," real or imagined, continues to be an open question. If challengers can successfully raise these points (and thus avoid their challenge being relegated to *Zauderer* analysis), such challenges have a much greater chance of success.

Whether it is a good idea or a bad idea to give the government such broad authority to require labels is a matter of opinion. As courts have correctly recognized, disclosures are inherently less burdensome to speech rights than outright restrictions. And disclosures do serve First Amendment interests themselves, by giving consumers information; recall that in *Virginia Pharmacy Board*, the initial justification for commercial speech protection itself involved the right of consumers to receive information. And similar arguments have been made in cases involving *political* speech.

And at the end of the day, it is also worth noting that labeling requirements are ultimately governed by the democratic process. Indeed, if a regulated entity objects to a factual labeling requirement, perhaps the best avenue for changing it is

through Congress or the administrative agencies — particularly so given the rather limited nature of judicial review in this area we have seen to date.