Common Law versus Regulatory Fraud:
Parsing the Intent Requirement of the Felony Penalty
Provision of the Food, Drug, and Cosmetic Act

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Beginning in the early 1980s, designer drugs became a threat to the United States drug control regime. Designer drugs are psychoactive compounds or synthetic steroids designed to evade the Controlled Substances Act (CSA) by altering the molecular structure of illegal drugs or using legal substances to construct new psychoactive compounds. The CSA criminalizes the manufacture and sale of dangerous recreational drugs and is the legal backbone for the United States's drug prohibition. To ensure that the extremely severe punitive measures included in the CSA are appropriate, the process to bring a drug within the CSA's prohibition, known as scheduling, is long and involved. Importantly, the Drug Enforcement Agency (DEA) must be satisfied that there is convincing scientific evidence of the danger posed by a drug before it may be placed within one of the CSA's five schedules, which determine the severity of regulation and punishment for manufacturers, distributors, and consumers of the now illegal drug.

Designer drugs challenge this model of careful but severe drug prohibition. As soon as one drug is scheduled, another is created that has similar psychoactive effects but does not fall within the CSA prohibition. MDMA, popularly known as ecstasy, is a famous example of


1 21 USC § 801 et seq (2000).
2 See Molly Sinclair, Tragedy Has Designer Label: Drugs Made from Common Chemicals, Grieving Parents Tell Senate Panel, Wash Post A1 (July 19, 1985) (“Drug laws are based on the molecular structure of drugs, so minor changes in the molecules of an illegal drug can create a new drug that is legal but produces a feeling of euphoria as powerful as heroin.”). See also Wikipedia, Designer Drug (“Designer drug is a term to used to describe psychoactive drugs which are created (or marketed, if they had already existed) to get around existing drug laws by modifying their molecular structures to varying degrees”), online at http://en.wikipedia.org/wiki/Designer_drug (visited June 28, 2005).
5 See DEA, Drugs of Abuse at 1-2 (cited in note 3).
a drug designed to fill the market for several previously scheduled club/rave drugs.\(^6\) Both GHB and GBL, club drugs often used in date rapes, are examples of designer drugs that challenged the CSA prohibitory scheme. GHB prohibition was slow because it was manufactured from legal substances.\(^7\) GBL, a similar though molecularly distinct drug, entered the market free from prohibition after GHB finally was scheduled.\(^8\) A very recent example is the synthetic steroids which plague professional sports.\(^9\) While the DEA sometimes spends years attempting to determine if these drugs need to be scheduled, the CSA provides no effective check on their supply.

Beginning in the late 1980s, prosecutors turned to the Food, Drug, and Cosmetic Act\(^10\) (FDCA, or "the Act") to establish effective disincentives for the manufacture and distribution of dangerous but unscheduled drugs. The FDCA was enacted in the early twentieth century to establish strict regulation of the legal food, drug, and cosmetic markets in order to provide sufficient protection for consumers.\(^11\) Unlike under the CSA, drugs are assumed prohibited under the FDCA and must be approved by the Food and Drug Administration (FDA) before they may be manufactured or distributed in the United States.\(^12\) In addition, the FDA can very quickly remove a drug from the market for public safety reasons.\(^13\) Distribution and manufacture of unapproved or removed drugs is punishable under the FDCA.\(^14\) The FDCA's provisions provide a far more flexible regulatory regime, meant to allow the safe distribution of drugs while preventing drugs that might harm the public from being distributed. Its provisions allow designer drugs to be regulated, even while a decision is being made about their prohibition.

A recent split among the federal circuit courts threatens the uniformity of national prosecutions for the manufacture of unscheduled

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\(^7\) See HR Rep No 106-340 at 1–2 (cited in note 4).
\(^9\) See Michael E. Hochman, New Drug Tests Attempt to Keep Up with Athletes, Boston Globe C1 (May 10, 2005) (noting that scientists were not even aware of the existence of one anabolic steroid being used by athletes).
\(^11\) See House Committee on Interstate and Foreign Commerce, A Brief Legislative History of the Food, Drug, and Cosmetic Act, 93d Cong, 2d Sess 3 (Comm Print 1974) (noting that government officials recognized the "failure of ... existing law to adequately protect the consumer").
\(^12\) Id at 16.
\(^13\) Id at 16–17 ("The Secretary ... on finding an imminent hazard to the public health, could immediately suspend a new drug approval.").
\(^14\) See 21 USC § 331(a), (p).
designer drugs. The FDCA has two punishment provisions. A misdemeanor violation of the Act is a public welfare offense that does not require proof that the defendant acted intentionally. A felony violation, as defined in § 333(a)(2) of the FDCA, requires proof that the defendant committed the violation "with the intent to defraud or mislead." The felony provision is the government's preferred charge in prosecuting manufacturers of unscheduled designer drugs. Decisions in GHB cases by the Ninth and Tenth circuits conflict with a recent Fourth Circuit decision on the scienter requirement necessary for a felony conviction under the Act. The Ninth and Tenth Circuits have held that the designer drug convictions do not demonstrate the appropriate specific intent to meet the felony requirement of the Act. The Ninth Circuit specifically stated that the FDCA is not the appropriate statute under which to bring designer drug prosecutions, rejecting the option of pounding "the square pegs of [a defendant's] conduct . . . into the round holes of the FDCA." The Fourth Circuit concluded that the intent standard is more general and found sufficient evidence to uphold the designer drug convictions under the FDCA.

In Part I, this Comment briefly lays out the procedures and history behind the CSA and the FDCA that present the background for the circuit split. Part I also presents the split itself in some detail, exploring the specific intent rationale of the Ninth and Tenth circuits and the general intent rationale of the Fourth Circuit. The Part concludes with a brief analysis of the options for resolving the split as presented by the federal circuit courts, suggesting that while the Fourth Circuit's general intent position is arguably more convincing, neither of the rationales proposed by the courts is dispositively convincing.

In Part II, this Comment proposes that the resolution of this circuit split actually turns on an unevaluated element of the cases, namely the textual definition of the "defraud or mislead" language in the felony provision of the FDCA. The Comment demonstrates that the courts'
understandings of intent likely arose from two very different interpretations of the language of § 333(a)(2). The Ninth and Tenth Circuits' interpretation is based on common law fraud, and the Fourth Circuit's interpretation is based on fraud language used in comprehensive regulatory regimes (that is, regulatory fraud). A model of the use of "defraud" language in federal statutory law rebuts the presumption that FDCA felony intent language should be given its common law meaning. This Comment argues that regulatory fraud provides a better interpretation of the "defraud" language based on the text, structure, and intent of the FDCA. Finally, in Part III, this Comment responds to the Ninth Circuit's obvious discomfort with applying an apparent regulatory statute in what appears to be a criminal prosecution.

I. UNDERSTANDING THE CIRCUIT SPLIT

This Part analyzes the circuit split over the interpretation of the intent requirement in the felony provision of the FDCA. Part I.A presents the necessary background, including a short explanation of the scheduling process under the CSA and a short history of the development of unscheduled drug regulation under the FDCA. Part I.B explores the circuit split, focusing on the courts' intent language. Finally, Part I.C provides a brief analysis of the circuit split to determine if it can be resolved based on the courts' justifications for their decisions.

A. The Statutes

Drug control at the federal level operates through two distinct regimes. Illegal drugs are regulated by the provisions of the Controlled Substances Act, which essentially provides the legal tools for the War on Drugs. The manufacture and distribution of legal drugs is regulated by the Food, Drug, and Cosmetic Act. Designer drugs fall somewhere in between these regimes, as they are banned for most legal manufacture and distribution by the FDA but are not yet illegal. In making determinations about the intent standard required by the FDCA's felony provision, the courts involved in the circuit split were very aware of the looming presence of the CSA's prohibitions.21

21 See United States v Ellis, 326 F3d 550, 557 (4th Cir 2003) (Michael dissenting) (noting that the designer drug at issue was "now a controlled substance" pursuant to the CSA); United States v Geborde, 278 F3d 926, 932 (9th Cir 2002) (recognizing that the drug in question was "now listed as a Schedule I controlled substance"); United States v Mitcheltree, 940 F2d 1329, 1336 (10th Cir 1991) (noting that the designer drug in question "was permanently scheduled in schedule I as a controlled substance").
1. The CSA and the War on Drugs.

The CSA's process for making a drug illegal is a crucial factor in understanding the FDCA intent standard circuit split. The length and probabilistic nature of this process makes the FDCA necessary to prosecute designer drug manufacturers.

The CSA's prohibitions do not take effect until a drug has been scheduled.\(^2\) In order for a drug to become scheduled, a party (private or governmental) needs to request a schedule proceeding from the DEA.\(^3\) The DEA publishes an intention to schedule and it requests an extensive scientific opinion from the Department of Health and Human Services (HHS).\(^4\) HHS must provide evidence, including clinical tests, to evaluate the eight scheduling factors in § 811(c) of the CSA. After HHS makes its recommendation, there is a further comment period before the DEA makes its final decision on scheduling, as authorized by delegation from the Attorney General.\(^5\)

The scheduling process is long and bureaucratic, taking years to complete. For example, it took nearly four years from the time that the DEA noticed its intention to schedule MDMA until the drug was actually made a Schedule I substance under the CSA.\(^6\) Recently, Congress has taken to forcing the issue by passing legislation demanding that the Attorney General schedule a drug within sixty days, but such legislation is subject to the typically slow deliberations of the legislative body. It took nearly three years to pass legislation mandating the scheduling of GHB.\(^7\) As a result, a significant period of time elapses between when the FDA bans manufacture and distribution of a drug and when it may be scheduled under the CSA.\(^8\) While the CSA prohibitions do not cover the designer drugs, or if the DEA determines they should not cover the drugs, prosecutors have turned to provisions of the FDCA.

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\(^2\) See DEA, Drugs of Abuse at 8 (cited in note 3) (noting that the penalties of the CSA “are basically determined by the schedule of the drug”).
\(^4\) Id.
\(^5\) HR Rep No 106-340 at 6 (cited in note 4). The five schedules that a drug may be placed in affect how severely its manufacture and distribution is controlled. Most commonly known illegal drugs are in Schedule 1—subject to the strictest prohibitions. See DEA, Drugs of Abuse 1–3 (cited in note 3).
\(^7\) See Hillory J. Farias Date Rape Prevention Act, HR 1530, 105th Cong, 1st Sess (May 5, 1997); Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000, HR 2130, 106th Cong, 2d Sess (became Pub L No 106-172 on Feb 18, 2000).
\(^8\) For example, the FDA banned the manufacture or distribution of GHB in 1990. See Ellis, 326 F3d at 552. However, it was not scheduled until 2000, leaving a ten-year gap in which prosecutors could not use the CSA to prosecute the manufacture or distribution of an admittedly dangerous drug. See HR Rep No 106-340 at 6–7 (cited in note 4).
Although the CSA provides harsher penalties, the FDCA, intended to regulate all available drugs, provides much more sweeping coverage.

2. The FDCA and the public welfare.

In 1937, "the Elixir of Sulfanilamide" killed hundreds of people after a manufacturer distributed a drug that it failed to test for safety. Riding the wave of public terror surrounding this disaster, Congress passed the FDCA, creating an integrated scheme for regulating the manufacture and dissemination of food, drugs, and cosmetics. Section 360 of the FDCA mandates that drug manufacturers register their products, factories, and labels used in drug distribution with the FDA. That information is available for public inspection, and it functions to provide notice to the FDA that a random inspection of the factory must be conducted at least biennially.

Importantly, no provision of the FDCA specifically prohibits the manufacture of banned drugs. The Act only prohibits the distribution of banned drugs or the manufacture of any drug in an unregistered facility. In designer drug prosecutions brought under the FDCA, failure to register a production facility functions the same as a ban on the manufacture of designer drugs because registration for that purpose would not be allowed.

The regulations contained in § 331 form the backbone of the modern regulatory regime that replaced the free market in drugs with a government-regulated market that insisted on high standards for the safe manufacture and distribution of legal drugs. The 1938 legislation also significantly expanded the penalties for violating the regulatory regime. In United States v Dotterweich, the Supreme Court noted that:

The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industri
alism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words.\(^3\)

The Court thus established a rule of FDCA statutory construction that favors the health and safety of the consumer over the market interests of producers and suppliers.\(^3\) This rule of construction is often cited by circuit courts in holdings about the FDCA.\(^4\)

### B. Felony Drug Prosecutions Under the FDCA

Within this general regulatory framework, the FDCA provides for two different criminal punishments for violations of the Act. Any violation of the Act is a misdemeanor under § 333(a)(1). But any violation committed "with the intent to defraud or mislead" is a felony under § 333(a)(2). Section 331 lists the FDCA violations punishable under the dual penalty provisions of § 333. The violations listed include: § 331(a), which prohibits the introduction into interstate commerce of an adulterated or misbranded drug; § 331(e), which prohibits the refusal to allow access to records mandated elsewhere in the act; § 331(f), which prohibits the refusal to allow inspection of production facilities; § 331(k), which prohibits alteration or removal of required labeling; and § 331(p), which prohibits the failure to register a drug production facility with the FDA as per the requirements in § 360. Importantly, each of these violations is subject to both felony and misdemeanor penalties.

\(^{38}\) Id at 280. The Court went on to say that misdemeanors under the Act would be prosecuted as public welfare offenses, requiring only proof of a violation to secure conviction:

> The prosecution [of misdemeanors under the Act] is based on a now familiar type of legislation whereby penalties serve as effective means of regulation. Such legislation dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger.

\(^{39}\) See, for example, United States v Park, 421 US 658, 672 (1975). The Court noted:

> The requirements of foresight and vigilance imposed on responsible corporate agents are beyond question demanding, and perhaps onerous, but they are no more stringent than the public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that supports them.

\(^{40}\) See, for example, Ellis, 326 F3d at 554; Nutritional Health Alliance v FDA, 318 F3d 92, 98 (2d Cir 2003) (“It is well-settled that the FDC Act should receive a liberal construction when . . . the FDA has taken remedial action in response to a perceived public health problem.”); United States v Sage Pharmaceuticals, Inc, 210 F3d 475, 479 (5th Cir 2000) (“The FDCA's comprehensive scheme of drug regulation is designed to ensure the nation's drug supply is safe and effective.”).
Courts interpreting the “intent to defraud or mislead” language of the felony provision often have used such synonyms as “deception” or “cheating” to further explain the intent requirement. They have found that evidence of misrepresentations about adulterated drugs introduced into interstate commerce, labels that are intentionally misleading, and sales of repackaged drugs as the original product satisfy the statutory intent requirement. In addition, courts have agreed that the intent requirement is satisfied regardless of what party the defendant intended to defraud. Courts have found felony violations of the Act for intending to defraud or mislead the FDA, the Canadian government, local law enforcement, neonatal doctors, and the general public. Where the circuits conflict is in their interpretation of how directly the intent to “defraud” must be tied to the specific violation of the Act.

The circuit’s split over the degree of intent that must be demonstrated to convict a defendant under § 333(a)(2). The Ninth and Tenth Circuits adopted a specific intent standard that requires prosecutors to show that a defendant explicitly intended to violate the FDCA in acting to defraud or mislead a party. The Fourth Circuit adopted a general intent standard that requires only that the prosecutors show that the defendant violated the FDCA while deliberately frustrating the purpose of the regulatory regime. The remainder of Part I.B explores the rationales of the circuits for these very different interpretations of the felony intent requirement.

41 See, for example, United States v Milstein, 401 F3d 53, 70 (2d Cir 2005) (deception); Ellis, 326 F3d at 556 (cheating).
42 United States v Industrial Laboratories Co, 456 F2d 908, 910 (10th Cir 1972).
43 United States v Hiland, 909 F2d 1114, 1121-22 (8th Cir 1990).
44 Milstein, 401 F3d at 70.
45 See, for example, United States v Arlen, 947 F2d 139, 143 (5th Cir 1991) (cabining the Fifth Circuit’s previous decision in United States v Haga, 821 F2d 1036, 1041 (5th Cir 1987), as dicta and misinterpreted, and concluding that government agencies can be the object of fraudulent intent); United States v Bradshaw, 840 F2d 871, 874 (11th Cir 1988). But see Haga, 821 F2d at 1041 (arguing that § 333(a)(2) should be construed to apply only to cases where a seller intends to defraud or mislead purchasers and “not on the theory that a defendant has defrauded or misled the government by evading or violating its regulatory systems”).
46 See United States v Cambra, 933 F2d 752, 755 (9th Cir 1991).
47 See Industrial Laboratories, 456 F2d at 911-12.
48 See Mitcheltree, 940 F2d at 1350.
49 See Hiland, 909 F2d at 1129.
50 See Milstein, 401 F3d at 69 (approving of the Tenth Circuit’s position in Mitcheltree, 940 F2d at 1347-50, that “[b]y misleading governmental agencies, and ‘thereby frustrating their efforts to protect the public,’ [the defendant] ‘indirectly misled and defrauded the public,’ thus contravening the ‘overriding congressional purpose [of] consumer protection’ embodied in [the FDCA]”).
51 See generally Geborde, 278 F3d at 926; Mitcheltree, 940 F2d at 1329.
52 See generally Ellis, 326 F3d 550.
1. Requiring specific intent.

Several circuits have held that in order to commit a felony violation of the Act, a defendant must have the specific intent to defraud or mislead. For instance, in United States v Geborde, the Ninth Circuit held that Lindley Geborde violated § 331(p) by failing to register his GHB production facility, but in so doing he did not specifically intend to defraud or mislead the FDA or his customers. Geborde made the GHB in his van and then gave it to friends and partygoers. He was convicted by a jury of one felony count of violating § 331(p) of the FDCA. The count charged that Geborde was operating a manufacturing facility that was not registered as required under § 360. The prosecution argued that he failed to register the van with the intent to defraud or mislead the FDA and his customers.

On appeal, the Ninth Circuit overturned the conviction. The court was wary of the prosecution of what appeared to be a traditional drug case under the regulatory scheme of the FDCA, noting, “We now have to decide whether the square pegs of Geborde’s conduct can be pounded into the round holes of the FDCA.” The court’s skepticism translated into a very narrow specific intent interpretation of § 333(a)(2). That Geborde was trying to evade law enforcement, in general, was insufficient to establish intent—the defendant had to perpetrate the violation with which he was charged with the specific intent to defraud or mislead. To prevail, the prosecution needed to show that Geborde intended to defraud or mislead the FDA by not registering his production facility. As the court put it, “Congress . . . required that the failure to register be activated by the specific intent to defraud or mislead.” The court found no evidence of this specific intent nor did it suggest any scenario that would satisfy the requirement.

Under this interpretation of the statute, in order to establish specific intent, the prosecution must establish that the defendant knew of the statute. Without knowledge of the registration requirement, the
defendant could not have the specific intent to defraud when violating it. In this case, the court concluded that Geborde did not have knowledge of the § 360(a) registration requirement. 60

The Tenth Circuit essentially agreed with the Ninth Circuit's specific intent interpretation of § 333(a)(2). In United States v Mitcheltree, 61 the defendant was charged with several felony counts of violating § 331, including introduction of misbranded drugs into interstate commerce and failure to register a production facility. The Mitcheltree court held that “there must be a demonstrated link between the § 331 violation and an intent to mislead or defraud an identifiable drug regulatory agency involved in consumer protection.”62 Further, the court held that the defendant must have knowledge of the provisions that he intends to violate to prove an intent to defraud.63 The court wrote that the specific intent interpretation of the felony penalty provision is necessary to give sufficient ground to the misdemeanor violation and effectively serve Congress's intentions. 64 Thus, to support a felony conviction under the FDCA, the Ninth and the Tenth Circuits required a demonstration of specific intent to violate the charged article of § 331.

2. Requiring general intent.

In United States v Ellis, 66 the Fourth Circuit adopted a general intent interpretation of § 333(a)(2). To establish a felony violation of the Act, the court required that the defendant only intend generally to defraud the FDCA's regulatory regime. 67 Ellis addressed another prosecution of an individual for a felony violation of the § 331(p) manufacturing facility registration provision. The evidence was very similar to Geborde. Gary Duane Ellis manufactured GHB in his kitchen and then sold it in interstate commerce. A jury convicted Ellis of a felony violation of § 331(p).

On appeal, Ellis argued for “a narrow statutory interpretation” of section § 333(a)(2), which was similar to the interpretation adopted by the Geborde court. 68 Over a strong dissent, 69 the Fourth Circuit upheld

60 Id (“There was no evidence of Geborde's intent in failing to register, assuming he even knew he was required to register.”).
62 Id at 1345.
63 Id at 1349. The Mitcheltree court also noted that “[d]istributing drugs in knowing violation of federal and state regulatory systems and rules is too general.” Id.
64 Id at 1351.
65 Id at 1349 (“These limitations are consistent with the Supreme Court's prior interpretation of the Act.”).
67 Id at 554.
68 Id at 553.
the conviction. The majority reasoned that the “defraud or mislead” language cannot be interpreted without reference to the underlying statute. According to the court, the felony intent language must be understood in light of the fact that the defendant was accused of violating a provision that “serves a disclosure role necessary for the effective regulation of drugs.”

The court took a broader view of the intent to defraud language, arguing that the FDCA as a whole established a regulatory regime “to protect the public's health and safety against the distribution of impure, adulterated, illicit, and noxious articles.” Following the Supreme Court’s interpretive rule in Dotterweich, the court concluded that the defendant’s intent to defraud need not be focused on the specific violation of the Act charged. The general intent must be to defraud or mislead the regulatory regime. The court stated:

In light of the function of the registration requirement in the FDA’s regulatory oversight scheme, we conclude that “intent to defraud or mislead” under § 333(a)(2) is shown when the evidence demonstrates that the defendant has deliberately frustrated the purpose for which registration is required under § 360(b) and (c), i.e., to provide the required information to the FDA and to facilitate public knowledge of the defendant’s operations. The inquiry, therefore, is whether the defendant designed his conduct to avoid the regulatory scrutiny of the FDA.

By not registering his kitchen while at the same time hiding GHB in unmarked, hidden canisters; and by lying to his suppliers of GHB ingredients about the purpose of his purchases and taking other evasive steps, Ellis exhibited the intent to “defraud” the drug regulatory regime.

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69 Id at 558 (Michael dissenting). The dissent argued:

The majority concludes that specific intent may be proven when the defendant acts with the broad purpose of evading the regulatory scrutiny of the FDA, regardless of whether he is aware of his particular § 331 violation. Such a generalized intent is not sufficient to establish a specific intent to defraud or mislead for a felony conviction under § 333(a)(2). ... [A] § 333(a)(2) felony requires “a knowing violation [of a § 331 provision] with the specific intent 'to defraud or mislead.'”

70 Ellis, 326 F3d at 554.

71 Id.

72 See note 38 and accompanying text.

73 It should be noted that in adopting this standard, the Fourth Circuit granted an argument that the government had repeatedly made in prosecutions under the FDCA. See, for example, Haga, 821 F2d at 1039 n 3 (“The government has advocated ... a liberal construction of the [FDCA] on the theory that ‘because the Act is a public health statute, it should be broadly construed to effectuate its public health purpose.’”).

74 Ellis, 326 F3d at 554.
The court concluded that a jury could have found beyond a reasonable doubt that Ellis violated § 331(p) with the general intent to “defraud or mislead.” Thus the court outlined its general intent interpretation of the FDCA felony punishment provision as applied to the manufacturing facility registration requirement.

C. Comparing Intent Requirements

Limiting the debate to the analysis used by the courts, legitimate arguments emerge for both the specific and general intent interpretations of the FDCA’s felony provision. While the general intent standard seems to give more effect to the way Congress has structured the statute, the specific intent standard is both more popular and more traditional. This Comment argues that the structural argument in favor of the general intent interpretation is stronger, though not dispositive of how the FDCA’s felony intent requirement should be interpreted.

As noted, both the Ninth and the Tenth circuits explicitly adopted the specific intent standard. Several other circuits, while not explicitly adopting the specific intent standard, have at least addressed similar language approvingly. Only the Fourth Circuit has adopted the general intent standard outright, though some language in opinions dealing with felony violations of other provisions of the FDCA moves toward this conclusion. In several prosecutions, though the evidence of the intent to defraud or mislead was not specific to the charged violation of the Act, the prosecutions were affirmed without comment by the court. Additionally, the Eighth Circuit rejected the claim that defendants must have knowledge that they are violating the FDCA, a claim inherent in the narrow specific-intent interpretation. Despite the fact that more circuits have adopted a specific intent standard, these examples demonstrate that, in practice, courts cannot consistently hold to the narrow interpretation.

Alternatively, a compelling structural consistency underlies the Fourth Circuit’s general intent interpretation. The FDCA is structured so that the two punishment provisions within § 333(a) are defined separately from the violations of the Act, which are enumerated in §

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75 It may also be important to note that Ellis had internet printouts concerning the laws regarding the manufacture of GHB. Id at 553.
76 Id at 555.
77 See, for example, Arlen, 947 F2d at 143; Hiland, 909 F2d at 1129.
78 See, for example, Cambra, 933 F2d at 755 (holding that, where the defendant was charged with specific violations such as selling anabolic steroids despite a ban, general efforts to keep the FDA from knowing what he was doing were sufficient to establish specific intent); Industrial Laboratories, 456 F2d at 911 (concluding that lying about whether tests had been done rather than the results of a test was sufficient to demonstrate fraud by distributing adulterated drugs).
79 See Hiland, 909 F2d at 1129 n 21.
The punishment provisions are applied uniformly to the violations of the Act, with several enumerated exceptions,\(^80\) such that each level of punishment should be available for each violation of the statute. Under the general intent standard, courts can actually find acceptable instances of fraudulent intent in violations of § 331(p).

The specific intent interpretation of § 333(a)(2) limits felony prosecution to a very small group of defendants sophisticated enough to directly evade the Act itself. In addition, the Ninth and Tenth circuits mandate some showing that even a defendant who has the requisite knowledge actually violated the Act with some specific fraudulent purpose. Evidence that a defendant was making misbranded drugs or was hiding his factory would not be sufficient if there was no discernable fraud in making the decision not to register.\(^81\) The courts claim that the language and the structure of the Act demand this conclusion and that the interpretation best reserves ground for both the felony and the misdemeanor provisions.\(^82\) Arguably, the actual result is that to prosecute a felony violation of § 331(p) of the Act, the government would have to show evidence that a defendant uttered a specific phrase asserting that his facilities are properly registered and have some additional evidence that he did not actually believe that assertion to be true. Practically, these requirements result in the elimination of the option of felony prosecution under § 331(p), despite the insistence among the circuits that the felony provision is applicable to all provisions of § 331.\(^83\) There appear to be no opinions in any circuit that subscribe to the narrow

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\(^{80}\) See 21 USC § 333(b).

\(^{81}\) See Geborde, 278 F3d at 930 ("[The defendant] may have had the intent to mislead those to whom he distributed GHB, but that is not what he was charged with in Count One."); Mitcheltree, 940 F2d at 1349 ("[Section] 333(a)(2) requires not only proof of misbranding under § 331, but also proof of an intent to mislead or defraud which is connected to the misbranding violation under § 331."). See also Arlen, 947 F2d at 143, which lays out a parallel scenario for the inspection requirement demonstrating this steep specific intent requirement:

For example, an operator of a drug storage facility must permit inspection of his premises when FDA personnel present him with proper credentials and written notice of inspection. If the operator refuses to permit the inspection of his facility because he feels it is an inconvenient time for an inspection, he has committed a willful violation of § 331(f) (failure to permit inspection by FDA), even if his facility fully complies with all FDA regulations. This violation would be punished as a misdemeanor under § 333(a). If, however, the operator refuses to permit inspection because he wants time to clean up his contaminated facility, he has willfully violated § 331(f) with the intent to defraud or mislead the government. This violation would be punished as a felony under § 333(b). Thus we are persuaded that adopting the government’s theory will not lead to felonious convictions for all willful violations.

\(^{82}\) See Mitcheltree, 940 F2d at 1351 ("We are unwilling to blur the distinction between the misdemeanor and felony provisions of § 333(a). The felony provision requires knowledge of the misbranding and proof of specific intent to mislead or defraud connected to the misbranding violation.").

\(^{83}\) See, for example, Arlen, 947 F2d at 142 (referring to the "plain inclusive language of § 333(b), which contemplates both misdemeanor and felony violations for all § 331 offenses").
The Fourth Circuit's general intent interpretation establishes two classes of offenders, both of which actually exist in the world regulated by the FDCA. The general intent interpretation reserves the felony violation for those who act "with bad purpose either to disobey or to disregard" the regulatory regime. Misdemeanor punishment is reserved for those who act innocently but do not take sufficient care to protect the public. It is plausible that Congress intended to punish only a very few offenders of § 331(p) with a felony violation, but the general intent standard seems to give more robust effect to the dual structure of the penalty provisions.

That said, limited to the terms in which the circuits actually debated the issue, namely specific versus general intent, neither of the rationales for how the courts interpreted § 333(a)(2) is very compelling. This Comment argues that by analyzing the source of the courts' intent interpretations a far more compelling solution to the circuit split becomes apparent.

II. FRAUD AND MARKETS

A closer analysis of the actual language of § 333(a)(2), "intent to defraud or mislead," is necessary to developing a more satisfying solution to the circuit split outlined in Part I.B.

At common law, fraud served as the background regulation in markets that were characterized by "sharp conduct, manipulative acts, or unethical transactions."

In such caveat emptor marketplaces, which favored sophisticated participants at the expense of the common public, common law fraud acted to prevent only the most egregious of antimarket behavior.

Under the FDCA, Congress heavily regulated the food, drug, and cosmetic markets with the explicit intent of protecting the public from

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84 Industrial Laboratories, 456 F2d at 911.
85 Ellis, 326 Fd at 554:

[While the inadvertent failure of an ordinarily dutiful and law-abiding operator to register its drug-manufacturing establishment gives rise only to a misdemeanor violation, a defendant's affirmative efforts to conceal his drug-making establishment from the FDA can serve as evidence of an intent to defraud or mislead, as provided in § 333(a)(2).]

This redrawing too has been long sought by the government. See Haga, 821 F2d at 1044 ("The prosecution's original theory of the case, which relied on the premise . . . that anything but an inadvertent distribution of prescription drugs in violation of section 331 should be regarded as a § 333 felony offense.").
86 United States v Brown, 79 F3d 1550, 1562 (11th Cir 1996) ("And, the fraud statutes do not cover all behavior which strays from the ideal; Congress has not yet criminalized all sharp conduct, manipulative acts, or unethical transactions.").
threats for which they lacked sufficient information to protect themselves. Manufacturers and sellers absorbed significant regulatory costs in order to secure the safety of the public. In this explicit public welfare statute, Congress used the word "defraud" to implement felony violations of the Act. This Part argues that determining whether there is a difference between free-market, common-law fraud and public-welfare, regulatory fraud—and if so, what that difference means—is central to resolving the circuit split.

Part II.A explains what the various circuit courts have yet to articulate: that their disagreement stems from differing understandings of "defraud." To differentiate between the courts' interpretations of defraud, Part II.B constructs a model that envisions two general types of fraud statutes in American law. In demonstrating that the FDCA falls into the category of a "focused" fraud statute, it argues that the intent requirement must be general to properly align marketplace incentives with congressional intent.

A. Textual Analysis: "Defraud or Mislead"

The "defraud or mislead" language of § 333(a)(2) is particularly common in American statutory law. Often in slightly different forms and not always used together, the words grace a significant number of criminal and civil statutes. "Mislead" is generally used colloquially, while "defraud" is generally considered a term of art. Neither word has been interpreted uniformly by American courts. As the only language in the FDCA differentiating a felony violation from a misdemeanor violation, the "defraud or mislead" language likely provides the textual basis for the interpretative disagreement among the circuits.

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87 See United States v Park, 421 US 658, 671 (1975); A Brief Legislative History of the Food, Drug, and Cosmetic Act, 93d Cong, 2d Sess at 6 (cited in note 11) ("In an effort to prevent another disaster such as the sulfanilamide poisonings, the Act did provide for pre-market clearance of new drugs to assure safety.").

88 Although courts are ostensibly interpreting the "mislead" language as well as the "defraud" language of § 333(a)(2), the reality is that most analysis focuses on the word with more historical baggage. While recognizing that Congress usually intends each word in a statute to have independent meaning, without more evidence of the reality of this claim in this specific circumstance, this Comment will focus on "defraud."

89 See Ellen S. Podgor, Criminal Fraud, 48 Am U L Rev 729, 731–33 (1999) (discussing how the concept of fraud as well as the term itself have been incorporated into various criminal statutes and molded by the legislature, the Justice Department, and the courts).

90 See United States v Watkins, 278 F3d 961, 966–69 (9th Cir 2002) ("Unlike fraud with its [common law] history in torts as a cause of action and term of art defined by its elements, 'intent to mislead' does not necessarily enjoy such a clear or distinguished pedigree.").

91 See id at 965–66 ("Where Congress uses terms [such as defraud] that have accumulated settled meaning under the . . . common law, a court must infer, unless the statute otherwise dictates, that Congress means to incorporate the established meaning of those terms.") (internal quotation marks omitted).
While none of the courts explicates the textual reasons behind their intent interpretation, this Part attempts to flesh out those reasons.

1. Specific intent and common law fraud.

Common law fraud requires specific intent to cheat or deceive. The common law resisted criminalizing the taking of another’s freely given possessions by deceptive means. Thus, common law intent requirements for fraud were steep, requiring a demonstration of specific intent to defraud. In traditional fraud prosecutions, judgment could not be made simply on the showing that a transaction was particularly lopsided, or that false statements had been made. Rather, prosecutors had to show that particular misrepresentations were made with the specific intent to effect the lopsided transaction. In relatively free markets, fraud law provided a backstop that prevented only the most egregious swindles.

The Ninth Circuit in Geborde implicitly read the “defraud or mislead” language of § 333(a)(2) to import this standard common law understanding of fraud into the FDCA. The court reasoned that “[t]o prove a case of felony failure to register, the government had to prove that the failure to register was committed with fraudulent intent.” In common law fraud, fraudulent intent cannot be inferred from a simple failure to do something; prosecutors must prove a defendant’s specific intent not to do that something. Likewise, the Geborde court noted that showing a failure to register is not sufficient to violate the Act, even if that failure is

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92 See Black's Law Dictionary 687 (West 6th ed 1990) (defining “promissory fraud” as a “promise to perform made when the promisor had no intention of performing the promise”).

93 See Sanford H. Kadish and Stephen J. Schulhofer, Criminal Law and Its Processes: Cases and Materials 976 (Aspen 7th ed 2001) (“The early common law, influenced by the ethic of caveat emptor, declined to treat as criminal situations in which a person acquired another’s property through simple deception.”).


95 See, for example, NY Penal Law § 155.05(2)(d) (McKinney 2000):

A person obtains property by false promise when, pursuant to a scheme to defraud, he obtains property of another by means of a representation. . . Such a finding may be based only upon evidence establishing that the facts and circumstances of the case are wholly consistent with guilty intent or belief and wholly inconsistent with innocent intent or belief, and excluding to a moral certainty every hypothesis except that of the defendant’s intention or belief that the promise would not be performed.

96 278 F3d at 930 (emphasis omitted).

97 See Club Car, Inc v Club Car (Quebec) Import, Inc, 362 F3d 775, 783 (11th Cir 2004), cert denied 125 S Ct 618 (2004) (holding that a conviction for mail fraud “requires proof of a specific intent to defraud or deceive”); William L. Prosser, Handbook of the Law of Torts 701 (West 4th ed 1971) (“An honest belief, however unreasonable, that the representation is true and the speaker has information to justify it . . . [is] no sufficient basis for [the crime of] deceit.”).
coupled with a general criminal intent. Instead, the court held, the fraud must be perpetrated with regard to the specific violation with which the defendant is charged. Thus the Geborde court interpreted the § 333(a)(2) felony provision to incorporate into the FDCA the common law definition of fraud, at least with regard to scienter.

The Ninth Circuit is not alone in concluding that the "defraud" language imports the common law fraud intent requirement. The "any scheme or artifice to defraud" language of the federal mail fraud statute is consistently interpreted to import the common law fraud intent requirement. The federal wire fraud statute, which uses identical language, is interpreted in the same manner. Courts' interpretations of the intent required under these federal fraud statutes are very similar to the narrow specific intent requirement adopted in Geborde. As one court put it, the defraud language in the federal fraud statutes requires "conscious knowing intent to defraud" directed specifically at the property rights of the victim.

The common law intent standard is very similar to the one used in Geborde. In addition, the practice of importing common law intent requirements into statutory fraud language is pervasive in American law. Thus, there is persuasive evidence that common law fraud is the source of the Geborde court's interpretation of the "defraud or mislead" language in § 333(a)(2). However, common law fraud is not the only source for fraud definitions in American law.

2. General intent and regulatory fraud.

The general intent interpretation of the "fraud" scienter requirement is an understanding of the term unique to comprehensive regulatory schemes. The Securities Exchange Act of 1934 ("Exchange Act") established a "fraud" crime with a significantly different intent requirement than common law fraud. In the wake of the 1929 stock market crash, the Exchange Act was imposed on a market previously

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98 278 F3d at 930 ("It is not enough for felony treatment that Geborde may have intended to evade the watchful eyes of local or federal authorities. That is already implicit in simple failure to register, which is itself an evasion of the FDA enforcement process.").

99 Id.

100 18 USC § 1341 (2000).

101 See, for example, United States v Walker, 191 F3d 326, 334 (2d Cir 1999) (requiring proof of fraudulent intent, or the "specific intent to harm or defraud the victims of the scheme").


103 See, for example, United States v Rivera, 295 F3d 461, 466 (5th Cir 2002) (holding that a conviction for wire fraud "requires proof of the specific intent to defraud or deceive").

104 United States v Autilori, 212 F3d 105, 116 (2d Cir 2000) (interpreting the language of both the mail and wire fraud acts) (internal citation omitted).

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regulated only by common law fraud limitations, with the express intent of providing more investor protection. Securities laws established a highly complex series of requirements that individuals and firms must adhere to in order to participate in regulated securities markets. To enforce these requirements, judges interpreting the Exchange Act expressly rejected the common law fraud specific intent requirement in favor of a general intent standard that coupled violation of a specific prohibition with the general intent to undermine the securities regulatory regime. Scholars have noted that a defendant may be convicted of a criminal violation of the securities laws given "any deceit that materially affects the purchase or sale of securities." Judge Friendly, in what is still the generally accepted standard for securities fraud, noted that in proving a violation, no specific intent on the part of the defendant need be demonstrated; the prosecution need only prove that the defendant "had some evil purpose."

The FDCA and the Exchange Act were adopted within four years of each other—contemporaries in a heady era of regulation. Importantly, the Exchange Act has been litigated significantly more often than the FDCA. Court decisions in these cases have fleshed out the Exchange Act's intent requirement, and some uniformity of interpretation has been achieved through Supreme Court guidance.

The comparison between the FDCA's statutory use of "defraud or mislead" and the penalty statute for securities fraud is not perfect

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106 See John C. Coffee, Jr., and Joel Seligman, Securities Regulation 2 (Foundation 9th ed 2003) (stating that one purpose for the Act was that "investors were vulnerable in a manipulated marketplace").

107 See Ernst & Ernst v Hochfelder, 425 US 185, 195 (1976) (noting that the Exchange Act was intended to protect investors through "regulation of transactions upon securities exchanges and in the over-the-counter markets, and to impose regular reporting requirements on [public] companies").

108 See Santa Fe Industries, Inc v Green, 430 US 462, 475 (1977) (holding breach of fiduciary duty required to violate Rule 10b-5 need not involve deception); United States v Lincecum, 2000 US App LEXIS 18047, *7–9 (2d Cir) (explaining that defendants need not be fully aware that their acts are unlawful for them to have acted fraudulently within the meaning of the securities laws). See also Paul Marcus, The Use of Criminal Statutes to Regulate Financial Markets in the United States, 46 Am J Comp L 589, 600 (Supp 1998) (explaining that "[n]ot all courts require a showing of intent to violate the law" in addition to the material misrepresentation or omission and that "realization" of noncompliance may be sufficient).

109 See, for example, Steven Amchen, Jessica Cordova, and Paul Cicero, Securities Fraud, 39 Am Crim L Rev 1037, 1042 (2002).


111 See Green, 430 US at 474–76 (requiring deception); Hochfelder, 425 US at 193 (requiring evidence of intentional misconduct).
because the latter uses the term "willfully,"\textsuperscript{112} which has its own intent and scienter connotations. Nevertheless, the Exchange Act does help to explain the Fourth Circuit’s understanding of "defraud." The Supreme Court has interpreted the intent requirement of the Exchange Act as the "intent to deceive, manipulate, or defraud."\textsuperscript{113} As an interpretation of fraud in a highly regulated market, the Exchange Act and its corresponding jurisprudence provide a viable alternative definition of the intent requirement established by "the intent to defraud or mislead" language.

The Fourth Circuit implicitly utilized this conception of what might be called regulatory fraud to interpret § 333(a)(2). The court concluded in \textit{Ellis} that the § 331(p) registration requirement plays a fundamental role in the FDCA’s regulation of the market for drugs by facilitating the FDA’s inspection responsibilities.\textsuperscript{114} From this understanding, the court concluded that "intent to defraud or mislead" under § 333(a)(2) is shown when the evidence demonstrates that the defendant has deliberately frustrated the purpose for which registration is required. . . . The inquiry, therefore, is whether the defendant designed his conduct to avoid the regulatory scrutiny of the FDA."\textsuperscript{115} This standard clearly does not require that the defendant have narrow specific intent with regard to the particular provision that he is accused of violating. Rather, like the Exchange Act’s interpretation of fraud, the \textit{Ellis} standard requires that the defendant intend to defraud the general statutory scheme through a violation of a specific statutory provision.\textsuperscript{116} With this relaxed standard, the regulatory fraud interpretation of "to defraud or mislead" maintains a scienter requirement while ensuring a greater ease of prosecution than with the background common law standard.

The Fourth Circuit is not alone in adopting a regulatory fraud interpretation of the "intent to defraud" language. Other courts have interpreted "fraud" language in other statutes to have a similar regulatory fraud–type meaning. For example, the Eighth Circuit, interpreting the "intent to defraud" language in the Federal Meat Inspection Act,\textsuperscript{117}

\begin{itemize}
  \item \textsuperscript{112} 15 USC § 78(ff) (2000).
  \item \textsuperscript{113} Hochfelder, 425 US at 193. Importantly Hochfelder actually tightens the mens rea standard for fraud under the securities laws, holding that negligence is insufficient to meet the fraud standard. Nevertheless, the Court still rejected a specific intent standard. Id at 214.
  \item \textsuperscript{114} 326 F3d at 554 ("This registration is the mechanism by which the Secretary is advised of premises subject to the Secretary's regulation and that a Department official must inspect periodically.").
  \item \textsuperscript{115} Id.
  \item \textsuperscript{116} Id at 556. Compare Dixon, 536 F2d at 1397.
  \item \textsuperscript{117} 21 USC §§ 601–95 (2000). The Federal Meat Inspection Act also imposes significant regulatory requirements on a market and is often interpreted in parallel with the FDCA. See, for example, United States v Hiland, 909 F2d 1114, 1128 n 18 (8th Cir 1990).
\end{itemize}
rejected a common law understanding of fraud in favor of a regulatory fraud interpretation. 118

Regulatory fraud, and a corresponding general intent requirement, is a viable interpretation of the statutory use of fraud language. Thus, the Ellis-Geborde circuit split arises out of competing, facially legitimate interpretations of the § 333(a)(2) “defraud or mislead” language. A recent Supreme Court case offers some guidance in choosing between these two different interpretations of the “defraud” language.

B. Neder v United States: Mandating the Common Law Interpretation?

To the extent that canons of construction can be determinative, 119 it is well established that where Congress uses a term which has a well-settled meaning under the common law, Congress intends, unless otherwise indicated, that the term incorporate its common law definition. 120 Determining which terms have a settled meaning under the common law usually poses the difficulty in using this canon. Given the varied nature of the common law in the United States, the terms that have reached such settled status are generally few. 121

In Neder v United States, 122 the Supreme Court was faced with determining whether the federal fraud statutes—the mail fraud, 123 wire fraud, 124 and bank fraud 125 statutes, each of which uses the “scheme or artifice to defraud” language—contain a materiality requirement. 126 The Court indicated, without debate, that “fraud” was a word that has “a well-settled meaning at common law.” 127 The Court therefore adopted a presumption that Congress, by using the term “defraud,” intended to incorporate the requirements of common law fraud into the federal fraud statutes. 128 The practice of importing of common law definitions

118 See United States v Jorgensen, 144 F3d 550, 559 (8th Cir 1998) (“Judicially adding a materiality requirement when none exists in the statutory text would not further congressional intent and would instead hinder it.”). The Eighth Circuit addressed the issue with regard to materiality, however, not intent.


121 See, for example, Nationwide Mutual Insurance Co v Darden, 503 US 318, 322–23 (1992) (using the common law definition of “employee”); Standard Oil Co of New Jersey v United States, 221 US 1, 59 (1911) (using the common law definition of “restraint of trade”).


126 527 US at 20.

127 Id at 22.

128 Id at 23.
into a settled term is relatively robust. The Court explained that even if other statutes explicitly specify the common law requirements of the terms, it cannot be assumed, expressio unius, that a statute not listing some or all of the terms intends to drop those requirements. Rather, the Court indicated that any rebuttal of the presumption of common law importation must “only come from the text or structure of the fraud statutes themselves.” The Court found no such rebuttal of a materiality requirement in the “scheme or artifice to defraud” language or any other aspect of the federal fraud statutes.

At first glance, this decision seems like a powerful argument in favor of the Ninth Circuit’s interpretation of § 333(a)(2). The “intent to defraud or mislead” language seems particularly well suited to the Neder argument that Congress meant to incorporate the intent requirement from the common law of fraud. Indeed, a different panel on the Ninth Circuit (curiously not cited by Geborde) followed the reasoning in Neder by applying the common law materiality requirement to § 333(a)(2) of the FDCA, though not for the specific intent requirement.

In United States v Watkins, the Ninth Circuit concluded that Congress incorporated the materiality requirement of common law fraud by adopting the “intent to defraud or mislead” language. The court held that interpretation of the meaning of a statute could not stop at the natural reading of the text if any of the words used have a settled meaning under the common law. The court then adopted Neder’s conclusion that the meaning of fraud is indeed settled and that it thus imports the materiality requirement from the common law.

A similar argument easily could be inserted into the Geborde court’s decision. The dual structure of § 333(a) establishes § 333(a)(1) as a strict liability misdemeanor; § 333(a)(2) allows for larger fines and more jail time, and thus must have a scienter requirement. Analyzing the “intent to defraud” language for that requirement provides an even better argument for the Neder analysis than materiality. The phrase itself directs the court to the “defraud” language to establish the statute’s scienter requirement. Under the Neder canon of construction, the common law specific intent requirement seems to be the natural interpretation of the language in the felony provision of the FDCA.

129 Id at 23 n 7.
130 Id at 24–25 (declining to use common law definitions for “justifiable reliance” and “damages” because a scheme to defraud need not be a “completed fraud,” so using the common law definitions would impose requirements upon the prosecutor not intended by Congress).
131 See Part II.A.
132 278 F3d 961 (9th Cir 2002).
133 Id at 966.
134 Id at 965.
135 Id.
Reading Watkins and Geborde together in this manner is a consistent application of the incorporation principle behind Neder. Given the history of common law fraud as an arbiter of last resort in free markets, the materiality requirement and the specific intent requirement seem to work in tandem. Both requirements find fraudulent conduct only where the conduct at issue is particularly underhanded, the kind that should not be allowed under any circumstances. Whereas the materiality requirement screens the trivial cases—where the fraud at issue will have little effect on the participants or the market—the specific intent requirement eliminates the borderline cases—one-sided, market transactions that might still be considered acceptable. Together, the reasoning in Watkins and Geborde establishes a common law interpretation of fraud at the center of the FDCA felony provision.

This conclusion that § 333(a)(2) incorporates the common law definition of “defraud” is only obvious and natural if the interpretation of the scienter requirement is limited to a narrow textual analysis of § 333. Neither Watkins nor Geborde gave sufficient weight to the structure and purpose of the FDCA in determining how to interpret § 333(a)(2). In addition, Neder stated that the structure of a statute can rebut the presumption that terms with settled meanings at common law retain those meanings. Watkins acknowledged that the purpose of the FDCA might also rebut the presumption that the statutory text incorporates the common law meaning. The next Part explains how the structure and purpose of the FDCA differentiate it from the federal fraud statutes in a way that effectively rebuts the presumption that “defraud” in the FDCA should be interpreted in accordance with the common law.

C. Structure and Purpose: Two Frauds

All language, including legal language, is multivalent. The word “defraud” reasonably can be interpreted to have two different meanings in two different statutes. Neder established a rebuttable presumption that Congress intended “defraud” to incorporate its common law meaning; rebuttal of this presumption requires evidence expressed in the characteristics of the individual statute. A specific textual rebuttal necessarily overcomes the presumption of absolute incorporation. For example, the False Claims Act uses fraud language in describing its

136 See Coffee and Seligman, Securities Regulation at 1–2 (cited in note 106) (arguing that while some markets demand government regulation to even out untenable inconsistencies, other markets can function efficiently with common law fraud as the only legal constraint).
137 See text accompanying note 129.
138 278 F3d at 966.
139 31 USC § 3729 et seq (2000).
violation, but explicitly states that specific intent is not required. However, this explicit modification does not establish that "defraud," as used in the False Claims Act, does not import the remainder of the common law fraud characteristics. Thus laws using "defraud" can be tailored to accommodate the explicit variations of the legislators without necessarily rebutting the more general presumption of common law importation.

Alternatively, "defraud" might be used in an entirely different context such that a whole new tradition develops within the law. If a tradition developed sufficiently, the significantly different purpose of a statute would be an effective rebuttal of the general incorporation presumption. When it is clear that a word is actually being used differently than at common law, Neder allows for complete rebuttal of common law incorporation.

This Comment contends that Congress uses entirely different meaning of "fraud" in a certain set of statutes, including the FDCA, and although the term "defraud" may have roots in the common law, the specific requirements of that heritage have been left behind.

1. Generic fraud statutes and focused fraud statutes.

Federal statutes that use the term "fraud" can be divided structurally into two separate categories. Generic fraud statutes consist of a statutory element to provide federal jurisdiction and general principles of common law fraud. The jurisdictional hook in these statutes plays almost no role in the offense. The federal mail, wire, and bank fraud statutes are good examples of generic fraud statutes in that they are essentially codified common law fraud with a variety of minimally intrusive jurisdictional elements. Generic fraud statutes are essentially federalized common law fraud, where the main focus of prosecutions under the statute is the establishment of fraud.

140 Id § 3729(a).  
141 Id § 3729(b)(3).  
142 See note 130 and accompanying text.  
143 See text accompanying note 129.  
144 Podgor, 48 Am U L Rev at 734 (cited in note 89).  
146 See Pereira v United States, 347 US 1, 8 (1954).  
147 See Neder, 527 US at 23.  
148 For example, courts have interpreted the mail fraud statute to diminish the importance of the mailing requirement. Courts have held that a defendant need not actually use the mail himself or even know that a mailing occurred; it is enough that a mailing was caused by his actions and that it was at least incident to an essential part of the scheme. Id at 8. The wire and bank fraud statutes have been interpreted in a similar manner. See, for example, United States v Garlick, 240 F3d 789 (9th Cir 2001).
In focused fraud statutes, fraud is required, but the violation prosecuted is specific to the statute's focus. The statute itself establishes a series of duties and the fraud language only defines the way in which an individual might violate those duties. The Exchange Act, for example, provides for prosecution of fraud, but only as part of a particular violation of a securities market regulation. The Federal Meat Inspection Act and the FDCA are other good examples of focused fraud statutes. In these statutes, "fraud" no longer defines the offense but rather implements the language of the specific violations enumerated by the regulation. "Fraud" establishes the requisite evil intent of a defendant who submits a faulty disclosure form or introduces a misbranded drug into interstate commerce.

The generic fraud statutes essentially fill the role that common law fraud holds at the state level. They act to enforce the upper boundary of acceptable conduct in unregulated markets. Chief Justice Burger referred to the mail fraud statute as a "stopgap device" and focused on its ability to "deal on a temporary basis with the new phenomenon, until particularized legislation can be developed." The mail fraud statute occupies this role in markets where Congress chooses not to pass particularized legislation for fear of overregulating efficient commerce.

It is thus no coincidence that Neder concluded that Congress incorporated the common law understanding of fraud in the federal fraud statutes. The statutes mirror the common law in scope, applying broadly to any fraudulent activity, subject only to the minimal constraint of their jurisdictional hook. If the structure and purpose of the fraud statute (its scope) are very broadly defined and the defini-
tion of what constitutes fraud (its applicability) is also very broad, the statute would risk arbitrary enforcement, interference in well-functioning markets to the detriment of all participants, and an over-criminalization of daily life. Statutes with such broad scope, reaching pervasively into markets in every aspect of modern American life, must naturally be alternatively limited in applicability. Neder incorporation limits the federal fraud statutes by imposing a materiality requirement and a very narrow specific intent requirement. The Neder incorporation rule thus makes particular sense in statutes where the structure and purpose of the statute provides no meaningful limitations on the crime. In effect, where a fraud statute is applied in a market that Congress has not regulated, the Neder doctrine limits federal fraud statutes to enforcing only the traditional fraud backstop. Rather than proceeding entirely without guidance by substituting their own interpretation for Congress’s, the courts are constrained by the characteristics of common law fraud. Thus potential defendants have notice of what activity is prohibited by the federal fraud statutes because of the narrow definition of common law fraud and the incorporation of that definition into the federal fraud statutes.

The limiting effects of Neder incorporation are unnecessary for “focused” fraud statutes. The structure and purpose of the Exchange Act and the FDCA (among other statutes) already provide a very specific framework within which the court is asked to punish fraud. Section 331 of the FDCA enumerates prohibited conduct that impedes federal oversight of the industry. Within the tightly delineated boundaries of the regulated market, the strict common law controls on fraud are not necessary. In regulated markets, judges have detailed enumerations of specific prohibitions to guide their discretion. Potential defendants are put on notice by the substantive provisions of the statute, which carefully lay out acceptable conduct. “Fraud” language


157 See text accompanying note 128.

158 See, for example, United States v Gay, 967 F2d 322, 329 (9th Cir 1992) (explaining that the mail fraud statute incorporates the traditional common law “puffery” defense and thus only truly fraudulent behavior will be punished).

159 See Neder, 527 US at 22.

160 See United States v Gartman, 145 F Supp 420, 421 (ED Pa 1956) (holding that the mail fraud statute is not unconstitutionally vague).

is still used because it is a traditional hallmark of market regulation. But the “focused” fraud statute requires different qualifications from its fraud language.

"Fraud" in this case is being used in a highly regulated market where the government has consciously placed burdens on suppliers in order to establish a regime that protects the uninformed public. Rather than the narrowly constrained common law characteristics that are appropriate in an unregulated market definition of fraud, a broader definition of fraud is appropriate to shift the burden onto knowledgeable parties in the regulated market context. In the illegal drug context, strict liability requires every person dealing in drugs to ascertain whether the drugs he is selling fall within the prohibitions of the Act. Similarly, the Court in *Dotterweich* applied this argument to regulated industries affecting the public interest. A broader definition of intent forces those dealing in drugs to ascertain the regulations applicable to them (for example, registration) and act accordingly. As is the case in the strict liability context, the broad intent requirement puts the burden of acting hazardously (by distributing and manufacturing drugs) upon a person who does not have knowledge but is standing in responsible relation to a public danger. Importing the common law restrictions risks enacting the high bar appropriate for generic fraud statutes and undermining the carefully calibrated regulatory incentives of the FDCA.

Thus, descriptively, there are two types of fraud statutes. The generic type incorporates the narrow specific intent requirements of the common law, regulating as an upper bound any markets absent substantive guidance from the legislature. The “focused” type, which operates in regulated markets with significant legislative guidance, uses a different definition of fraud given the entirely different circumstances in which it operates. The general intent interpretation of § 333(a)(2) requires a specific violation of the statute coupled with the intent to undermine the regulatory scheme. This standard embodies the inter-

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162 See *Dotterweich*, 320 US at 285:
Balancing relative hardships, Congress has preferred to place it upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless.

163 See *United States v Balint*, 258 US 250, 254 (1922).
165 See *Balint*, 258 US at 254. The theory has been applied to justify broader application of statutes in other regulatory contexts. See *Mueller v Sullivan*, 141 F3d 1232 (7th Cir 1998) (applying this principle to the regulation of securities fraud).
166 See note 87 and accompanying text.
pretation of fraud used in "focused" fraud statutes to implement the rigorous regulations.

This two-fraud model is supported by *McNally v United States*, a Supreme Court decision that fleshed out the model's regulation-versus-implementation distinction. That case is discussed in the next Part.


*McNally* addressed whether the mail fraud statute could be applied to defend "certain intangible rights" (specifically, in honest government operation) from schemes or artifices to defraud using the mail. The Court cited many of its own prior rulings that indicate that at common law prosecutions for fraud were limited to deprivations of property rights. After an interesting analysis invoking the rule of lenity, the Court concluded that the mail fraud statute should be understood to incorporate the common law understanding of fraud and thus is limited in scope to the protection of property rights. The Court answered specifically the claim that the mail fraud statute should be interpreted to protect general public interests by preventing any type of fraud against the government, concluding that "any benefit which the Government derives from the statute must be limited to the Government's interests as a property holder.

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168 Id.
169 Id at 352.
170 Id at 358 ("[T]he Court long ago stated . . . the words 'to defraud' commonly refer 'to wronging one in his property rights by dishonest methods or schemes.'"), quoting *Hammer-schmidt v United States*, 265 US 182, 188 (1924); 483 US at 359 n 8, quoting *Carley v United States*, 130 F.1, 6 (1st Cir 1904) ("Quite likely the word 'defraud,' as ordinarily used in the common law, and as used in English statutes and in the statutes of our states, enacted with the object of protecting property and property rights of communities and individuals . . . has reference to frauds relating to money and property.").
171 *McNally*, 483 US at 360. The Court's ruling was partially reversed by Congress, but only with regard to the particular "intangible right to honest services." *Cleveland v United States*, 531 US 12, 20 (2000) (indicating that federal courts have found the federal fraud statutes inapplicable to a wide variety of "intangible rights" despite the legislative reversal). Congress passed a new fraud statute, Anti-Drug Abuse Act of 1988, Pub L No 100-690, § 7603(a), 102 Stat 4181, 4508, codified at 18 USC § 1346 (2000), which specifically defined "scheme or artifice to defraud" for the purposes of the particular statute as "scheme or artifice to deprive another of the intangible right of honest services." Id. However, this statutory revision should not be understood to overturn the *McNally* conclusion that common law fraud is limited to enforcing property rights. First, Congress made a statutory change in the law. Interpreting the common law is the province of the Court and that historical interpretation is unaffected by Congress's legislating. See *United States v Sawyer*, 239 F3d 31, 39 (1st Cir 2001). Second, *McNally* still applies to all other intangible rights, preventing the federal fraud statutes from reaching the "rights" at issue in the FDCA. See *Cleveland*, 531 US at 20.
McNally fleshes out the two-fraud model, which is sufficiently elaborate to rebut the presumption of common law incorporation. Common law fraud, and by extension, the federal fraud statutes, may be applied only to market transactions—that is, those cases where property is at stake. In contrast, "focused" fraud statutes like the Exchange Act and the FDCA, establish multiple duties that do not involve property issues. For example, the central issue in the specific-intent-versus-general-intent circuit split involves the duty to register a production facility with the government. As in McNally, there is no plausible deprivation of money or property that is a key element of this violation, yet registration is necessary to the regulatory scheme because it makes inspections possible. If the "defraud" language in § 333(a)(2) incorporated its common law characteristics, there could be no felony violation of § 331(p) because no property rights are at stake. Consider the situation in United States v Arlen, in which steroids were mislabeled not to deceive the customer, who has a property interest, but to mislead the government agency in charge of regulating the conduct at issue. There was no tax interest, as the sale simply would not have happened without the fraud that allowed Arlen to avoid the government, which otherwise would have stopped the sale. Once again, there was no property interest on the part of the government, the party being defrauded. If § 333(a)(2) incorporated common law characteristics, Arlen and other similar defendants would not be subject to felony punishment. To avoid this scenario, courts have consistently found that § 333(a)(2)’s “intent to defraud or mislead” language applies to non-property interests, thereby avoiding “frustrating their efforts to protect the public.”

McNally is not simply dispositive of the circuit split in the facially obvious manner—demonstrating that the common law fraud interpretation of the § 333(a)(2) language must be wrong because it eliminates felony punishment for a significant number of the § 331 prohibitions. This interpretation is obviously flawed. As discussed in Part II.B.2, Neder reasoned that if the text or structure of a statute contradicts any of the imported common law characteristics of fraud, that specific element of the imported characteristics can be severed. Just as the explicit denouncement of specific intent in the False Claims Act may sever only that characteristic of common law fraud, so too may this

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173 See text accompanying note 143.
174 See 21 USC § 331(p).
175 See Ellis, 326 F3d at 554.
176 947 F2d 139 (5th Cir 1991).
177 Id at 143–44.
178 See United States v Milstein, 401 F3d 53, 69 (2d Cir 2005), quoting Mitchellree, 940 F2d at 1348.
obvious structural contradiction sever only the property-exclusive characteristic of common law fraud. At first glance, *McNally* demonstrated only that the Ninth Circuit’s common law fraud interpretation does not import the *McNally* doctrine along with the other characteristics of common law fraud.

This limited specific rebuttal is an overly narrow understanding of the implications of *McNally*. The decision should be understood to solidify the argument that Congress actually uses “fraud” language in two important and independent ways. Generic fraud statutes have wide scope to arbitrate those property law disputes that fall within their narrow applicability (materiality, specific intent, property-focus). These qualifications establish generic fraud statutes as a “stopgap” for egregious violations in unregulated markets.

Focused fraud statutes, however, are narrowly constrained in scope by the contours of their numerous regulations. With the issues that will arise thus narrowly tailored, focused fraud statutes have broad applicability to implement the statutes’ regulations against defendants violating property or less tangible rights under those statutes. The FDCA has a significant list of statutory prohibitions, which attempt to clearly outline the duties of market participants. As discussed in Part II.A.2, it is clearly a focused fraud statute. Attempting to apply the narrow applicability standards of the Ninth Circuit’s specific intent interpretation to the FDCA felony punishment provision, even without the burden of *McNally*, disturbs the regulatory balance of the model. It overly constrains the ability of judges to enforce felony violations of the act per the dictates of the Supreme Court. The narrow applicability of common law fraud is perfect for the role of generic fraud statutes structured to prevent only the most egregious market violations. But focused fraud statutes like the FDCA are structured specifically to prevent not only egregious violations, but also serious ones, medium ones, and even little ones. The dual punishment provision of § 333(a), which punishes even accidental violations, makes this clear. To punish only the most egregious violations with felonies does not comport with the structure of the Act. Thus the two-fraud model demonstrates that the structure and purpose of the FDCA rebuts the *Neder* presumption of the incorporation of common law fraud qualifications through statutory fraud language. The use of “fraud” in the FDCA felony punishment provision is best interpreted in light of the regulatory fraud model used in statutes like the Exchange Act. A gen-

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179 See notes 38–39 and accompanying text.
180 For one thing, the federal fraud statutes would likely apply, even despite the Act, to punish egregious property violations in the legal drug market, thus making the use of a similar conception of fraud in acts like the FDCA somewhat redundant.
eral intent requirement, such as that adopted by the Fourth Circuit, best provides the flexibility required by these regulatory statutes. The FDCA's "intent to defraud or mislead" language thus should be read to incorporate a regulatory fraud scienter requirement.181

III. SQUARE PEG, ROUND HOLE: REVISITING THE NINTH CIRCUIT'S CONCERNS

The Ninth Circuit in the Geborde decision seemed to apply such a narrow intent standard partially because the court reasoned that the narrow standard was the appropriate interpretation of the § 333(a)(2) language, but also because the court was concerned that the prosecution had applied an inappropriate statute to prosecute Geborde for his GHB-related activities.182 In light of this Comment's argument that the structure and purpose of the FDCA establish it as a comprehensive regulatory regime implemented to protect the health and safety of the public, how could it possibly apply the square peg of drug prohibition to the round hole of legal drug market regulation?

The first response is that Geborde's distribution of GHB is a severe threat to the public health.183 The Supreme Court's decision in Dotterweich expressly states that the intent of the Act is to protect a particular public—those at risk from lack of information, deceptive marketing tactics, and lack of safety testing.184 The Act puts the onus on manufacturers like Geborde, who choose to enter a highly regulated market, to find out the relevant regulatory standards.185 If the CSA applied, the same argument would hold for manufacturers and dealers in the illegal market.186 But, the CSA does not provide an adequate response because of the significant time delay in scheduling drugs and the inability of the schedulers to keep pace with evolving drug threats. Congress, perhaps sensing that there were situations in which it would be unable to criminalize drugs for whatever reason, made the FDCA a prior-approval statute, mandating that a drug receive approval before distribution. The FDCA thus has the flexibility necessary, and the tools available, to protect the public from the problem of designer drugs.

181 Whether the FDCA also demands an interpretation of the materiality requirement at odds with the common law is beyond the scope of this Comment. However, the same logic of the two-fraud model implies that the Ninth Circuit also got the materiality interpretation wrong in Watkins, 278 F3d at 966. See United States v Lagrou Distribution System, Inc, 2004 US Dist LEXIS 1276, *8 (ED Ill) (arguing that the conclusion in Watkins is not an appropriate reading of Neder).
182 See text accompanying note 19.
183 Remember, one of Geborde's customers died from GHB toxicity. See note 55.
184 See note 38 and accompanying text.
185 See text accompanying notes 163–165.
Second, GHB is a drug explicitly regulated by the FDCA. When regulated by a focused fraud statute with a uniform penalty provision, the standards of the statute should be the same for all regulated parties. Imagine that the drug at issue was a dangerous unapproved pill being given away as a promotion for a big drug company. The system’s incentives would be inappropriately calibrated if that corporation could avoid felony punishment by not learning of the appropriate registration requirements. Geborde manufactured a regulated drug, and he knew that it was not something that he could just buy over the counter. The duty is placed on the manufacturer to find out what he had to do to manufacture the drug within the bounds of the FDCA.

It could be argued that Geborde is essentially a de minimis violator, not nearly the threat to the public health that larger corporations might pose. However, that claim ignores the history of the FDCA, which was passed in the early 1930s in part to regulate the small-time charlatans and hustlers who were peddling cures like the “Elixir of Sulfanilamide” town-to-town and door-to-door.\(^{187}\) Congress intended to sweep up threats to the public health both large and small in its comprehensive regulation. When someone like Geborde acts to defraud the government or his customers with his illegally manufactured drugs and hides from the government by not registering his production facility, he should be punished with a felony violation like any other drug manufacturer.

Finally, that the FDCA is used somewhat as a stopgap measure for prosecuting Geborde until GHB is scheduled does not make it like the federal fraud statutes. GHB is regulated by the FDCA—even if it is soon to be regulated in a different manner. The FDCA does not reach out to apply its fraud provisions to something that is not within the narrow scope of the Act. That narrow scope justifies the broad general applicability of the fraud standard. The federal fraud statutes are barely limited in scope and need to be otherwise restrained by the strict confines of common law fraud. Thus, despite concerns about overreaching, the general intent standard is the appropriate standard to apply to the fraud language of the FDCA’s felony provision.

**CONCLUSION**

The FDCA establishes a comprehensive regulatory regime for all drugs that do not fall within the prohibitions of the CSA. The purpose of this regime, to protect the public health, has been recognized by the Supreme Court as the key principle in interpreting the statute. Thus,

\(^{187}\) See A Brief Legislative History of the Food, Drug, and Cosmetic Act, 93d Cong, 2d Sess at 3 (cited in note 11).
the circuit split that has arisen over the interpretation of the felony punishment provision of the FDCA must be analyzed with this concern in mind. The courts involved in the split have not provided sufficient rationales to resolve the split based on only the distinction between specific intent and general intent. But looking beyond the rhetoric of the courts to the basis for their distinctions reveals that the split actually involves two conceptions of fraud, one identified with the common law of fraud and the other associated with more modern regulatory regimes. Adopting the regulatory conception of fraud, with its broader intent standard, best gives effect to Congress's purpose in enacting the FDCA and effectively rebutts the presumption in favor of common law incorporation.