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# THE PERVASIVELY REGULATED BUSINESS EXCEPTION AND THE FDA

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Section 704 of the Federal Food, Drug and Cosmetic Act<sup>1</sup> authorizes the Food and Drug Administration to conduct inspections of regulated business establishments. In the statute, Congress required that the inspections be at reasonable times and within reasonable limits and in a reasonable manner.<sup>2</sup> Congress further restricted the inspections from including general financial and personnel data, and research data not relating to specially regulated drugs.<sup>3</sup>

The inspections authorized by the Federal Food, Drug, and Cosmetic Act are an extremely important tool for FDA enforcement. In 1989, FDA conducted 17,740 factory inspections.<sup>4</sup> The FDA enforcement scheme is premised on the belief that most businesses will comply with regulations voluntarily.<sup>5</sup> Litigation, as a primary enforcement tool, would waste much time and money on a few individual cases while leaving the rest of the industry without policing or even information concerning legal duties. Inspections, however, allow FDA officers to point out to businesses any regulatory infractions. Business owners, in the majority of cases, can then correct the infractions voluntarily.

The Federal Food, Drug and Cosmetic Act does not require FDA

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<sup>1</sup>21 U.S.C. 374.

<sup>2</sup>21 U.S.C. 374 (a)(1)(D).

<sup>3</sup>*Id.* See 505(i), 505(j), 507(d), 507(g), 519, and 520(g) for the more specific drug provisions.

<sup>4</sup>Peter B. Hutt and Richard A. Merrill, *Food and Drug Law: Cases and Materials* 1205 (2nd ed., 1991).

<sup>5</sup>Edward S. Allera, *Warrantless Inspections of the Food Industry*, 34 *Food Drug Cosm. L.J.* 260, 267 (1979).

to get warrants prior to inspections. Although Congress authorized warrantless administrative inspections in the statute<sup>6</sup> the FDA has to deal with constitutional constraints as well. The Fourth Amendment protects the people of the United States<sup>7</sup> against unreasonable searches and provides that no warrants shall issue, but upon probable cause, supported by oath or affirmation, and particularly describing the place to be searched.

FDA has avoided the general constitutional requirement of a warrant prior to a search through the pervasively regulated industry' exception. This paper will examine first the history of the exception and how the FDA has operated within it. I will then look at some recent cases involving the exception and the impact, if any, that they will have on FDA policy.

In 1967, the Supreme Court decided two companion cases involving warrantless administrative searches.<sup>8</sup> In each case the Court upheld the property owner's right to refuse entry to an inspector.<sup>9</sup> Most importantly, the Court held that unless the inspector receives the property owner's consent, he must have a warrant to conduct an administrative search.<sup>10</sup> The Court mitigated the warrant requirement for administrative searches by defining a lesser probable cause standard for administrative inspections than that used for criminal search warrants. Rather than needing specific reason to believe that the particular

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<sup>6</sup>Hutt and Merrill. *supra* note 4, at 1045 (quoting Peter B. Hutt. *Philosophy of Regulation under the Federal Food. Drug and Cosmetic Act*, 28 Food Drug Cosm. L.J. 177 (1973)).

<sup>7</sup>u.s. Const. amend. IV.

<sup>8</sup>Prior to 1967. the Court had not applied the warrant requirement of the Fourth Amendment to civil inspections at all. See Lynn S. Searie, *The Administrative Search from Dewey to Burger: Dismantling the Fourth Amendment*, 16 Hastings Const. L.Q. 261 (1989).

<sup>9</sup>*Camara v. Municipal Court*, 387 U.S. 523 (1967), involved the inspection of a private residence for violations of the San Francisco Housing code. See *v. City of Seattle*, 387 U.S. 541 (1967), involved a similar administrative search but with a commercial establishment.

<sup>10</sup>See *Camara*, 387 U.S. at 539.

building to be searched was in violation, probable cause for the inspection could be based on the reasonable goals of code enforcement.<sup>11</sup> For the requisite probable cause, the agency seeking the warrant need only show that a valid public interest justifies the intrusion.<sup>12</sup>

Three years later, the Court laid the foundation for the pervasively regulated industry exception. In *Colonnade Catering Corp. v. United States*<sup>13</sup> the Internal Revenue Service searched a catering business which had a liquor license.<sup>14</sup> The IRS agents did not have a warrant and the owner did not consent to the search. The Court held that, because the liquor industry had long been regulated. Congress did have the power to authorize warrantless searches in the regulatory schemes that it passed.<sup>15</sup>

In 1972, a pawn shop operator challenged a warrantless search conducted pursuant to the Gun Control Act of 1968.<sup>16</sup> Citing *Colonnade*, the Court upheld the search. There was no forced entry, and the officers stayed within their statutory right of inspection. The Court noted that there would be no question of the validity of the search if the business in this case had been in the liquor industry.<sup>17</sup> The Court admitted that the gun industry does not have the same history of regulation that the liquor industry does. It relied on

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<sup>11</sup> *Id.* at 535.

<sup>12</sup> *Id.* at 539.

<sup>13</sup> 397 U.S. 72 (1970).

<sup>14</sup> *Colonnade* was the first case of a warrantless inspection conducted pursuant to a federal statute. See Edward M. Basile, *The Case Law on Inspections*, 34 Food Drug Cosm. L. 3, 20, 22 (1979).

<sup>15</sup> *Colonnade*, 397 U.S. at 76. The Court overruled the specific search in this case because the statute, while authorizing a warrantless search, did not authorize the agents to make a forcible entry.

<sup>16</sup> *United States v. Biswell*, 406 U.S. 311 (1972).

<sup>17</sup> *Id.* at 314-15.

the extensive regulation and the important government interest in regulating firearms to prevent violent crime<sup>18</sup> [U]nannounced, even frequent, inspections are essential to effective enforcement and deterrence; and a person involved in this pervasively regulated business must expect periodic inspections.<sup>19</sup>

The Court focused on the statutory scheme as it dismissed Biswell's argument that his consent to the search was not voluntary. Unlike the *Camara* and *See* standard, the *Biswell* court held that neither consent nor a warrant were necessary. When inspecting a business in a pervasively regulated industry, the legality of the search depends not on consent but on the authority of a valid statute.<sup>20</sup>

Together. *Colonnade* and *Biswell* firmly established the pervasively regulated industry exception to the warrant requirement for administrative searches. The FDA responded to these cases by adopting the policy that warrants were not necessary for inspections, even when consent was refused.<sup>21</sup> Subsequently, several district court decisions upheld the FDA's opinion that its regulatory inspections fit into the *Colonnade* *Biswell* exception for pervasively regulated industries.<sup>22</sup> *Marshall v. Barlow's, Inc.*<sup>23</sup> was the next important

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<sup>18</sup> *Id.* at 315.

<sup>19</sup> *Id.* at 316.

<sup>20</sup> *Id.* at 315. The only indication as to what would constitute a search pursuant to a valid statute was the Court's requirement that it be carefully limited in time, place, and scope. *Id.* The Court would have to further define this issue in later cases. *See infra.* notes 48650, 62 and accompanying text.

<sup>21</sup> Deborah B. Norton. *The Constitutionality of Warrantless Inspections by the Food and Drug Administration*, 35 Food Drug Cosm. L.J. 25, 33 (1980). FDA had first instructed its inspectors to seek warrants when consent was refused after the *Camara* and *See* decisions in 1967. *See Id.* at 30.

<sup>22</sup> *See, e.g.,* United States v. Business Builders, 353 F.Supp. 1333 (D.D.C. 1973); United States v. Del Campo, 354 F.Supp. 141 (ND. Okla. 1973). *But see* United States v. I. D. Russell Labs. 439 F.Supp. 711 (W.D. Mo. 1977) (relying on *Camara* and *See* in requiring a warrant, and mentioning neither *Colonnade* or *Biswell*)

<sup>23</sup> 436 U.S. 307 (1978).

decision for the pervasively regulated industry exception. The

Occupational Safety and Health Administration (OSHA) attempted to inspect an electrical and plumbing plant, but the owner refused to let the inspectors in. OSHA argued that its inspections were authorized by statute<sup>24</sup> and that these inspections did not require warrants because the *Colonnade* and *Biswell* doctrine authorized warrantless inspections of pervasively regulated businesses.<sup>25</sup> According to OSHA, its regulation of health and safety conditions constituted pervasive regulation.

Although the Court accepted the pervasively regulated business exception of the *Biswell* case, it rejected OSHA's broadening of the exception. To fit this exception, the Court held, regulation of the industry must be so extensive and of such long tradition that any person who chooses to enter such a business must already be aware of the extent of the regulation.<sup>26</sup> OSHA did not regulate the electrical and plumbing industry, but rather the general health and safety conditions of workplaces in all industries.<sup>27</sup> OSHA's regulation of workplace safety simply was not involved enough to be pervasive, neither was it adequate to give notice of inspections to the affected businesses. The Court flatly refused to expand the exception, as OSHA requested, to allow warrantless administrative searches of all businesses involved in interstate commerce.

The FDA did not change its policy in the wake of *Barlow's*, but

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<sup>24</sup>29 U.S.C. 657. The Occupational Safety and Health Act of 1970 neither required a warrant nor explicitly excepted OSHA inspections from the general warrant requirement. Its limits of reasonableness and notice were actually very similar to the inspection provisions of the Federal Food, Drug and Cosmetic Act. *See supra* note 1.

<sup>25</sup>*Barlow's*, 436 U.S. 307.

<sup>26</sup>*Id.* at 313.

<sup>27</sup>*Id.*

commentators disagreed, about the implications *Barlow's* would have for FDA policy. The primary lesson of *Marshall v. Barlow's* was that the *Colonnade* and *Biswell* exception is the exception, only for pervasively regulated industries, and not the rule for all somewhat regulated businesses. Edward Basile, the then Assistant Chief Counsel for Enforcement at the FDA, said in a 1979 article that the Court recognized the continuing vitality of the *Biswell* and *Colonnade* exceptions to the search warrant requirement for 'pervasively regulated businesses' and merely rejected OSHA's proposed application of these exceptions.<sup>28</sup> In Basile's opinion, *Barlow's* would have no effect on the FDA because FDA's regulatory scheme fit easily within *Barlow's* rubric for the pervasively regulated business exception. The Federal Food, Drug and Cosmetic Act is addressed to particular industries, the FDA has a long history of closely supervising those industries, and the whole statutory scheme and its history provides notice to businessmen of the regulatory burdens that accompany doing business in those industries.<sup>29</sup>

On the other hand, Deborah B. Norton concluded a 1980 article that *Barlow's* called into question much of FDA enforcement policy.<sup>30</sup> Norton argued that, while some FDA regulated industries were clearly pervasively regulated businesses, many others were not. *Barlow's* did not begin to sort them out.<sup>31</sup> Although the FDA did not change its policy in response to *Barlow's*, it

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<sup>28</sup>Basile, *supra* note 14, at 246-25.

<sup>29</sup>*Id.* at 27.

<sup>30</sup>Norton, *supra* note 21.

<sup>31</sup>Norton actually argued that FDA should require warrants for all inspections after *Barlow's* because the analysis of each individual industry which FDA regulates would be so complex and costly. Congress could then examine each industry's enforcement difficulties as needed. *See Id.* at 38.

did believe that *Barlow's* left the validity of warrantless FDA inspections as an open question.<sup>32</sup>

The debate over where *Barlow's* left the FDA was quickly resolved. In a 1981 case,<sup>33</sup> executives of a drug company charged with counterfeiting, adulteration, and misbranding drugs argued that their Fourth Amendment rights had been violated. The threshold question was whether the drug manufacturing industry should be included within this class of closely regulated businesses.<sup>34</sup> The Court held that the drug industry did fit the exception, noting the history of heavy regulation, the urgent public health interests at stake, the difficulties of enforcement, and the statute's provisions which were more narrow than those at issue in *Barlow's*.

Both *United States v. New England Grocers Supply Co.*<sup>35</sup> and *United States v. Gel Spice Co., Inc.*<sup>36</sup> involved FDA inspections of food warehouses in 1976 and 1977. The courts upheld the inspections under *Biswell*; the defendants then appealed those judgments in the light of the 1978 *Barlow's* decision. [Given the pervasive nature and long history of federal regulation of the food and drug industry, considering that, in contrast to the situation in *Barlow's*, these regulations apply to a particular industry and not a wide range of business establishments, and mindful of the urgent public health interests that are served by the inspections, the *New England Grocers* court upheld the

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<sup>32</sup> *See id.* at 35 & n.70. The prominence of the FDA statutory scheme and case law in the *Barlow's* briefs combined with the lack of their mention in the Court's opinion causes one to wonder whether the Court may have deliberately left this question open.

<sup>33</sup> *United States v. Jamieson McKames Pharmaceuticals, Inc.*, 651 F.2d 532 (8th Cir. 1981).

<sup>34</sup> *Id.* at 536.

<sup>35</sup> 4ee F.Supp. 230 (1980).

<sup>36</sup> 601 F.Supp. 1214 (1985).



inspection as fitting within the pervasively regulated business exception.<sup>37</sup>The *Gel Spice* inspection was upheld on the same grounds<sup>38</sup>

Although the district court food industry decisions of *New England Grocers* and *Gel Spice* are not as authoritative as the circuit court drug industry decision of *JamiesonóMcKames*. there has been no real debate in this area since *Gel Spice*: these cases squarely placed the national food and drug industries within the pervasively regulated business exception. However, as the above debate between Basile and Norton illustrates, *Colonnade*, *B.zswell*, and *Barlow's* had failed to clearly define the parameters of the exception. Later cases first elaborated on the standards alluded to in *Barlow's* and then expanded the scope of the exception. *New York v. Burger*,<sup>39</sup> in particular, loosened the requirements for the pervasively regulated industry exception.

Prior to *Burger*, and shortly after *Barlow's*, the Supreme Court examined the exception in *Donovan v. Dewey*.<sup>40</sup> The procedural situation was not wholly different from that in

*Barlow's*: in *Barlow's*, an inspection pursuant to the Occupational Safety and Health Act had been invalidated; in *Dewey*, a different statute's warrantless inspection provisionóó the Federal Mine Safety and Health Actóówas challenged. In this case. the Court upheld the application of the pervasively

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<sup>37</sup>*New England Grocers*. 488 F.Supp. at 238. As early as 1909, the Supreme Court recognized the duty of the State to protect and guard. as far as possible, the lives and health of its inhabitants... (from] food which is unfit for human consumption. *North American Storage Co. v. Chicago*, 211 U.S. at 315 (1909).

<sup>38</sup>*Gel Spice*, 601 F.Supp. at 1229. *Contra* *United States v. Roux Laboratories, Inc.*, 456 F.Supp. 973 (1978) (an early postóó *Barlow's* decision requiring warrants for FDA inspections)

<sup>39</sup>4e2 U.S. 691 (1987).

<sup>40</sup>452 U.S. 594 (1981).

regulated business exception to the mining industry, one of the most hazardous in the country.<sup>41</sup> The opinion focused on the extent of the regulation and its effect on the expectations of privacy rather than on a long history of the regulation.<sup>42</sup>

*Dewey* not only expanded the *Colonnade*/*Biswell* exception to include the mining industry; it also outlined clearer standards for the exception than had been provided in previous cases.<sup>43</sup> In 1987, the Court revisited the *Dewey* standards in *New York v.*

*Burger*.<sup>44</sup> The defendant in *Burger* was a junkyard owner who challenged a search conducted pursuant to New York state traffic law.<sup>45</sup> Police officers had inspected the junkyard after Burger admitted that he did not have the required administrative records. When the search revealed stolen vehicles and parts, they arrested Burger for possession of stolen property.<sup>46</sup> The defendant contended that the §4156a5 authorization of warrantless inspections was unconstitutional; the state argued that the junkyard business was a pervasively regulated industry and that warrantless inspections were appropriate. The Court upheld the statute and the search.

The Court first held that a junkyard was a closely regulated business and that the owner had a reduced expectation of privacy.<sup>47</sup> The Court

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<sup>41</sup> *Id.* at 602.

<sup>42</sup> *Id.* at 606.

<sup>43</sup> Because the focus of recent debate has been on *Burger*, I will discuss the specifics of the *Dewey* standards in the discussion of *Burger*.

<sup>44</sup> U.S. 691 (1987).

<sup>45</sup> *Y. Veh. & Traf. Law* §4156a5 (McKinney 1986).

<sup>46</sup> *Burger*, 487 U.S. at 694-695.

<sup>47</sup> at 707. (See also 703-607 for the Court's support for this holding. Automobile junkyards are subject to detailed licensing, registration, and record-keeping regulations. Though *Dewey* did not focus on the duration of the regulation, it is relevant. The salvage industry has long

then examined three other criteria expressed in *Dewey* and held that the state met them in *Burger*. According to *Dewey*, warrantless inspections of pervasively regulated businesses (1) must serve a substantial government interest, (2) must be a necessary enforcement tool, and (3) the statute must provide a constitutionally adequate substitute for a warrant.<sup>48</sup> The Court found that deterrence of automobile theft was the substantial government interest at work in the regulation and that the surprise element of warrantless inspections was a necessary weapon in fighting automobile theft.<sup>49</sup> Finally, the Court held that the New York statute provided the requisite substitute for a warrant in that its procedure was specific and limited enough to give the junkyard owner notice of the search and its scope, and it restricted the discretion of inspectors.<sup>50</sup>

After the question of the pervasively regulated industry exception, *Burger* also examined the question of whether an administrative search which may disclose criminal as well as civil violations raises constitutional difficulties.<sup>51</sup> The Court argued that an administrative scheme that serves narrow regulatory goals may very well serve the same ultimate purposes as a parallel penal law.<sup>52</sup> The Court rejected this challenge to the *Burger* search as well, holding that the discovery of evidence of crimes in the course of an otherwise proper administrative inspection does not render that search illegal or the administrative scheme suspect.<sup>53</sup>

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been regulated: automobile junkyards are simply a new specialty within that old industry.)

<sup>48</sup>at 702603 (citing *Dewey*)

<sup>49</sup>*Id.* at 708, 710.

<sup>50</sup>*Id.* at 703, 711.

<sup>51</sup>*Id.* at 693.

<sup>52</sup>*Id.* at 712613.

<sup>53</sup>*Id.* at 716. *Cf.* *United States v. Branson*, 21 F.3d 113 (6th Cir. 1994) (allowing into

This issue of overlapping criminal and civil violations has been the focus of *post-Burger* cases. Although agencies are unlikely to have their administrative inspections declared illegal under the pervasively regulated business analysis of *Burger*, subsequent cases indicate that warrantless administrative searches which serve as a pretext for criminal investigations will often not be upheld.<sup>54</sup>

Commentators have been seriously concerned about the expansive nature of *Burger*. Although the Court used the same doctrinal language in *Burger* that it had used in *Dewey*, the Court would have provided far more protection for the defendant's constitutional rights had it actually followed the *Dewey* standards.<sup>55</sup> As Brennan points out in his dissent, the tests articulated in *Dewey* were interpreted far more broadly in *Burger*: the registration and record-keeping regulations of the junkyard industry are a far cry from the pervasive mine safety regulations of *Dewey*. With this broad interpretation, most businesses fit the pervasively regulated exception, and the warrant requirement of *See* has been constructively overruled.<sup>56</sup>

More than the Court's distortion of the *Dewey* test, commentators have decried *Burger's* emasculation of privacy interests under the Fourth Amendment.<sup>57</sup> The Court expanded the scope of the pervasively regulated business evidence marijuana plants discovered during administrative search of auto repair shop).

<sup>54</sup>United States v. Seslar, 996 F.2d 1058 (10th Cir. 1993) (suppressing evidence obtained through stop of rental truck with no justification for criminal stop or administrative search); United States v. Johnson, 994 F.2d 740 (10th Cir. 1993) (reversing conviction for illegal possession of wild animals because administrative search of taxidermy shop was solely for the purposes of a criminal smuggling investigation).

<sup>55</sup>See Searle, *supra* note 8.

<sup>56</sup>*Burger*, 482 U.S. at 721 (Brennan, 3., dissenting).

<sup>57</sup>generally Searle, *supra* note 8; John S. Morgan, *The Junking of the Fourth Amendment: Illinois v. Krull and New York v. Burger*, 63 Tul. L. Rev. 335 (1988).

ness exception by linking Fourth Amendment privacy interests with the amount of regulation and by taking an insignificant view of the individual's privacy interests. For example, an element of surprise would benefit any enforcement effort. The Court's reliance on the necessity of surprise<sup>58</sup> is weak and ignores legitimate privacy interests.<sup>59</sup> The Court argued that operation of a closely regulated business leads to reduced expectations of privacy which leads to less warrant and probable cause protection.<sup>60</sup> This reasoning 'cancels the petitioner's commercial fourth amendment rights simply because he operates a closely regulated business.<sup>61</sup> Thus, Congress need only increase the regulation of an industry to provide the basis for warrantless inspections. Under the *Burger* scheme, virtually any statute would pass constitutional muster if the industry is heavily regulated and the search occurs during business hours.<sup>62</sup> That hardly sounds like the notice and limited discretion of a constitutionally adequate warrant.

Although *Burger* opens the door for many abuses of Fourth Amendment rights, it will actually have very little effect on FDA enforcement policy.<sup>63</sup> There are two main reasons for this lack of impact. The first is that most businesses consent to FDA inspections, and warrants are never required when the proprietor consents. The *Camara* and *See* decisions required very little change

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<sup>58</sup> See *Burger*, 482 U.S. at 710; *supra* note 49 and accompanying text.

<sup>59</sup> Morgan, *supra* note 57, at 372.

<sup>60</sup> See *Burger*, 482 U.S. at 701-02.

<sup>61</sup> Morgan, *supra* note 57, at 363.

<sup>62</sup> *Id.*

<sup>63</sup> Neither Morgan nor Searle discussed *Burger* in the context of FDA enforcement. One is hard-pressed to find a federal court citing *Burger* in an FDA case. *Contra* United States v. Fogari, 1987-61988 F.D.L.I. Jud. Rec. 144 (D.N.J. 1988) (*cited in* Hutt and Merrill, *supra* note 4, at 1107, note 3.).

in FDA policy for precisely this reason. Inspectors were told to continue business 'as usual' and to seek warrants only when businesses refused to consent.<sup>64</sup>

The second reason that FDA is not impacted by *Burger* is that the FDA already had the power which *Burger* gave to regulatory agencies. There was never any real question about whether FDA inspections qualified for the pervasively regulated industry exception.<sup>65</sup> *Barlow's* raised a minor question because it limited the exception; however, *Burger* can only be read to expand the exception so it does not threaten FDA.

Moreover, even if *post-Burger* cases were to narrow the view of the criteria for warrantless inspections, the FDA would be unaffected because its regulatory scheme meets the requirements. The substantial government interest in food and drug safety is well established.<sup>66</sup> Much more than the registration scheme of the New York state traffic law, the Federal Food, Drug and Cosmetic Act provides specific provisions concerning scope and discretion and the notice of regular inspections that substitute for the constitutional warrant requirement. Without unannounced inspections, harmful drugs and food could be destroyed or even released to the public before FDA employees could discover them. Edward Basile goes even further on this issue and argues that warrantless inspections are necessary for administrative cost and manpower reasons. If warrants were required when a business refused consent, as little as a 1% initial refusal rate could result in FDA employees and Assistant United States Attorneys appearing before magistrates all over the country about twice every court

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<sup>64</sup>Norton, *supra* note 21, at 30.

<sup>65</sup>See *supra* notes 21-22, 33-38 and accompanying text.

<sup>66</sup>See, e.g., *supra* note 37.

date.<sup>67</sup>

Even in the area of criminal sanctions, *Burger* will not affect FDA enforcement. FDA regulation certainly raises the issue of joint civil and criminal investigations and penalties. But the FDA rarely uses its criminal sanctions.<sup>68</sup> Where the FDA does impose criminal sanctions, the current 'good faith' standard for challenging evidence obtained in an administrative search is very difficult to meet.<sup>69</sup> A defendant cannot even get a hearing on the issue without a preliminary showing of bad faith. To establish bad faith, defendants must show that the sole purpose of the investigation was investigatory, rather than regulatory.<sup>70</sup> It is virtually inconceivable that a defendant could show the complete absence of any regulatory purpose in an FDA administrative search.

To conclude, the law allowing the FDA to conduct warrantless administrative searches is well-established and not currently in debate. FDA authority seems unaffected by recent developments which may redefine the pervasively regulated business exception. Thus, the FDA is free to continue with business as usual as it protects the safety of our food and drug supply.

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<sup>67</sup>Basile, *supra* note 14. at 27.

<sup>68</sup>See Hutt and Merrill, *supra* note 4, at 1205. The incidence of criminal prosecutions by the FDA steadily and dramatically decreased from 1939. There were only 16 criminal prosecutions by FDA in 1989.

<sup>69</sup>See *Gel Spice*, 601 F.Supp. 1214, 1218 (1985).

<sup>70</sup>*Id.* (emphasis added)