

Vivian L. Madison Pratt  
Associate General Counsel

December 22, 1999

0626 '99 DEC 29 P1 53

Dockets Management Branch  
Division of Management Systems and Policy  
Office of Human Resources and Management Services  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061 (HFA-305)  
Rockville, MD 20852

Re: Docket No. 99D-4130 -- Comments on Guidance on Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems

Dear Sir or Madam:

Siemens Medical Engineering Group (Siemens) is a manufacturer of diagnostic x-ray systems and computed tomography systems (CT Systems). Siemens submits the following comments on the Food and Drug Administration's (FDA's) guidance document, Guidance for Industry: Guidance on Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems, 64 Fed. Reg. 54901 (Oct. 8, 1999) (Docket No. 99D-4130) [hereinafter Guidance Document]. The Guidance Document states that manufacturers of diagnostic x-ray systems are required to disclose certain types of information, at cost, to assemblers of those devices and to other persons upon request. For the reasons stated herein, Siemens requests that the FDA rescind its Guidance Document to the extent that it requires the giving away, at cost, of software programs used for the assembly, installation, adjustment, and testing (AIAT) of diagnostic x-ray systems under 21 C.F.R. §§ 1020.30(g), (h), and § 1020.33(c) (computed tomography equipment). Instead,

99D-4130

C3

Siemens requests that the FDA follow the required notice and comment rulemaking process to amend the above regulations in order to allow manufacturers of diagnostic x-ray systems an opportunity to adequately respond to this far-reaching initiative. As currently written, the Guidance Document will result in an unconstitutional taking of private property in violation of the Fifth Amendment to the U.S. Constitution.<sup>1</sup>

### **Introduction**

On December 24, 1997, the FDA issued a guidance document entitled "Manufacturer Obligations Under 21 C.F.R. 1020.30(g)." The guidance document noted that pursuant to 21 C.F.R. § 1020.30(g)

[M]anufacturers [are not required] to supply diagnostic or maintenance equipment (including software) or service manuals as part of the assembly instructions. However, all the information necessary to install and adjust the equipment to meet the regulations must be provided in order for the assembly instructions to be adequate. If specialized equipment or software is necessary to properly follow the assembly instructions . . . an alternative

---

<sup>1</sup> See U.S. Const. amend. V ("[P]rivate property [shall not] be taken for public use, without just compensation.").

means for adequately installing the equipment must be provided to meet the requirements of the performance standard.<sup>2</sup>

When issuing the guidance document, the FDA failed to recognize that in many instances “an alternative means for adequately installing the equipment” does not exist. The Agency anticipated that a manufacturer would be able to provide written instructions that could act as a sufficient substitute for software or any other tools that are needed for installation and testing. That assumption was false.

In consideration of comments submitted to the Agency, the FDA, on October 8, 1999 issued a second guidance document. The specific purpose of the new Guidance Document is to address the “scope of information the performance standard requires manufacturers to disclose, and whether computerization of that information affects the basic requirement or the cost [to the manufacturer].”<sup>3</sup> The Guidance Document requires manufacturers to disclose, at cost, information, regardless of its source or format, to third-party service organizations (and others) that would fulfill the manufacturer’s obligations under 21 C.F.R. § 1020.30. The Guidance Document, however, does not adequately

---

<sup>2</sup> FDA, Manufacturer Obligations Under 21 C.F.R. 1020.30(g), (Dec. 24, 1997).

<sup>3</sup> Guidance Document at 2.

address AIAT information that is included in software programs in excess of federal requirements. Often, this "excess" software is inextricably bound with the basic software. Equally important, the Guidance Document fails to acknowledge that the FDA is changing the diagnostic x-ray performance standard without going through the rulemaking process and without adequately explaining the basis for the Agency's assertion of statutory authority to require a manufacturer to give away "at cost" its proprietary software.

Siemens supports the FDA's efforts to ensure that diagnostic x-ray systems meet applicable federal performance standards through the proper assembly, maintenance, and operation of diagnostic x-ray equipment. The FDA's Guidance Document, however, is unjustified, and a clear example of Agency overreach. The FDA's broad and unsubstantiated interpretation of the x-ray performance standard would amount to an unwarranted taking of property in violation of the Fifth Amendment to the United States Constitution. The effect of the Guidance Document is twofold: 1) it places manufacturers of diagnostic x-ray equipment in an unfair position of supplying software programs to third parties at a cost that does not begin to compensate the manufacturer for its investment in the software product; and 2) in some cases, the Guidance Document may compel manufacturers to violate contractual obligations with software developers that prohibit the dissemination or distribution of the software to any party outside of the developer-manufacturer relationship. Therefore, the FDA should rescind the Guidance Document and

initiate notice and comment rulemaking as required by the Administrative Procedure Act (APA) to determine how to balance industry concerns about protecting the value of its software investments with the legitimate objectives of ensuring that third-party service organizations have access to software on an equitable basis.

**I. The APA Demands that the FDA Follow the Appropriate Notice and Comment Rulemaking Process to Amend or Modify a Regulation**

The FDA's Guidance Document purports to instruct manufacturers of diagnostic x-ray equipment that they must provide certain software at cost to third-party service organizations and others. The FDA is obligated to follow the notice and comment procedures of the APA to modify the x-ray performance standard in this fashion.<sup>4</sup> Because the FDA has not done so, the Guidance Document should be rescinded and reissued as a proposed rule in the Federal Register. The improved notice will permit the diagnostic x-ray equipment industry and other affected parties an adequate opportunity for comment, and, if necessary, judicial review.

---

<sup>4</sup> See 5 U.S.C. § 553(b), 21 C.F.R. § 10.40 (requiring notice and comment for proposed regulations).

**A. The FDA did not Intend Diagnostic X-ray Software to be Covered in its Regulations**

The FDA did not intend diagnostic x-ray software to be covered in its current regulations. The Agency's new interpretation of regulation, as evidenced in the Guidance Document, would include software under the penumbra of information a manufacturer of diagnostic x-ray equipment must disclose to a third-party service organization "at cost." This outcome is clearly at odds with the FDA's historical interpretation of the regulations at issue.

The regulatory histories of 21 C.F.R. § 1020.30 and 21 C.F.R. §1020.33 show that the FDA never contemplated requiring manufacturers of diagnostic x-ray equipment to provide proprietary software at cost, but rather limited the disclosure of information to third-party service organizations to manuals, instructions, instruction sheets, and technical and safety information. The performance standards for diagnostic x-ray and CT systems provide in relevant part:

- "[m]anufacturers of [diagnostic x-ray systems] shall provide to assemblers . . . at a cost not to exceed the cost of publication and distribution, *instructions* for [AIAT];"<sup>5</sup>

---

<sup>5</sup> 21 C.F.R. § 1020.30(g) (performance standard for diagnostic x-ray systems)

- “[m]anufacturers of x-ray equipment shall provide to purchasers . . . at a cost not to exceed the cost of publication and distribution, *manuals or instruction sheets* [with] technical and safety information;”<sup>6</sup> and
- [e]ach manufacturer of a CT x-ray system shall provide . . . *technical and safety information*, in addition to that required under § 1020.30(h) . . . at a cost not to exceed the cost of publication and distribution of such information. This information shall be identified and provided in a separate section of the user’s *instruction manual or in a separate manual devoted only to this information.*<sup>7</sup>

Inherent in the language of §§ 1020.30 and 1020.33 is the FDA’s *exclusion* of software from the information manufacturers of diagnostic x-ray systems must disclose to third-party service organizations and others at cost. The Agency has continuously envisioned the use of relatively inexpensive printed material as the mechanism through which relevant information is conveyed to third-party service organizations. This supposition is buttressed by a comment in the preamble to the final rule on CT systems issued in 1984, in which the Agency patently declined to include software in the

---

(emphasis added).

<sup>6</sup> 21 C.F.R. § 1020.30(h) (performance standard for diagnostic x-ray systems) (emphasis added).

<sup>7</sup> 21 C.F.R. § 1020.33(c) (performance standard for CT systems) (emphasis added).

information a manufacturer is required to disclose to third-party service organizations. In the final rule, the FDA stated:

FDA believes that availability of information regarding software available for hardware/software diagnosis would *be more appropriately a matter for negotiation between the vendor and purchaser* during the procurement process.<sup>8</sup>

This statement makes clear that the Agency has historically regarded diagnostic software as a proper subject of commercial negotiation rather than compulsory licensing. The Guidance Document, by requiring a manufacturer of diagnostic x-ray systems to give away proprietary diagnostic software “at cost,” necessarily broadens the scope of regulation into a realm the Agency has long considered the domain of commercial negotiation. A change in regulatory policy of such magnitude necessarily requires notice and comment.<sup>9</sup>

---

<sup>8</sup> 49 Fed. Reg. 34698, 34699 (Aug. 31, 1984) (emphasis added).

<sup>9</sup> See American Mining Congress v. Mine Safety & Health Admin., 995 F.2d 1106, 1112 (D.C. Cir. 1993) (a rule is legislative, not interpretive if it “effectively amends a prior legislative rule.”).

**B. The FDA's Interpretation of "Cost" is Unsupported by the Statute and Lacks a Rational Basis**

The FDA's requirement that manufacturers provide AIAT software "at cost" lacks any statutory support or rational basis. Even if the FDA does have the statutory authority to require manufacturers to provide software "at cost," the FDA must permit research and development costs to be included in the "at cost" price. However, it is clear that the legal authority the FDA identifies as a basis for the Guidance Document does not even begin to support the proposition that the FDA may require the giving away of software "at cost" as a factor to determine a manufacturer's compliance with the law.

The Guidance Document posits that:

[f]or instructional materials encoded in software, the principle used to calculate the permissible charge for printed materials means that *manufacturers may at least recover costs of man/hours, computer disks, and packaging materials used to produce each additional unit of instructional materials. . . . [I]f a manufacturer licenses its instructional software from a developer, and must pay an additional fee for each unit*

licensed, *it may be appropriate to permit the manufacturer to recover licensing fees* for materials provided under 1020.30(g).<sup>10</sup>

How did the FDA develop the definition of “cost”? Absent from the FDA’s definition of allowable costs is a manufacturer’s investment in research and development. Why has the FDA not permitted manufacturers to include research and development expenses in computing cost? In other device regulations, the FDA explicitly allows a manufacturer to recover these costs. For example, a manufacturer of an investigational device is explicitly allowed to recover costs associated with the research and development of the device.<sup>11</sup> In addition, a device manufacturer who provides a device for humanitarian use may recover charges for the “device’s *research, development, fabrication, and distribution.*”<sup>12</sup> In light of the FDA’s practice to allow device manufacturers to recover research and development costs, and as a matter of regulatory uniformity and fairness to the manufacturer, the costs a manufacturer of diagnostic x-ray systems expends for the research

---

<sup>10</sup> Guidance Document at 7 (emphasis added).

<sup>11</sup> “A sponsor, investigator, or any person acting for or on behalf of a sponsor or investigator shall not commercialize an investigational device by charging the subjects or investigators for a device a price larger than that necessary *to recover costs of manufacture, research, development, and handling.*” 21 C.F.R. § 812.7(b) (emphasis added).

<sup>12</sup> 21 C.F.R. § 814.104(b)(5) (emphasis added).

and development of diagnostic software must be included in the "at cost" price to a third-party service organization. Without the ability to recover these costs, a manufacturer is not fairly compensated for the true cost of software development. At a minimum, this is a proper subject for notice and comment rulemaking.

The FDA identifies §§ 535(e) and 538 of the Food, Drug and Cosmetic Act (FDCA) as the legal basis for requiring a manufacturer of diagnostic x-ray systems to disclose proprietary software to third-party service organizations "at cost." The FDA's citation of their statutory provision as support for the "at cost" requirement is flawed. These sections of the statute do not identify cost as a factor of a manufacturer's statutory compliance. Section 535(e) simply provides the FDA with the power to determine if an electronic product complies with a performance standard or contains a safety-related defect. If so, § 535(f) gives the FDA the power to require the manufacturer to bring the product into compliance "without charge," to replace the product or to refund "the cost of such product." No where does this provision give the FDA the power to require manufacturers to give away valuable software at cost.

Section 538 proscribes certain activities that would cause a manufacturer to fail to comply with the statute. For example, a manufacturer may not "fail to furnish any

notification or other material or information required [under the statute].”<sup>13</sup> Although this “material or information” may include certain technical and safety data, the statute does not authorize the FDA to require a manufacturer to provide software at cost. Therefore, the FDA’s reliance on §§ 535(e) and 538 of the FDCA as legal authority for requiring a manufacturer to provide software “at cost” is misplaced.

**C. The Guidance Document is a Substantive Rule that Requires Notice and Comment**

The Guidance Document represents a substantive rule that carries the weight of the law rather than an interpretation of regulation and, therefore, requires notice and comment. The principal criterion for determining whether a rule is substantive is the effect of the rule on the rights and obligations of the parties involved. Stated somewhat differently, do the rules have the force and effect of law? As the District of Columbia Circuit held in American Mining Congress, if an agency effectively amends a prior legislative rule, then it must go through rulemaking.

---

<sup>13</sup> FDCA § 360oo(a)(2).

The Guidance Document suggests that its “recommendations” are “guidance . . . [that] does not operate to bind FDA or the public.”<sup>14</sup> The Agency contends that the public is not legally bound to the Guidance Document, but that “[a]n alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.”<sup>15</sup> But what alternative is available to providing software “at cost”? Is there an alternative way that a manufacturer can calculate “cost” in the FDA’s view? The Guidance Document does not even suggest that there is another way of doing so. Therefore, manufacturers are effectively bound by the requirements in the Guidance Document. Moreover, 21 C.F.R. § 10.90(b) clearly states that the FDA is obligated in most cases to follow guidelines.<sup>16</sup> In this case, the FDA would be obligated to enforce the policy contained in the Guidance Document to the detriment of the manufacturers of diagnostic x-ray equipment. In light of this, it is clear that the Guidance Document acts as a substantive rule because it has a significant effect on the rights and obligations of diagnostic x-ray

---

<sup>14</sup> Guidance Document at 2.

<sup>15</sup> Id.

<sup>16</sup> See also, Washington Legal Foundation v. Kessler, 880 F. Supp. 26, 34-36 (D.D.C. 1995) (finding that various informal agency guidances from the FDA to regulated industry was to effectuate Agency policy without resorting to the rulemaking process).

manufacturers. Adherence to the tenets of administrative law dictate that the notice and comment rulemaking process should have been used by the FDA.<sup>17</sup>

**II. The FDA's Guidance Document Violates the Fifth Amendment to the U.S. Constitution by Taking Property Without Just Compensation**

The Fifth Amendment to the U.S. Constitution forbids the taking of private property for public use without just compensation. The intellectual property embedded in the very design and use of the software undoubtedly qualifies as property entitled to constitutional protection.<sup>18</sup> Requiring manufacturers who have expended significant resources in developing this software to provide the software at cost of publication and distribution would effectively deprive the manufacturer of the intellectual property contained therein.

---

<sup>17</sup> See Chocolate Manufacturers Ass'n of United States v. Block, 755 F.2d 1098, 1102 (4th Cir. 1985) (stating that "[t]he requirement of notice and a fair opportunity to be heard is basic to administrative law.")

<sup>18</sup> See, e.g., Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1001-04 (1984) (determining that health, safety, and environmental data in pesticide registration applications were trade secrets that constituted property entitled to protection under the Fifth Amendment).

Government action that has *the effect* of diminishing the value of private property is also an unwarranted taking under the Fifth Amendment.<sup>19</sup> Regulatory actions are judged on “the character of the governmental action, its economic impact, and its interference with reasonable investment-backed expectations.”<sup>20</sup> The last factor, “reasonable investment-backed expectations,” formed the crux of the Court’s holding in Ruckelshaus. The Court held that the plaintiff could not have reasonably expected the loss of private intellectual property resulting from a change in regulations.<sup>21</sup> In the same manner, manufacturers of diagnostic x-ray equipment have “reasonable investment-backed expectations” that regulation will not act as a subterfuge for supplying third-party service organizations with free proprietary software programs. Federal copyright laws clearly provide manufacturers with a strong expectation of a right to exclude others from using their copyrighted software for the life of the copyright. In most cases, the expectation of financial return serves as the primary incentive for the manufacturer to develop the software, and it is based on the reliance on that expectation that manufacturers have conducted their business. Any interpretation by the FDA that 21 C.F.R. § 1020.30 requires a manufacturer to provide

---

<sup>19</sup> See id. at 1004-12.

<sup>20</sup> Id. at 1005 (quoting Prune Yard Shopping Center v. Robbins, 447 U.S. 74, 83 (1980)).

<sup>21</sup> See id. at 1010-11.

software without adequate compensation for the value of the software would divest the manufacturer in violation of the Fifth Amendment.

Finally, by requiring diagnostic x-ray manufacturers to provide, free of charge, proprietary programs embedded in a software package, the FDA might be compelling manufacturers who contract with third-party software developers to violate their agreements. The effects on the software development industry if such a requirement were indeed enforced could be tremendous. It would, in effect, either make the contract void, or would subject the manufacturer to great liability.

### **Conclusion**

Siemens fully supports the FDA's efforts to protect patient health by ensuring compliance with diagnostic x-ray performance standards. However, the FDA's current proposal to accomplish that goal by requiring manufacturers of diagnostic x-ray equipment to distribute software programs to third-party service organizations and others without full compensation for the cost of developing such software is inherently unfair and amounts to an unwarranted taking in violation of the Fifth Amendment. Furthermore, the FDA's failure to provide adequate notice and comment on this patently technical issue before issuing the Guidance Document violates the APA. We therefore respectfully request that

Dockets Management Branch  
December 23, 1999  
Page 17

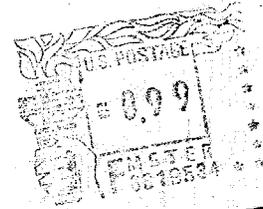
the FDA rescind the Guidance Document and initiate the notice and comment rulemaking process as soon as possible.

Sincerely,

A handwritten signature in cursive script that reads "Vivian Madison Pratt". The signature is written in black ink and is positioned to the right of the word "Sincerely,".

Vivian Madison Pratt

*Legal Dept*  
**SIEMENS**



# SIEMENS

**Siemens Corporation**  
186 Wood Avenue South, Iselin, NJ 08830

Dockets Management Branch  
Division of Management Systems and  
Policy  
Office of Human Resources & Management  
Services  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061 (HFA-305)  
Rockville, MD 20852