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Potential Legal Barriers to Increasing CMS/FDA Collaboration: The Law of Trade Secrets and Related Considerations

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I. INTRODUCTION

Sponsors of potentially beneficial medical technologies engage in two important processes to translate their discoveries into broadly employed drugs or devices. Initially, they must secure approval or clearance by the Food and Drug Administration (FDA) to legally market their products. Second, the sponsor must obtain coverage from third-party payers, the largest of which is Medicare, administered by the Centers for Medicare and Medicaid Services (CMS). In most cases these two processes occur sequentially, creating the potential for increased regulatory efficiency if FDA and CMS were to collaborate. Greater cooperation between FDA and CMS may enable them to process their respective applications simultaneously. Moreover, increased communication between the two agencies may prevent potentially conflicting regulatory decisions and increase the safety and clinical benefit derived from new healthcare technologies. Not surprisingly, the Department of Health and Human Services (DHHS) continues to seek means of making interaction between its agencies more efficient.¹

Coordination between CMS and FDA is limited by restrictions on FDA's ability to share sponsors' proprietary information that may be useful to CMS in making its coverage determinations, different quantities and qualities of data sought by either agency in its decisionmaking process, and some uncertainty surrounding the definition of CMS's "reasonable and necessary" standards.² In approaching effective coordination, the fundamental differences between FDA and CMS must be recognized: FDA is concerned primarily with preserving the public health by ensuring that certain medical products are safe and effective for their marketed indications, while CMS is a purchaser of healthcare

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¹ See Dep't of Health and Human Servs., Regulatory Reform Initiative, at <http://www.regreform.hhs.gov> (last visited Oct. 23, 2003).

² Medicare coverage is limited by statute to services that are "reasonable and necessary" for diagnosis or treatment of illness or injury. See 42 U.S.C. § 1395y(a) (2002).

products and services, under a statutory mandate to limit its purchases to products and services deemed reasonable and necessary.

Furthermore, efforts to achieve cooperation would be implemented in the context of different organizational cultures, limited staff and technological resources, divergent regulatory structures and inputs, and industry concerns that regulatory barriers will be created or increased. For example, in approving or clearing products for market, FDA generally interacts with a single sponsor for any given product, greatly simplifying communication and coordination. CMS, however, has to deal with a multitude of parties when considering whether to extend coverage to a product or service, including Medicare beneficiaries, the healthcare providers and institutions who treat those beneficiaries, and potentially FDA itself, all in addition to what may be multiple concerned industrial sponsors. These stakeholders may have substantially different agendas, all of which need to be reconciled by CMS in its coverage processes.

Increased collaboration between FDA and CMS raises a large number of potential questions, including the type and quantity of data to be exchanged between the two agencies, the appropriate weight to place on FDA approval or clearance in the CMS coverage process, and the proper role of the large number of interested stakeholders. While acknowledging that many obstacles to full harmonization of FDA and CMS regulation exist, this paper addresses a discrete aspect of the data-sharing question, namely trade secrets law as a potential legal barrier to the interagency transfer of information that may be considered proprietary or confidential. This body of law will be examined following an overview of the FDA and CMS regulatory processes.

II. FDA MARKETING APPROVAL OR CLEARANCE PROCESS

A basic understanding of the process by which FDA approves or clears new drugs, medical devices, and biologics for market is a crucial foundation to increasing collaboration between FDA and CMS.³ Where the product at issue is a new drug, the sponsor submits an investigational new drug application, containing a description of the drug, results of comprehensive animal and human tissue tests, and protocols for clinical studies.⁴ Following a study protocol approved by FDA and reviewed and accepted by a local institutional review board, the sponsor undertakes clinical trials in three phases that are progressively expansive in scope⁵ and usually take five or more years to complete.⁶ If the trials are adequate to demonstrate the new drug's safety and effectiveness for a specific indication, the sponsor submits a new drug application (NDA)⁷ and, upon approval of the NDA, may sell the new drug subject to FDA requirements.⁸ Notably, the drug may be promoted only for the indication(s) reflected in its labeling, though healthcare providers are free to use the product for other indications in the treatment of their patients.

FDA applies a different regulatory framework in assessing new devices. New devices that are unlike any existing device or pose a potentially unreasonable risk to patient

³ The regulatory steps for securing FDA approval for new drugs are described in 21 C.F.R. part 312 (2002). FDA assessment of new devices is codified in 21 C.F.R. subchapter H. For a review of FDA history and law, see generally Richard A. Merrill, *Symposium on Regulating Medical Innovation: The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753 (1996).

⁴ 21 C.F.R. §§ 312.20-.23.

⁵ *Id.* § 312.21.

⁶ James A. Henderson, Jr. & Aaron D. Twerski, *Drug Designs Are Different*, 111 YALE L.J. 151, 164 (2001).

⁷ 21 C.F.R. § 314.50.

⁸ *Id.* § 314.80.

safety undergo a premarket approval (PMA) process similar to the NDA process, requiring demonstration of reasonable safety and effectiveness.⁹ Alternatively, the sponsor of a new device that is similar to an existing device already approved by FDA can obtain permission to market the new device upon establishing that it and the existing “predicate” device are substantially equivalent.¹⁰ This process, referred to by its section number 510(k), does not require clinical proof of safety and effectiveness *per se*, although both are implied from the new device’s similarity to a proven device. An important exception is that devices approved after 1976 that are categorized as Class III devices on the basis of having high or unknown risks or use in life-threatening conditions cannot serve as predicate devices for a 510(k) application.¹¹

III. CMS COVERAGE PROCESS

Many Medicare coverage decisions are made locally by private insurance companies serving under contract to administer the Medicare program.¹² These contractors consider input from beneficiaries, industry representatives, and practicing physicians when making local coverage decisions, which are binding only within the region served by the contractor.¹³ Although the localized nature of this process provides contractors the flexibility to adapt their coverage to regional needs and customs, it may produce inconsistent results between regions. Where conflicting local policies exist, CMS may make a national coverage decision that is binding on all contractors.

The criteria for assessing the propriety of Medicare coverage of new products or services are set forth by statute:

no payment may be made under [Medicare] for any expenses incurred for items or services [that] are not *reasonable* and *necessary* for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member[.]¹⁴

This language is interpreted by CMS as requiring that adequate evidence exist to show that a medical product or service improves clinical outcome in order to qualify for Medicare coverage.¹⁵

CMS may determine the need for a national coverage decision on its own initiative in a number of situations, including the presence of “conflicting carrier or intermediary

⁹ *Id.* §§ 814.1 et seq. The term “reasonable,” as used in the medical device regulatory framework, is not equivalent to the identical term used in the Social Security Act, but merely reflects the same term incidentally being used in two different regulatory contexts. Standards underlying the terms “safe” and “effective” are set forth in 21 C.F.R. § 860.7.

¹⁰ 21 U.S.C. § 360c(f) (FDCA § 513(f)). See generally Benjamin A. Goldberger, *The Evolution of Substantial Equivalence in FDA’s Premarket Review of Medical Devices*, 56 FOOD & DRUG L.J. 317 (2001).

¹¹ 21 U.S.C. § 360c (FDCA § 513). See generally John J. Smith, *Regulation of Medical Devices in Radiology: Current Standards and Future Opportunities*, 218 RADIOLOGY 329 (2001); John J. Smith, *Physician Modification of Legally Marketed Medical Devices: Regulatory Implications Under the Federal Food, Drug, and Cosmetic Act*, 55 FOOD & DRUG L.J. 245 (2000).

¹² Judith L. Bragdon, John Whyte & Sean Tunis, *The Perspective of the Centers for Medicare and Medicaid Services*, in GUIDE TO MEDICARE COVERAGE DECISION-MAKING AND APPEALS (Eleanor D. Kinney, ed., American Bar Ass’n, 2002); John B. Reiss, *Commentary on Payment and Reimbursement Issues Affecting the Marketing of Drugs, Medical Devices, and Biologics, with Emphasis on the Anti-Kickback Statute and Stark II*, 52 FOOD & DRUG L.J. 99, 101 (1997).

¹³ Bragdon et al., *supra* note 12.

¹⁴ 42 U.S.C. § 1395y(a) (emphasis supplied).

¹⁵ Bragdon et al., *supra* note 12.

policies.”¹⁶ More commonly, CMS undertakes a national coverage decision in response to a formal request from industry, providers, or beneficiaries. Formal requests must contain documentation describing the innovation and its proposed benefit category, the clinical context within which the technology is to be used, a summary of relevant literature, a description of completed and ongoing clinical trials, and background on FDA’s assessment of the technology, if applicable.¹⁷ After determining whether the submission fits one of over fifty broad “benefit categories” defined by statute, CMS begins an initial review of the technology and evidence supporting its use. Where a submission involves complicated, ambiguous, or controversial evidence, or for products that may impact Medicare significantly, CMS has discretion to invoke two different mechanisms to assist in reviewing the application.¹⁸ Initially, CMS may request a technology assessment from the Agency for Health Research and Quality (AHRQ) pursuant to an interagency agreement.¹⁹ In general, these assessments are performed by Evidence-based Practice Centers (EPCs), research organizations under contract to AHRQ. Alternatively, CMS may refer submissions to the Medicare Coverage Advisory Committee (MCAC).²⁰

While CMS has published proposed regulations in an effort to clarify the meaning of the terms “reasonable and necessary,” final regulations have not been successfully implemented. The agency’s most recent attempt to delineate specific criteria came in May 2000, and generated significant controversy over the proposed inclusion of comparative effectiveness and cost as factors in making coverage determinations.²¹ Aside from a Town Hall meeting, no further action has been taken. In the absence of formal regulatory criteria, CMS has established the practice of granting coverage where there is adequate evidence that a technology improves healthcare outcomes for Medicare beneficiaries, although the lack of formal criteria make application of this evidence-based standard quite controversial in some instances.

FDA’s treatment of innovative medical products plays an important role in coverage analysis, although it is only one factor in coverage determinations—a situation that often leads to considerable confusion in the stakeholder community when Medicare coverage is refused for FDA-approved or cleared products. As noted previously, one fundamental reason for confusion is differing statutory missions of the two agencies; FDA is charged with a public health mission and CMS functions as a third-party payer of medical services. Another key factor is wide variation in the data that FDA accepts in making its approval or clearance decisions, particularly with regard to medical devices. In the latter setting, a determination of “substantial equivalence” may involve data that falls far short of the clinical testing or experience often required to demonstrate health benefit to the satisfaction of CMS or its contractors.

In practice, devices that are not FDA-approved for at least one clinical indication generally do not receive coverage under Medicare²² unless the product has received a Category B designation under an investigational device exemption (IDE) as described below.²³ Off-label uses of FDA-approved drugs or devices may be covered. With regard

¹⁶ General Notice, Procedures for Making Coverage Decisions, 64 Fed. Reg. 22,619, 22,621 (Apr. 27, 1999).

¹⁷ *Id.* at 22,621-22.

¹⁸ *Id.* at 22,622-23.

¹⁹ Bragdon et al., *supra* note 12.

²⁰ *Id.*

²¹ Notice of Intent to Publish a Proposed Rule, Criteria for Making Coverage Decisions, 65 Fed. Reg. 31,124 (May 16, 2000).

²² Hugh Hill, *Criteria for Health Care Insurance Coverage*, 6 B.U.J. Sci. & Tech. L. 4 (2000).

²³ 42 C.F.R. § 405.205; Procedures, 64 Fed. Reg. at 22,622.

to drugs that have been approved by FDA, CMS and regional contractors historically have approved coverage for inpatient use under labeled indications, as well as for accepted off-label uses provided that these uses are not contraindicated and FDA has not specifically denied labeling for these uses.

Pursuant to an interagency agreement between FDA and CMS,²⁴ FDA assigns new medical devices being evaluated under an IDE to one of two categories, a process that allows for coverage of some products prior to formal FDA marketing approval or clearance.²⁵ Category A devices include those that are considered to be experimental or investigational, such as innovative Class III devices for which safety and effectiveness have not been proven, and cannot be covered by Medicare until FDA marketing approval is granted. Category B encompasses nonexperimental or noninvestigational devices, such as Class I or II devices, or Class III devices whose “underlying questions of safety and effectiveness [already] have been resolved[,] for example [where] other manufacturers have obtained FDA approval for that device type.”²⁶ Devices in Category B are eligible for Medicare coverage prior to FDA marketing approval or clearance, subject to coverage criteria that contractors apply for making decisions on legally-marketed devices.²⁷ Recategorization may occur upon the initiative of FDA or CMS, on their own initiative or in response to an external petition.²⁸

IV. AGENCY POLICIES ON DISCLOSURE

A review of FDA regulations regarding the confidentiality of trade secrets reveals the tension between the desire to protect sponsors’ work product and the effort to keep the public informed. Disclosure of a marketing application’s contents is governed by regulations found in 21 C.F.R. part 20, reflecting agency policy to:

make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade secrets and confidential commercial or financial information, and the need for the agency to promote frank internal policy deliberations and to pursue its regulatory activities without disruption.²⁹

Sponsors may find the “fullest possible disclosure” phrase to be troubling, particularly because the contents of applications for FDA approval are archived and, once submitted, may not be withdrawn.³⁰ FDA specifically exempts categories of information from disclosure to the public, however, including

trade secrets [the definition of which is discussed below] and commercial or financial information which is privileged or confidential (§20.61); personnel, medical, and similar files, the disclosure of which constitutes a clearly unwar-

²⁴ Final Rule, Criteria and Procedures for Extending Coverage to Certain Devices and Related Services, 60 Fed. Reg. 48,417 (1995).

²⁵ 42 C.F.R. §§ 405.201-.203.

²⁶ *Id.* § 405.201(b).

²⁷ *Id.* §§ 405.205, 405.211.

²⁸ *Id.* § 405.213.

²⁹ 21 C.F.R. § 20.20(a).

³⁰ *Id.* § 20.29. FDA does provide for protection of PMA contents prior to an FDA approval decision, and will not disclose whether a given PMA file even exists until the sponsor itself has publicly disclosed the PMA’s existence. *Id.* § 814.9(b). The same policy applies to the contents of the PMA as well. *Id.* § 814.9(c).

ranted invasion of personal privacy (§20.63); and at the discretion of FDA, interagency or intra-agency memoranda or letters, except for factual information which is reasonably segregable (§20.62).³¹

Nevertheless, to enforce this exemption, the sponsor must take affirmative steps to defend against such disclosure when it is requested.³²

Where disclosure is unavoidable, for example due to a judicial proceeding, agencies within the DHHS, such as CMS, have pledged to “take appropriate measures ... to reduce [any] disclosure to the minimum necessary under the circumstances.”³³

V. LEGAL BARRIERS TO COLLABORATION AND THE LAW OF TRADE SECRETS

CMS recognizes the need for expeditious processing of certain new technologies undergoing FDA approval, stating that interested parties “may contact [CMS] with an informal request while the drug or device is proceeding through the FDA process” and that CMS is “willing to meet and discuss these situations ... so that [it] may make a rapid coverage decision if FDA approval or clearance for marketing is obtained.”³⁴

Nevertheless, among the several obstacles that have discouraged greater collaboration between CMS and FDA is the law of trade secret misappropriation. Sponsors fear disclosure of the valuable data contained within their FDA applications to their competitors, even though there is broad federal regulatory protection for such data, as detailed below. Regulators at FDA and CMS may be reluctant to share information with each other out of fear of liability for misappropriating trade secrets under an extensive body of state and federal law, also discussed below. To the extent that conferring legal protection on regulators would make them more willing to collaborate across agencies, sponsors will be less willing to support such collaboration for fear that reduced liability on regulators may lead to reduced care in protecting valuable trade secrets.

Underlying any perceived statutory, regulatory, and case law limitations on increased collaboration is the overarching consideration of the constitutional theories at issue. For example, whenever the government interferes with an individual or corporation’s property so as to deprive him or her of the economic benefit of its use, the Constitution requires the government to compensate the individual or corporation. Absent compensation, such interference is unconstitutional.³⁵

Relevant recent litigation involved the Massachusetts Tobacco Ingredients and Nicotine Yield Act (MTINYA),³⁶ which required tobacco manufacturers to disclose cigarette ingredients in detail for public release. In *Philip Morris, Inc. v. Reilly*, the First Circuit overturned a judgment enjoining the enforcement of MTINYA, which was based on an

³¹ Proposed Rule, Availability for Public Disclosure and Submission to FDA for Public Disclosure of Certain Data and Information Related to Human Gene Therapy or Xenotransplantation, 66 Fed. Reg. 4688, 4688 (Jan. 18, 2001). See also 21 C.F.R. § 803.9 (requiring FDA to delete trade secrets and confidential commercial information from public reports on medical devices); *id.* § 814.9 (providing confidentiality for PMAs).

³² 21 C.F.R. § 20.53.

³³ Criteria, 60 Fed. Reg. at 48,421.

³⁴ Procedures, 64 Fed. Reg. at 22,622.

³⁵ U.S. CONST. amend. V. Whereas “categorical takings” generally involve permanent physical occupation or control of property, more applicable are “regulatory takings” in which government rule deprives the private entity of significant benefit. In regulatory takings cases, courts evaluate the factual circumstances of each case to determine whether government regulation is sufficiently excessive as to constitute a taking. *Penn. Coal Co. v. Mahon*, 260 U.S. 393 (1922).

³⁶ MASS. GEN. LAWS ch. 94, § 307B (2000).

“uncompensated taking” argument.³⁷ In doing so, the court enumerated three factors to be considered in determining whether a taking has occurred—“the character of the government action, its economic impact, and its interference with reasonable investment-backed expectations.”³⁸ The court quoted the Supreme Court’s conclusion in *Corn Products Co. v. Eddy* that

[t]he right of a manufacturer to maintain secrecy as to his compounds and processes must be held subject to the right of the state, in the exercise of its police power[,] to require that the nature of the product be fairly set forth.³⁹

In addition, the court cited another Supreme Court case, *Ruckelshaus v. Monsanto Co.*, in affirming that the Federal Trade Secrets Act (FTSA) “is not a guarantee of confidentiality to submitters of data, and, absent an express promise, [petitioner] had no reasonable, investment-backed expectation that its information would remain inviolate[.]”⁴⁰ As the Third Circuit stated in *Westinghouse Electric Corp. v. U.S. Nuclear Regulatory Commission*, “[a] voluntary submission of information by an applicant seeking the economic advantages of a license can hardly be called a taking.”⁴¹

Thus, while the case for an unconstitutional taking in the context of increased coordination between FDA and CMS is weak, any attempt to restructure the regulatory demand for and protection of trade secrets must take into account constitutional dimensions such as the takings doctrine and the right to privacy.⁴²

VI. TRADE SECRETS LAW

To understand the meaning of FDA’s protection of trade secrets, an overview of the legal doctrine of trade secrets provides helpful context. The common law action of trade secret misappropriation is somewhat controversial. Supporters campaign for the extension or federalization of trade secrets law in full,⁴³ whereas detractors argue for its restriction.⁴⁴ Justifications for the doctrine include encouraging innovation by accord- ing protection to discoveries that have not been patented or copyrighted, reduction of costly behaviors to protect or discover secrets, and potential consistency with stan- dards under international agreements like the North American Free Trade Agreement and the General Agreement on Tariffs and Trade.⁴⁵ Criticisms include conceptual dis- cord,⁴⁶ administrative inefficiencies resulting from state-to-state variability in laws,⁴⁷ and misapplication of the doctrine.⁴⁸

³⁷ *Philip Morris, Inc. v. Reilly*, 267 F.3d 45 (1st Cir. 2001).

³⁸ *Id.* at 57.

³⁹ *Id.* at 60 (quoting *Corn Prods. Co. v. Eddy*, 249 U.S. 427 (1919)).

⁴⁰ *Id.* (quoting *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1008 (1984)).

⁴¹ *Westinghouse Electric Corp. v. U.S. Nuclear Regulatory Comm’n*, 555 F.2d 82, 95 (3d Cir. 1977).

⁴² FDA regulation states that “names or other information which would identify patients or research subjects” should be withheld from public disclosure because it would constitute “a clearly unwarranted invasion of personal privacy.” 21 C.F.R. § 20.63(a).

⁴³ See, e.g., Christopher Rebel J. Pace, *The Case for a Federal Trade Secrets Act*, 8 HARV. J. LAW & TECH. 427 (1995).

⁴⁴ See, e.g., Robert G. Bone, *A New Look at Trade Secret Law: Doctrine in Search of Justification*, 86 CALIF. L. REV. 241 (1998).

⁴⁵ Pace, *supra* note 43, at 436.

⁴⁶ According to one critic, “trade secret law is merely a collection of other legal norms—contract, fraud, and the like—united only by the fact that they are used to protect trade secret[s.]” Bone, *supra* note 44, at 245.

⁴⁷ Pace, *supra* note 43, at 445.

⁴⁸ Some feel that “judges . . . view trade secret law as a relatively open-ended delegation of authority to police the morality of commercial relationships.” Bone, *supra* note 44, at 245.

Regardless of any controversy, trade secret theory exists in some form in every state and at the federal level, and its comprehensive nature provides at least a partial explanation of FDA's trade secret regulations. Among states, there is significant variation in trade secrets law. Generally, jurisdictions can be grouped into two categories based on major theoretical legal constructs: those that have followed the *Restatement* version and those that have adopted a version of the Uniform Trade Secrets Act (UTSA).⁴⁹ A minority of jurisdictions, including Massachusetts, New Jersey, New York, Pennsylvania, and Texas, protect trade secrets under the common law, as described by section 757 of the *Restatement (First) of Torts*.⁵⁰ Under the *Restatement*,

A trade secret may consist of any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it. It may be a formula for a chemical compound, a process of manufacturing, treating or preserving materials, a pattern for a machine or other device, or a list of customers.⁵¹

For a trade secret to receive legal protection under the *Restatement*, the owner of the trade secret must behave as if s/he desires to keep it a secret. Section 757 requires that:

The subject matter of a trade secret must be secret. Matters of public knowledge or of general knowledge in an industry cannot be appropriated by one as his secret. ... It is not requisite that only the proprietors of the business know it. He may, without losing his protection, communicate it to employees involved in its use[, or] communicate it to others pledged to secrecy. ... Nevertheless, a substantial element of secrecy must exist, so that, except by the use of improper means, there would be difficulty in acquiring the information. ... Some factors to be considered in determining whether given information is one's trade secret are:

- (1) The extent to which the information is known outside of his business;
- (2) the extent to which it is known by employees and others involved in his business;
- (3) the extent of measures taken by him to guard the secrecy of the information;
- (4) the value of the information to him and to his competitors;
- (5) the amount of effort or money expended by him in developing the information;
- (6) the ease or difficulty with which the information could be properly acquired or duplicated by others.⁵²

Once identified as a trade secret, liability attaches if the trade secret is misappropriated:

One who discloses or uses another's trade secret, without a privilege to do so, is liable to the other if

⁴⁹ The Uniform Trade Secrets Act (UTSA) is model legislation drafted by the National Conference of Commissioners on Uniform State Laws. Forty-one states have enacted statutes modeled after the UTSA.

⁵⁰ Pace, *supra* note 43, at 430. While the doctrine of trade secrets was dropped from the *Restatement (Second) of Torts* (1979) and reappeared in the *Restatement (Third) of Unfair Competition* §§ 39-45 (1995), courts in these jurisdictions generally follow the original *Restatement (First) of Torts* § 757 (1939). *Id.*

⁵¹ RESTATEMENT (FIRST) OF TORTS § 757 cmt. b (1939).

⁵² *Id.*

- (a) he discovered the secret by improper means, or
- (b) his disclosure or use constitutes a breach of confidence reposed in him by the other in disclosing the secret to him, or
- (c) he learned the secret from a third person with notice of the facts that it was a secret and that the third person discovered it by improper means or that the third person's disclosure of it was otherwise a breach of his duty to the other, or
- (d) he learned the secret with notice of the facts that it was a secret and that disclosure was made to him by mistake.⁵³

Perceiving the *Restatement* approach to be too narrow, the great majority of states, including California, District of Columbia, Florida, Illinois, and Maryland, have adopted some version of the UTSA, which is considered somewhat broader than the *Restatement* view.⁵⁴ Under the UTSA, a trade secret is:

- information, including a formula, pattern, compilation, program, device, method, technique, or process, that:
 - (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and
 - (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.⁵⁵

As in the *Restatement* approach, once an item is defined as a trade secret under the UTSA, liability attaches when misappropriation occurs, as with:

- (i) acquisition of a trade secret of another by a person who knows or has reason to know that the trade secret was acquired by improper means; or
- (ii) disclosure or use of a trade secret of another without express or implied consent by a person who
 - (A) used improper means to acquire knowledge of the trade secret; or
 - (B) at the time of disclosure or use, knew or had reason to know that his knowledge of the trade secret was
 - (I) derived from or through a person who had utilized improper means to acquire it;
 - (II) acquired under circumstances giving rise to a duty to maintain its secrecy or limit its use; or
 - (III) derived from or through a person who owed a duty to the person seeking relief to maintain its secrecy or limit its use; or
 - (C) before a material change of his position, knew or had reason to know that it was a trade secret and that knowledge of it had been acquired by accident or mistake.⁵⁶

State-based suits under trade secrets misappropriation doctrine may hamper the ability of local Medicare contractors to collaborate or to transfer protected information to CMS for use in coverage analysis.⁵⁷ As applied to federal agencies like FDA and

⁵³ *Id.* § 757.

⁵⁴ Pace, *supra* note 43, at 432.

⁵⁵ Uniform Trade Secrets Act § 1(4) (1985).

⁵⁶ *Id.* § 1(2).

⁵⁷ Notably, state courts continue to claim jurisdiction in determining “what rights a submitter of information to a governmental entity may have to restrain disclosure of exempt information by that entity.” *Globe Newspaper Co. v. Boston Ret. Bd.*, 388 Mass. 427, 442 n.24, 446 N.E.2d 1051 (1983).

CMS, however, the doctrine of sovereign immunity precludes application of state-based common law doctrines. To protect sponsors who submit valuable data to federal agencies, Congress passed the Federal Trade Secrets Act (FTSA), which states

Whoever, being an officer or employee of the United States or of any department or agency thereof . . . publishes, divulges, discloses, or makes known in any manner or to any extent *not authorized by law* any information coming to him in the course of his employment or official duties or by reason of any examination or investigation made by, or return, report or record made to or filed with, such department or agency or officer or employee thereof, which information concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or association; or permits any income return or copy thereof or any book containing any abstract or particulars thereof to be seen or examined by any person except as provided by law; shall be fined under this title, or imprisoned not more than one year, or both; and shall be removed from office or employment.⁵⁸

The FTSA does not closely track either the *Restatement* or the UTSA. A key distinguishing feature is the phrase “not authorized by law,” which implies that the FTSA would not prohibit disclosures that were otherwise legally permitted or required. Agency regulations that specifically provide for disclosure of such information qualify as legal authorization for the release of such data.⁵⁹

In addition, the FTSA does not explicitly define trade secrets, as do the *Restatement* and UTSA. Agencies are left to define the term in regulations, and the Environmental Protection Agency (EPA) has adopted a *Restatement* approach.⁶⁰ DHHS implemented regulations in 1988, however, adopting a different definition of trade secrets:⁶¹

A trade secret is a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process.⁶²

In reference to this definition, CMS stated that it will “withhold trade secrets and confidential information that is obtained from a person and is privileged and confidential.”⁶³

The DHHS approach is similar to the UTSA paradigm in that it requires only that the information be “commercially valuable,” similar to the UTSA’s requirement of having “independent economic value” and much more inclusive than the *Restatement’s* requirement that the information “give [the sponsor] an opportunity to obtain an advantage over competitors.” Likewise, the DHHS definition requires that the information be “secret,” falling significantly short of the *Restatement’s* requirement that the informa-

⁵⁸ 18 U.S.C. § 1905 (2002) (emphasis added).

⁵⁹ FDA Disclosure, 66 Fed. Reg. at 4694 (citing *CNA Financial Corp. v. Donovan*, 830 F.2d 1132, 1138-39 (D.C. Cir. 1987)).

⁶⁰ 40 C.F.R. § 350.1 (2002); *id.* pt. 350, subpt. A, app. A.

⁶¹ 53 Fed. Reg. 47,700 (1988).

⁶² 45 C.F.R. § 5.65(a). FDA’s definition is virtually identical. *See* 21 C.F.R. § 20.61.

⁶³ 45 C.F.R. § 5.65.

tion be shrouded by “a substantial element of secrecy.” Two additional requirements in the DHHS definition are that the information be the result of “innovation or substantial effort” and that it bears a “direct relationship to the productive process.” The former is not dissimilar to the requirement that the information not be well-known or easily obtained, as present in both the *Restatement* and UTSA definitions, but the requirement of a “direct relationship” may limit the scope of the FTSA. Without such a relationship, however, information may be less likely to have commercial value.

Third, and most significant, DHHS extends confidentiality to another category of data described as “commercial or financial information” if the data is “obtained from a person” and is “privileged or confidential.”⁶⁴ The DHHS regulation further defines each of these elements:

- (1) Information is “commercial or financial” if it relates to businesses, commerce, trade, employment, profits, or finances We interpret this category broadly.
- (2) Information is “obtained from a person” if [generated by] someone outside the Federal Government or from someone within the Government who has a commercial or financial interest in the information Information is not “obtained from a person” if it is generated by HHS or another federal agency. However, information is “obtained from a person” if it is provided by someone, including but not limited to an agency employee, who retains a commercial or financial interest in the information.
- (3) Information is “privileged” if it would ordinarily be protected from disclosure in civil discovery by a recognized evidentiary privilege, such as the attorney-client privilege or the work product privilege. Information may be privileged for this purpose under a privilege belonging to a person outside the government, unless the providing of the information to the government rendered the information no longer protectable in civil discovery.
- (4) Information is “confidential” if it meets one of the following tests:
 - (i) Disclosure may impair the government’s ability to obtain necessary information in the future;
 - (ii) Disclosure would substantially harm the competitive position of the person who submitted the information;
 - (iii) Disclosure would impair other government interests, such as program effectiveness and compliance; or
 - (iv) Disclosure would impair other private interests, such as an interest in controlling availability of intrinsically valuable records, which are sold in the market by their owner.⁶⁵

Another extension of confidentiality involves DHHS’ policy of allowing sponsors to designate specific information in their applications as confidential.⁶⁶ Finally, prior to disclosure of information, DHHS provides sponsors with notification and opportunity to respond to the anticipated disclosure, with some exceptions.⁶⁷

⁶⁴ *Id.* § 5.65(b).

⁶⁵ *Id.* In determining whether information meets one of these criteria for confidentiality, DHHS considers the following questions:

Is the information of a type customarily held in strict confidence and not disclosed to the public by the person to whom it belongs? What is the general custom or usage with respect to such information in the relevant occupation or business? How many, and what types of, individuals have access to the information? What kind and degree of financial injury can be expected if the information is disclosed?

Id. § 5.65(b)(4).

⁶⁶ *Id.* § 5.65(c).

⁶⁷ *Id.* § 5.65(d)-(e).

Taken together, the FTSA and DHHS regulations cover virtually all data contained in FDA and CMS applications, but only as long as they are in their respective domains. Interagency transfer of such information would be problematic if it resulted in discoverability of the contents by the public through, for example, requests under the Freedom of Information Act (FOIA).⁶⁸

FOIA imposes on federal agencies a general requirement to disclose information contained in their files to the public when requested so as "to ensure an informed citizenry, vital to the functioning of a democratic society, needed to check against corruption and to hold the governors accountable to the governed."⁶⁹ Trade secrets are explicitly exempted, however, from mandatory disclosure under FOIA.⁷⁰ In addition, discretionary disclosure under FOIA is prohibited for information obtained under certain sections of the FTSA, including "any method or process which as a trade secret is entitled to protection."⁷¹

A discretionary exemption also exists for "commercial or financial information obtained from a person and privileged or confidential,"⁷² a category that includes much of the data found within FDA approval applications.⁷³ Nevertheless, FDA regulations provide that such information is not disclosable⁷⁴ unless "an approval letter has been sent [or] the application has been terminated, abandoned, or otherwise no longer has commercial value."⁷⁵

Notably, sponsors may explicitly waive these regulatory safeguards if they choose to, to facilitate interagency transfer of information and to expedite the approval and coverage processes. Moreover, waiver may be implied from the sponsors' actions. Once a manufacturer itself has disclosed its confidential data publicly, such information is no longer confidential under FOIA and may be disclosed.⁷⁶ Also, once a PMA is approved or denied by FDA, all safety and effectiveness data in the application become publicly available.⁷⁷

VII. OVERCOMING BARRIERS

Given CMS' potential ability to expedite review using data submitted in FDA approval or clearance applications that may be considered proprietary or confidential, strategies for increasing interagency coordination can succeed only if the concerns over trade secrets disclosure and misappropriation are addressed. Several mechanisms have the potential of reducing these impediments to greater collaboration.

FDA and CMS could implement regulations that facilitate collaboration by eliminating the remaining concerns of both regulators and sponsors. Current regulatory author-

⁶⁸ Pub. L. No. 89-487, 80 Stat. 250 (1966), as amended 5 U.S.C. § 552 (1994).

⁶⁹ *NLRB v. Robbins Tire & Rubber Co.*, 437 U.S. 214, 242 (1978). *See also* FDA Disclosure, 66 Fed. Reg. at 4688, 4692.

⁷⁰ *See* 5 U.S.C. § 552(b)(4).

⁷¹ 21 U.S.C. § 331(j) (FDCA § 301(j)) (prohibiting the use "by any person to his own advantage or revealing, other than to the Secretary or officers or employees of [DHHS] ... any method or process which as a trade secret is entitled to protection[.]").

⁷² 5 U.S.C. § 552(b)(4).

⁷³ FDA Disclosure, 66 Fed. Reg. at 4693 (citing *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280 (D.C. Cir. 1983)).

⁷⁴ 21 C.F.R. § 20.61. Note that the trade secret exemption extends to data contained in abbreviated FDA applications as well. *See, e.g., id.* § 314.430.

⁷⁵ FDA Disclosure, 66 Fed. Reg. at 4693.

⁷⁶ *Id.* (citing *CNA Financial Corp. v. Donovan*, 830 F.2d 1132, 1154 (D.C. Cir. 1987)).

⁷⁷ 21 C.F.R. § 814.9(e).

ity exists to protect sponsors' proprietary submissions to FDA. In 1982, FDA implemented 21 C.F.R. § 85, which states that records

otherwise exempt from public disclosure may be disclosed to other Federal government departments and agencies, except that trade secrets and confidential commercial or financial information prohibited from disclosure by [21 U.S.C. § 331(j) and other sections] may be released only as provided by those sections. Any disclosure ... shall be pursuant to a written agreement that the record shall not be further disclosed by the other department or agency except with the written permission of the Food and Drug Administration.⁷⁸

Additional FDA regulations restrict the ability of the Commissioner to make discretionary disclosures with respect to trade secrets, although not necessarily confidential commercial information where prior notice is given, as discussed above.⁷⁹ Beyond this regulatory authority, legislative prohibitions on the disclosure of trade secrets apply when disclosure is made outside of DHHS, not when disclosure is between DHHS agencies.⁸⁰ In contrast, CMS analysts are not subject to FDA's regulations protecting trade secret information from disclosure; rather, CMS has strived to increase agency transparency by making available publicly the bases for its coverage decisions. Trade secret regulations similar to those used by FDA would be needed to protect sponsors' proprietary interests and to shield CMS analysts from potential liability for disclosing proprietary information. Such regulations also would foster interagency collaboration by allaying FDA reviewers' concerns about disclosure of sponsors' data. Protective regulations would contravene, however, CMS' desire for agency transparency.

To reassure FDA and CMS regulators' fears of contravening the FTSA in the process of regulating collaboratively, the agencies could implement a memorandum of understanding or issue formal regulations that explicitly "authorize by law" the exchange of trade secrets specifically between the two agencies. As discussed earlier, such mechanisms could serve as the predicate upon which interagency transfer is "otherwise authorized by law" under the FTSA.⁸¹ Because of CMS' transparency and lack of the same confidentiality provisions as those FDA possesses, sponsors' proprietary submissions would be vulnerable, however, to public disclosure. In August 2002, CMS proposed a rule to implement portions of section 522 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA).⁸² If implemented, this rule would allow for beneficiaries to appeal local and national coverage decisions. Proposed 42 C.F.R. § 426.505(c)(11) authorizes the Departmental Appeals Board (DAB) to subpoena related documents,⁸³ which presumably would include any trade secret information provided to CMS by FDA in the course of interagency collaboration. Such information would then be available for review by DAB members and staff, and become part of the record. Thus, sponsors seeking concurrent review by the two agencies would run the risk of their proprietary data falling into competitors' hands.

To tailor the risk of disclosure to sponsors willing to trade confidentiality for interagency communication and potentially shorter reviews, the agencies could condition

⁷⁸ *Id.* § 20.85; 47 Fed. Reg. 10,804 (1982).

⁷⁹ 21 C.F.R. § 20.82(b)(1).

⁸⁰ 21 U.S.C. § 331(j) (FDCA § 301(j)). FDA is not justified in withholding trade secrets from Congress. *Id.*

⁸¹ 18 U.S.C. § 1905 (2002); *see supra* note 58 and accompanying text.

⁸² Proposed Rule, 67 Fed. Reg. 54,534 (Aug. 22, 2002), implementing section 522 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. No. 106-554, 114 Stat. 2763 (2000).

⁸³ *Id.* at 54,558-59.

collaborative review on voluntary consent by the sponsor to permit the agencies to share data. If such coordination significantly reduces the time to market for a new product, sponsors would have considerable incentive to provide such consent. Voluntary consent could be memorialized in a writing that serves as a waiver of claims against FDA or CMS for interagency information exchange, thus rendering moot any concerns of liability under the FTSA. Waiver also may be implied from the sponsor's voluntary participation in prospective meetings with FDA to determine data requirements and clinical trial design, if CMS officials also are present. To promote the latter, sponsors could be offered the opportunity to have CMS staff present in prospective meetings with FDA, as discussed below.

Waiver, memorandum of understanding, or formal regulation would allow for the inclusion of CMS in the prospective process through which FDA often guides sponsors in designing their studies. In this setting, CMS may provide substantial guidance to the sponsor regarding the amount and quality of data required for a favorable coverage decision. Such data may be collected more efficiently in a prospective setting rather than following the completion of clinical trials. Moreover, CMS officials could prospectively specify any additional or different data not requested by FDA that would be necessary or helpful to coverage decisions.

Of course, no matter which strategies are utilized, the agencies must remain cognizant of the potential constitutional restraints on regulatory takings described above.⁸⁴ If efforts to protect trade secrets are adequate or participation by sponsors is voluntary, a constitutionally-derived legal challenge against either agency would be difficult to maintain, however, and unlikely to succeed. Neither FDA nor CMS seeks to compel disclosure by private actors, distinguishing the nature of regulations associated with interagency collaboration from those that force companies to make public confidential data without compensatory benefit.

Regardless of the choice of strategies, increased funding to expand CMS coverage analysis resources likely would speed coverage determinations and reduce overall administrative delay. Operating with a fraction of FDA's manpower, CMS manages extraordinary amounts of information and products.⁸⁵ Increased resources would speed review of coverage applications and facilitate CMS representation at prospective meetings between sponsors and FDA. Funding could come either directly from the government or perhaps from a user fee program similar to that created by the successful Prescription Drug User Fee Act (PDUFA)⁸⁶ for expediting FDA reviews.⁸⁷ Given the potential reduction in administrative lag time and the general acceptance of PDUFA by industry, there may be support for a CMS analog of PDUFA. It is unclear that any given manufacturer would be willing to provide resources to expedite a decision that would potentially benefit its competition as well, given that coverage decisions are granted to classes of products (for example, left ventricular assist devices) and several manufacturers usually are involved.

The issue of multiple manufacturers highlights an important difference between FDA approval or clearance decisions and CMS coverage determinations, namely that mul-

⁸⁴ See *supra* notes 35-42 and accompanying text.

⁸⁵ The General Accounting Office (GAO) estimated that each year Medicare alone "serves about 40 million elderly and disabled Americans and processes about 900 million claims submitted by nearly 1 million ... healthcare providers. In fiscal year 2000, the program spent over \$200 billion—about 11 percent of the federal budget." U.S. GENERAL ACCOUNTING OFF., *MEDICARE MANAGEMENT: CMS FACES CHALLENGES TO SUSTAIN PROGRESS AND ADDRESS WEAKNESSES*, GAO-01-817, at 3 (July 2001).

⁸⁶ Pub. L. No. 102-571, 106 Stat. 4491 (1992).

⁸⁷ See generally Linda A. Suydam & Milan J. Kubic, *FDA's Implementation of FDAMA: An Interim Balance Sheet*, 56 *FOOD & DRUG L.J.* 131 (2001).

multiple parties typically have interests in any given CMS coverage decision. FDA operates in an environment in which a single sponsor interacts with the agency to receive approval or clearance for a given product marketing indication. Given that sponsors most often are manufacturers who stand to gain economically from the product's marketing, interests and benefits are relatively straightforward. CMS, as administrator for the Medicare program, has a number of distinct shareholders—often with competing interests.

Initially, CMS coverage decisions typically cover types of technology represented by multiple products and manufacturers. This means that on a given coverage decision, the agency may interact with multiple manufacturers with widely divergent interests. In addition to manufacturers, coverage decisions often involve healthcare providers such as physicians and medical institutions—parties that often have competing agendas. Finally, and most importantly, CMS is accountable to its beneficiaries—Medicare patients and their families.

In light of the diversity of the stakeholders involved in the FDA and CMS processes and the issues of sponsor confidentiality discussed above, it is easy to see the complexity involved in fashioning effective FDA-CMS coordination. For example, Medicare beneficiaries may prefer interacting with a single combined entity that makes both marketing and coverage decisions; and some sponsors, willing to risk disclosure of proprietary information, may think it is worthwhile to have collaborative review of new medical technologies (NMTs). On the other hand, other members of industry, familiar with the present FDA and CMS systems and concerned about the confidentiality of trade secrets, may advocate keeping the existing agencies in place. Ultimately, balancing such competing interests will be difficult, but crucial, to instituting meaningful interagency cooperation.

Finally, the sheer diversity of the CMS stakeholder community and the arguable need for these parties to access data on which coverage decisions are made raises the question of why CMS would need access to proprietary or confidential data that could not be made public. Initially, CMS access to such data early in product development and testing may allow CMS to offer sponsors crucial information as to how to conduct clinical trials so as to provide the agency the information necessary to make an informed coverage decision. This subsequent coverage-specific data could be made public, while the confidential data that allowed the productive interaction would remain protected. There also is the possibility that on seeing confidential data, CMS could identify the data necessary for making a coverage determination and come to an agreement with a product sponsor on making such key data public. In either case, effective CMS action rests on a complete knowledge of what product data is available.

VIII. CONCLUSION

Closer collaboration between CMS and FDA holds substantial promise for increased regulatory efficiency. Although they are of understandable concern to those contemplating the implementation of such collaboration, potential legal issues related to the law of trade secrets are not insurmountable. A variety of strategies are possible, without resorting to legislation. Given the lack of true legal barriers under the law of trade secrets, the success of collaborative efforts between the agencies will depend largely on nonlegal, but significant, considerations such as integrating agency cultures and achieving industry and beneficiary acceptance in light of conflicting interests between and within those stakeholder groups.

