Statement of Celgene Corporation
Before the Subcommittee on Regulatory Reform, Commercial and Antitrust Law,
United States House of Representatives Committee on the Judiciary

Hearing, "Antitrust Concerns and the FDA Approval Process"
July 27, 2017

Celgene Corporation (Celgene) thanks the Subcommittee for the opportunity to submit this statement in connection with the above-entitled hearing. Our testimony focuses on H.R. 2212, the "Creating and Restoring Equal Access To Equivalent Samples Act of 2017" (the CREATES Act or the Act).[1]

Celgene respectfully submits that the CREATES Act is not the appropriate mechanism for ensuring that generic drug and biosimilar manufacturers (termed "eligible product developers" in the Act) have access to samples of innovative medicines for purposes of bioequivalence or biosimilarity testing. The CREATES Act frustrates this objective by adding inefficiencies, costs, and risks rather than promoting competition, as intended. Celgene is concerned that the CREATES Act would undermine biopharmaceutical companies' efforts to advance the public health by developing lifesaving medicines that require special restrictions to assure their safe use and to make those medicines available to patients while protecting patient safety.

First, rather than addressing the important safety issues involved in the provision of certain drugs—particularly those subject to special restrictions necessary to protect patient and researcher safety and the public health, i.e., risk evaluation and mitigation strategies (REMS) with elements to assure safe use (ETASU)—the Act's samples provisions establish an inefficient and unworkable litigation regime that creates incentives to litigate rather than negotiate appropriate terms for the transfer of samples in good faith. Under the bill, eligible product developers could argue that they are permitted to recover significant monetary damages even if there is no demonstrable harm to competition and even if they never seek approval of generic or biosimilar drugs. Second, the CREATES Act potentially puts patients and researchers at risk by failing to ensure that eligible product developers implement appropriate safeguards when conducting testing of samples of medicines that require REMS with ETASU to mitigate serious safety risks. Third, the Act discourages the development of innovative medicines that might be subject to REMS with ETASU by increasing the cost and liability associated with developing those medicines.

I. Background

Celgene is a global biopharmaceutical company dedicated to delivering innovative and life-changing drugs to patients, particularly those with unmet medical needs. Our focus is on therapies designed to treat cancer and immune-inflammatory related diseases in patients with limited treatment options. Celgene has demonstrated a nearly-two-decade commitment to managing the risks associated with our medicines, including teratogenic risk, and has shown operational excellence in risk management to minimize burden to the health care system.

The Food and Drug Administration (FDA) has long recognized that a small number of medicines require risk mitigation strategies to address known serious risks of the drugs and to

[1] *See* H.R. 2212, 115th Cong. (2017).

ensure that their benefits outweigh their risks. These critical safety tools for patients are of particular importance to Celgene. Our first product to receive FDA approval was Thalomid® (thalidomide) in 1998 for two uses in erythema nodosum leprosum (ENL), a skin condition caused by leprosy,[2] and, in 2006, it was approved in combination with dexamethasone for the treatment of patients with newly diagnosed multiple myeloma, a deadly blood and bone marrow cancer. Celgene has also developed two additional cancer medications that share certain teratogenic properties with thalidomide: Revlimid® (lenalidomide), which is approved for two uses in patients with multiple myeloma,[3] as well as for use in patients with myelodysplastic syndrome and mantle cell lymphoma,[4] both blood cancers, and Pomalyst (pomalidomide), which is approved for a use in patients with multiple myeloma.[5] Celgene has safely distributed these critically important drugs, which are associated with known serious risks, because of their risk mitigation strategies.

Thalidomide is well-known as a teratogen that can cause devastating birth defects. In the late 1950s and early 1960s, the use of thalidomide in Europe and Canada to treat morning sickness and insomnia in pregnant women resulted in the birth of thousands of children with severe deformities, many of whom did not survive. Spurred by this tragedy, in 1962, Congress enacted the Kefauver-Harris Amendments to the Federal Food, Drug and Cosmetic Act (FDCA), which created the modern FDA approval system for medicines.[6] The 1962 amendments required manufacturers to demonstrate drug effectiveness, in addition to safety, and mandated that FDA approve a new drug application *before* marketing of the drug. Prior to the 1962 amendments, new drug applications were required only to demonstrate safety and automatically became effective 60 days after submission unless FDA affirmatively disapproved them.

In developing Thalomid for use in areas of high unmet medical need, Celgene believed in the efficacy of the drug, but also recognized the significant teratogenic risk it presented. Celgene committed to developing and implementing strategies to mitigate that risk and to prevent even a single birth defect caused by exposure to the drug. It is important to recognize that children continue to be born in Brazil and other countries with congenital malformed limbs (phocomelia) as a result of lower safety standards in the administration of powerful medicines like Thalomid. When FDA approved Thalomid, Celgene, in conjunction with FDA and in consultation with organizations representing thalidomide victims, created the System for Thalidomide Education and Prescribing Safety (S.T.E.P.S.) program, imposing a number of elements and restrictions to manage thalidomide's risk. The S.T.E.P.S. program included required registration of all prescribers, patients, and pharmacists; patient acknowledgement/consent forms; validation of

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[2] Thalomid is indicated for the acute treatment of the cutaneous manifestations of moderate to severe ENL. Thalomid is not indicated as monotherapy for such ENL treatment in the presence of moderate to severe neuritis. Thalomid is also indicated as a maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence.

[3] Revlimid, in combination with dexamethasone, is indicated for the treatment of patients with multiple myeloma. Revlimid is also indicated as maintenance therapy in patients with multiple myeloma following autologous hematopoietic stem cell transplantation.

[4] Revlimid is indicated for the treatment of patients with transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities. Revlimid is also indicated for the treatment of patients with mantle cell lymphoma whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib.

[5] Pomalyst, in combination with dexamethasone, is indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy.

[6] Pub. L. No. 87-781, 76 Stat. 780 (1962).

authorization prior to dispensing the drug; a required telephonic survey for patients and prescribers; required pregnancy testing; compliance with measures to prevent pregnancy; educational materials and patient counseling; limitations on prescriptions; and distribution from certified pharmacies. Celgene was, and remains, committed to maintaining the best risk management system possible and to operating this system consistently. In this commitment, Celgene is aligned with thalidomide victims groups, which insist on the utmost care and rigor in the safe distribution of these drugs, and which have vowed that such tragedies should never occur again.

In September 2007, President Bush signed into law the Food and Drug Administration Amendments Act of 2007 (FDAAA).[7] FDAAA provided FDA with enhanced authority to regulate the safety of marketed drugs, including authority to require manufacturers to conduct postmarket clinical studies and to make safety-related labeling changes. FDAAA also authorized FDA to require manufacturers to develop, implement, and comply with REMS for certain drugs, codifying and expanding the agency's practice of requiring risk minimization action plans (RiskMAPs) and other similar programs for certain drugs, including Thalomid and Revlimid.[8]

Under the FDCA as amended by FDAAA, FDA will impose a REMS if the agency determines that a REMS "is necessary to ensure that the benefits of the drug outweigh the risks of the drug."[9] REMS elements include Medication Guides, patient package inserts, and communication strategies.[10] FDA may require a REMS with additional "elements . . . to assure safe use" when, because of its "inherent toxicity or potential harmfulness," the drug "can be approved only if . . . such elements are required as part of [the REMS] to mitigate a specific serious risk" of the drug.[11] After enactment of FDAAA, the risk mitigation programs for Thalomid and Revlimid were deemed to be REMS with ETASU to mitigate the teratogenic risk of the drugs.[12] Subsequently, Pomalyst was approved with a REMS with the ETASU to address the same risk. We have an integrated REMS program for these three drugs at CelgeneRiskManagement.com.

ETASU imposed as part of REMS may include specific requirements for training or certification of prescribing health care providers, requirements for certification of pharmacies and health care practitioners that dispense the product, restrictions on the setting in which the drug can be dispensed (*e.g.*, only in hospital settings), requirements that the product be dispensed only to patients with evidence of safe use (*e.g.*, laboratory results), patient monitoring requirements, or requirements that patients be enrolled in a registry.[13] Drug and biologic manufacturers are responsible for implementing the REMS with ETASU, including developing a system through which the manufacturer can monitor and evaluate the implementation of the ETASU by healthcare providers, pharmacists, and others in the healthcare system.[14]

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[7] Pub. L. No. 110-85, 121 Stat. 823 (2007).

[8] Pub. L. No. 110-85 at Title IX, Subtitle A, 121 Stat. at 992-51.

[9] FDCA § 505-1(a)(1).

[10] FDCA § 505-1(e).

[11] FDCA § 505-1(f)(1)(A).

[12] *See* 73 Fed. Reg. 16313, 16314 (Mar. 27, 2008).

[13] FDCA § 505-1(f)(3).

[14] FDCA § 505-1(f)(4).

The FDCA generally requires a generic drug and reference listed drug "to use a single, shared [REMS with ETASU] system,"[15] unless FDA waives this requirement and permits the generic applicant to use its own system. The statute does not define "single, shared system." FDA may (but need not) waive the single, shared REMS requirement (1) if the burden of creating a single, shared system outweighs its benefit; or (2) if an aspect of the ETASU is patented or entitled to trade secret protection and the generic manufacturer was not able to obtain a license.[16] Further, there is no legal requirement for a biosimilar applicant or an applicant filing a section 505(b)(2) application to have a single, shared REMS with the innovator.

Celgene is resolutely dedicated to ensuring patient safety, and we are proud of our record of no congenital malformations associated with Thalomid, Revlimid, and Pomalyst in over one million prescription cycles. We firmly believe that our commitment to developing the most effective risk mitigation systems and our unwavering efforts to operate these systems have allowed hundreds of thousands of patients to benefit from these lifesaving medications without putting them, their families, their providers, or the public at undue risk. Our commitment to patients extends to ensuring, without exception, that other companies that utilize Celgene products subject to REMS with ETASU in clinical testing share our commitment to safety and implement necessary safeguards. Celgene consistently offers to sell its products that are subject to REMS with ETASU in response to requests from both other innovator companies and generic manufactures for use in clinical testing, subject to necessary safety-related requirements.

The CREATES Act does not hold eligible product developers to these standards, however. Instead, the Act creates a civil right of action that would allow eligible product developers to recover significant monetary damages from the innovator if no agreement on samples is reached within 31 days, even if, plaintiffs will argue in litigation, there is no demonstrable harm to competition or commitment of the eligible product developer to actually develop the product and even if the developer does not act in good faith. This unworkable litigation regime creates unacceptable risks for patients, researchers, and innovator companies because it fails to ensure that eligible product developers will implement appropriate safeguards when conducting clinical testing with samples of medicines that require REMS with ETASU to mitigate serious safety risks. The Act also discourages the development of innovative medicines that might be subject to REMS with ETASU by increasing the cost and liability associated with developing those medicines. Finally, its single, shared REMS provision, though apparently well-intentioned, is not tailored to achieve its objective.

II. The CREATES Act Would Spur Unnecessary Litigation

The CREATES Act establishes an inefficient and unworkable regime that creates incentives to litigate, rather than to efficiently resolve the safety and liability issues involved when innovators receive requests for samples of medicines subject to REMS with ETASU. As discussed, a drug subject to a REMS with ETASU poses a significant safety concern for patients and potentially even researchers who come into contact with it. Innovator companies could face legal liability and reputational harm if eligible product developers (or third parties they engage) mishandle such products and patients or researchers are harmed as a result. Given the stakes, innovators seek assurances that new purchasers will comply with the safety standards for the

[15] FDCA § 505-1(i)(1)(B).

[16] *Id*.

drug, and negotiations to achieve those assurances therefore can be time-consuming and complex.

Passing the CREATES Act would not resolve these substantive concerns. Rather, it shifts responsibility for these difficult issues to the courts without providing a framework to guide their analysis. The Act creates a wholly new federal cause of action against an innovator where the innovator fails to provide samples on "commercially reasonable, market-based terms" within 31 days of the request. This cause of action is untethered to any existing legal duty. Because there is no comparable legal regime or existing framework to provide content to this vague standard, courts would have to evaluate each request on a case-by-case basis. Thus, litigation is likely to result in inconclusive or even contradictory outcomes that would not provide clear guidance for parties or future courts on how to resolve the complicated safety and liability issues posed by such requests. Innovators negotiating access to samples in good faith may face suits based on disagreements over whether specific terms meet this standard, particularly where the sale of samples may differ significantly from the usual sale and distribution terms for the product due to the innovator's lack of control or oversight of the developer's safety systems and differing nature of the intended use of the product.

Worse, the Act enables eligible product developers to engage in strategic litigation rather than genuine efforts to bring generic drugs to the market. The Act does not preclude an eligible drug developer from bringing suit even when it could readily purchase the samples in the open market—instead the Act requires the innovator to assert an affirmative defense to this effect and defend the lawsuit. Further, the conditions for establishing this affirmative defense are unreasonably demanding: the innovator must show that it has placed "no restrictions" on sale of the samples,[17] despite the fact that the FDA-mandated REMS itself may impose such restrictions,[18] as might other laws (*e.g.*, prescription laws). More fundamentally, nothing in the Act would prevent an opportunistic company from declaring that it sought to develop a product for FDA approval, submitting sparse documentation to FDA (if the drug had a REMS with ETASU), demanding samples from an innovator, negotiating in bad faith for 31 days, and then promptly filing suit in the hope of forcing a nuisance settlement from the innovator. This outcome is a distinct possibility given that the bill does not require eligible product developers to certify that they actually intend to submit an abbreviated application to FDA, or are close to the point at which samples of the brand product are reasonably necessary, and yet provides for potentially significant monetary awards.

Even for legitimate eligible product developers, the Act establishes an incentive to litigate in the hopes of obtaining substantial monetary awards—perhaps equal to the innovator's entire revenues for the duration of the litigation, and much greater than the developer could achieve by competing in the marketplace—rather than going through good-faith negotiations and the process to seek approval of a safe and effective generic drug with a serious enough safety profile to require a REMS. The Act will encourage eligible product developers to bring suit in the absence of any cognizable harm—such as a delay in market entry. Further, the recoverable

[17] H.R. 2212, 115th Cong. § 3(b)(3)(B).

[18] Furthermore, the CREATES Act fails to address how innovators can adhere to the FDCA's REMS with ETASU provisions—which contain no exception for providing samples to eligible product developers—and also comply with the Act's mandate to provide samples. The Act merely provides that the notice that the eligible product developer has received an authorization from FDA will also state that the provision of samples pursuant to the authorization will not be a violation of the REMS. But such a statement does not effectuate an exemption from existing statutory requirements, and innovators may remain subject to substantial penalties under the FDCA for providing a drug subject to REMS with ETASU in violation of the REMS requirements.

"damages" have no connection to any alleged harm to the developer but instead to deterrence of future conduct by the innovator. For example, an eligible product developer who has just filed an abbreviated application but is years from marketing its product due to patents on the innovator's product could demand samples, negotiate in bad faith, and then sue—even if the failure to obtain samples will not delay entry by the eligible product developer. Creating this litigation alternative—with the prospect of recovering attorney fees and windfall damages—would disrupt the existing balance and potentially slow generic and biosimilar development.

III. The CREATES Act Potentially Puts Patients and Researchers at Risk

The CREATES Act lacks a meaningful mechanism for ensuring that eligible product developers use adequate safety protections to mitigate the risks of the involved drugs. In failing to acknowledge the serious safety risks of drugs subject to REMS with ETASU and the critical role the ETASU systems play in protecting the public, the CREATES Act exposes patients and researchers in clinical trials to serious risks.

As discussed above, FDA requires a drug to have a REMS with ETASU only when the agency could otherwise not approve the drug because the ETASU are necessary to mitigate specific serious risks associated with the drug. These special safety measures are critical to patient and researcher safety, including as part of any clinical trial conducted by an eligible product developer. For instance, for drugs that are teratogens, mitigation of risks to both researchers and patients is of paramount importance. The serious risks of such drugs require diligent application of risk mitigation strategies in all settings, including during bioequivalence or biosimilarity testing.

The CREATES Act calls for the eligible product developer to obtain an FDA authorization to receive medicines subject to a REMS with ETASU; however, the authorization process includes no meaningful FDA oversight of the developer's proposed safety measures. To receive authorization to obtain samples for clinical testing, the eligible product developer must either: (1) "submit[]" protocols, informed consent forms, and related documents "that include protections that provide safety protections comparable to those provided by the REMS" with ETASU; or (2) otherwise satisfy FDA that such protections will be provided.[19] To obtain authorization to receive samples for nonclinical testing, the eligible product developer must agree to comply with any conditions FDA deems necessary.

The Act provides insufficient protections for researchers and patients in the clinical testing setting for several reasons. First, the Act permits, but does not require, the eligible product developer to submit a clinical protocol, informed consent form, and related documentation to FDA. Second, the Act requires that, if submitted, the proposed protocol, informed consent, and related documents provide "comparable"—not equivalent—protections to the REMS with ETASU. Third, FDA need not assess the information submitted to determine that it sufficiently protects human subjects before the start of clinical testing, even though this testing might raise different safety concerns (*e.g.*, the acceptability of risks to healthy volunteers) than those addressed by the REMS with ETASU system (which is designed to mitigate risks during clinical use). Fourth, the Act does not require FDA to consider the eligible product developer's compliance history or qualifications in reviewing the request. Yet, some eligible product developers have had significant compliance issues, as embodied in some cases

[19] H.R. 2212 § 3(b)(2)(B)(ii)(II). The developer must also meet "any other requirements the Secretary may establish." *Id.*

in prosecutions or import alerts prohibiting importation of their products to the United States. Fifth, the developer is not expressly required to comply with any conditions that FDA deems necessary in clinical testing, although this requirement is explicit for use of the same samples in nonclinical testing. Sixth, FDA cannot extend the review period—even if FDA has concerns regarding the safety protections for patients or researchers or the eligible product developer's qualifications. (Some eligible product developers have no prior experience with such products.) Instead, within 90 days of the request, FDA "shall" authorize the eligible product developer to obtain samples if the developer submitted appropriate paperwork or "otherwise" satisfied FDA that it will provide comparable protections.

Compounding these limitations, the CREATES Act also lacks any mechanism for FDA to ensure that an eligible product developer complies with the terms of the authorization and implements the safety protections described in the submission to the agency. The bill grants FDA no authority to suspend, modify, or revoke an authorization if the eligible product developer does not comply with its proposed safeguards or if the agency becomes aware of a risk to patients as a result of the eligible product developer's actions.

Despite the lack of a robust FDA review of the eligible product developer's safety measures during the authorization process, the CREATES Act fails to provide any other mechanism for addressing safety concerns related to the eligible product developer's acquisition of samples. No element of a lawsuit or affirmative defense explicitly addresses safety concerns. On the face of the Act, an eligible product developer could seek recovery in court without having adequate patient safety protections in place. Indeed, an eligible product developer could argue for damages even if the innovator requested necessary safety protections as part of the terms for the transfer of samples and the eligible product developer declined to agree to the protections. At best, the CREATES Act could be read to task the federal courts with adjudicating what, if any, safety protections imposed on the transfer of samples constitute commercially-reasonable, market-based terms. But the federal courts are not equipped to evaluate which risk mitigation measures are necessary and appropriate to protect patients and researchers in light of the drug's risks and the eligible product developer's planned clinical testing.

IV. The CREATES Act Would Undermine Incentives to Develop Life-Saving Medicines

The CREATES Act meaningfully increases the cost of developing and distributing a drug subject to a REMS with ETASU by exposing innovators of these drugs to substantial liability and costs. In doing so, the CREATES ACT discourages development of potentially life-saving medications that would be subject to a REMS with ETASU.

As discussed, the Act subjects these innovators to significant liability based on requests to obtain samples, even when they act in good faith. Further, these innovators are not adequately protected from liability arising from the actions of the eligible product developer or third parties it engages in clinical testing. First, the Act does not protect innovators from liability that may arise due to the activities of contractors or other third parties acting on behalf of the eligible product developer, such as contract research organizations. Second, the CREATES Act does not explicitly require the eligible product developer to indemnify the innovator for the costs of defending and resolving product liability suits arising from the actions of the developer or these third parties. Nor does the Act require eligible product developers to maintain sufficient insurance to ensure that the developer can provide effective indemnification. Third, the legislation does not protect innovators from reputational harm or lost sales that may be caused by actions of the eligible product developer or its agents. Finally, the Act constrains innovators' ability to manage these risks through contractual terms (for example, by requiring

certain minimum safety protections or reasonable indemnification and insurance provisions in contracts for sample sales) because these terms could later be judged by a court not to be "commercially reasonable" or to lack "legitimate business justification."

V. The Single, Shared REMS Provision of the CREATES Act Is Not Tailored to Achieve Its Objective

Celgene supports the apparent goal of section 4 of the CREATES Act: to provide FDA with greater flexibility in determining whether to require a single, shared system of ETASU or to allow generic applicants to implement a separate REMS with ETASU system, in order to ensure that legal requirements for single, shared systems neither impede approval of generic drugs nor unreasonably burden innovators. Nevertheless, Celgene is concerned that this section is not appropriately tailored to achieve this goal. It fails to acknowledge the possibility of innovators' intellectual property rights, further decreasing incentives for development of potentially lifesaving medicines that might have REMS with ETASU.

Section 4 of the CREATES Act seems to reflect a well-intentioned effort to grant FDA broader authority to allow separate ETASU systems for generic drugs. Indeed, Celgene encourages FDA to more broadly exercise its *existing* authority to waive the single, shared system requirement when the burdens of a single, shared system outweigh its benefits. In evaluating whether a separate ETASU system for a generic drug is appropriate, a number of factors should be considered—either under current law or under proposed legislation—including:

- The safety of patients, individuals who handle the drug, and the public.

- The efforts and good faith of the eligible product developer and innovator in attempting to reach agreement on a single, shared REMS and the length of time during which good-faith negotiations have been undertaken with or without progress (including the reasonableness of such time given the complexity of the ETASU and the risks it mitigates and the number of parties involved, among other things).

- The time remaining before the generic application may receive final approval (including whether the application has been received for review) and the likelihood that lack of agreement over a single, shared REMS would result in delay of market entry of the generic product.

- The interests of healthcare providers, patients, the innovator, and the generic applicant. The availability of multiple REMS programs may be a source of stakeholder confusion, additional administrative burdens, and potentially decreased product access.

- Whether the parties have the capabilities and resources to create and implement their own ETASU systems by the time of generic approval and whether coexisting systems provide at least the same level of safety as a single ETASU system.

- Whether commercial terms for a single, shared REMS have been defined and accepted by at least one generic applicant.

- Official action indicated or undertaken from REMS post-marketing inspections such that merging with or incorporating a company into a single, shared system would not be advisable.

Celgene thus supports the objective of section 4 of the CREATES Act, but this section does not achieve this goal in a balanced and tailored manner. First, the CREATES Act would eliminate the statute's current express recognition of intellectual property rights on REMS with ETASU. Innovators devote significant resources to develop and implement appropriate REMS with ETASU systems and may hold intellectual property rights in these systems. Congress acknowledged the need to protect innovators' intellectual property rights when enacting the single, shared REMS provision of the statute in 2007. The FDCA permits FDA to waive the general requirement for a single, shared REMS system when an element of a REMS with ETASU system is patented or subject to trade secret protection and the generic applicant was unable to obtain a license.[20] Congress has thus recognized that the benefits of a single, shared system must be balanced with the protection of innovators' intellectual property rights. In contrast, the CREATES Act allows FDA to require a single, shared system in certain circumstances, presumably even if the system is subject to patent or trade secret protection.[21] Any revised version of section 505-1(i)(1)(B) of the FDCA should include an explicit exception, subject to the parties agreeing otherwise, from a requirement for a single, shared REMS in situations where an element of a REMS with ETASU system is patented or subject to trade secret protection, as under current law.

Second, the Act empowers the FDA to compel innovators to change their carefully designed and in-use REMS with ETASU systems to "accommodate" a generic manufacturer's different approved REMS with ETASU system even where the system is working flawlessly and the repercussions of such changes are not clear.[22] These forced changes would serve the developer's commercial interests and would not reflect changes necessary to address any safety concerns, given that FDA would have already decided that separate REMS were appropriate. Further, such forced changes could directly undermine innovators' intellectual property rights in REMS with ETASU and conflict with innovator risk management processes developed through their long experience implementing their REMS with ETASU systems. Finally, these changes appear unnecessary given that other provisions of the Act enable generic manufacturers to adopt separate ETASU systems in most circumstances; in all of these cases, there would be no need to align the innovator's *separate* system with the generic's ETASU.

VI. Conclusion

The CREATES Act would create an unworkable litigation scheme and, at the same time, would put patients at risk and discourage the development of lifesaving medications that would be subject to REMS with ETASU. The Act frustrates the very goals Congress intends to achieve with respect to samples: promoting competition through efficient negotiations and access to samples. And while Celgene supports the Act's intent to provide FDA with greater flexibility in determining whether to require single, shared systems of REMS with ETASU, the Act is not tailored to achieve this objective.

Celgene respectfully urges the Committee to set aside the CREATES Act and to consider legislation better crafted to the stated purpose. Celgene would support appropriate federal legislation that is enforced by FDA and that provides for innovators to sell samples to eligible product developers on commercially reasonable terms while ensuring appropriate safety and

[20] FDCA § 505-1(i)(1)(B).

[21] H.R. 2212 § 4(2) (proposed section 505-1(i)(1)(B)(ii) of the FDCA).

[22] *Id.* § 4(1)(C) (proposed section 505-1(g)(4)(B)(iii) of the FDCA).

liability protections. Any such legislation must include a robust process for FDA review and authorization of the safety protections that will be implemented by eligible product developers in testing samples of drugs that are subject to REMS with ETASU. If the legislation requires innovators to provide samples to eligible product developers, the legislation should also protect innovators from liability that may arise from the developer's actions and those of third parties engaged by the developer and provide for indemnification and insurance requirements that ensure this liability protection is meaningful and require good faith negotiations. The legislation could include a provision granting FDA greater flexibility to waive the single, shared REMS requirement based on factors such as those described above, in the interests of patients, the healthcare system, and competition and with appropriate recognition of intellectual property rights on ETASU systems. This federal legislation should preempt state laws that impose requirements that overlap with, but may duplicate or contradict, the federal legislation. Finally, Congress should clarify that provision of samples to an eligible product developer pursuant to the legislation does not violate the innovator's REMS with ETASU.